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Brief Feedback-Focused Interventions

Brian Borsari*, \$\\$, Nadine R. Mastroleo\$

*Mental Health and Behavioral Sciences Service, Providence, RI, USA \$Center for Alcohol and Addiction Studies, Brown University, Providence, RI, USA

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DEFINITION

Opinions vary regarding what exactly constitutes a brief intervention – many terms and definitions have been developed over the years, such as brief advice, feedback interventions, feedback evaluations, brief intervention, and minimal intervention. For the purpose of this entry, a brief feedback-focused intervention (BFI)

will be defined as an interaction addressing an addictive behavior lasting typically from 15 min to an hour in duration. The number of sessions can range from one to six, with the potential for follow-up contacts used to monitor the individual's progress. BFIs have been used therapeutically with a wide range of problem behaviors (e.g. alcohol and other drug use), with a typical goal of identifying a real or possible problem and motivating

the individual to take steps to change the behavior. These BFIs are delivered by trained interventionists, who provide the recipient personalized information regarding his or her substance use. The source of this feedback is typically an assessment of the behavior of interest. The complexity of this assessment varies as some assess only basic information (e.g. quantity and frequency of drinking), while others may also include problems and beliefs the individual may have related to their addictive behavior. Other BFIs may include laboratory analysis of blood or urine to evaluate the individual's health (e.g. liver damage).

BFIs can be confused with minimal interventions due to their shared emphasis on limited contact with the individual. Minimal interventions are defined as consisting of one contact with the individual, resulting in a therapeutic effect, which can be as short as 5 min. These treatments are usually based on self-help principles, and in some minimal interventions there is no face-to-face contact with a therapist: bibliotherapy (the use of books or written materials to address a behavioral or emotional problem) is an example. Minimal interventions have also been called "simple" or "brief" advice because it prescribes a certain change, yet does not specify a specific way to achieve this objective. In contrast, BFIs provide specific information regarding the behavior of interest as well as recommendations and strategies for change.

THE DEVELOPMENT OF BRIEF FEEDBACK-FOCUSED INTERVENTIONS

Over the past 30 years, BFIs have emerged as a promising option for reducing addictive behaviors. For example, such interventions have been used in the treatment of heroin addiction, helping individuals quit smoking, promoting cardiovascular health. Brief interventions have been used extensively in the treatment of alcohol abuse, with clients ranging from adolescent to elderly.

Since 1980, the World Health Organization (WHO) has been developing and implementing BFIs for individuals experiencing problems with alcohol. These efforts began with the recognition that there was not an efficient way to identify individuals who were experiencing a problem with alcohol. Therefore, Phase I of the WHO Collaborative Project in Identification and Treatment of Persons with Harmful Alcohol Consumption began in 1982, and led to the development of the Alcohol Use Disorders Identification Test (AUDIT). The AUDIT was developed to identify individuals who could benefit from a BFI in primary care settings. Phase II consisted of implementing a randomized

clinical trial implementing screening and BFI in primary health care settings, and Phase III focused on identifying the barriers to the widespread adoption of the BFI by general practitioners. Phase IV, currently underway, is to develop and implement strategies that would successfully implement the BFI in primary care settings in 13 countries around the world.

The Drinker's Check-Up (DCU) represents one of the first applications of administering BFIs in the general population. Advertisements were placed in newspapers and on a college campus that described the check-up as follows: "The check-up is not part of any treatment program, and it is not intended for alcoholics. Rather, it is an informal health service. Participants will not be labeled or diagnosed, and consultation is completely confidential. Objective personal feedback of results will be provided. It is up to the participant to determine what, if anything, to do about the feedback received." Individuals who responded to the advertisements were given the DCU, which consisted of a 2-h assessment followed by a 1-h feedback session. The assessment component consisted of measures that evaluated the quantity and frequency of alcohol consumption, blood tests designed to detect alcohol-related liver damage, and neuropsychological tests that were sensitive to drinking-related impairment. At a later date, the results of these tests were then provided to the individual in an empathetic, nonjudgmental way. Then, the participant was asked to discuss his or her feelings about the assessment results. Finally, the interviewer discussed possible change options with the participant.

The feedback interview in the DCU was done in the style known as motivational interviewing (MI). Such an interview approach is defined as a counseling style that is both client centered and directive and seeks to explore and resolve the client's ambivalence about engaging in a particular behavior. This exploration and resolution of ambivalence is done by the individual and not the interviewer, fostering a greater awareness of his or her problems with alcohol and the need to change. The interviewer's role is to listen and provide the necessary information and advice regarding the changes the client feels is needed. Above all, the interviewer takes care to avoid confrontation, a style that has been observed to result in client resistance and even increase in drinking.

ROLE IN OVERALL TREATMENT

In the context of the continuum of prevention developed by the Institute of Medicine in 2004, BFIs are typically used as a selective and indicated prevention strategy. Selective prevention targets individuals who are at risk for developing the problem behavior

(e.g. substance use). Indicated prevention efforts are appropriate for those who are already experiencing harm from the target behavior (e.g. individuals who are experiencing alcohol-related problems). In contrast, universal prevention efforts are provided to the entire population, and tend to be more didactic in nature and may not include the personalized feedback provided in BFIs. Furthermore, BFIs are not intended as a standalone treatment for individuals exhibiting alcohol dependence. Although these individuals may significantly change their alcohol use following a BFI, often the desired outcome is engagement in more intensive treatment.

GOALS OF BFIs

The nature of the outcome goal may play a role in the success of brief interventions. Recent BFIs, such as those conducted with college students, tend not to present abstinence as the only acceptable option. Rather, they reflect an approach more oriented toward raising the awareness of students about their drinking habits and the potential risks associated with it. This approach, identified as harm reduction, has become the focus of the majority of BFIs regardless of the target population (adults, college students, adolescents). This flexibility has been spurred by research indicating that a mandatory goal of abstinence may not be very productive for several reasons. First, the majority of individuals may not view themselves as problem drinkers, and may view abstinence as too drastic a response to their drinking, where instead, moderation of their drinking may be more appealing. Second, the limited contact the interventionist has with the BFI recipient may make it more productive to view abstinence as an ideal outcome but not as a necessary result of brief interventions. Third, long-term follow-ups of traditional alcohol treatment programs indicate that a goal of abstinence following an intervention may not be realistic. Research with adult drinkers indicates that about a third of the participants remained abstinent after 1 year; 4 years after treatment, less than 10% have remained abstinent.

For these reasons, many BFIs often adopt a harm reduction approach. Any movement of an individual on this continuum that reduces the amount of alcohol one consumes (and concordantly reduces the risk of negative consequences as a result of their drinking) is seen as a desirable result. This approach has been used with a number of addictive behaviors ranging from alcohol and drug use to gambling and has influenced several college drinking reduction efforts. An intervention approach that promotes moderate and responsible drinking may be received more positively by the

individual, and may in fact help to reduce the more problematic consequences of the targeted behavior.

A harm reduction approach is not without controversy, however, especially if the behavior is risky even in moderation (e.g. IV drug use) or illegal (e.g. underage drinking and smoking). In these situations, there is an ethical trade-off between encouraging a reduction in a risky behavior as opposed to focusing on an abstinence-only goal, which in turn may result in reactance or dismissal from the recipient.

PROPOSED ACTIVE INGREDIENTS OF BFIs

FRAMES

In a seminal article published in 1993, Miller and Sanchez reviewed the literature and developed an acronym to capture six important components of BFIs. These six elements can be remembered by the acronym FRAMES. First, Feedback is given to the client concerning his or her current addictive behavior. This can include such components as comparing individual use with national averages, problems resulting from use, and the harmful effects the behavior has on physical and emotional well being. This information alone can often motivate the client to realize the severity of his or her behavior, resulting in a desire for change. Second, an emphasis is placed on the client's Responsibility for bringing about such changes. The client is told that he or she alone is the one that can bring about desired changes. Third, clear Advice given to the client about how specifically to change one's current behavior can be influential and helpful. This advice may also consist of seeking further, more involved treatment. Fourth, providing a Menu of options for the client to follow is also helpful, instead of prescribing a predetermined or uniform change strategy. This provision of a range of options to decrease one's drinking lets the individual decide which approach is the most realistic. This decision, made by the individual and not the counselor, tends to enhance a commitment to change by one's self-selected method. Fifth, Empathy from the person conveying the information is vital to the process. It helps reduce the suspicion that the counselor may be judgmental, or have a hidden agenda to coerce the client into a form of treatment against his or her will. Confrontational attitudes (e.g. "you have a problem and you are going to listen to me") can often lead to resistance and even increased drinking. The goal of using an empathetic approach is to maintain the client's receptivity to the feedback and avoid defensiveness. A nonconfrontational, empathetic approach is especially important as many individuals are not likely to accept labels such as

alcoholic or problem drinker. Sixth, when a sense of Self-efficacy can be fostered, the client will be much more likely to change his or her behavior. Self-efficacy has been described as a person's belief in one's own ability to succeed in obtaining a certain goal or task. With a sense of self-efficacy, an individual can develop a sense of optimism and hope to change their addictive behavior.

The use of personalized graphic feedback summaries during the brief motivational intervention helps illustrate an individual's drinking behaviors and associated risks as reported in previously collected self-report data. Participants may complete a comprehensive battery of instruments examining the addictive behavior and other risk factors. A personalized feedback form is then created using the participant's most current information related to a summary of behavior, comparison to population drinking norms, risk factors (e.g. family history), cognitive factors (e.g. beliefs about the behavior's effects), and consequences associated with the addictive behavior. The personalized feedback offers an outline and structure for client discussions about current and past behavior. It is believed that providing participants with results from survey data in a graphic form contributes to increased comprehension and retention of material.

MI

Many BFIs are delivered using MI. MI is a therapeutic style of communication that is directive and client centered that facilitates behavior change through the exploration and resolution of ambivalence regarding a specific behavior (e.g. alcohol use). MI has also been described as an approach that combines both style (e.g. empathy) and technique (e.g. reflective listening). Specifically, the interviewer helps the individual explore and resolve ambivalence about reducing one's alcohol use. The interviewer creates an atmosphere of collaboration during the session: the individual is not told what to do. Instead, the interviewer adopts the role of a consultant who listens to and gently directs the individual toward a greater understanding of problems and options for change. It is emphasized that the individual alone is responsible for any changes that are made. Above all, the interviewer avoids being confrontational, a style observed to result in client resistance and even increased drinking. Overall, this gently guided self-evaluation of personal drinking fosters a greater awareness of the individual's problems with alcohol and the need to change. It is possible that the style of the interviewer (expressed empathy, collaboration, etc.) and the individual (e.g. disclosure, cooperation, engagement) may also influence changes that occur following an intervention.

Readiness to Change

Many recipients of BFIs are at risk for problems related to their addictive behaviors but have not looked for information or help for their problem. Individuals may be unaware that their behavior is not typical, and most likely have not sought formal treatment previously. Therefore, any BFI should be adaptable to differing willingness to recognize a drinking problem, a range of severity of problems experienced as a result of drinking, and variable motivation to change.

It has been difficult to specify exactly what process occurs when an individual seeks to change an addictive behavior. The transtheoretical model of behavior change, initially conceptualized in the early 1980s by James Prochaska and Carlo DiClemente, proposes that the individual progresses through five phases, or stages, of change. The stages of change model posit five phases of the change process. First, an individual is in the *pre*contemplation stage when he or she is unaware of any potential problems related to his or her addictive behavior, and as a result see no reason to change. If individuals in this stage are told they have a problem, they will often react with surprise instead of evasiveness and anger. In this stage, others may see the individual as having difficulties, and may urge the individual to seek treatment (family members, concerned friends, employers). The next stage is one of contemplation, where the individual experiences more ambivalence. A student may know that he/she has a problem, but also feels changing current behavior is too drastic a response. The person can see the advantages and disadvantages of either continuing or cutting down on the addictive behavior, and feels ambivalent regarding the two options. At this point, arguments emphasizing the negative consequences of drinking can often drive the individual to defend the benefits of his/her current addictive behavior.

Eventually, the individual may arrive at the realization that he or she has to reduce the current level of use. This can be brought about by a particular event, personal enlightenment, or the BFI. The individual has entered the *preparation* stage, in which a willingness to cut down on the addictive behavior is present. The motivation is there, and there is likely to be some small changes in the behavior – the individual now just needs to take effective action. The next phase is the action stage, when the individual sets about changing the addictive behavior. Once the individual has initiated changes and begins moving toward reducing the addictive behavior, there are two possible paths he or she may take. The first is maintenance of the desired changes can occur. Maintenance is defined as continued commitment to sustaining a new behavior, typically lasting between 6 months or more. During this period, individuals develop a plan for follow-up support, they reinforce internal rewards, and, critical to the continued success of behavior change, they discuss coping with potential relapse. Often during the maintenance stage the integration of family, friends, and other support services is essential to sustained behavior change. The second path after an initial behavior change is a *relapse*. Relapse is identified as resuming old addictive behaviors and can often be the result of a trigger, a lack of motivation to maintain reductions in the addictive behavior, influence by barriers to sustained behavior change, and a lack of strong coping strategies. Once relapse has occurred, the individual may return to the earlier stages (except contemplation).

The benefit of a BFI is that it can provide a flexible mechanism to increase an individual's readiness to change, regardless of the baseline stage occupied. Using heavy drinking as an example, those that are unconcerned about their heavy drinking could benefit from the BFI through raising personal awareness of alcohol-related problems, altering their perceptions of surrounding alcohol norms, and increasing their knowledge about alcohol's effects on their body and mind. Being exposed to such information, especially when presented in a nonconfrontational manner, may move people farther along the stages of change. As for the individuals who recognize that they drink excessively and are prepared to change their alcohol consumption, the goal of the intervention can be to mobilize them into action. The content of their brief intervention can focus on concrete options that help them attain this goal. Therefore, a major advantage of BFIs are their flexibility in dealing with individuals at different levels of readiness to change. For those individuals who are ready to change, this type of intervention may bring about self-initiated reductions in the addictive behavior and related risks. For individuals who are precontemplative or contemplative, the awareness raising may increase their receptivity to change at a later date.

Assessment Reactivity

The simple act of collecting such information may also bring about a change following a BFI. Very often, control group individuals decrease their drinking after being evaluated. This occurs in research with adults as well as college students. Therefore, assessment does not appear to be a neutral event and its influence on alcohol use is not fully understood. In most brief interventions, the information gathered during assessment is presented to the individual in another session, and care is taken to present such material in an empathetic, nonjudgmental way. The assessment feedback is discussed, and options are formulated to reduce alcohol

consumption or otherwise reduce the risk of harm to the individual.

BEHAVIORS ADDRESSED BY BFIs

BFIs have addressed a wide range of addictive behaviors. Perhaps alcohol use has received the most attention, and there have been many BFIs developed for alcohol use, in the adult (e.g. drinker's check-up) and adolescent population. These interventions traditionally use personalized feedback, however, the information provided varies widely (e.g. basic quantity-frequency of the behavior, consequences experienced laboratory results of liver functioning). These interventions have been associated with significant reductions in both alcohol use and alcohol-related problems.

Smoking

BFIs have also been developed for smoking, with feedback topics including costs of smoking, results of carbon dioxide levels in the lungs, and other physical markers related to cigarette use (e.g. genetic susceptibility to cancer). Perceptions about cigarette use (expectancies about use, aspects of smoking that are particularly troubling or enjoyable, motivation to quit) have also been provided in BFIs with smokers.

Gambling

Gambling has been addressed using BFIs with personalized feedback including frequency and time spent gambling, money lost and won while gambling, types of gambling activity, and costs of gambling behaviors (legal, relationships with others). Recent research suggests that these interventions can significantly reduce gambling behaviors and consequences.

Sexual Risk

BFIs have addressed sexual risk behaviors in the context of addictive behaviors and as a multi-risk approach (combined alcohol and sexual risk behaviors) to intervention. Topics of personalized feedback have included frequency and type of protected and unprotected sex, consequences of sexual behaviors, perceptions of sexual risk, expectancies regarding sexual behaviors, and the use of drugs and alcohol while engaging in risky sex. These interventions have been associated with reduction in the occurrence of risky sex and an increase in protective behaviors. To date, however, multi-risk BFIs have had limited success in reducing concurrent risky behaviors.

Other Behaviors

BFIs have been implemented with marijuana use, caffeine use, smokeless tobacco, indoor tanning, and a variety of other addictive behaviors. However, these approaches have been studied much less than BFIs for alcohol use, and their efficacy has yet to be determined.

FEEDBACK CONTENT

Occurrence of Target Behavior

The BFI most often contains a description of the behavior the BFI is targeting. For example, in a BFI addressing alcohol use, the individual's typical and quantity of drinking would be provided (e.g. you reported that in the past month you typically consume alcohol 5 days per week, consuming 3–5 drinks per occasion). A number of other aspects of the behavior may be reported such as peak episodes of consumption, percent days abstinent or using over a certain time frame, or types of alcohol typically consumed.

Personal Problems Associated with Target Behavior

BFIs can also include a section detailing problems related to the target behavior. This section typically consists of two types of problems – problems the individual has already experienced as a result of his/her use (e.g. fights, hangovers), and/or problems that he/she is at risk of experiencing if they continue to use substances (e.g. cancer, death).

Norms

Norms can be conceptualized as a perception of the behaviors and values that are deemed acceptable by members of a group. Two types of norms have been commonly assessed in the addictive behavior research literature: descriptive and injunctive norms. Descriptive norms refer to the perception of other's quantity and frequency of the addictive behavior (the norms of "is") - these are largely based on observations of the addictive behavior. Injunctive norms refer to the perceived approval of the addictive behavior (the norm of "ought"). These norms represent the perceived moral rules of the peer group. Injunctive norms assist an individual to determine what is acceptable and unacceptable social behavior. Both descriptive and injunctive norms have been linked to addictive behaviors, perhaps most extensively to alcohol use in the college setting. Descriptive and injunctive norms have therefore been incorporated most commonly in brief motivational interventions (BMI) with this population. It is hypothesized that when personal alcohol consumption levels, and their approval of drinking, are revealed to be higher than relevant norms, a decrease in alcohol use may be triggered as the individual attempts to conform to the actual, more conservative norm. Indeed, changes in estimates of drinking norms mediated reductions in alcohol use following a BMI.

Alcohol-Related Expectancies

Alcohol expectancies are beliefs about the cognitive, affective, or behavioral effects of alcohol use and can be both positive (e.g. "drinking allows me to relax around others") and negative (e.g. "when I drink, I often say things I regret later"). Expectancies appear to have both etiological and maintaining influences on alcohol use, especially positive expectancies and social/physical pleasure expectancies. Dose-related expectancies have been addressed in "expectancy challenge" interventions with college students. For instance, a person who believes that he/she has to consume four to five beers in an hour to become fully relaxed and sociable is provided information on how certain amounts of alcohol affect one's mood and judgment and how lower blood alcohol levels have corresponding positive effects on mood. In this way, expectancy challenges may prompt one to consume less alcohol without sacrificing the desired and expected positive effects of drinking. Expectancies appear linked to subsequent reduction in alcohol use following expectancy challenges with college students, although they have not yet been formally demonstrated to mediate drinking reductions following a BMI. It is possible that students with fewer positive alcohol expectancies may be more responsive to an intervention addressing their drinking.

Strategies to Reduce Risk

BFIs can often include specific strategies to reduce risk, often linked to the behaviors and consequences the recipient has endorsed. These are often identified as "protective behaviors." For example, if drinking and driving have been endorsed, a provided strategy may be "Always designate a sober driver at the beginning of the evening." Other feedback can endorse specific skills, such as alternating alcoholic drinks with nonalcoholic drinks (alcohol use), staying away from casinos, and not carrying a credit card or checkbook (gambling).

Other Feedback

BFIs have a wide range of topics. For example, over 60 types of feedback have been presented in BFIs

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addressing college student drinking, such as estimated blood alcohol levels, personal motives for drinking, caloric intake, and the financial costs of drinking. Many of these feedback components have been used to address other addictive behaviors (e.g. financial costs of smoking), as well as ones specific to the addictive behavior (e.g. gambling losses). Undoubtedly, more feedback components will be developed through advancements in our and understanding of addictive behaviors.

MODALITIES

Individual

The most common form of BFIs is still one-on-one, in person. In this context, the individual is provided personalized feedback and discusses it with a professional. The content and depth of discussion of these BFIs vary widely.

Group

While group therapy has a long history, group BFIs have a more recent development. Specifically, group BFIs provide the entire group of individuals with information regarding the addictive behavior of interest. Within BFIs delivered to college students surrounding alcohol use, group-based BFIs have been shown to reduce drinking behaviors with students mandated to treatment following a campus alcohol violation. To date, group-based BFIs success has been limited to this specific population; however, similar approaches for other addictive behaviors (gambling, smoking cessation) and other populations (adults, adolescents) are currently being explored. One promising approach that has been implemented is the real-time presentation of normative feedback. Specifically, members of the Greek system used personal digital assistants (PDAs) to provide estimates of their own drinking, that of their peers in the room, and of the typical student on campus. The students type in their estimates on the PDA and then the results of this survey are displayed immediately to the group. As a result, the students were able to see the accuracy of the estimates they had made seconds before regarding the drinking behaviors and approval of drinking of the individuals in the room with them. Reductions of both normative perceptions and alcohol use have been observed following this BFI in members of the Greek system. However, this innovative approach has yet to be implemented in other populations.

Mailed

In the early days of BFIs, personalized feedback forms were mailed to individuals via standard mail and the content of the feedback was discussed via telephone. However, given the advances in the Internet and concerns regarding confidentiality (e.g. someone else opening the mail), email and the use of encrypted files (which can only be opened by the intended recipient) have become much more common. Usually, these interventions have contact numbers to call to discuss the provided information or to engage in formal treatment for the behavior addressed.

Internet

In the past 10 years, there has been a considerable increase in websites that can generate personalized feedback regarding a variety of behaviors, ranging from alcohol use, marijuana use, to eating habits. These websites simply require the individual to provide personal information about their current drinking and/or other drug use behaviors. Once information is entered, a personalized web-based feedback is immediately generated offering concrete information use patterns, risk profiles, and consequences of current use. The information presented is similar to what is created for oneon-one, in person BFIs, however, no face-to-face meeting occurs and the individual views the information independently. Early research suggests this approach has some benefits with high-risk drinking populations (e.g. first-year college students).

Peer-Based Intervention Approaches

Peer-based intervention and education programs have been found to be effective in creating behavior change in college students for a variety of behaviors (e.g. safe sex, alcohol and drug use). It is possible that students relate better to peers than to older adults, peer-delivered programs have a stronger influence on students' attitudes and behavior, and using upper class students to implement substance abuse programs may be effective for first-year students. More recently, a trend toward incorporating peer counseling into alcohol interventions has led to new applications for motivational feedback approaches. A number of studies have examined the use of peer-based techniques to effectively impact drinking behaviors and consequences. Only skills-based group approaches, an education approach based on norms information, and an individually based motivational intervention have been efficacious in reducing alcohol use and consequences. Peer-led BFIs have also been found to be efficacious for enhancing drinking behavior changes. This intervention includes a one-on-one discussion about personal drinking behaviors, accurate normative drinking information with comparisons to perceived normative beliefs, negative consequences, and information on drinking reduction techniques.

POPULATIONS

Adolescents

A range of BFIs for adolescent populations have been tested to reduce and eliminate harmful behaviors associated with substance use. Specifically, in person BFIs, family-based BFIs, and parent-based BFIs. Each approach works toward the goal of reducing harms associated with substance use.

College Students

As a reaction to high levels of alcohol use and associated negative consequences among college students, various BFIs aimed at reducing harm and high-risk drinking behaviors have been developed. Specifically, BFIs with peers and professional counselors, personal feedback (mailed or computerized) on drinking behaviors, group-based education and/or motivation feedback classes, and expectancy challenge based interventions have all been evaluated in recent years.

Noncollege Adults

Community samples, including those recruited from hospital emergency departments, in- and out-patient psychiatric hospitals, and general community members have also been the target population for a range of BFIs. These have been delivered in person, via telephone, and web-based with general success in reducing harmful behaviors.

SUMMARY

BFIs have been implemented in a wide range of settings due to their ability to address a wide variety of behaviors. Research supports their efficacy, although further work is needed to better understand exactly how individual behavior change is facilitated. Furthermore, the different types of feedback that can be provided in the context of a BFI has increased exponentially as a result of ongoing dissemination efforts addressing different behaviors and populations. Advances in research have also led to innovative feedback topics such as genetic susceptibility to alcoholism and smoking, as well as more sophisticated presentation delivery

methods (e.g. via web or video). In sum, the combination of empirical support, improved understanding of how BFIs can bring about change in recipients, increased dissemination efforts, and ongoing innovation regarding the content and presentation of feedback topics have ensured a central role of BFIs in future prevention and intervention efforts addressing addictive behaviors.

List of Abbreviations

AUDIT Alcohol Use Disorders Identification Test

BMI brief motivational interventions

DCU Drinker's Check-UpPDA personal digital assistantWHO World Health Organization

Glossary

Brief feedback-focused Interventions (BFI) an interaction addressing an addictive behavior lasting typically from 15 min to an hour in duration.

Feedback verbal or written information regarding the addictive behavior that is provided and discussed during a BFI.

Motivational interviewing (MI) a counseling style that is both client centered and directive and seeks to explore and resolve the client's ambivalence about engaging in a particular behavior.

Norms a perception of the prevalence of addictive behaviors (descriptive norms) and approval of these behaviors (injunctive norms) by members of a group.

Transtheoretical model a theoretical conceptualization of the process the individual undergoes when attempting to reduce or cease an addictive behavior (stages of change).

Further Reading

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FURTHER READING 11

Relevant Websites

http://notes.camh.net/efeed.nsf/feedback – Centre for Addiction and Mental Health, Personalised Alcohol Use Feedback.

http://pubs.niaaa.nih.gov/publications/aa66/aa66.htm – National Institute on Alcohol Abuse.

http://nrepp.samhsa.gov/ViewIntervention.aspx?id=14 - SAMH-SA's National Registry of Evidence-Based Programs and Practices (NREPP).

http://www.echeckuptogo.com/usa/ – The electronic CHECKUP TO GO, an on-line alcohol intervention and social norming program developed by San Diego State University.

http://www.who.int/substance_abuse/activities/sbi/en/index. html# – Wealth Health Organisation, substance abuse activities. 2

Motivational Enhancement Approaches

Steve Martino

Yale University School of Medicine and VA Connecticut Healthcare System, West Haven, CT, USA

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INTRODUCTION

Enhancement of an individual's motivation to change is an important component of interventions for addictive behaviors. People who believe they have alcohol or drug use problems and commit to changing them are more likely to engage in treatment and have outcomes. Motivational enhancement improved approaches for substance-use disorders have become increasingly popular during the past two decades. Foremost among them is motivational interviewing (MI) developed by William Miller and Stephen Rollnick. This chapter describes what MI is and is not, its basic principles and techniques, empirical support, applications to areas likely to co-occur with addictions, how to learn MI, dissemination of the approach, and future research directions.

WHAT IS MOTIVATIONAL INTERVIEWING?

Miller and Rollnick have defined MI as a personcentered counseling method for eliciting and strengthening personal motivation for change. The approach is grounded in humanistic psychology, especially the work of Carl Rogers, in that it employs a very empathic, nonjudgmental style of interacting with peoples and presumes that the potential for change lies within everyone. MI is distinct from nondirective approaches, however, in that practitioners intentionally attend to and selectively reinforce people's motives that support change. Over the course of the interview, practitioners help people identify these change-oriented motives, elaborate upon them, and resolve ambivalence about change. If successful, people become more likely to commit to changing their behaviors and initiating a change plan.

The process of enhancing motivation in MI can be thought of as having two different phases. The first phase involves building motivation for change. In this phase, practitioners work with people to understand and resolve their resistance to change and develop their sense of the importance and perceived ability to change. When people show signs of readiness to change (e.g. reasons for change are prominent, they ask for advice or direction, they state their intention to change), practitioners shift to the second phase of motivational enhancement in which they work toward strengthening commitment to change, most often through the development of a change plan (described below). This process activates or mobilizes people's motivations in that individuals identify how they will try to change and begin to enact these steps to reduce or stop their addictive behaviors.

Skilled practitioners try to match their use of MI strategies to the individual's level of motivation. For example, practitioners move more quickly to change planning with people who are already motivated to change. Extensive exploration of their motives for change might frustrate people who want to move forward. In contrast, attempting to develop change plans with people who are not yet committed to change will likely increase resistance in that this strategy would put people in a position in which they might assert in words or in actions how they are not yet ready. This latter interaction illustrates how motives to change (called "change talk") and motives to stay the same (called "sustain talk") can be thought of as opposite sides of the same coin, meaning that if practitioners give insufficient attention to addressing important issues that impede change, people are likely to raise these issues again during the interview. Concomitantly, practitioners expect people who initially argue against change to have some intrinsic motivation for change within them. It is the responsibility of the practitioners to look for opportunities to draw it out.

MI is best construed as a style of communication that informs the way in which practitioners interact with others throughout the change process. In this regard, MI often is discussed within the context of the stages of change model by James Prochaska and Carlo DiClemente. The stage of change model posits that behavior change occurs sequentially across recurring stages. The earlier stages include precontemplation (people are unaware or do not believe there is a problem or need to change it), contemplation (people are ambivalent about recognizing a problem and shy away from changing it), and preparation (people are ready to work toward behavior change in the near future and develop a plan for change). The later stages include

action (people consistently make specific changes) and maintenance (people work to maintain and sustain long-lasting change). Tailoring treatment strategies to achieve stage-related tasks is a hallmark of this model (e.g. conducting a cost-benefit analysis for someone contemplating change).

MI naturally fits into the stage of change model in that it can be used to help move people from one stage to another, especially in the early stages. Person-centered counseling skills may build rapport and engage people who are less motivated to change. Eliciting additional change talk might lead ambivalent individuals to conclude it is relatively worth it for them to change rather than to keep drinking or using drugs. Working with people to identify steps they are able to take might help them feel more prepared to initiate a change plan. In later stages, MI strategies are useful for attending to wavering motivation as people take action or try to maintain changes in stressful situations. Finally, the stages of change model illustrates how MI integrates well with other treatment approaches that are more action-oriented. For example, MI might be used to engage people in treatment that then teaches them relapse prevention skills. The combining of MI with more action-oriented treatments, such as cognitive behavioral therapy, is becoming more prevalent.

MI emerged out of early efforts to establish brief interventions for alcohol problems. These interventions shared a harm reduction approach in that they aimed to help people move toward reduced drinking to lower risks rather than to automatically advocate for total abstinence as the only acceptable goal. Common components of these brief interventions, as represented in a FRAMES acronym, were Feedback, emphasis on personal Responsibility, Advice, a Menu of options, an Empathic counseling style, and support for Self-efficacy. With FRAMES as a guidepost, William Miller and his colleagues developed the "drinker's checkup" in which people received feedback about their drinking relative to population or clinical norms and then explored what it might suggest about their drinking and motivation for reducing or stopping it. Early studies found the drinker's checkup to be quite effective. Given this success, MI with personalized assessment feedback then became adapted into a more structured and manualized format and termed motivational enhancement therapy (MET). The efficacy of MET, compared to cognitive behavior therapy and 12-step facilitation, for alcohol-dependent adults, subsequently was tested in a large-scale, multi-site study conducted in the United States called Project MATCH. MET was found to be as effective as the other treatments overall, though it achieved these effects using fewer treatment sessions.

Finally, as implied in the above discussion, MI is behaviorally specific and has direction. This means

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that practitioners need to be clear about what it is that they are trying to motivate people for. Motivation for change in one area does not guarantee motivation for change in another (e.g. a person may commit to cocaine abstinence, but not agree to reduce or stop drinking or smoking marijuana or to enter an addiction treatment program). Each behavior may require a separate motivational enhancement process. MI also requires that practitioners take a stance about the preferred direction for change. For addictive behaviors, this decision is relatively clear in that most people would agree that it is ethically sound to enhance motivation for the reduction or cessation of substances that are potentially harmful or hazardous. However, some behavioral issues do not have a clear change direction. For example, decisions about organ donation or pregnancy termination likely would require a nondirective approach in which practitioners suspend their own values or goals and assume a position of "equipoise" (i.e. indifference or no clear attachment to a position or recommendation). In these situations, a person-centered counseling approach, devoid of evocation, would allow people to explore their ambivalence without intentional practitioner influence.

WHAT IS NOT MOTIVATIONAL INTERVIEWING?

For clarification purposes, it is helpful to consider what MI is not. Most antithetical to MI is a disease concept model of addiction in which individuals are seen as denying or rationalizing their addictive behaviors and needing to "hit bottom" before they will change. The use of direct confrontation, surrendering and accepting one's powerlessness and loss of control in the face of addiction, and emphasis on total abstinence as the only acceptable goal are hallmarks of this approach and quite inconsistent with MI. Less obvious are several common misconceptions about MI. As noted above, MI is not based on the stages of change model, though it is complementary to it. Stages of change is more of a comprehensive way of thinking about how people change, whereas MI is a clinical method that helps people prepare for change. Likewise, MI is not cognitive behavioral therapy. The latter approach supplies people with education and coping skill development and encourages the repeated practice of these skills to better manage their problems. MI is fundamentally humanistic, not behavioral, in origin in that it elicits the people's motivations for change rather than putting in place what is missing (knowledge and skills). MI also is not a way of manipulating others or making them change when they do not want to. Behavior change in MI is born out of a person's intrinsic motivations. Practitioners can only call forth motivations that already

exist within people, not impose upon them other people's concerns or wishes when individuals do not see these issues as in their best interests. Finally, MI does not require that practitioners conduct a decisional balance or provide personalized feedback. These are techniques that often are helpful for eliciting change talk, but they are not essential to the conduct of MI, and they often are used in other treatment approaches. In this regard, MI is not a series of techniques, but rather a way of being with people in which principles organize the practice, as Miller and Rollnick put it, like music to words of a song.

PRINCIPLES

Four key principles, embodied in the REDS (rolling with resistance, express empathy, develop discrepancy, support self-efficacy) acronym, compose the manner in which practitioners interact with people when using MI.

Roll with Resistance

Resistance in MI traditionally has referred to people's statements about what sustains their problematic behaviors. These expressions may be about the reasons for the behaviors ("Drinking relaxes me") or the difficulties of trying to change them ("I can't resist the urge to smoke"). Resistance informs practitioners about dilemmas faced by individuals, thereby providing opportunities for addressing obstacles to change. Practitioners avoid adopting a confrontational, authoritative, warning, or threatening tone (all inconsistent with MI), which might cause others to become even less engaged in treatment.

Express Empathy

Practitioners attempt to accurately understand people's dilemmas without judgment or criticism. Being able to listen carefully to what people mean and reflect this back to them is a critical skill. People are more likely to explore their motivations for change and speak candidly when they feel comfortable with and understood by their practitioners.

Develop Discrepancy

Motivation for change often depends on the existence of a discrepancy between an individual's current behavior and important values or goals. For example, a teacher who prides herself in being a positive role model for her students might stop smoking marijuana if she believes this behavior is discrepant with what she would want her students to know about her. In MI, practitioners reflect these discrepancies and explore how behavior change might help people feel they are acting in accordance with their preferred selfperceptions and aims.

Support Self-Efficacy

People typically become more motivated when they believe they can change their behavior. When people lack confidence, they often shy away from change. Practitioners look for opportunities to support people's self-efficacy by helping them recognize their personal strengths and available resources. Likewise, they pay attention to people's past successful change efforts, which might inform how these individuals approach their current dilemmas.

By embracing these principles, practitioners adopt a style of interaction, that is, (1) collaborative by demonstrating respect for people's ideas and goals and seeing others as equal partners in the therapeutic process, (2) evocative by intentionally searching for the people's motives that favor change, and (3) supportive of people's autonomy and capacity to make decisions and initiate change. These three components embody the spirit of how practitioners interact with others (formally referred to MI spirit in this approach).

TECHNIQUES

While MI is more of a style or spirit of being with others based on the above principles rather than a mere application of techniques, MI incorporates several techniques that operationalize how practitioners use MI. These techniques include fundamental strategies, sometimes called microskills (open questions, affirmations, reflections, and summaries), and direct methods for evoking change talk. Practitioners attend to the balance of statements made by people that support or thwart behavior change (i.e. change versus sustain talk) to gauge individuals' level of motivation and adjust their use of MI techniques accordingly. Practitioners' capacities to recognize and elicit change talk and reduce sustain talk through the use of these techniques, with the aim of strengthening people's commitment to change, are seen as necessary elements in MI.

Fundamental Strategies

Open questions, affirmations, reflections, and summaries (OARS) are the mainstay of all MI sessions. In particular, MI relies heavily on the skilled use of reflective listening in which practitioners restate or paraphrase their understanding of what people have said to express empathy, as well as to bring attention to

ambivalence, highlight change talk, and explore and lessen resistance. Reflections are coined "simple" in MI when practitioners essentially repeat what others have said and "complex" when practitioners have articulated new meaning implied by the original statements. Complex reflections demonstrate a deeper understanding of people's experiences. For example, a person concerned about her HIV status says, "I've played around a bit in the past several months, but last year when I had a HIV test, I was negative." A practitioner could use a simple reflection to encourage more discussion about her risk behavior ("You've played around a bit"). A complex reflection would capture her implied concern and show more empathy ("You're a little worried that you have put yourself at risk for HIV").

Open questions encourage people to talk more and may be used to strategically draw out motivations for change (e.g. "What would be good about not smoking?"). They stand in contrast to closed questions, in which, practitioners seek specific information (e.g. demographics, history, symptoms), often with questions that can be answered with a "yes" or a "no" response. For example, a practitioner might ask, "Has your depression worsened with your crystal meth use?" A person's positive response would support not using crystal methamphetamine; however, he or she would not have fully elaborated on the negative effects of depression resulting from drug use, which an open question might have elicited (e.g. How has using crystal meth negatively impacted your depression?). Affirmations (i.e. acknowledgment of a person's strengths, attitudes, and efforts that promote behavior change) build collaboration between practitioners and others and promote self-efficacy. Sometimes, this entails reframing a behavior in a manner that helps people see it in a more positive light (e.g. "You were quite determined to get high, and now you are trying to use that same determination to stop using cocaine").

Summaries provide opportunities for practitioners to demonstrate fuller understanding of other people's experiences and help them consider the bigger picture of their motivations for change. Summaries also allow practitioners to collect multiple change talk statements as a strategy to enhance motivation, link discrepant statements that capture ambivalence, and shift focus to other behavioral areas (e.g. move from discussing drinking to prescription opiate use). The following is an example of a collection summary of change talk: "You're concerned that you have been taking more pain meds than you are prescribed, and you've noticed you need more pills to get the same effect. You feel badly about going to a doctor other than your primary care physician to get percocet when you ran out. Most importantly, you almost fell asleep at the wheel last week with your kid in the car, and you think that this literally is TECHNIQUES 17

your wake-up call to do something about this problem before something terrible happens to you and others."

Direct Methods

Direct methods for evoking change talk hinge on the capacity of practitioners to recognize how people talk about change. Practitioners' selection of direct methods for motivational enhancement depends on the type and strength of change talk provided by people as the interview unfolds. Hence, an individual's statements continuously signal the practitioner about how to conduct the interview.

Change talk is embodied in the acronym DARN-CAT (desire, ability, reasons, need, commitment, activation, taking steps). DARN (desire, ability, reasons, need) is sometimes referred to as preparatory language in that these statements represent the building of motivation that prepares people to make a commitment to change (consistent with the first phase of motivational enhancement). Desire statements indicate a clear wish for change ("I don't want my liver disease to get worse" or "I want to get my life back"). Ability statements indicate people's beliefs that they can change, given their skills and available resources ("I was able to stop using speed 5 years ago, so maybe I have a chance now"). Reason statements note the benefits of change and the costs of not changing ("I will have more money in my pocket" or "If I don't stop, I will go more in debt"). Need statements underscore how the problem behavior interferes with important areas of an individual's life and how changing the behavior would likely improve matters ("I don't even recognize myself; I can't go on like this anymore").

CAT (commitment, activation, taking steps) represents statements that suggest people are mobilizing themselves for change (consistent with the second phase of motivational enhancement). Commitment statements convey the stated intention to change ("My quit date will be this Thursday"). Activation statements indicate how people are getting ready to change ("I am going to an AA meeting tonight"). Statements about taking steps to change are the strongest demonstration of commitment in that the people have put their words into action and are reporting these early efforts to the practitioner ("Instead of going out to drink after work, I went to the gym and worked out").

During the interview, practitioners identify the extent to which people express motivation in each of these areas, use their fundamental skills to support and develop people's change talk and have them elaborate further, and in a goal-oriented fashion, directly attempt to draw out more motivations for change. MI offers multiple techniques for these purposes. For example, people who consistently report obstacles to being able to stop smoking marijuana might be asked about past

periods when they have smoked less marijuana or none at all (appealing to past successes to enhance ability). People who do not express much concern about their current levels of drug use might be asked to look to the future at some time interval (e.g. 1 year from now) and consider where their lives might be headed with continued use (attempting to reveal potential reasons or need to change to enhance the importance of change). Alternatively, a practitioner could ask someone to rate how important it would be to reduce or stop drug use on an 11-point scale, with zero representing "not at all important" and ten representing "extremely important." Providing this person gives a response higher than zero, the practitioner would follow-up by asking, "Why not lower, like a zero?" to elicit what lends some importance to changing drug use now.

Other Useful Techniques

Addiction treatment typically requires simultaneous attention to several behavioral issues (e.g. multiple substance, HIV risk behaviors, psychiatric, and health concerns), and this reality often is overwhelming to people and their practitioners during any one appointment where time is limited. Practitioners can use a simple agenda setting chart in which they record the pertinent behavior change issues on paper and have people indicate which of them they want to discuss during the interview. These priorities are then dovetailed with any pressing practitioner concerns as a means to organize the conversation.

Education, advice-giving, and direction are commonplace in the addiction treatment, particularly because practitioners often have a natural tendency to try to fix people's problems (referred to as the "righting reflex"). When people have not solicited professional input, however, they may not be receptive to it. Instead, practitioners ask permission to provide information or advice and employ an elicit-provide-elicit (or ask-tell-ask) technique in which practitioners (1) elicit from people what they know about the topic being discussed, (2) provide information as needed, and (3) elicit people's reactions to the shared information. For example, a practitioner may wish to recommend a treatment program to someone. Instead of providing the recommendation in an unsolicited manner, the practitioner would first ask the person what he or she knows about the program and then, with permission, talks about it and concludes by getting the person's reaction. This technique promotes collaboration and reduces the chance that people experience their practitioners as lecturing or telling them what to do.

Use of a decisional balance activity (i.e. exploring the costs and benefits of changing and not changing) is common in MI. This activity provides a structured method for understanding the basis of a person's

ambivalence in that the benefits of change ("I'll have more money if I get a job") and the costs of not changing ("If I don't seek employment, I will feel like I have given up on myself") provide reasons to change, whereas the benefits of not changing (I don't have to present myself in an interview") and the costs of changing ("I don't have transportation") provide reasons to remain the same. By strategically eliciting more reasons for change and, to the extent possible, resolving reasons to remain the same (e.g. practice interviewing, resolving transportation issues), a practitioner might help the person tip the balance toward change.

Another important skill is how to gauge patients' readiness to change and to transition from the first to second phase of motivational enhancement. Practitioners typically recapitulate what others have said, especially those statements that suggest how they are now ready to change. Following this summary, practitioners then pose a key question to solidify commitment to change ("What's your next step?" or "From what you've told me, how do you want to proceed?"). Miller and Rollnick have used the analogy of a person as a skier standing at the summit (assisted up the mountain by the practitioner). The key question provides a supportive nudge that helps the person go down the mountain.

Change planning is an overall strategy practitioners use to negotiate a plan with people about how they will change their behavior. Critical to this process is maintaining a person-centered stance in which the plan is derived by the individual, with the assistance of the practitioner, rather than the practitioner becoming prescriptive at this point. Practitioners ask people to set their targeted behavior change goal ("I am going to stop using heroin"), describe steps they will take to change ("I want to try buprenorphine", "I need your help to get PTSD counseling"), identify who might support them and how ("I am going to stay with my parents"), anticipate obstacles ("I have to change my cell phone number to keep people from calling me"), and reaffirm their commitment to the plan. If during the process of mobilizing their commitment people become uncertain again (the cold-feet phenomenon), the practitioner reflects this ambivalence rather than trying to press through it and provides another opportunity to revisit the plan in the current session or at another time. Being in a hurry to complete the plan when people are not ready is a common trap into which practitioners fall.

HANDLING RESISTANCE

Changing addictive behaviors is difficult for several reasons. People may like the effects of drinking or using drugs. They may be involved with others who use substances. People may feel unable to manage their urges to drink, smoke, or get high. They may not see their lives improving in the absence of alcohol or drug use. Moreover, they may have obstacles (transportation, financial, child care, safety concerns) that impede their treatment involvement. These issues may sustain people's addictive behaviors, and practitioners must attend to them in an MI consistent manner, rather than with confrontation or warning, when people raise them.

Some strategies for handling resistance include (1) simply reflecting the resistance to buy time or better understand the issue ("You don't believe you have any problems even though others do" in response to a person who says, "I don't care what everyone else thinks; I don't have any problems"); (2) amplified reflections to determine the degree of commitment to a resistant statement ("Your wife has no basis for concern about your drinking" in response to a person who complains how his wife needs to stop bothering him about his drinking); and (3) double-sided reflections to pair the resistant statement with other things said that favor change, thereby introducing some ambivalence back into the conversation ("You feel like dropping out of the program, and you worry that you won't be able to remain drug free without it"). These strategies are delivered with an attitude of genuine interest, not sarcasm or manipulation, and of seeing resistance as a natural part of the change process.

It is also useful to make a distinction between sustain talk and more contemporary notions of resistance in MI. Sustain talk is the stated motive to not change behavior. Resistance is the interpersonal style in which people interact with practitioners that conveys tension or trouble in the relationship (e.g. arguing, interrupting, negating, dismissing, ignoring). Often sustain talk and resistance occur together. However, this is not necessarily the case and could lead to missed opportunities for motivational enhancement. For example, a person who says he is willing to drink less might become quiet when a practitioner warns him about the hazards of drinking any amount of alcohol. The person initially provided change talk, but his interpersonal style is now marked by resistance. The practitioner might mistakenly assume the person is unmotivated for change even though the person has indicated a desire to reduce his quantity or frequency of drinking. A more empathic practitioner stance that supported and reinforced change talk, rather than a cautionary one, would have been preferable (e.g. "How come you think drinking less would be better for you?").

EMPIRICAL SUPPORT

Several reviews of the large body of MI research have come to some conclusions about how well MI works across a wide range of problem areas (e.g. alcohol, tobacco, illicit drugs, gambling, diet/exercise, treatment adherence/engagement). The most recent review was conducted by Brad Lundahl and his colleagues. It included 119 studies that isolated the unique effect of MI on treatment outcomes. They showed that across problem areas MI exerted small yet clinically significant effects, consistent with effects produced by other behavior change interventions but in less time. MI also significantly increased people's treatment engagement. The effects were durable, lasting up to 1 year. Specific to substance use problems, the evidence suggested that compared to other wellestablished addiction treatments, MI was as effective for treating problematic drinking, marijuana dependence, and other drugs (e.g. cocaine and heroin) and less effective for promoting tobacco cessation. MI used in its basic form seemed to work best as a pretreatment intervention to prepare people for more intensive treatment, whereas MET (manualized MI with personalized feedback) worked best as a stand-alone treatment.

Studies examining how MI works have supported the underlying theory of MI. Miller and Rose provide a helpful summary of this literature. In brief, these studies have shown that practitioners who adhere to MI are more likely to elicit change talk in others, whereas those who are MI nonadherent experience corresponding increases in resistant statements. Studies vary in the degree to which the presence of commitment language, or the strength of it, is uniquely predictive or whether the mere accumulation of change talk across categories per se is most essential. Nonetheless, people with increased in-session change talk have improved treatment outcomes (e.g. drinking, drug use, gambling) over the subsequent follow-up periods of up to 1 year. Terri Moyers and her colleagues have documented how MI consistent interventions cause increased change talk in others which in turn mediates outcome. These findings underscore the importance of practitioners selectively eliciting and reinforcing change talk when conducting MI.

OTHER APPLICATIONS

The empirical base of MI and the ubiquitous nature of motivational issues as part of most behavior change efforts have created substantial interest and broad application of MI into many areas other than addictions. Of particular interest to the addiction field is the integration of MI into the treatment of psychological (e.g. depression, anxiety, or psychosis) and health-related behavior problems (e.g. diet, exercise, or risky behavior), both areas of high comorbidity for people with substance use disorders. Extensive reviews of this literature and

demonstrations of these kinds of clinical applications are now available. Moreover, given that many offenders are adjudicated on drug-related crimes, the corrections field has become increasingly interested in applying MI to rehabilitate offenders. Many parole and probation officers and other correction professionals are now learning how to use MI to interact with offenders at all stages of legal supervision. Empirical evidence for the use of MI for these new applications awaits controlled clinical research.

LEARNING MOTIVATIONAL INTERVIEWING

A variety of training resources exist to learn MI. These resources include textbooks, treatment manuals, training videotapes, a supervision toolkit, and an international training group called the Motivational Interviewing Network of Trainers.

Literature on how to train practitioners in MI is emerging. The most popular approach has been the use of several day workshops. Research on the effectiveness of MI workshops (expert facilitated didactics and skill-building activities delivered in a group format) shows practitioners consistently improve their attitudes, knowledge, and confidence in MI, but immediate skill gains resulting from the training diminish within a few months.

Clinical supervision that includes direct observation of practitioners' sessions (via audio recordings), use of treatment integrity rating-based performance feedback, and individualized coaching has been shown to be more effective in improving practitioners' MI skills when it is used at least monthly for 3-4 months following workshop training. Several practitioner performance rating scales are now available that can be used to reliably supervise MI practice in this manner. This approach to supervision is particularly important given that practitioners typically evaluate their performance more positively than when the same sessions are reviewed by their supervisors or independent judges. Moreover, in the absence of supervision in MI, practitioners may be more prone to initiate informal discussions (i.e. chat) about matters that are unrelated to their patients' treatment. Careful training and supervision in MI may help practitioners better adhere to the approach.

Even with supervision, practitioners will vary in their capacity to learn MI and their performance may vacillate under different clinical circumstances posed by the people they treat or by the settings in which they work. For example, Miller has speculated that a minimum level of pretraining empathic abilities might be necessary for practitioners to learn MI. Screening

practitioners for their capacity to demonstrate empathy might be useful when making judgments about who to train or hire if the intention is to have these practitioners use MI.

Characteristics of people may also affect the proficiency with which practitioners use MI. For example, people who are most resistant to change likely make the application of MI more difficult. The organizational context of treatment programs (e.g. institutional resources, staff attributes and stability, and organizational climate and philosophical consistency with MI) also may affect the extent to which practitioners learn MI. One study by John Baer and colleagues found that practitioners showed the greatest gains in MI skills when they worked within programs they felt were more open to change and less supportive of practitioners functioning completely independently within the agency. Organizational factors likely can help or hinder practitioners' efforts to learn and use MI.

Finally, learning MI may require that practitioners sequentially build their skills in different stages. Miller and Moyers proposed eight stages for learning MI. First, practitioners need to develop openness to the spirit of MI such that they grasp the overriding philosophy of the approach (stage 1). Next, they must master the patient-centered counseling skills embodied in the OARS (stage 2), the foundation from which they then learn how to recognize and reinforce change talk (stage 3). Practitioners then learn strategies for evoking change talk (stage 4), rolling with resistance (stage 5), and developing a change plan (stage 6). Training in consolidating and strengthening commitment comes next (stage 7). If MI is to be used with other treatment approaches, learning how to switch between the methods or integrate MI into other practices is the last stage (stage 8). Practitioners may vary in the sequence and degree to which they learn the skills embedded within each stage. Nonetheless, the stages of learning MI imply a training progression that might be used to organize the design of training programs. Moreover, they suggest that MI involves a complex set of skills that practitioners must use flexibly and adaptively in response to what people say within sessions.

DISSEMINATION OF MOTIVATIONAL INTERVIEWING

MI has become very popular in the United States and internationally. Single State Authorities throughout the United States and their equivalent bodies in other countries frequently recommend MI as an empirically supported clinical approach they want practitioners to learn. The MI textbook has been translated into at least 22 languages, and there are now MI trainers in

over 40 different countries. It may be that the personcenteredness of the approach and, hence, sensitivity to diverse cultural perspectives that make MI broadly attractive worldwide. Moreover, the number of publications about MI has increased exponentially in the past two decades as well as funded research grants examining applications of MI to a variety of clinical problems and populations.

FUTURE RESEARCH DIRECTIONS

Many questions remain about MI that could be addressed in future research. Given the widespread application of MI, establishing how well MI works with nonaddictive problem behaviors, populations, and varying age groups remains an open question. In particular, the internationalization of MI suggests more study is need about the efficacy of MI with diverse ethnic and cultural groups. The efficacy using MI in modalities other than individual treatment (e.g. group, family, or couples) also has not been established. The relative contributions of the fundamental or personcentered strategies and those used for selectively eliciting and reinforcing change talk to MIs effectiveness remain unclear, including the role of personalized feedback as used in MET. In addition, more work is needed to identify effective strategies for training practitioners in MI, sustaining adequate practitioner performance over time, and linking these training efforts to improved patient outcomes. Finally, innovations in the delivery of MI might make the approach more feasible and acceptable for use in busy clinical settings where it is increasingly being applied. The degree to which MI can be programmed for computer or web-based applications needs to be established.

CONCLUSIONS

MI is a recognized empirically supported treatment for addictive behaviors. It has a clear set of principles and techniques that guide implementation and substantial training resources to prepare practitioners to conduct MI proficiently. The popularity of MI is likely to grow and the field will be challenged to study if and how it works within its new applications and to ensure that practitioners implement it with integrity if it is to improve treatment outcomes.

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FURTHER READING 21

SEE ALSO

Evidence-Based Treatment, Harm Reduction Approaches, Dissemination of Evidence-Based Treatment into Practice, Economic Analysis of Addiction Treatment Programs, Cognitive Behavioral Therapies, Brief Feedback-Focused Interventions, Screening and Brief Alcohol Intervention for Adolescents and Young Adults in Primary Care and Emergency Settings, Individual Prevention of College Student Alcohol Misuse

Glossary

- **Affirmations** acknowledgment of a person's strengths, attitudes, and efforts that promote change.
- Change planning a formal strategy used in motivational interviewing in which practitioners help people who have expressed an intention to change develop a plan for how to achieve it.
- Change talk a category of language in motivational interviewing in which a person expresses his or her motives for change (e.g. "If I keep using cocaine, it will destroy my marriage").
- **Closed questions** questions that call for a "yes" or "no" response or that seek specific information or details (e.g. "Have you had more than four drinks on any one occasion in the past 3 months?").
- Commitment language the way people speak about their commitment to change (e.g. expressed intentions to change, plans and steps taken toward change).
- **Complex reflection** a reflection in which a practitioner paraphrases what someone has said in a manner that adds meaning to it, often based on implications within the person's spoken words (e.g. "You sound frustrated by your predicament").
- **DARN-CAT** an acronym used in motivational interviewing that describes different categories of change talk (desire, ability, reasons, need, commitment, activation, taking steps).
- **Decisional balance** an approach used to help people consider the costs and benefits of making changes versus not changing something.
- **Developing discrepancy** a strategy used in motivational interviewing in which a practitioner has someone consider the way in which his or her current behavior conflicts with important values or goals (e.g. drinking with parenting) and how behavior change (e.g. not drinking) might resolve the discordance.
- **Direct methods** strategies used in motivational interviewing for identifying and reinforcing people's motives for positive behavior change.
- EPE an acronym used in motivational interviewing that stands for elicit, provide, elicit, which is a technique for collaboratively sharing information or giving advice.
- **Equipoise** a stance in which someone is indifferent or has no clear attachment to a position or recommendation for another person.
- **Evocation** the general practitioner stance in motivational interviewing that presumes all people have motivations for change and that underpins the direct methods of this approach for drawing out these motivations.
- **Key question** a question used in motivational interviewing when someone has shown signs of readiness to change and is poised to make a commitment to change (e.g. What do you think you want to do at this point?).
- **Microskills** fundamental or basic strategies used in motivational interview (open questions, affirmations, reflections, and summaries) that underpin the person-centered aspect of the approach.
- MINT an acronym for an international training group called the Motivational Interviewing Network of Trainers.

MI spirit the style in which practitioners interact with people when they are using motivational interviewing, incorporating the elements of collaboration, evocation, and supporting autonomy.

- Motivational enhancement therapy a manualized version of motivational interviewing, which includes a personalized feedback intervention that was developed for a large-scale, multi-site study conducted in the United States called Project MATCH.
- Motivational interviewing (MI) a person-centered counseling method developed by William Miller and Stephen Rollnick that aims to elicit and strengthen personal motivation for change.
- **OARS** an acronym used in motivational interviewing to describe fundamental or basic strategies of the approach (open questions, affirmations, reflections, and summaries).
- **Open questions** questions or requests that invite discussion, exploration, or elaboration about a topic and are phrased in a manner that cannot be answered with a "yes" or "no" response (e.g. "What do you think about that?" "Tell me more about that").
- **Personalized feedback** a strategy in which a practitioner gives someone information from an assessment about his or her behavior relative to norms (e.g. describes how much the person is drinking compared to peers) or other important factors (e.g. "Your boss said you can keep your job if you do something about your drinking") to cause the person to consider changing.
- **Person-centered counseling** a nondirective humanistic psychotherapeutic approach based largely on the work of Carl Rogers.
- **Preparatory language** the way people speak about what motivates them to change, often involving statements about their desire, ability, reasons, and need for change, often as a prelude to making a commitment to change.
- Project MATCH a large-scale, multi-site study conducted in the United States in which the efficacy of motivational interviewing, cognitive behavior therapy, and 12-step facilitation for alcoholdependent adults was compared.
- **REDS** an acronym used in motivational interviewing that details the basic principles of the approach (rolling with resistance, express empathy, develop discrepancy, support self-efficacy).
- **Reflection** a statement about what a person said to indicate one's understanding about what that person meant.
- **Resistance** the interpersonal style in which a person interacts with someone in a manner that indicates tension or trouble in the relationship (e.g. arguing, interrupting, negating, dismissing, ignoring).
- **Righting reflex** the natural tendency of others to try to fix people's problems when they are told about them.
- **Simple reflection** a reflection in which a practitioner repeats or rephrases what someone has said without adding any meaning to it.
- **Solicited advice** advice that is given only when someone has specifically sought or requested it or granted permission for it to be shared.
- Stages of change a transtheoretical model of behavior change developed by James Prochaska and Carlo DiClemente that posits that behavior change occurs sequentially across recurring stages (precontemplation, contemplation, preparation, action, and maintenance).
- Summaries a technique used in motivational interviewing to reflect back to people multiple things that they had said for the purpose of:
 (1) collecting ideas to convey the bigger picture or to reinforce a person's motives for change; (2) linking statements to fully capture both sides of a person's ambivalence; or (3) capturing a common understanding of what has been said before transitioning to another topic.
- Sustain talk a category of language used in motivational interviewing in which a person expresses his or her motives to not change one's behavior (e.g. "I like the way drinking makes me feel").
- **Unsolicited advice** advice that is given to someone when they have not requested it or granted permission for it to be shared.

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Relevant Websites

- http://www.stephenrollnick.com A website from Stephen Rollnick that provides several motivational interviewing resources and a discussion forum about health behavior change.
- http://www.williamrmiller.net A website from William R. Miller that summarizes and provides access to Dr. Miller's research over the past four decades.
- http://www.motivationinterview.org The official Motivational Interviewing Network of Trainers website, which is hosted by the Mid-Atlantic Addictions Technology Transfer Center. The website contains a list of MI trainers and training events, an extensive bibliography, and recommendations for conducting MI trainings.
- http://www.nattc.org Website from the U.S. National Addiction Technology Transfer Center where the National Institute on Drug Abuse and Substance Abuse and Mental Health Administration blending product for supervising motivational interviewing called MIA: STEP (Motivational Interviewing Assessment: Supervisory Tools for Enhancing Proficiency) is downloadable.
- http://casaa.unm.edu Website of the University of New Mexico Center on Alcoholism. Substance Abuse, and Addictions, where several coding instruments for assessing practitioner use of motivational interviewing are available.

3

Cognitive Behavioral Therapies

Kathleen M. Carroll

Yale University, West Haven, CT, USA

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INTRODUCTION

Cognitive behavioral treatments are among the most well-defined and rigorously studied psychotherapeutic interventions for substance use disorders. While this entry will focus primarily on cognitive-behavioral therapy (CBT) for addictive behaviors, it should be noted that CBT shares several features with other empirically supported behavioral approaches. First, it is applicable across a broad range of addictive behaviors. That is, well-controlled trials have supported its efficacy across alcohol-, nicotine-, cocaine-, marijuana-, stimulant-, and opioid-dependent populations and also extended to other forms of addiction such as gambling, eating, and internet disorders (although this entry will focus primarily on applications to substance use disorders). Second, CBT was developed from well-founded theoretical traditions with established theories and principles of human behavior. Hence, CBT has also been shown to be effective with a wide range of other disorders and problems, including those that frequently cooccur with addictive disorders, such as depression and anxiety disorders as well as behavioral health issues such as insomnia and eating disorders. Third, CBT is highly flexible and can be implemented in a wide range of clinical modalities and settings, and delivered in a wide range of formats (individual, group,

computer assisted). CBT can also be integrated with a range of other empirically supported therapies described elsewher e in this volume, including motivational interviewing (MI), contingency management, and structured family approaches. Moreover, it is compatible with a variety of pharmacotherapies and, in many cases, can foster compliance and enhance the effects of pharmacotherapies for specific substance use disorders including methadone, buprenorphine, and naltrexone (for opioid addicted individuals), naltrexone and disulfiram (for alcohol-dependent individuals), and nicotine replacement therapies (for nicotine-dependent populations). Finally, CBT is highly focused and relatively brief/short-term, emphasizing rapid, targeted change in substance use and related problems. Thus, CBT is highly compatible in the evolving health care environment, where substance use problems may be identified and treated in a range of nontraditional settings (schools, correctional settings, primary care, etc.).

HISTORY AND THEORETICAL UNDERPINNINGS

Cognitive behavioral treatments have their roots in classical behavioral theory and the pioneering work of Pavlov, Watson, Skinner, and Bandura. Pavlov's work on classical conditioning demonstrated that a previously neutral stimulus could elicit a conditioned response after being paired repeatedly with an unconditioned stimulus. Furthermore, repeated exposure to the conditioned stimulus without the unconditioned stimulus would eventually lead to extinction of the conditioned response. These classical conditioning concepts play an important role in CBT, and particularly in interventions directed at reducing some forms of craving for drugs. For instance, the clinician attempts to help the patient understand and recognize conditioned craving, identify his/her own idiosyncratic array of conditioned cues for craving, avoid exposure to those cues, and cope effectively with craving when it does occur without using drugs so that conditioned craving is reduced and eliminated over time.

Skinner's work on operant conditioning demonstrated that behaviors that are positively reinforced are likely to be exhibited more frequently. Behavior therapies assume that addictive behaviors are learned through their association with the positively reinforcing properties of abused substances as well as their secondary association with other environmental stimuli. CBT attempts to disrupt this learned association between drug-related cues or stimuli and drug craving or use by understanding and changing these behavior patterns. Operant conditioning concepts are used several ways in CBT. First, through a detailed examination of the antecedents and consequences of substance use, the clinician attempts to develop an understanding of the reasons the patient may be more likely to use in a given situation and to understand the role that the substance plays in their life. This "functional analysis" of substance use is thus used to identify the high risk situations in which the patient is likely to use drugs or alcohol and thus to provide the basis for learning more effective coping behaviors in those situations. Second, the clinician attempts to help the patient develop meaningful alternate reinforcers to substance use; that is, other activities and involvements (relationships, work, hobbies) that serve as viable alternatives to the addictive behavior. Finally, a detailed examination of the consequences, both long- and short-term, of the substance use, is used as a strategy to build or reinforce the patient's resolve to reduce or eliminate the addictive behavior.

CBT conceives substance use disorders as complex, multi-determined issues, with a number of influences playing a role in the development or perpetuation of the disorder. These may include family history and genetic factors; the presence of comorbid psychopathology; personality traits such as sensation seeking or impulsivity; and a host of environmental factors, including drug availability and lack of countervailing influences and rewards. Though CBT for substance use

primarily emphasizes the reinforcing properties of drugs and alcohol as central to the acquisition and maintenance of addictive behaviors, these etiological influences are seen as heightening risk or vulnerability to the development of substance use problems. For example, some individuals may find drugs and alcohol unusually highly rewarding secondary to genetic vulnerability, comorbid depression, a high need for sensation seeking, and modeling of family and friends who use substances or environments devoid of alternative reinforcers.

Cognitive behavioral treatments also reflect the pioneering work of Ellis and Beck that emphasizes the importance of the person's thoughts and feelings as determinants of behavior. CBT evolved in part from dissatisfaction with the extreme positions of radical behaviorism (e.g. emphasis on overt behaviors) and classical psychoanalysis (emphasis on unconscious conflicts or representations). CBT emphasizes how the individual perceives and interprets life events as important determinants of behavior. A person's conscious thoughts, feelings, and expectancies mediate an individual's response to the environment. Thus, a central strategy is to help individuals become aware of maladaptive cognitions and change them.

Just as CBT assumes that many individuals essentially "learn" to become substance users over time, through complex interplays of modeling, classical conditioning, or operant conditioning, each of these principles is invoked in CBT to help the individual stop using drugs and alcohol. For example, modeling is used to help the patient learn new behaviors (e.g. how to refuse an offer of alcohol, how to break off or limit a relationship with a drug-using associate) by having the patient participate in role plays with the clinician during the treatment. That is, the patient learns to respond in new, unfamiliar ways by first watching the clinician model those new strategies and then practicing those strategies within the supportive context of treatment.

Learning serves as an important metaphor for treatment process. CBT clinicians tell patients that a goal of the treatment is to help them "unlearn" old, ineffective behaviors and "learn" new ones. Patients, particularly those who are demoralized by their failure to change their substance use, or for whom the consequences of addiction have been severe, are frequently surprised to think about substance use as a type of skill, as something they have learned to do over time: In effect they have learned a complex set of skills that enabled them to acquire the money needed to buy drugs and alcohol (which often led to another set of licit or illicit skills), avoid detection, and so on. Patients who can reframe their self-appraisals in terms of being "skilled" in this way can often see that they also have the capacity to

learn a new set of skills, this time, though, skills that will help them remain abstinent.

DEFINING ELEMENTS OF CBT

CBT has two critical components and defining features: First, a thorough functional analysis of the role the addictive disorder plays in the individual's life. For each instance of substance use the patient experiences during treatment, the clinician and patient will identify the patient's thoughts, feelings, and circumstances before the substance use, as well as the patient's thoughts, feelings, and circumstances after the episode of substance use. Early in treatment, the functional analysis plays a critical role in helping the patient and clinician assess the determinants, or high risk situations, that are likely to lead to substance use, as well as shed light on some of the reasons the individual may be using drugs. The second critical component of CBT is skills training. In CBT, this consists of a highly individualized training program that helps individuals with addictive behaviors modify old habits and behaviors and learn and implement more effective ones.

Specific techniques vary widely with the type of cognitive-behavioral treatment used, and there are a variety of manuals, protocols, and training programs available which describe the techniques associated with each approach. As described earlier, the two key defining features of CBT for illegal drug use are (1) functional analysis of drug use, that is, understanding drug use with respect to its antecedents and consequences and (2) skills training. CBT approaches include a range of skills to foster or maintain abstinence. These typically include strategies for (1) understanding the patterns that maintain substance use and developing strategies for changing these patterns. This often involves selfmonitoring of thoughts and behaviors that takes place before, during, and after high-risk situations or episodes of substance use, (2) fostering the resolution to stop substance use through exploring positive and negative consequences of continued use (also known as the decisional balance technique), (3) understanding craving, craving cues, and the development of skills for coping with craving when it occurs. These include a variety of affect regulation strategies (distraction, talking through a craving, "urge surfing" and so on), (4) recognizing and challenging the cognitions that accompany and maintain patterns of substance use, (5) increasing awareness of the consequences of even small decisions (e.g. which route to take home from work), and the identification of "seemingly irrelevant" decisions which can culminate in high-risk situations, (6) development of problem-solving skills, and practicing application of those skills to substance-related and more general

problems (e.g. managing the various social and legal problems associated with drug and alcohol use) (7) planning for emergencies and unexpected problems and situations that can lead to high-risk situations. (8) developing skills for assertively refusing offers of drugs, and reducing exposure to drugs and drug-related cues.

These basic skills are useful in their application to helping patients control their substance use, but it is essential that clinicians also point out how these same skills can be applied to a range of other problems. For example, functional analysis can be used to understand the determinants of a wide range of behavior patterns, skills used to cope with craving can easily be applied to other aspects of affect tolerance, the principles used in the sessions on seemingly irrelevant decisions can easily be adapted to understand a wide range of behavior chains, and drug/alcohol refusal skills can easily be transferred to more effective and assertive responding in a number of situations. It is essential that when clinicians teach coping skills, they emphasize and demonstrate that the skills can be applied immediately to control substance use, but also can be used as general strategies that can be useful across a wide range of situations and problems the patient may encounter in the future.

CBT is typically highly structured. That is, it is generally brief (12-24 weeks) and organized closely around well-specified treatment goals. An articulated agenda exists for each session and the clinical discussion remains focused around issues directly related to substance use. Progress toward treatment goals is monitored closely and frequently, with frequent monitoring of drug use through urine toxicology screens, and the clinician takes an active stance throughout treatment. In broad spectrum cognitive-behavioral approaches, sessions often are organized roughly in thirds (the 20/ 20/20 rule), with the first third of the session devoted to the assessment of the patient's substance use, general functioning in the past week, and report of current concerns and problems; the second third is more didactic and devoted to skills training and practice; and the final third allows time for clinician and patient to plan for the week ahead and discuss how new skills will be implemented. The therapeutic relationship is seen as principally collaborative. Thus, the role of the clinician is one of consultant, educator, and guide who can lead the patient through a functional analysis of his/her substance use, aid in identifying and prioritizing target behaviors, and consult in selecting and implementing strategies to foster the desired behavior changes.

The early sessions in CBT focus on gathering history, building a therapeutic relationship, introducing the CBT model, and teaching some of the more fundamental skills to achieve abstinence (e.g. functional analysis for identifying triggers, coping with craving, building motivation). As the patient progresses, later sessions build on these basic skills by addressing more complex topics, such as problem solving and cognitive reframing.

While structured and didactic, CBT is also a highly individualized and flexible treatment. The clinician carefully matches the content, timing, and nature of presentation of the material to the individual patient. The clinician attempts to provide skills training that are highly tailored to the individual's strengths, weaknesses, and current level of functioning. For instance, the clinician does not belabor topics such as breaking ties with drug suppliers with a patient who's highly motivated and has been abstinent for several weeks. Similarly, the clinician does not race through material in an attempt to "cover" all of it in a few weeks; for some patients, it may take several weeks to master a basic skill. Along these lines, clinicians should also be careful to use language that is compatible with the patient's level of understanding, making frequent attempts to check with patients to be sure they understand a concept and are comfortable with a specific skill. For example, while some can readily understand the concept of conditioned craving, others may require further explanation through use of concrete examples and more familiar language. Therefore, clinicians should be always be aware of patients' comprehension of the material, and should feel free to repeat session material as many times and in as many different ways as needed.

In CBT, clinicians encourage patients to practice new skills; as such practice is a central, essential, component of treatment. The degree to which the treatment is a "skills training" versus merely a "skills exposure" approach has to do with the degree to which there is opportunity to practice and implement coping skills, making extra-session practice and homework all the more important. It is critical that patients have opportunity to "try out" new skills within the supportive context of treatment. Through first-hand experience, patients can learn what new approaches work or don't work for them, where they have difficulty or problems, and so on. There are many opportunities for practice within CBT, both within sessions and outside of them. Within each session, there are opportunities for patients to rehearse and review ideas, raise concerns, and get feedback from the clinician.

EMPIRICAL SUPPORT FOR CBT

Among existing treatments for addictive behaviors, CBT has been among the most-studied and has garnered a high level of empirical support. It is notable that CBT has been included in most of the multisite clinical trials that have shaped the field of treatment of addictive

behavior; including Project MATCH (a 9-site trial comparing manualized CBT, MI, and 12-step facilitation for alcohol use disorders), the Cocaine Collaborative Study (a randomized trial evaluating cognitive therapy versus drug counseling versus interpersonal therapy among abstinent cocaine users), and the Marijuana Treatment Project (a three-site randomized trial comparing a nine session MI-CBT combination to three sessions of MI to a delayed treatment control condition among marijuana-using adults). Multiple meta-analyses have pointed to its efficacy across a range of addictive behaviors (including alcohol, illicit drug, and behavioral addictions), its compatibility and efficacy when combined with available pharmacotherapies, and particularly its durability. That is, several studies have pointed to continuing improvement in the targeted addictive behavior after the end of CBT treatment.

The converging evidence suggesting that CBT is a particularly durable approach has led to increased focus on unique or distinctive aspects of CBT that might account for its durability. Encouraging clients to implement and practice skills outside of sessions via homework assignments is one possible mechanism for this effect. Homework encourages practice of skills outside of sessions and possibly generalization of skills to other problems, and emphasis on extra-session practice assignments is a critical defining feature of CBT (see Table 3.1). Thus, homework and skill acquisition/implementation are two likely "active ingredients" of CBT.

NOVEL METHODS OF DELIVERY AND DISSEMINATION

Although many clinicians are familiar with aspects of CBT, efforts to successfully implement it in community settings have been mixed. CBT is a comparatively complex and demanding approach, for both clinicians and patients, and thus may be more infrequently or "weakly" implemented than would be ideal. Thus, implementation and training efforts have tended to emphasize that one does not learn CBT optimally from reading a manual or attending a single workshop; rather, extensive practice, supervision, and feedback are needed for most clinicians to implement CBT effectively. Because training and supervision of individual clinicians are costly and time-consuming, there is a dearth of well-trained CBT clinicians and dissemination efforts have begun to focus on novel methods of CBT delivery.

The last decade has been characterized by exponential growth in the development of technology-based interventions for psychiatric disorders, and in particular the creation of computer-delivered versions of CBT. Given the structure and didactic nature of CBT, it

TABLE 3.1 Defining Elements of CBT

Essential interventions in CBT

- Conducting functional analyses of substance use
- Providing individualized skills training in strategies such as recognizing and coping with craving; monitoring, challenging, and changing thoughts about substance use; problem-solving skills; planning for emergencies; recognizing seemingly irrelevant decisions; and refusal skills.
- Examination of the patient's cognitive processes related to substance use and related issues
- Identification and debriefing of past and future high-risk situations
- Encouragement and review of extra-session implementation of skills via homework
- Practice of skills within session

Recommended interventions

- Discussing, reviewing, reformulating the patient's goals for treatment
- · Monitoring substance use and craving
- · Monitoring general functioning
- Exploring positive and negative consequences of substance use
- Exploring the relationship between affect states and substance use
- · Providing feedback on urinalysis results
- · Setting a clear agenda for the session
- · Making process comments as indicated
- Discussing the advantages of an abstinence goal and exploration of the patient's ambivalence
- Meeting resistance with exploration and a problem-solving approach
- Supporting patient efforts to institute behavior change, assessing the level of family support

Acceptable interventions

- Involvement in self-help activities (e.g. NA meetings) as a coping skill
- Identifying means of self-reinforcement for abstinence
- Exploring discrepancies between patient's stated goals and actions
- Eliciting concerns about substance use and consequences (e.g. decisional balance)

Proscribed interventions

- Extensive self-disclosure by the therapist
- Use of a confrontational style or a confrontation-of-denial approach
- Requiring the patient attend self-help groups (as in 12-step facilitation)
- Use of disease model language or slogans (as in 12-step facilitation)
- Extensive exploration of interpersonal aspects of substance use (as in interpersonal or supportivepsychodynamic approaches)
- Extensive discussion or interpretation of underlying conflicts or motives (as in supportive-psychodynamic approaches)
- Provision of direct reinforcement for abstinence (e.g. vouchers, tokens, as in contingency management approaches)

appears to be one of the more easily transferrable empirically supported treatments into a computerized format, which offers the benefits of standardized delivery and broader access. CBT may be particularly well suited to translation to as direct-to-patients computer-assisted learning model for many reasons. First, the key elements of CBT are didactic, skills based, progressive, and often require repetition and modeling for effective learning – all of which can be facilitated through computer programs. Use of the multimedia format associated with computer-based training (e.g. graphics, audio prompts, cartoons, videotaped vignettes and role plays, self-assessment of progress, prompts, and so on) can facilitate skills building by individuals who have different learning styles. Although computer-assisted means of delivering CBT have great potential to make empirically supported therapies more widely available and to broaden the base of substance abuse treatment, and some of the early data on their effectiveness is very encouraging, substantially more testing and evaluation is needed before they can be widely distributed.

SUMMARY

Cognitive behavioral therapy is a structured, manualized approach to the treatment of addictive behaviors. It is one of the most frequently studied treatments and has among the highest level of empirical support. It is compatible with and effective when integrated with several other empirically supported therapies, including behavioral therapies and medications. One of its defining features is its durability, as effects of CBT tend to persist, and even increase, after the end of treatment.

SEE ALSO

Dissemination of Evidence-Based Treatment into Practice, Contingency Management

List of Abbreviations

CBT cognitive behavioral therapy MI motivational interviewing

Glossary

- Affect/craving regulation strategies specific strategies that can be helpful in managing strong feelings or powerful cravings. These include mindfulness techniques, "thinking" through the behavior, "urge surfing," self-talk, and recognition that strong affects and cravings grow, peak, and eventually dissipate over time.
- Assertive refusals an important strategy in changing addictive behaviors in situations where the behavior is encouraged by another person. In assertive refusals, the individual says "no" clearly, with good eye contact, assertive body language, and use of "I" statements (e.g. "I don't want to have a drink, and I'd appreciate it if you wouldn't ask me again"). Assertive refusals can be distinguished from passive refusals ("Not now") or aggressive refusals ("Get away, you jerk") which tend to be much less effective.
- Cognitive reframing also called cognitive restructuring, refers to the strategy used in CBT where maladaptive or distorted thoughts are identified and challenged.
- **Collaborative stance** the therapeutic style used by CBT clinicians with the group or individual to foster a positive working relationship with shared development and agreement on the goals and tasks of the treatment.
- Conditioned craving craving that occurs as a result of classical conditioning (Pavlovian conditioning). This occurs when certain cues or triggers (e.g. settings such as bars, drug-using friends, casinos) are repeatedly paired with an addictive behavior (drinking alcohol, using drugs, gambling). After multiple repeated pairings, the cue itself can elicit strong conditioned craving for the behavior.
- **Decisional balance** a systematic evaluation of the pros and cons of engaging in a specific addictive behavior versus forgoing it. This is a strategy used in CBT to address ambivalence about the addictive behavior and help the individual temporize their behavior or delay the decision to engage in the behavior.
- Functional analysis observing/evaluating behaviors in terms of their antecedents and consequences (i.e. understanding the "function" of a given behavior). When applied to treatment of addictive behavior, this refers to understanding the thoughts, cues, situations, or "triggers" that occur just prior to an episode of substance use/craving, understanding the thoughts, behaviors, and feelings that occur within an episode of substance use, and understanding the changes/behaviors/thoughts that occur after the episode.
- **High-risk situations** situations in which the addictive behavior is highly likely. These are typically situations, settings, or internal states previously paired with the addictive behavior.
- **Homework** homework in CBT refers to practice and evaluation of new skills outside of therapy sessions. These can be formal, as in written assignments, or informal, as in "trying out a new thought."

- Problem-solving skills a systematic process that can be applied to a wide range of addictive behaviors and related problems. Steps in a typically problem-solving process include (1) recognizing a problem exists, (2) defining the problem and if possible breaking the problem down into manageable components, (3) identifying multiple strategies to address the problem (brainstorming), (4) selecting a problem-solving strategy, and (5) implementing and evaluating the effectiveness of the strategy selected.
- Seemingly irrelevant decisions decisions that, on first consideration, may seem to be unrelated to the addictive behavior but can lead to a chain of events that result in a high risk situation or relapse. Examples include the "seemingly irrelevant decision" to take a route home from work past a place where the individual previously engaged in the addictive behavior cashing instead of depositing one's paycheck.
- Triggers situations, states, cognitions, or cues previously paired with addictive behavior that can elicit strong craving or desire for the addictive behavior.

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4

Cue Exposure Treatments for Substance Use Disorders

Damaris J. Rohsenow

Brown University, Providence, RI, USA

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The last few decades saw major advances in the development of effective behavioral treatments for substance use disorders (SUDs), particularly with the recognition that effective pharmacotherapies had not been developed for some SUDs (such as cocaine use disorders) or were limited in effectiveness such as naltrexone for alcohol use disorders (AUD), were limited in who could receive them, and were always more effective when combined with behavioral treatments. Cue exposure treatment (CET) approaches were one of these advances.

THEORETICAL RATIONALE FOR CET

Exposure-based treatments for SUDs were derived from a foundation in classical learning principles and broadened to incorporate coping skills training within the exposure sessions as derived from cognitive social learning theory. These theories indicate that SUDs are acquired on a foundation of individual biological predisposing factors using the same learning principles by which any other behaviors are learned. The most relevant of these principles for CET is respondent learning, sometimes called classical conditioning or associative learning, in which a response becomes associated to a stimulus that does not inherently elicit (call forth) that response. We call these stimuli "cues." Pleasurable physiologic reactions to drug ingestion become associated with all the sights, sounds, and smells that were associated repeatedly with drug use, including even places, times of day, or days of the week. For cocaine-dependent patients, after snorting cocaine repeatedly, the sight of any white powder, a mirror, a bank card, or a certain neighborhood can elicit increased heart rate and cravings. The types of cues (conditioned stimuli) associated with substance use become complex and broader than the sight and smell of the drug itself and can include emotions, people, environments, and temporal cues. This learning is not considered to occur in a mechanistic

manner but instead is affected by cognitive processes such as encoding, organizing, and retrieving information to mediate between environmental events and behavior.

Cues associated with drug use can pose a risk for relapse through three different mechanisms. First, the conditioned responses learned through respondent conditioning include a variety of physiological and emotional responses, and these can result in an urge (desire, or craving) to use the substance. (The terms "urge" or "desire" will be used instead of "craving" because they represent the full range of desires to use rather than just extreme desire.) Second, when people are reacting to these cues, these learned reactions can interfere with the ability to use coping skills or motivational messages by reducing the amount of cognitive resources available for efforts to stay clean and sober. Third, the learned responses can lead to operant behavior (i.e. substance use) designed to decrease aversive aspects of the reactions and to obtain the pleasurable drug responses associated in the past with these cues.

GENERAL PRINCIPLES OF CET

Associations cannot be unlearned, so CET is not designed to cause unlearning. Instead, CET approaches have focused on two mechanisms of effect: (1) the first is to reduce the strength of these learned associations by repeatedly presenting these cues while preventing the substance use from occurring. These unreinforced exposure trials are designed to make the client react less strongly and automatically to the cues through habituation so as to make them less susceptible to the cues when they later encounter such cues in the environment. Exposure must be in an environment where substance use can be prevented, exposure must be long enough to result in within-session habituation, and a wide variety of different cues need to be used in the CET sessions since many cues are associated with substance abuse. (2) The second is to provide practice in using coping skills while under the influence of these conditioned responses to cues so that reactions to cues will be less likely to disrupt coping efforts when the client is in the natural environment after treatment. For the maximum benefit, coping practice during each exposure needs to occur when urges to use and other reactions are at their peak. Furthermore, while some CET approaches have focused only on the unreinforced exposure aspects, the practice of coping with urges while urges are being elicited makes sense to clients and thereby makes clients more willing to engage in the treatment sessions in addition to providing them with a useful set of coping methods. Therefore, it makes sense to use both the exposure and the coping practice under exposure conditions in CET.

The earliest uses of CET, used for people with AUDs in Britain, involved having clients expose themselves to their favorite alcohol beverage repeatedly while resisting drinking. However, in addition to exposure sessions, sobriety-oriented skills training was usually provided as well, although not integrated into the exposure as described in the above paragraph. The clients were given advice about how to change high-risk situations, they role-played how to handle high-risk situations, and alternative activities were discussed, as described by Blakey and Baker. An approach using only exposure was developed for people with AUDs by Drummond, and for people with opiate or cocaine use disorders by O'Brien and his colleagues. The method developed by Monti, Rohsenow, and their colleagues that is discussed in more detail below includes urge-specific coping skills training integrated into the series of sessions of exposure to a variety of drinking cues. This approach has been supported in several randomized controlled clinical trials.

The nature of the cues to be used in the treatment sessions is important to consider. The sight, smell, and feel of the substance itself are usually used since it is the final common pathway immediately before use. However, other cues can occur earlier in the chain of events that lead to substance use and can trigger drugseeking so are important to address in the sessions as well. Most of these cues cannot be brought into a treatment room (e.g. drug-dealing neighborhood; getting off work) or are not physical (e.g. anger or loneliness) or cannot be planned (e.g. fight with one's kids, call from an ex-spouse). Therefore, imaginal imagery produced through prompts or scripts are commonly used for more complex situations. While virtual reality methods have been proposed for research purposes and photographs of drinks have been used to elicit reactions in teens, these inherently involve sets of standardized cues rather than personalized cues. Since studies have consistently found individually personalized cues to elicit stronger reactions than standardized cues, these methods are likely to be weaker approaches. Furthermore, such visual methods cannot present nontangible cues such as emotions, conflicts, and times of day. Thus, beverages or simulated drugs with their associated equipment, and imaginal methods to present other cues for drinking, are the recommended ways to present a wide range of cues.

ASSESSMENTS USED IN CET

Drinking Triggers Interview

The primary assessment to use before conducting CET is the Drinking Triggers Interview, used as the foundation for the imaginal imagery used in CET

sessions. The DTI is a structured interview designed to identify the situations most strongly related to urges to drink or relapse for the individual client. A copy of the full measure is available in a treatment guide for therapists by Monti and his colleagues. In the DTI, we asked a client to describe all the situations or events that have been associated with past heavy drinking or relapse. These "triggers" include situations, environments, objects, people, or emotional experiences that lead to drinking episodes or to urges to drink for them. After writing down the key elements of each trigger, we ask the client to rate each one for their confidence that they could handle the situation today without drinking, using a 0-10 scale from "not at all confident" to "completely confident." Then the client rates each trigger for the urge to drink they would experience if out of the treatment program and confronted with that trigger today, rated from 0 "no urge at all" to 10 "extremely strong urge to drink." Finally, the client rank orders the situations for the frequency with which they occur. We choose the order to present triggers in CET based on the anticipated strength of the urge, highest urge first, with ties broken by choosing the more frequent one first.

Urge-Specific Coping Skills

The therapist could also obtain a pretreatment assessment of the extent to which the client knows and uses the skills for coping with urges that have been found to be related to less drinking after treatment (evidence is reviewed below). The Urge-Specific Strategies Questionnaire is also available in the treatment guide. First, clients are asked to describe everything they have done to keep themselves from drinking when they have had an urge to drink; this open-ended list can be coded into the types of strategies found effective (e.g. reminding oneself of the positive consequences of staying sober or substituting an alternative activity) or ineffective (e.g. self-punishment or willpower alone). Then the client is given a list of key coping strategies worded in plain language; the client indicates the frequency with which they used each one when having an urge to drink and trying to stay sober. This tool can be used to identify existing strengths and weaknesses to work on in treatment.

CUE EXPOSURE WITH URGE COPING SKILLS FOR AUDS

Overview

The CET method described here is the one that has the most evidence-based support, the one by Monti, Rohsenow, and their colleagues and described in several of the further readings. Some other versions of CET rely on just exposure to the alcohol beverage alone or exposure with limited drinking followed by resisting further drinking. The method described here follows exposure to the beverage with exposure to a variety of imagined trigger situations, with learning and repeated practice of a specific set of urge coping skills while the urge to drink is at its highest in the CET session. The approach described here involves six to eight 50-min sessions. While most evidence is for individual sessions, it was adapted for small groups as well.

Explaining CET to Clients

The therapist needs to explain why this approach is being done, because it is so unusual. We tell clients that trouble staying sober is often due to the reactions they have to triggers associated with drinking in the past. While many people stop having cravings while in treatment and away from these triggers, many of these triggers are unavoidable (such as conflicts or getting off work) and they may have strong urges to drink when first experiencing their triggers again after treatment, with no one there to help them. Therefore, this treatment is designed to help them learn to resist their drinking triggers while in the safety of the program. One way is by experiencing their drinking triggers until they feel the urge to drink decreasing so they will know through experience that the urges will decrease if they do not drink. The second way is by teaching them some skills for handling urges without drinking and letting them practice using these skills while they are experiencing real urges to drink. This practice will make it so they use these skills more quickly and effectively later on. We warn them not to try any exposure on their own, because if they test themselves and fail, all the treatment will have been wasted. The goal is simply to help them handle the unavoidable triggers more effectively.

Beverage Exposure

Each session begins with exposure to their usual alcoholic beverage, since this is the final common pathway to drinking and usually a strong trigger. The beverage should be their own most commonly consumed beverage, using the same brand they use, prepared the way they usually drink it. The urges are stronger if they pour the drink themselves. We always provide a glass, even though many never use a glass in real life, because it allows the smell to be stronger. Since the time it takes for the urge to decrease always becomes shorter across sessions, we time the exposure so we can give them feedback on this aspect in later sessions. We start a stopwatch when we first bring the beverage

into view, then ask the client to pour and mix the beverage but without filling the glass more than halfway. We ask if the urge would be stronger when holding the can or bottle than the glass. Since most alcoholics never remove their hand from what they drink from, we have them keep their hand on that item throughout. While we have them smell the glass of alcohol at least once; if this results in less urge than looking at and holding it, we do not repeat that. "Focus on whatever aspect of the drink that gives you the greatest urge - the sight, smell, feel of the glass, or your thoughts. Try to experience the greatest urge you can." We redirect their attention if they are trying to avoid the stimulus so as to avoid the urge. We ask them to report their urge level on a 0-10 scale (from none to the strongest urge possible) every few minutes to track the timing of the increase and later the decrease in urge level, and stop the exposure when this level reaches a 2 or less (whatever the client thinks is the lowest the urge could go).

Imaginal Exposure to Trigger Situations

We use the answer sheet from the Drinking Triggers Interview to guide the imagery. We start with the highest ranked trigger but try to cover all the triggers across the different sessions to maximize generalization. We ask the clients to vividly imagine being in the situation without imagining drinking and to focus on the aspects of the situation that give the greatest urges. We ask them to report their urge level every time it changes on the 0–10 scale, and track the time to peak and back to minimum. If the urge level fails to increase or stays high after coping skills have been applied, ask the person to describe their thoughts and images and give corrective feedback (e.g. stay in that same situation without adding new elements, do not imagine drinking). Some clients deliberately block their urges; we stress the importance of allowing themselves to feel the urges to drink while in these treatment sessions.

Integrating Urge Coping Skills Training

Each 50-min session has time for one or two beverage exposures and two to about five imagery exposures. In between exposures, we teach a new coping skill or review one taught in the previous session and tell the clients that they will be asked to imagine using the skill when we tell them to. Only one new skill is taught in each session. When the urge is as high as the client believes it will go, we ask them to imagine still being in the same situation but to imagine using the coping skill to deal with the urge in the situation. Then we terminate the exposure when the urge is a 2 or less and as low as the client believes it will go. We match

most of the strategies with many of the drinking triggers over the sessions and ask them to notice which strategies work best for them in which situations (for example, imagining negative consequences of drinking can increase bad moods and be less effective for negative mood triggers than imagining positive consequences of sobriety or imagining using an alternative activity). After the third or fourth session, rather than prescribing specific coping tools, we ask them to "use any tool or combination of tools to bring the urge down," to encourage generalization, and to practice recalling and implementing strategies on their own. The last session includes a review of all the coping strategies, which worked best for which triggers, and a reminder of the importance of using these in their own environment.

Urge Coping Strategies

We have empirically determined the strategies that are associated with the best drinking outcomes after treatment. Two popular but ineffective strategies we discourage: self-punishment and willpower alone. Other ineffective strategies are listed by Rohsenow. One pair of highly effective strategies not used in CET are escape and avoidance; these are not used because they prevent the exposure aspects of the session. We recommend avoidance and escape as the first methods to use always and to use the other tools we are teaching whenever escape or avoidance is not possible. Clients are told it is important to have as many "tools" in their "toolbox" as possible to stay sober. We write down the tools, and the ways they personalized the tools for themselves, on a written list that we give them to keep. The following coping strategies are taught:

- 1. Delay. During the first beverage exposure, we have clients simply keep looking at the beverage until the urge has gone down to a low level. Most clients expect that their urge would never decrease, but it always does. We then teach them delay ("wait it out") as an active coping strategy, that they can always tell themselves that they can wait out the urge until it goes down, and that it will go down without drinking. We then repeat the beverage exposure while having them practice the active version of this tool and see the difference in time for the urge to decrease.
- 2. Negative consequences of drinking. We ask the client to "think about all the bad things that could happen if you took that drink." This is future oriented since past consequences are associated with self-blame (self-punishment) and may not recur so would be less powerful than imagining what actually would be likely to happen. We have them evaluate the personal importance of each consequence and write up their own personal list of meaningful potential consequences on the "Toolbox" handout.

- 3. Positive consequences of staying sober. We do parallel procedures for positive consequences, focusing on relatively immediate positive consequences they could expect to experience. For feeling sad or lonely or bored, thinking of the positives is less likely to aggravate the trigger situation, as well as providing positive incentives across any situation.
- **4.** Alternative food or drink. Have the client imagine eating or drinking something pleasurable and write down his or her preferred substitutes.
- 5. Alternative behaviors. Have the client imagine doing some activity that could distract him/her from the urge, whether it is pleasurable, it involves the satisfaction of accomplishing something, or it is seeking support such as through a sponsor or supportive relative. It needs to be something they could engage in immediately in the trigger situation.

EVIDENCE-BASED EFFECTIVENESS OF CET

CET for Smoking Cessation

Effectiveness has not been demonstrated for the use of CET, even when combined with coping skills training, for smoking cessation. A large randomized clinical trial by Niaura's group showed there was no benefit to adding CET to cognitive-behavioral skills training and nicotine gum. Several small studies with various methods also failed to show beneficial results. An approach to using CET by means of virtual reality did not investigate effects on smoking outside the sessions so its effectiveness is unknown. Therefore, CET for smoking cessation is not recommended for clinical use at this time.

CET for Cocaine or Opiate Dependence

While a study of CET for methadone-maintained clients with opiate dependence by McLellan's group found it to reduce craving, the clients treated with psychotherapy with no CET did equally well in terms of abstinence from drugs at follow-up after the end of treatment. A small study by Dawe and colleagues found no effect for CET on craving, withdrawal, or drug use. O'Brien and colleagues found that CET with recently abstinent clients with cocaine dependence resulted in significant decreases in craving and withdrawal ratings over 15 sessions, with craving near zero by the seventh session, and time to relapse was longer and self-reported drug use lower after CET compared to control groups. However, drop-out rates were high, almost everyone in both CET and comparison treatment did relapse, and there were no differences in drug use at a followup after treatment had ended. CET has not been studied

in controlled trials for other drugs of abuse. Therefore, CET is not recommended for clinical use at this time for cocaine or opiate use disorders.

CET for Alcohol Use Disorders

CET's effectiveness has been investigated with or without integrated urge coping skills training; clients in a comprehensive treatment program have better outcomes when they also receive either form of CET. CET is not designed to be a stand-alone treatment.

Several studies used CET based on simple exposure to the sight and smell of clients' usual alcohol beverage without teaching skills to cope with the urges. First, a small study by Drummond's group with 35 alcoholdependent clients who were participating in inpatient treatment programs randomly assigned clients to receive ten 40-min sessions of either relaxation training or CET. Clients who received CET drank significantly less during follow-up after treatment and took longer to relapse to heavy drinking. Second, a study by Sitharthan and colleagues with nondependent problem drinkers who sought to drink moderately, randomly assigned 42 clients to either cognitive-behavioral treatment without cue exposure or to CET that included drinking a moderate amount of alcohol and then holding and smelling another drink without drinking it, with sessions occurring both in the clinic and at home. They were also taught various strategies for limiting their drinking along with self-monitoring their drinking. Compared to the clients in the control treatment, those who received CET drank less often and drank fewer drinks per occasion during the 6 months after treatment. Third, in another study of CET for moderate drinking goals, Heather's group randomly assigned 91 clients with alcohol use disorders to eight 90-min sessions of either CET or behavioral self-control training. The CET involved consuming one drink and then resisting continued drinking in sessions in both the clinic and at home. Clients in both types of treatment reduced their drinking by similar amounts over the 6 months after treatment. Thus, there is some evidence for exposure without urge coping skills training for training moderate drinking in clients with alcohol use disorders but only a small study of its effectiveness for abstinence goals.

CET with integrated urge coping skills training has considerable evidence for effectiveness as an adjunct to a comprehensive treatment program for clients with alcohol dependence in a series of studies by Monti, Rohsenow, and their colleagues. The first initial small study of this approach randomly assigned half of the 34 alcohol-dependent clients in an abstinence-oriented inpatient treatment to CET. The CET was six 50-min individual sessions of the combined CET described

above (beverage and imaginal cues, with integrated urge coping training). While clients in both CET and control treatment had equivalently low drinking during the first 3 months after treatment, only clients who received CET continued to show decreased quantity and frequency of drinking during the second 3 months after treatment. About two-thirds of clients with AUDs reacted to alcohol cues with increased urge to drink at the pretreatment assessment, and among these clients, those randomly assigned to CET showed greater reductions in urges to drink, were more likely to use coping skills after treatment, and had more abstinent days 4–6 months after treatment. Thus, the clients with the strongest reactions to beverage cues received the most benefit from CET.

The second larger study used a 2×2 experimental design: 100 clients with AUDs in an intensive day treatment program ("partial hospital") were randomly assigned to eight individual sessions of the CET (almost the same as in the first study) or a control procedure (relaxation training), and clients in each of these conditions were also randomly assigned to Communication Skills Training (CST: a type of cognitive-behavioral treatment discussed in another chapter) or to an alcohol education control procedure. This type of experimental design allows a statistical analysis of the effects of CET while controlling for the effects of CST. CET resulted in fewer heavy drinking days among clients who relapsed to any drinking during the 12 months after treatment, compared to the clients who received the control training sessions as their addition to the intensive treatment program. Clients received an average of eight CET sessions added to a full day treatment program (i.e. very few people dropped out before completing all the sessions) and this brief addition resulted in improvements in drinking out to at least 12 months.

The third study compared CET (exposure with integrated urge coping skills training for 45 min) combined with CST with the alcohol beverages still displayed (for another 45 min) to a combined control treatment (relaxation and alcohol education) in a 2×2 design that also randomly assigned half the clients in each behavioral treatment to receive a medication (naltrexone) or a placebo pill for 12 weeks. The behavioral treatments were conducted in group format and each lasted 90 min per session for at most six sessions, with clients completing an average of 4.6 sessions. These occurred during the intensive day treatment program that lasted an average of 13 days, and the medication or placebo was started on the day of discharge to the outpatient aftercare program. The CET combined with CST had a lasting effect up to at least 12 months while the medication effects lasted only slightly longer than the 12 weeks of medication. After CET with CST, clients were less likely to relapse and reported fewer heavy drinking days during the subsequent 12 months than did clients in the intensive treatment program who received the control condition, even though only four to five sessions of the experimental treatment were completed due to the constraints of managed care.

The mechanism of effect of this form of CET seems to be primarily by increasing use of coping skills when having urges to drink. CET resulted in greater selfreports of use of urge-specific coping strategies after treatment and use of these strategies correlated with less frequent drinking. The CET combined with CST also resulted in more frequent use of the urge-specific coping strategies, with a significant relationship between coping strategy use and frequency of drinking and with relapse (Monti et al., 2001). CET did not result in more decrease in salivation or urge to drink in response to the sight and smell of an alcohol beverage in a cue-reactivity assessment compared to the control group, although cue-elicited urge to drink among those who reacted at all pretreatment decreased more after CET than after no additional treatment in one study. Clients who received CET with CST showed less urge in response to the sight and smell of an alcohol beverage in a cue-reactivity assessment after the behavioral treatment than clients in the control condition, but relapse status at 3, 6, and 12 months was largely unrelated to degree of urge in this assessment. Therefore, there is no good support for the mechanism of effect of CET being via effects on reactions to alcohol beverage stimuli but good evidence of its effects resulting from increasing use of certain types of coping skills after treatment.

Summary of the Evidence

The controlled studies of use of CET for clients with AUDs consistently show beneficial effects on outcome. The evidence is most compelling when CET is integrated with urge-specific coping skills training, with lasting effects throughout a 12-month follow-up even when only 4-8 sessions of CET were delivered. The studies based on exposure to alcohol beverage stimuli without integrating practice coping with the urges also showed significant reductions in drinking throughout 6 months after treatment, although one study did not use alcohol-dependent clients and two of the studies focused on practicing drinking moderately rather than practicing abstinence. Therefore, it is less clear how well the CET without coping skills training would work for abstinence in a large study. The evidence on mechanisms of effect suggests that the practice of coping with urges elicited in a safe environment may have been the primary way that clients benefitted from this form of treatment. Given that without such practices, urges to drink can lead to impulsive drinking and disrupts cognitive abilities, including such practices is likely to FURTHER READING 35

provide an advantage over exposure without urge coping skills training, with no disadvantage to this combination.

SEE ALSO

Cognitive Behavioral Therapies

List of Abbreviations

AUDs alcohol use disorders
CET cue exposure treatment
CST communication skills training
DTI Drinking Triggers Interview
SUDs substance use disorders

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Contingency Management

Sheila M. Alessi

Calhoun Cardiology Center - Behavioral Health, University of Connecticut Health Center, CT, USA

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INTRODUCTION

Contingency management (CM) therapy is primarily a process of systematically using positive reinforcement to promote clinically relevant behaviors. CM has demonstrated efficacy for improving abstinence and other substance use disorder (SUD) treatment outcomes in a diverse range of treatment populations and settings. This technique is based on behavioral principles of

operant conditioning; specifically, that presenting an incentive or reward soon after a specific behavior occurs increases the likelihood that the behavior will reoccur. Grounded in behavioral economics theory, extensive research demonstrates that consumption of drugs and alcohol is sensitive to environmental consequences like the availability of alternative reinforcers, supporting the application of CM to treating SUD. The primary goal of CM is to reinforce behaviors that are compatible

with a drug-free lifestyle so that those behaviors increase in frequency, which might translate into improved long-term outcomes.

There are four central tenets of CM. First, select a specific and clinically relevant, objectively verifiable target behavior (e.g. abstinence verified by a drugnegative urine test). Second, monitor the target behavior frequently to maximize reinforcement opportunities and minimize failing to detect competing behaviors (drug use). Third, deliver a tangible incentive soon after the behavior occurs that is sufficiently valuable to the recipient to drive the desired behaviors, with encouragement and support. Fourth, withhold incentives when the target behavior does not occur. These elements are essential to CM.

Recent meta-analyses suggest that CM is among the most efficacious behavioral therapies for the treatment of SUD. These procedures are generally used to target abstinence directly by reinforcing urine and breath samples that test negative for substances of abuse. As discussed below, CM has demonstrated efficacy for increasing abstinence from alcohol, cocaine, opiates, benzodiazepines, marijuana, and cigarette smoking compared to standard care without CM. CM can also be used to increase other clinically relevant behaviors like counseling attendance, medication adherence, and completion of activities related to treatment goals. Central to the efficacy of CM treatment is the type of reinforcer or incentive used to motivate behavior change.

REINFORCERS

In CM therapy, appropriate incentives are tangible goods and services that are consistent with a drug-free lifestyle. For an incentive or reward to successfully reinforce a goal behavior, it needs to be sufficiently valuable to motivate individuals toward the desired behavior (e.g. abstinence) and away from competing behaviors (e.g. substance use). Practical considerations include the availability of incentives in the treatment environment and associated costs, which affect feasibility, sustainability, and acceptability.

Clinic Privileges

Clinic privileges are tangible, readily available, lowor no-cost commodities that can be used to promote increases in desired behaviors in the context of CM. Before the formalization of CM, privileges and contingencies on behavior were used in various settings for behavior modification purposes but often with a focus on punishment and nonsystematic use of rewards. Dr Maxine Stitzer and colleagues at Johns Hopkins University largely initiated exploring effects of systematic positive reinforcement for specific therapeutic behaviors in the context of SUD treatment and did so in the context of the methadone maintenance clinic. Potentially powerful incentives readily available in methadone treatment include take-home methadone doses, dose adjustments, access to early dosing windows, and other privileges. Early studies also examined effects of behavior-contingent cash, although noncash incentives are typically used as they are less easily diverted. Researchers observed differential preference for some rewards over others, individual differences in reward preferences, and that differences in sensitivity to CM were attributable at least in part to patients' substance abuse histories. This initial body of research was seminal in shaping the abundance of subsequent research on CM techniques in an array of populations and settings.

Voucher-Based CM

Persistent substance use is a common problem in psychosocial outpatient treatment as it is in methadone treatment. An additional problem is poor treatment retention. Earlier success with CM for cocaine use in methadone patients suggested that CM might be efficacious for improving outcomes in cocaine-dependent psychosocial treatment patients, but a challenge was the relative lack of low or no-cost incentives. Research on effects of CM in this setting required a contrived reinforcement system, and Dr Stephen Higgins at the University of Vermont developed and conducted seminal research on what became voucher-based CM. Vouchers are essentially promissory notes with a monetary equivalent that are redeemable for goods and services consistent with treatment goals (e.g. payment of an electricity bill, groceries, and recreational items). Vouchers occur on a fixed ratio reinforcement schedule, meaning that patients earn a voucher every time a target behavior occurs. When the target is cocaine abstinence, urine samples are tested two to three times weekly on nonconsecutive days (e.g. Monday and Thursday). Vouchers start at \$2.50 for the first negative test and escalate by \$1.25 for each consecutive negative test, with a bonus (e.g. \$10.00 voucher) for every three negative tests in a row. Vouchers reset to \$2.50 with a positive test or unexcused absence, and the highest amount is reinstated with three consecutive negative tests following a reset. Vouchers are stored in a clinic "bank account" until redeemed. In a typical 12-week voucher program for cocaine abstinence, maximal earnings tend to be about \$1000-\$1200, and actual earnings are about half of that on average. Vouchers are redeemed REINFORCERS 39

for goods and services individualized to patients' preferences, and there is more control over what is acquired with vouchers than possible with cash incentives. One limitation is that there is some delay between earning and redeeming vouchers (referred to as the exchange delay), and longer delays are associated with decreased treatment effect size. By contrast, the relatively large reinforcement magnitudes typical of voucher CM are associated with increased effect sizes, although cost may limit feasibility and sustainability, depending on many factors (see Dissemination and Uptake Challenges below).

Prize-Based CM

In response to concerns about the cost of voucher CM, Dr Nancy Petry at the University of Connecticut Health Center developed prize-based CM, a low-magnitude reinforcement system by design relative to voucher CM. In prize CM, patients earn at least one chance for a reward, or "prize," for each target behavior. A standard prize bowl contains 500 cards, with 250 cards containing a supportive statement (e.g. Good job for being abstinent!) and not a prize, 230 small prize cards worth about \$1(e.g. toiletries, snacks), 19 large prize cards worth about \$20 (e.g. gift certificate, phone cards), and 1 jumbo prize card worth about \$100 (e.g. DVD player, mp3 player). Thus, there is a 50% chance of receiving any prize, and the chance of earning a small, large, and jumbo prize is inversely related to prize magnitude. Draws escalate, reset, and can include bonuses, akin to voucher CM procedures. Prize inventory is kept onsite which minimizes exchange delays and patients are encouraged to redeem earnings immediately but can bank them if working toward a specific item. Maximal earnings for a 12-week prize CM program are typically on the order of about \$400-\$600 in prizes, with actual earnings about half of that on average. Voucher CM and prize CM seem comparably efficacious when reinforcement earnings are relatively equivalent. Prize CM has small exchange delays, prizes are individualized based on patient preferences, goods are purchased in bulk shopping trips, and programmed incentive costs are relatively low. The possibility of large magnitude reinforcement early in treatment may be associated with treatment effects, although that is not clear. One concern about prize CM is that the element of chance may jeopardize individuals in recovery for pathological gambling, and those individuals are therefore typically excluded in research, although there is no evidence of increased gambling with prize CM. A possible limitation of prize CM and low-magnitude reinforcement generally is that the magnitude of treatment effects decreases with decreased reinforcement magnitude.

Housing and Employment

In substance abusers with chronic housing and employment problems, opportunities in these areas can be used to improve treatment outcomes while also addressing patients' limited employment options and lack of stable housing. To that end, Dr Ken Silverman and colleagues established a potentially self-sustaining data entry business, referred to as the Therapeutic Workplace, in conjunction with a methadone maintenance program. Access to job training and employment is made contingent on drug-negative urinalysis and treatment attendance. Aspects of employment settings that make them particularly suited to CM interventions include ongoing long-term opportunity for monitoring with ready access to monetary consequences for substance use. Other efforts have also examined abstinence-contingent employment/work training as well as contingent access to housing. Overall, the cost of establishing and maintaining such programs is relatively high, but may be justified by the benefits of achieving some progress on chronic problems in these populations.

Cash

Cash incentives avoid some of the costs associated with maintaining goods-based programs. A disadvantage is the clinical safety concern that cash could be used to purchase drugs and alcohol, although frequent monitoring and reinforcement of abstinence may decrease the likelihood of that happening. Surveys indicate that cash is generally preferred over goods or privileges, suggesting that it might be possible to retain efficacy at a lower cost in situations in which provision of cash proves to be safe.

Onsite Retail

With onsite retail-based CM, commodities are prepurchased and stored onsite. Exchange delays are minimized, shopping can be done in bulk which requires fewer resources than shopping on a per patient basis, and some tailoring to accommodate patient preferences is possible.

Refunds

A patient-sided approach for providing reinforcers is to have patients make a deposit using their own funds and then reacquire portions of the deposit by meeting goals like testing negative on urinalysis. Deposit contracting transfers the cost of incentives from the service provider to the service user, but limits participation to those willing and able to make deposits.

ISSUES CENTRAL TO CM

Key elements of CM that affect treatment efficacy include the behavior targeted for change; the monitoring and reinforcement schedule; reinforcement immediacy, magnitude, and exposure; and the contingent nature of reinforcement.

Target Behaviors

The target or goal behavior is the behavior identified for change via reinforcement contingencies. Objective verification of the target behavior is required, with the form of objective evidence agreed upon beforehand. Verbal reports are more subject to interpretation and influenced by external factors, and are not adequate. The most common target behavior is abstinence verified by drug-negative urinalysis or breath test, and sample validity checks are available if needed, including temperature and creatine tests. Other types of target behaviors include treatment attendance, as verified by direct observation or clinical chart review, and completion of treatment goal-related activities like attending a doctor appointment or developing a resume, verified by receipt. Behavioral targets should be achievable and might already occur at a low level in the intended population. Else, manageable steps toward a larger goal can be reinforced. There is little need to reinforce behaviors that already occur frequently, and behaviors that are too difficult to accomplish will result in little or no exposure to reinforcement and improved outcomes will be unlikely.

Monitoring and Reinforcement Schedule

The monitoring schedule should maximize opportunities to detect the target behavior, and in the case of abstinence, minimize carryover effects of any substance use from one test to another. Monitoring might mimic the natural occurrence of the behavior (e.g. every therapy session). "Reinforcement schedule" refers to the rules used to present reinforcers following a behavior. Examples include the provision of reinforcement with certainty for every occurrence of a goal behavior as in voucher CM, or when the probability of reinforcement is less than certain, as with prize CM. Reinforcement schedules with specific characteristics designed to promote sustained abstinence are typically used in effective CM programs. Specifically, reinforcement escalates with consecutive target behaviors. Reinforcement is reset to a low level when the target behavior does not occur, and it is reinstated to a previously high level after the behavior occurs a set number of times after reset. Further, bonuses are often available for sets of target behaviors.

Reinforcement Magnitude

Another factor that can affect the efficacy of CM therapy is reinforcement magnitude. Incentive magnitude needs to be sufficiently large to compete with drug use and related undesirable behaviors. What constitutes sufficient depends on factors that can affect the subjective value of reinforcers including reinforcer immediacy, response cost, and patient characteristics like severity of dependence. Higher reinforcer magnitudes can increase response rates, although it is important to monitor for "ceiling effects," in which there is little or no room for improvement because the target behavior already occurs frequently or for other reasons. Importantly, CM programs that have relatively lowmagnitude reinforcement but that adhere to the behavioral principles discussed in this chapter can be efficacious.

Reinforcement Immediacy

Relatively immediate reinforcement can produce better outcomes than delayed reinforcement. This may be explained by a phenomenon from the field of behavioral economics referred to as delay discounting, which refers to the decrease in the subjective value of a reinforcer as time until it is available increases. Delays between earning and receiving rewards (the "exchange delay") can weaken the strength of the reinforcement; hence, the goal generally is to keep reinforcers relatively readily available to facilitate redemption and minimize delays to reinforcement.

Reinforcement Exposure

For CM to be effective, exposure to reinforcement is required. Conditions that prevent or limit exposure will negatively affect outcomes, as in the case of when a target behavior is particularly difficult, resulting in few patients meeting criterion. One option in such cases may be to shape behavior, a process by which incremental steps toward the desired behavior are reinforced. For example, given that 2–3 days of cocaine abstinence is required to test negative on urinalysis, a daily cocaine user will be less likely than an infrequent user to achieve this goal on day 1 of a contingent reinforcement protocol or even at all. In that case, abstinence can be shaped by making reinforcement contingent on increasing percentage reductions in cocaine metabolites (e.g. 25% reduction on day 1, 50% reduction on day 2, etc.), until a negative test is achieved. A disadvantage of such quantitative EFFICACY 41

testing is that it is more expensive and less readily available than the semiquantitative onsite urine dipstick tests used widely, and sending samples out for quantitative testing imposes delays, which can decrease treatment effects. Increasing exposure to reinforcement can also be accomplished through priming, a process of delivering incentives independent of abstinence or another target behavior and at a time before the goal behavior is possible or likely. For example, for a patient unlikely to test negative on day 1 of a protocol, submission of the urine sample itself independent of urinalysis results might be reinforced, to ensure exposure to incentives and encourage engagement. Another option might be to adjust reinforcement density, which refers to the magnitude of reinforcement over time. For example, a typical prize CM program has a 50% chance of drawing a prize each time that abstinence occurs, but there might be conditions in which a modified version with guaranteed reinforcement could be beneficial, like during the early stages of recovery.

Contingent Reinforcement

Finally, the contingent nature of reinforcement is essential to the efficacy of CM. Contingent reinforcement reliably produces increased abstinence and other goal behaviors compared to noncontingent, or the absence of, reinforcement.

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Methadone Maintenance

Methadone maintenance is efficacious for reducing heroin use and related high-risk behaviors. However, a relatively common problem that jeopardizes treatment outcomes for many patients is persistent substance use during treatment. Detection of ongoing substance use often results in punitive measures like premature detoxification and treatment discharge, which is associated with increased likelihood of high-risk behaviors like drug use, needle sharing, and other criminal activity and is therefore counterproductive. Medication compliance can also be problematic. For example, in the case of disulfiram (Antabuse) therapy for alcohol abuse, the medication causes highly aversive effects if alcohol is consumed, and many patients avoid those effects by simply not taking the medication. Further, while patients go to the clinic daily to receive their methadone medication, some patients nevertheless do not attend counseling as prescribed.

Early studies on CM in methadone patients investigated effects of contingent methadone take-home doses, dose adjustments, and cash to improve

abstinence, medication compliance, and treatment attendance. These were relatively small-scale studies, but results generally supported improvements with contingent incentives. For example, one study examined effects of abstinence-contingent methadone takehome doses and other privileges on benzodiazepine use and found that contingent reinforcement increased rates of drug-negative urine samples. Other studies found similar effects of contingent incentives on unsanctioned opioid use and cocaine use in polysubstance abusing patients, as well as increased adherence to disulfiram therapy and naltrexone therapy. Importantly, a few early studies compared the effects of not only the availability of methadone dose adjustments up with drug-negative tests, but also effects of contingent dose adjustments down with drug-positive tests, in polysubstance abusers. While both contingencies increased abstinence rates, dose-adjustments down lead to increased rates of treatment dropout, which is associated with significant adverse consequences like increased drug use and related criminal activity and risky behavior. That observation largely lead to the emphasis on positive incentives in all subsequent research on CM techniques. More recently, research has established the efficacy of both voucher CM and prize CM for improving during treatment abstinence and treatment attendance in cocaine-dependent methadone patients, as well as increased abstinence during periods of methadone dose tapering or detoxification with CM. Effects of CM extend beyond abstinence and treatment attendance to decreases in risky behaviors like needle sharing. Moreover, voucher CM has been used to improve abstinence in women who are pregnant, postpartum, or with children, a particularly vulnerable population. Other findings related to CM in methadone patients can be found in specific sections below.

Psychosocial Treatment

In psychosocial treatment, continued substance use can precipitate high rates of early treatment dropout, with negative effects on outcomes. The absence of an approved pharmacotherapy for cocaine dependence makes treating the disorder particularly challenging. In seminal research, Dr Stephen Higgins and colleagues examined effects of voucher CM for improving outcomes in psychosocial treatment patients. In that research, CM was explored as an adjunct to community reinforcement approach therapy, an intensive behavioral therapy that involves extensive outreach to garner social sources of reinforcement supportive of a drugfree lifestyle. Results indicated about a doubling in retention and abstinence rates with CM compared to

standard treatment. Subsequent research supported the importance of the contingent nature of reinforcement and isolated treatment effects to the CM component. Findings of improved abstinence and retention in psychosocial treatment patients with both voucher-based and prize-based CM, and in conjunction with intensive as well as less intensive counseling, have been replicated and extended. Abstinence-contingent incentives have also been used to prevent relapse in cocaine treatment patients immediately following release from residential treatment. Other findings of benefits with CM in psychosocial treatment settings are found in specific sections below.

As discussed further below, one challenge concerns the sustainability of CM treatment effects, which often dissipate after behavioral contingencies and reinforcement end. However, a reliable predictor of abstinence long-term is the longest duration of sustained abstinence (LDA) achieved during treatment, and CM increases LDA. This association between CM and LDA has been reported in psychosocial and methadone treatment patients, with voucher and prize CM, and under a variety of conditions.

While efficacious, it is also important to recognize that, as with treatments generally, CM does not improve outcomes for all patients. CM procedures that adhere to the principles and elements discussed in this chapter are associated with medium to large treatment effect sizes, but not all patients respond, and individuals differ on magnitude of response. One known factor that affects treatment response is addiction severity. Patients who have a negative versus positive urinalysis on admission, a proxy for addiction severity, seem to be more likely to respond to CM than those who test drug-positive. Marijuana-dependent and cocaine-dependent patients who have a positive urinalysis early in treatment are less likely to achieve significant periods of sustained abstinence during treatment. Upward adjustments to reinforcement magnitude or other modifications may be needed to improve outcomes in patients expected to be low- or no-responders to CM treatment (see Issues Central to CM below).

Other Substance Use

The research literature on CM for improving abstinence from marijuana, cigarette smoking, methamphetamines, and alcohol is relatively small but generally supports increased abstinence with CM.

Nicotine

Even with recommended pharmacological and behavioral treatments for smoking, many people do not quit, and relapse rates are high. CM in combination with

pharmaco and/or behavioral therapy may improve smoking outcomes. Research in the general population of smokers consists of laboratory studies and relatively small trials but results generally support feasibility and at least short-term efficacy. CM for smoking in a few specific populations has received more attention. The adverse consequences of smoking unique to pregnant and postpartum women are well-documented, and pharmacotherapy remains contraindicated, increasing the need for effective behavioral treatments. CM can increase short- and long-term smoking abstinence in this population, possibly with beneficial effects on birth outcomes. In people with other SUD, the prevalence of smoking is several times higher than in the general population, and smoking-related morbidity and mortality are disproportionately high. CM can reduce smoking and increase LDA from smoking in methadone and potentially other substance abuse treatment patients, but research is needed on combining CM with pharmacotherapy when appropriate or other methods to improve response rates and long-term benefits. Importantly, concerns that SUD treatment outcomes might be jeopardized if smoking is addressed have not borne out. CM for smoking in adolescents, young adults, and people with schizophrenia has also received some attention, with promising results.

Challenges of addressing smoking in the context of CM include technological limitations surrounding detection of the biologic indicators of smoking – expired carbon monoxide, a combustion byproduct, and cotinine, a major metabolite of nicotine. Issues with carbon monoxide include the possibility of environment exposure; an elimination rate of about 3–8 h, requiring multiple tests daily to detect all smoking; and the ability to avoid detection by adjusting smoking around scheduled tests. In response to the latter two, researchers have examined remotely monitoring and administering CM for smoking abstinence via webcam, e-mail, and the Internet. Results support feasibility, and there is increased interest in Internet-, computer-, and mobile technology-based interventions generally, for smoking and otherwise. Regarding cotinine, it can take about 4 days of abstinence to test negative for smoking, complicating reinforcement of abstinence.

Marijuana

There are a few well-controlled trials on CM in persons seeking treatment for a primary marijuana SUD, with results suggesting beneficial effects of combining CM with motivational enhancement therapy and cognitive behavioral therapy. It has been suggested that adolescent marijuana users might particularly benefit from CM. Adolescents do not typically initiate treatment themselves, likely due in part to having not

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yet experienced the serious adverse consequences of chronic use that can motivate older individuals to treatment. In this context of low motivation, the concrete rewards with CM might be one way to incentivize change. Initial research in this population indicates increases in LDA from marijuana during treatment with CM compared to that without it. Another population of specific interest is people with schizophrenia, in whom marijuana use is highly prevalent, with feasibility studies suggesting that CM might be beneficial in this population.

Monitoring marijuana abstinence in the context of CM has challenges. In chronic heavy users, it can take 3 weeks of abstinence to test negative. A 2-week notice prior to contingencies or a baseline period without reinforcement consequences on urine tests can be used in the interim. Another option may be to reinforce percentage reductions in metabolite levels during initial weeks (and after lapses), although approximately daily testing may be necessary for reliable results and testing equipment is expensive. Moreover, factors that can change the rate of cannabinoid release from fat cells, like exercise, can obscure results.

Methamphetamines

As with cocaine dependence, there are no approved pharmacotherapies for methamphetamine dependence, underscoring the need for effective behavioral treatments. CM can improve abstinence and LDA in methamphetamine treatment patients, particularly when reinforcement magnitude is relatively high. The literature on effects of CM in methamphetamine abusers outside of traditional drug abuse treatment settings is mixed. Issues that challenge use of CM techniques for methamphetamine problems include that use tends to occur more periodically, and methamphetamine has a longer elimination rate, than with cocaine, with implications for urinalysis testing.

Alcohol

There are efficacious behavioral treatments for alcohol problems but there is much room for improvement, and adherence with pharmacotherapy regimens (e.g. disulfiram, naltrexone) is generally low because of aversive direct or side effects of medications. CM can increase adherence to alcohol treatment medications. Currently, CM that directly targets alcohol abstinence is difficult due to by issues similar to those discussed above in relation to detecting smoking (quick elimination rate, ability to adjust use around scheduled sessions). Advances in technology like continuous alcohol monitoring devices and potentially Internet-based or other mobile procedures provide a potential means to overcome monitoring issues.

Non-Abstinence Behavioral Targets

Goal-Related Activities

A comprehensive treatment plan not only not only supports abstinence, but also supports steps toward goals in other problem areas, such as family and social functioning and employment. A needs assessment can be conducted with patients to identify goal areas, and activities related to those goals identified for completion and reinforcement, with the difficulty of activities adjusted depending on psychosocial functioning. Few studies have compared CM for abstinence and CM for activities, with mixed results. There is demonstrated efficacy for CM when abstinence and activities are independently reinforced.

Employment

As introduced above, the Therapeutic Workplace intervention is an intensive integrated approach to treating chronic unemployment in persons with long histories of SUD who are unsuccessful in standard treatment. The Workplace involves regular urinalysis monitoring with access to job skills training and subsequently employment, both contingent on negative drug tests and workplace attendance. Positive or missed urine tests result in pay reductions, which can be earned back by submitting negative drug tests and attending work. Initial research in pregnant and postpartum women demonstrated increased cocaine and opioid negative drug tests and LDA in CM compared to usual care patients, with improvements in abstinence evident at year 3. Subsequent studies in methadone maintained cocaine users and injection drug users suggest that exposure to reinforcement early on may be critical. Moreover, there is some evidence that similar procedures may be effective in alcohol-dependent homeless persons.

Housing

SUD is prevalent among the homeless, as is serious mental illness. It can contribute to risk of homelessness, and the homeless are at increased risk for illness and psychosocial deficits in myriad domains, with severely limited access to services. Dr Jesse Milby and colleagues developed an integrated approach to SUD treatment and housing for homeless crack cocaine users seeking treatment. Day treatment involves daily individual and group therapy with objective goal setting and random urinalysis, transportation, and a midday meal. Contingent housing involves access to an apartment or group home contingent on drug-negative tests, and drug-positive tests or unexcused absences result in transition to a shelter, with an opportunity to return to housing after a set number of drug-negative tests. Contingent work therapy/employment consists of training and paid experiences, and with positive tests or unexcused absences resulting in a reset to a lower hourly wage. In clinical trials on contingent housing and employment/training with day treatment or cognitive behavioral therapy in this population, LDA during treatment predicted long-term abstinence regardless of treatment condition as well as long-term housing and employment stability. In another study, prize CM was used to engender increased abstinence in homeless persons with both substance use and psychiatric problems. Perhaps not surprisingly, an integrated and comprehensive approach to treating these chronic issues seems to produce the best outcomes.

Medication Adherence

Several pharmacotherapies exist for SUD (agonists, antagonists, aversive medications, anti-craving medications) and for problems common in SUD populations (e.g. human immunodeficiency virus, comorbid psychiatric conditions). Adherence with agonist medications is generally relatively high because of the reinforcing effects of the medications, but diversion to nonprescription use can occur. Adherence is more problematic when medications produce adverse effects with continued substance use or aversive side effects themselves. The delayed benefits to health with many medications and low motivation to change in general can further undermine medication adherence. Notably, CM can introduce immediate rewarding effects and increase medication adherence.

DISSEMINATION AND UPTAKE CHALLENGES

As discussed in this chapter, there is strong empirical support from well-designed randomized clinical trials demonstrating that CM interventions that adhere to the key principles reviewed above are efficacious, and there is growing interest in translation of CM from research to practice. There have been several relatively large efforts to integrate CM into practice. New York City Health and Hospitals Corporation successfully provided CM services to five SUD treatment facilities. CM workshops were provided to 432 therapists in South Carolina. Virgin Healthcare initiated a multimilliondollar employee program in which insurers fund prizes for behavior change. The Veteran's Administration called for use of CM nationwide in substance abuse treatment programs in 2011, and as of 2012, it has been successfully implemented in over 60 clinics. In England, efforts to introduce CM into the National Health Care System have been undertaken. Some variables that influence the dissemination and uptake of evidence-based treatments in general as well as those specific to CM are discussed below.

Costs

Cost is a primary concern. Various aspects of CM have associated costs. Training and oversight directly affect treatment fidelity and need to be provided to staff who will be administering CM. There are operating costs, including those incurred by the frequent urinalysis schedule required for effective CM, which exceed standard testing practices. Incentive costs are another concern, and even low-magnitude incentives are a cost that many programs cannot absorb. One way to reduce costs might be automated procedures like that possible via computers. It might also be possible to contain some costs by integrating CM into settings like government programs, workplaces, and the criminal justice system which have large infrastructures already in place and have advantages like long-term relationships and large target audiences. Another option might be to identify appropriate low or no-cost incentives. Soliciting community donations might also be viable, which has been done to sustain CM programs for treating cigarette smoking in pregnant, postpartum, and parenting women, although the extent to which communities are willing to support these programs may or may not generalize to other populations. Deposit contracts are an example of a patient-sided approach to funding incentives, but access is limited to patients willing and able to provide the required funds. In dual diagnosis patients, one possibility may be to make receipt of disability payments contingent on therapeutic behaviors. Options for combinations of patient, provider, and third party subsidizing of costs may offer the flexibility to best accommodate the needs of a wide range of potential service providers and users. In terms of overall costs, the relative cost-effectiveness of CM treatment depends in part on the referent treatment, incremental cost-effectiveness ratios, and threshold values on acceptability curves. There is empirical support for the cost-effectiveness of CM, but larger scale research is required to more fully determine the conditions under which it is so. Ultimately, the research and treatment communities, insurers, political forces, treatment service users, communities at large, and other stakeholders will determine the acceptability of cost-effectiveness and cost-benefit ratios and willingness of society to pay for this evidence-based treatment.

Sustainability of Treatment Effects

One aspect that will affect determinations of costeffectiveness and cost-benefit is the sustainability of treatment effects. Treatment gains generally drop off after discontinuation of incentives. It may be that some situations warrant a continuing care approach, which is the case in drug abuse treatment more generally and not unlike treatment and treatment response with diabetes, hypertension, and asthma, for which a return of symptoms and signs precipitates a continuation or reinstatement of care. Another consideration is that the best approach to defining treatment response is subject to debate, with important implications for observed (or lack thereof) treatment effects, long-term or otherwise. Some have explored tapering reinforcement at the end of a treatment episode to possibly increase the durability of benefits. Another approach might be to combine CM with cognitive behavioral therapy or potentially other therapies, as CM increases abstinence during treatment while cognitive behavioral therapy has more substantial benefits long-term. Notably, there is some evidence in the literature of improved long-term outcomes with this combined treatment approach in cocaine-dependent methadone patients and marijuana treatment patients.

Generalizability and Fit

Randomized Clinical Trials

Concerns that the methodology and outcomes of wellcontrolled randomized clinical trials may not generalize to "real-world" treatment could hamper uptake of CM. Narrow inclusion criteria may produce research samples that appear dissimilar to patients at large. Interventions may appear disconnected from the complicated reality of practice. Further, well-trained research staff have largely administered and managed CM interventions to date, raising doubts about feasibility and effectiveness in non-research settings. Recognizing these issues, some researchers have loosened eligibility criteria to improve generalization. Further, studies have been conducted in which community treatment staff have been successfully trained and then administered CM, with improved outcomes observed with CM versus usual care. One example is a National Institute on Drug Abuse Clinical Trial Network large multisite trial in which cocaine and methamphetamine psychosocial treatment patients were randomly assigned to usual care only or usual care plus prize CM, with reinforcement contingent on testing negative for amphetamine, cocaine, and methamphetamine and alcohol, and bonuses for opioid- and marijuana-negative tests. Treatment retention and abstinence were increased in the CM condition, and CM patients were more likely to achieve specific durations of LDA compared to usual care patients. In a analogous trial in methadone patients, CM patients were twice as likely to submit negative tests and were several-fold more likely to achieve specific durations of LDA compared to usual care patients. Ultimately, an ongoing dialogue about the benefits and limitations of scientific research, along with efforts that demonstrate effectiveness under conditions that promote feasibility and generalizability, is needed.

One versus Multiple Drug Targets

The tendency in research to focus on one drug and the clinical tendency not to may contribute to a perceived lack of fit between research and practice. Research often focuses on a primary SUD that is targeted for reinforcement, and there are no reinforcement consequences on other substance use. Advantages include that having a single drug target is associated with increased treatment effect size relative to studies with multiple drug targets. By contrast, the nonresearch treatment scenario is largely one of polysubstance abusers and all patients receive treatment for all SUD. Typically, CM is employed against a backdrop of usual care in which all patients are treated for all SUD, but the misalignment between approaches may provoke opposition. If there is concern or evidence that a goal of complete abstinence might be too difficult for some polysubstance abusing patients and results in little or no reinforcement opportunities, one option may be to make reinforcement contingent on abstinence from the primary substance of abuse, with bonuses for abstinence from secondary substances. Improved understanding of these and other conditions under which targeting one or multiple substances is most beneficial may increase acceptability of CM.

Abstinence versus Attendance

Most CM research has focused on abstinence. Although highly clinically relevant, disadvantages in practice include that urinalysis frequency rarely meets ideal monitoring and reinforcement schedule requirements of CM, and the resources necessary to increase testing are unlikely to be available at many programs. Attendance is more easily verifiable via review of daily census records and at little or no additional cost, and reinforcing attendance may sufficiently improve outcomes in some patients. However, there are circumstances in which reinforcing abstinence is more likely to improve outcomes and the costs of doing so especially justified. For example, patients with a positive urinalysis test at treatment admission tend to have worse treatment outcomes than individuals who test negative, and reinforcing abstinence can decrease drug use and increase retention in those patients. Additional research is needed to inform decisions about the pros and cons of targeting abstinence versus attendance under various conditions relevant to practice settings.

Individual versus Group Treatment

Another area of apparent mismatch between research and practice is the typical practice of private meetings with patients to conduct CM in research compared to the preponderance of group therapy in practice. It follows that interventions that can be administered in group may be more easily integrated into usual care. Research on prize CM delivered in a group setting indicates feasibility and efficacy of reinforcing attendance as well as reinforcing both attendance and abstinence (with precautions to protect patients' confidentiality) in this setting, when CM is administered by research staff and when conducted by community therapists.

Therapeutic Process

There is some concern that the focus on external reinforcers with CM might interfere with internal motivation to change. Comprehensive treatment plans address a multitude of issues underlying addiction and recovery, and all patients benefit from those services, some of which may improve motivation or not. How CM interacts with motivation is an empirical question, and the few studies that have addressed motivation with CM have mixed results. Related, there is some evidence that CM delivered in group therapy may be associated with improved therapeutic alliance and group cohesion. It will be important for future research to examine relations between CM, therapeutic process variables, and treatment outcomes.

SUMMARY

CM is the systematic application of behavioral principles of positive reinforcement to the treatment of SUDs. CM interventions that adhere to specific key principles have demonstrated efficacy for improving outcomes in a wide range of substance abuse treatment populations and settings, and CM is among the most efficacious evidence-based treatments for substance abuse. Some areas for further research include identifying conditions and methods that can lead to increased treatment response and sustained treatment benefits long-term, in substance abuse patients generally as well as in specific populations; useful combinations of CM and other effective treatments for SUDs; and, methods to facilitate translation of CM techniques from research to practice.

SEE ALSO

Behavioral Treatments for Smoking, Community Reinforcement Approaches: CRA and CRAFT

List of Abbreviations

CM contingency management LDA longest duration of abstinence SUD substance use disorder

Glossary

Agonist a chemical substance that can produce the same reaction or activity when it binds to a receptor on a cell as some endogenous substance that typically binds to the receptor.

Antagonist a chemical substance that tends to nullify the action of another substance by, for example, blocking binding of that substance to a cell receptor, but without producing a response itself.

Buprenorphine a semisynthetic narcotic analgesic that is administered sublingually to treat opioid dependence.

Effect size a standardized measure of the strength of an effect of an independent variable on a dependent variable. It represents the change (measured in standard deviations) in an average person's outcome (the dependent variable) if given the treatment (the independent variable).

Longest duration of abstinence The greatest period of time (usually in weeks) during which all breath and urine samples collected test negative for all substances targeted, ostensibly when samples are collected and tested sufficiently frequently and at adequate intervals to detect substance use if it occurs.

Opioid a substance that possesses some properties characteristic of opiates but unlike opiates not themselves contained in the resin of the opium poppy. Examples include heroin, oxycodone, and methadone.

Priming refers to an increased sensitivity to certain stimuli (reinforcement, in the sense used in this chapter) due to prior experience.

Reinforcement in behavioral science, the presentation of a stimulus following a response that increases the frequency of subsequent responses.

Shaping a process through which successive approximations of a desired behavior are reinforced to increase the likelihood of the desired behavior in the future.

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6

Community Reinforcement Approaches: CRA and CRAFT

Robert J. Meyers*, Jane Ellen Smith*, Brian Serna**, Katherine E. Belon*

*University of New Mexico, Albuquerque, NM, USA **Isleta Behavioral Health Services, Isleta, NM, USA

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COMMUNITY REINFORCEMENT APPROACH: CRA

Overview

The Community Reinforcement Approach (CRA) is a behavioral treatment for individuals with substance use disorders that was introduced by George Hunt and Nate Azrin approximately 40 years ago. As the name implies, it is based on the belief that one's "community" (i.e., family, romantic partners, friends, coworkers, teammates, congregations) plays a significant role in reinforcing (rewarding/supporting) recovery. Thus it is not unusual for a critical member of the client's family community (i.e. a partner) to accompany the client to several therapy sessions. Overall, the goal of CRA is to help clients develop a clean and sober lifestyle that is more rewarding than a lifestyle filled with substance use. CRA accomplishes this through the use of behavioral procedures based on reinforcement principles that steer clear of confrontation. Given that CRA is

a behavioral and not a cognitive-behavioral treatment, it does not focus on cognitions. Importantly, CRA has been used successfully to treat individuals with varying degrees and types of substance use problems and across different treatment settings (inpatient, outpatient, day treatment). The first half of this chapter provides an overview of the treatment for the substance-abusing individual (CRA), whereas the second half reviews the treatment for the loved ones of treatment-refusing alcohol or illicit drug users (Community Reinforcement and Family Training; CRAFT).

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CRA Functional Analyses

CRA's Functional Analysis for Aubstance Use is a semi-structured interview that outlines triggers and consequences (both positive and negative) of substanceusing behavior, thereby providing a framework for a conversation about the context within which the use occurs. This wealth of information is a map that guides the selection of other CRA procedures in subsequent sessions. Specifically, this functional analysis is important for (1) recognizing and interrupting internal and external triggers to assist in relapse prevention, (2) providing a measurement of quantity and frequency of use that can be contrasted later in therapy, (3) identifying and amplifying the client's reported reasons to change (i.e. long-term negative consequences) in order to activate him/her to begin the change process, and (4) identifying the factors that reinforce the substance use (i.e. shortterm positive consequences) so that healthy behaviors offering somewhat similar rewards can be found. Identifying the most rewarding aspects of using substances appears to be one of the most powerful parts of the functional analysis exercise. Clients always are pleasantly surprised that a therapist is interested in discussing this topic, and they readily outline their perceived alcohol/ drug-associated rewards (e.g. mellows them out, makes social activities more fun, addresses their boredom). This information is critical as far as helping clients build and maintain a healthy new lifestyle that addresses their particular needs in the process. The CRA Functional Analysis for *Pro-Social* Behavior is used to highlight enjoyable activities and eliminate barriers so that these behaviors may be selected over substance use more often.

Sobriety Sampling

Sobriety Sampling is a "gentle" approach to abstinence; an alternative to the traditional message that an individual can never drink/use again for the rest of his/her life. CRA recognizes that the notion of long-term

abstinence may seem overwhelming at treatment onset and consequently could lead to dropout. So instead, CRA therapists first discuss the advantages of a "trial period" of sobriety, such as the opportunity to gain family support and test new coping strategies. Once a client agrees to sample sobriety, the negotiation begins. Regardless of whether the client settles on 3 or 30 days, the next appointment should occur prior to the end of the contracted period of sobriety so that additional trial periods of abstinence can be linked.

Agreeing to a time-limited period of abstinence is only the beginning, since a plan for accomplishing this goal must be established. The triggers that were outlined in the CRA functional analysis for substance use are examined and strategies for addressing them are devised. For example, if a client had reported previously that he/she often dealt with his/her frustration (internal trigger) by getting high, the sobriety sampling plan would include both a strategy for minimizing the client's frustration at high-risk times, and for coping with frustration, once it appeared, in some manner besides getting high. In subsequent sessions, the therapist would highlight the positive consequences experienced by the client as a result of being clean/sober and would introduce problem-solving if abstinence had been threatened.

The Treatment Plan: Happiness Scale and Goals of Counseling

The Happiness Scale is a versatile tool that assesses the client's perceived happiness in 10 life areas (e.g., social life, job/school) on a 10-point scale ranging from 1 (completely unhappy) to 10 (completely happy). It is administered at the onset of therapy, and then periodically throughout to monitor progress. Clients are informed that the Happiness Scale highlights potential avenues for increasing healthy rewards in their life.

The Goals of Counseling mirrors the Happiness Scale's categories and is used to list clients' goals and strategies. Clients are trained to word their goals in terms that are brief, specific, positive (what the client wants as opposed to what the client does not want anymore), under the client's control, and realistic. Furthermore, CRA stresses the importance of successive approximations toward goals. For example, if a client rated money management a "6" on the Happiness Scale, the clinician might ask, "What could you do over the next week to increase that rating to a 7?" Such a question invites clients to identify specific tasks that could incrementally increase their happiness.

Communication Skills

Being able to communicate effectively is a critical part of a rewarding lifestyle. CRA therapists explain that CRA PROCEDURES 49

positive communication is not only "contagious," but it also increases the likelihood that clients will get what they want. Communication skills are taught by describing the components of effective communication while supplying examples, by practicing the skills in role-plays, and by having the client apply the skills to real-world situations for homework. CRA's positive communication components are: be brief, refer to specific behaviors, use positive wording, state your feelings, give an understanding statement, take partial responsibility, and offer to help.

As an example, assume that a female client was upset because her husband was unwilling to accompany her to new nondrinking social activities. Below are attempts by the client to phrase her request for her husband to attend a movie with her:

Attempt #1: "How am I supposed to find new sober things to do if you won't ever try any of them with me? What's so awful about going to a movie with me?"

Attempt #2 (after therapist feedback): "I know you'd rather stay home on Friday nights because you're really tired from a hectic week of work [understanding statement], but I really need to get out of the house. Can't we go to a movie?"

Attempt #3 (after further therapist feedback): "I know you'd rather stay home on Friday nights because you're really tired from a hectic week [understanding statement], but Friday nights are really stressful if I don't have something fun planned [feelings statement]. What if I ordered a pizza so we could have a quick dinner on Friday, and then we could head out the door to a movie without any hassle [offer to help]?"

Problem-Solving Skills

It is imperative for clients to learn how to solve problems, even complex or emotionally charged ones, so they can focus on meeting their goals. CRA's problemsolving procedure is adapted from D'Zurilla and Goldfried. To illustrate both the problem-solving procedure and a reasonable time for introducing it in a therapy session, assume that a 35-year-old male client made a goal to incorporate more clean/sober social activities into his week. He decided to play basketball at least weekly with his nonusing buddies, but a dilemma arose when his wife said she did not want him to go as he was heading out the door. The problem became apparent to the therapist when the homework assignment was reviewed at the start of the next session. The therapist asked, "Phil, how did the basketball assignment go this week?" Phil replied, "Not so good. My wife got upset as I was leaving on Wednesday to play, so I didn't go. She said she was afraid that I was going to get high; that I might run into my former using buddies. I got mad at her and left, but I just went for a quick walk." The therapist responded, "Well, it sounds like you're using some of your skills for handling your anger, so that part is good. But what do you think about your goal of playing more basketball with your nonusing friends? Is this something you'd still like to do?" Phil answered, "Yes, but I don't know how it's going to happen without creating a war at home." The therapist remarked, "Sounds to me like it's a problem for which we could use some problem-solving skills. Shall we give it a shot?" The therapist would explain the objective of the procedure and define each of the steps while working on the relevant problem. In the problemsolving "worksheet" below, sample responses are supplied for this case.

- **1.** *Define the problem*: This step distills complex problems into one that is specific and manageable.
 - 1st (vague) definition: "My wife doesn't trust me anymore"
 - Refined definition: "My wife doesn't trust me to stay away from my old using friends if I play basketball in the park."
- **2.** *Generate alternatives (brainstorm)*: Brainstorming demands quantity. Suggested alternatives should not be censored, as unrealistic or counterproductive ones will be vetted in subsequent steps.
 - Sample suggestions: have brother go too; call or text wife every 45 min; play at new indoor court; just tell wife that I won't use; have one of my nonusing friends call her to reassure her.
- **3.** *Eliminate unwanted suggestions*: The client is empowered to eliminate solutions without explanation.
- **4.** *Select a solution*: The client chooses one possible solution from those remaining, and describes how it will be implemented.
 - Play at the new indoor court (ride with Sal; check for open court nights)
- **5.** *Check for obstacles*: Numerous obstacles should be generated, even when the client initially reports that there are none.
 - No courts free
 - One of the friends can't go
- **6.** Address each obstacle: If an obstacle cannot be addressed, another potential solution should be selected instead.
 - No courts free (reserve one in advance)
 - One of the friends can't go (have a back-up friend lined up)
- 7. *Evaluate the outcome*: The outcome of the assignment is reviewed at the subsequent session.

The therapist's job is not to solve their clients' problems, but to teach them a technique that will help them solve their own problems. It is often necessary to repeat this procedure with several problems until the client has internalized the steps and can apply them with proficiency and confidence outside of the session. The CRA therapist always links the accomplishments that grow out of the problem-solving exercise (e.g. the wife no longer objecting her husband leaving to play basketball with his nonusing friends) with the client's own goals (i.e. to increase his nonusing social activities).

Drink and Drug Refusal Skills

Clients seeking assistance to change substance abusing patterns often struggle with the ability to refuse substances assertively. This occurs for many reasons, not the least of which is that the clients have no reference point for how to conduct themselves in social situations without using substances. Many clients also do not have appropriate models for assertive behavior and find themselves vacillating between passivity and aggression. To complicate this further, clients frequently overestimate their ability to refuse drugs/alcohol. Statements such as "All I have to do is just make up my mind not to drink" are common and are often said in sessions that precede a relapse. Unfortunately, most clients can become overwhelmed by social cues and external reinforcers to use, even if they are motivated to remain abstinent.

Teaching clients drink/drug refusal skills can be broken down into four parts, starting with reviewing high-risk situations. Frequently these are extrapolated from the functional analysis. Next, a person who can provide support in the high-risk situation is identified. This individual is often a family member or a significant other who is invested in the client's ability to remain substance free. Then options for assertive refusal are reviewed and applied to the high-risk situation. Finally, a series of role-plays follow, often starting with a *reverse* role-play (with the clinician taking on the role of the client). This reversal allows the clinician to effectively model the refusal skills and gives clients a chance to add some authenticity to the conversation, as they may have pressured their own peers to use in the past.

Job-Finding Skills

In order to maximize "community" reinforcement, most individuals not only need a job, but also a satisfying one. In addition to providing the obvious financial rewards, a job can offer access to other reinforcers as well (e.g. pleasant social interactions, increased self confidence). For the many substance-using clients who do not have the skills to find or keep a meaningful job, CRA's job-finding training can be worthwhile. In brief, CRA's successful job acquisition involves the client

and therapist working together to develop a resume, generate job leads, complete applications, practice telephone inquiries and follow-up calls, and rehearse for job interviews.

Azrin firmly believed that finding a job was a fulltime job. Consequently the CRA approach to obtaining a job is very structured, comprehensive, and efficient. This deliberate job-finding approach offers a stark contrast to many newly sober individuals' common practice of taking the first job they can find without carefully weighing its pros and cons. So, for example, when generating ideas for the types of job of interest, the CRA therapist asks whether the desired job would place the client in a high-risk environment in terms of substance use. In generating and following up on job leads, clients are taught to be appropriately assertive, but to be prepared to cope with rejection in a healthy manner if they are faced with it. Role-plays are used extensively in preparation for initial telephone inquiries about job openings, as well as for actual job interviews. Importantly, clients are assisted with identifying their strengths so that these can be highlighted on applications and in interviews.

CRA's job maintenance component focuses on checking in with clients regularly, usually through the Happiness Scale, to be sure that the expected job reinforcers are present. Also, time is devoted to addressing possible threats to keeping the job. For example, if a client was fired from past jobs due to arguments with the boss, anger management exercises or problem-solving would be practiced as a precaution. A full description of the job-finding procedures was published in a comprehensive manual by Azrin and Besalel.

Social/Recreational Counseling

It is common for the social lives and friendships of substance-abusing individuals to center around drugs and alcohol. Given that such relationships and activities can be powerful triggers for relapse, CRA places a major emphasis on helping clients develop and nurture a happy and healthy social life. This task is usually quite difficult, since many clients are simply unaware of nonusing options for fun, or they doubt that they will find pleasure in clean/sober activities. CRA has several methods for addressing these issues.

As noted earlier, the functional analysis for pro-social behavior may be used to increase the likelihood of a client selecting a healthy social activity (that is already occurring occasionally) over substance use. For example, assume a client routinely has been going to a bar after work to drink with coworkers. However, approximately twice a month he opts to play racquetball with a friend for a few hours after work instead. The functional analysis for pro-social behavior could be

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used to examine the factors that set the stage for the client to choose racquetball over the bar periodically, and the barriers that interfere with him selecting racquetball more often. So imagine the client reports that the main positive consequences of playing racquetball (i.e. decreasing his job-related stress, allowing for fun time with a friend) are very similar to the positive consequences he experiences in the bar. Importantly, racquetball offers additional benefits (e.g. provides a healthy workout, boosts confidence in his athletic skills). This functional analysis would also highlight the barriers to choosing racquetball over drinking after work and would provide an opportunity to address them. For instance, if the client says he feels sore after playing racquetball and needs time to recover before playing again, the CRA therapist could help the client develop a plan for minimizing the soreness. The plan could even include additional enjoyable activities, such as getting a set of weights or setting up some other fitness routine that would improve his level of fitness overall. The details would need to be carefully planned out regarding when this new workout would take place, and the importance of the activity being pleasant enough to compete with drinking would be stressed. Given that one of the positive consequences of drinking at the bar was to socialize, the therapist might suggest that the new fitness regime be scheduled at a gym or at least with a friend. Together the therapist and client would develop an assignment for the week, such as to go to a gym as the guest of a member/friend and sample some weightlifting under the guidance of a trainer. The therapist would inquire at the next session about the amount of pleasure obtained from the assignment and would help modify the plan if the activity did not appear to be sufficiently enjoyable to compete with drinking at the bar.

The problem-solving procedure was illustrated earlier with an example of how to address barriers for participating in a social activity, but it also can be used to generate ideas for novel social activities. Assume a 30-year-old, single client states that she has no idea how she might replace her weekend "partying" with a fun but healthy activity. The problem-solving procedure would first narrow down the problem (e.g. to Saturday nights), and the therapist would help the client brainstorm an array of potential activities (e.g. take an evening dance class, go out to dinner with nonusing friends). Eventually the client would settle upon one new activity to sample in the upcoming week, and obstacles would be addressed. As always, the outcome would be reviewed in the next session.

Taking the first step toward sampling a new activity, particularly when one is clean/sober, can seem monumental to some clients. CRA's systematic encouragement may be warranted in these cases. It entails

helping clients make that first contact during the session, such as a phone call to obtain a recreation facility's hours of operation, or a call to a family member to line up transportation. Role-plays are frequently conducted prior to placing these calls. Importantly, the therapist follows up in the next session to determine whether the client enjoyed the activity, and if any problems arose that needed resolving. For situations in which numerous CRA clients are being seen at one site, a social club has sometimes been established to provide positive social experiences. Clients who have become isolated because of their drinking/drug use are the prime candidates for the social club, because it enables them to practice their social skills in a nonthreatening sober environment, and to experience pleasure from clean/sober activities. Typically these clubs hold their activities during high-risk times, such as weekend nights. The substance-free activities themselves may include having pot-luck dinners, watching rented movies as a group, playing cards, or having local musicians entertain. Not surprisingly, social clubs are most successful when the *clients* play a major role in selecting the weekly activities.

Relationship Therapy

Another potential source of reinforcement that is part of many individuals' "community" is their relationship with a significant other. CRA includes several sessions of behavioral couple therapy for clients with romantic partners. This relationship therapy begins with each partner completing the Relationship Happiness Scale; a couple's version of the Happiness Scale. The Relationship Happiness Scale asks both the client and the partner to rate their happiness with the *other person* in 10 different areas (e.g. household responsibilities, social activities). Each individual selects one category in which he/she would like to see a change in the other person in the upcoming week, and the therapist helps them develop brief, positive, and specific requests. The positive communication skills that have already been taught to the client are reviewed for the partner, and the request for change is made using these skills. Negotiation ensues until an assignment is agreed upon; sometimes problemsolving skills are introduced to facilitate the process. The goals and assignments are documented on the Perfect Relationship form, which is the couple version of the Goals of Counseling.

The Daily Reminder to Be Nice is an exercise to "jump start" pleasant interactions at home in the early stages of therapy. This seven-item form includes items such as: expressing appreciation for something the partner does, and giving a pleasant surprise. Each individual makes a commitment to do at least one of these pleasant acts for the partner daily, and session time is devoted to practicing several of them. The therapist checks on

progress toward increasing these behaviors at the next session and troubleshoots any problems. Subsequent couple sessions are devoted to selecting additional categories from the Relationship Happiness Scale and negotiating goals.

Relapse Prevention

Although CRA procedures overall are designed to prevent relapse, several additional procedures specifically target high-risk situations. The Early Warning System entails identifying a suitable family member or friend who is in a position to recognize the client's early warning signs for relapse, and establishing a plan of action for that individual to help deal with an impending relapse. Assume, for example, that a male client asked his wife to support his decision to abstain while out to dinner with friends. Given that the wife knew her husband started stammering and fidgeting when he was battling over a decision to drink, the plan was for her to announce that she had received a text from the sitter that their child was sick, and so they needed to leave. An Early Warning System is only incorporated into treatment if both the client and the family member/ friend agree to the terms, and both individuals demonstrate that they can be supportive of each other in the

In the event that a relapse does occur during treatment, a CRA Functional Analysis for Relapse may be used to identify the specific contributing factors. Alternatively, the therapist may outline the behavioral chain of events leading to the relapse and assist the client in realizing that different decisions can be made at various "links" throughout the chain of events in the future so that relapse is thwarted.

Medication Monitoring

The Medication Monitoring component of CRA was introduced initially as a method for ensuring that clinically appropriate individuals took their disulfiram (Antabuse). Disulfiram, a "deterrent" to drinking, causes an acute physical illness that can range from mild to very severe if a person who is taking it drinks alcohol. It is essential to have a physician involved in its prescription and management. Primary candidates for disulfiram as a temporary adjunct to treatment are clients who are having tremendous difficulty achieving even short periods of abstinence, or those who will face very serious consequences if they drink again.

A monitor is a critical aspect of disulfiram treatment. Typically a family member, this monitor attends a therapy session with the drinker so that a daily routine for administering the disulfiram can be established, and positive communication can be practiced as part

of this ritual. For example, a couple may start breakfast each morning with the disulfiram administration. The family member might give the disulfiram to the drinker and say, "I can't tell you how much it means to me that you've made this commitment to being sober. You're doing a wonderful thing for yourself and our family." The drinker would respond with a comment such as, "Thanks for always being here to support me. It's made a big difference in my recovery."

Still, the monitor also serves as part of an Early Warning System, since the client's refusal to take disulfiram for several consecutive days could be a signal that a relapse is imminent. Thus, an agreed-upon plan would already be in place regarding how the monitor should respond in such a situation (e.g. call the therapist). In more recent years, this monitoring system has been used with other medications for clients with comorbid disorders, such as adolescents with attention deficit hyperactivity disorder (ADHD) or adults with bipolar disorder.

CRA SCIENTIFIC SUPPORT

CRA was first tested by Hunt and Azrin on inpatient alcoholics back in the 1970s. Two studies found that inpatients who received CRA improved significantly more than patients who received the hospital's standard treatment; 12-step groups. These improvements were found in the areas of drinking, hospitalization, employment, and time with family. Next CRA was tested in two outpatient studies. The first study discovered abstinence rates that favored the CRA + disulfiram monitoring condition over the two 12-step conditions. A larger outpatient study detected roughly similar findings for the first 6 months after treatment began, but some of the effects were lost in the later follow-ups. CRA's effectiveness also was demonstrated with homeless individuals in a day treatment setting. Overall, meta-analyses and comprehensive reviews routinely have ranked CRA near the top of the list of alcohol

CRA has been used to effectively treat illicit substance problems as well; primarily cocaine or opioid dependence for adults and marijuana abuse for adolescents. Much of this CRA research with adults has added a voucher component, in which vouchers representing "prizes" are used to reward abstinence in the early stages of treatment (a full review is beyond the scope of this chapter). CRA's demonstrated effectiveness with adolescent marijuana abusers is reviewed in this volume in a chapter devoted to adolescent treatment.

One of the "unknowns" with CRA is *why* it works, and so studies are under way in which that question is being addressed. Additionally, we are attempting to

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determine why a subset of individuals does not seem to respond to CRA treatment. A modified CRA program for treating obesity is also in the planning stages.

COMMUNITY REINFORCEMENT AND FAMILY TRAINING: CRAFT

Overview

CRAFT is a scientifically supported treatment designed by Robert Meyers to work through the family members (concerned significant others; CSOs) of treatment-refusing substance abusers (identified patients; IPs) in an effort to get the IPs to seek treatment. CRAFT teaches CSOs to rearrange their own behavior toward the IP so that clean/sober behavior is rewarded and drinking/drug use is experienced by the IP as less pleasant. CRAFT grew out of CRA; the science-based treatment intended for working directly with the substance abusers. Early CRA researchers recognized that the family members of problem drinkers were an underutilized resource, as the family members had access to powerful reinforcers and contingencies in the clients' lives which could serve to influence change.

Another CRAFT goal is to enhance the psychological functioning of CSOs, regardless of whether their IP enters treatment. These family members experience extremely stressful lives, much of which is the result of the IP's ongoing substance use. CSO problems include depression, anxiety, legal issues, parenting problems, emotional and sexual relationship issues, financial instability, and domestic violence.

Until recently, distressed CSOs primarily had Al-Anon and the Johnson Intervention as options. Al-Anon, a 12-step program that advocates "loving detachment," has been shown to enhance the well-being of CSOs but has not been successful in getting resistant substance abusers into treatment. The Johnson Intervention is a "surprise party" during which CSOs confront IPs about their substance use and demand treatment entry. It has high engagement rates when the intervention is fully carried out, but the vast majority of CSOs who begin the Johnson Intervention dropout.

CRAFT PROCEDURES

Enhancement of CSO Motivation

During the first CRAFT session, CSOs are given time to describe the problems created by their IP's substance use and their own associated distress. Next, CRAFT's goals and procedures are outlined, and the expected role of CSOs is highlighted. Finally, in an effort to instill positive expectations for change, an overview of the

scientific support for CRAFT is presented. This includes a summary of CRAFT's success in engaging treatment-refusing IPs into treatment and enhancing CSOs' functioning, and an overview of the types of individuals and relationships who have responded well (e.g., IPs with various drugs of choice; CSO-IP relationships that included spouses, parents, adult children, etc.).

Functional Analysis of IP's Substance-Using Behavior

CRAFT uses a variation of the CRA Functional Analysis of substance using behavior, with the CSOs completing the form for their IPs. Recognizing triggers and consequences is necessary to formulate points of influence CSOs have over their IP's using behavior. Assume, for example, that a sister (CSO) who is completing the functional analysis for her brother (IP) reports in the positive consequences column that the brother likes smoking marijuana after a stressful workday because it helps him relax. The clinician would inquire about other ways that the IP has relaxed after work in the past and would see whether the CSO could play a part in increasing the likelihood that the brother would choose these healthier methods over smoking. At the same time, care would be taken to make sure the CSO understands that although the objective is to influence her brother's behavior, ultimately she cannot control it, nor is she culpable for negative outcomes resulting from his substance use decisions.

Domestic Violence Precautions

CRAFT-trained CSOs are taught to change their behavior toward their IP during times of substance use; behavior changes that are intended to be experienced by IPs as unpleasant. Given the already strong correlation between substance use and domestic violence, it is critical to assess the potential for violence when determining which behavior changes on the part of the CSO are safe to introduce. Domestic violence was an exclusionary factor in the original CRAFT studies, and so the therapist also must decide whether it is safe for CSOs to receive CRAFT treatment. If it is deemed reasonable to proceed, a functional analysis of IP aggression may help illustrate the triggers for IP violence and offer insight into its maintenance. Relevant CRA procedures may be woven into CRAFT as well, such as roleplays of positive communication, and problem-solving to develop any necessary prevention or protection plans.

Communication Skills

Communication skills training is a critical component of CRAFT, since the CSO-IP communication style

commonly swings between aggressiveness and silence. The training follows the same procedure as that introduced in CRA, with the exception that the *CSO* is being taught the skills instead of the substance abusing client. Learning how to communicate in a positive manner lays the foundation for other CRAFT procedures. For instance, positive communication is essential for minimizing IP defensiveness when it is time for CSOs to explain changes in their behavior toward the IP (such as the withdrawal of rewards during substance-using times), or when CSOs are ready to invite the IP to sample treatment.

Assume that a CSO (the wife) rehearses the conversation she hopes to have with the IP (her husband) when they sit down to dinner that evening. With much practice and feedback during the session, the CSO arrives at: "Martin, I know you're unhappy with your job these days and you like to unwind with your friends after work (understanding statement) by stopping for a few drinks. And I guess it doesn't help your stress level when I immediately start going down our long list of financial problems as soon as you walk through the door each night (partial responsibility), so I could do my best to stop that (offer to help). I know if you come straight home you like to eat earlier. I could move dinner up about 20 min (offer to help). What do you think?" The CSO would have role-played this conversation repeatedly and decided when to approach her husband. Furthermore, she would have discussed how she might react if the IP responded negatively.

Positive Reinforcement for Clean and Sober IP Behavior

CRAFT is built upon the principle of positive reinforcement; namely, people are more likely to repeat a behavior if it is rewarded. CSOs are taught to systematically reward their IP's clean/sober behavior. Since many CSOs mistake positive reinforcement for "enabling," the therapist explains that enabling inadvertently makes it easier for the substance-using behavior to continue, whereas positive reinforcement is paired exclusively with clean/sober behavior. Once the principle is understood, CSOs are assisted in identifying several small, inexpensive rewards which can be introduced when the IP is clean and sober. Popular examples include: watching the IP's favorite TV show with him/her, making a special dessert, or giving a compliment or a hug. Details regarding when and how the reward will be delivered are addressed, and the conversation with the IP about why the reward is being delivered is practiced. An example of a polished conversation about a positive reinforcement that a husband (CSO) might prepare for his wife (IP) is: "Honey, how about we go to that antique mall you like so much and do a little window shopping before dinner? I can see that you haven't been using today, and I love spending time with you when you've stayed away from those medications."

Negative Consequences for Substance-Using Behavior

The counterpart to rewarding nonusing IP behavior is to withdraw rewards when substance use occurs. This "time-out" from positive reinforcement is relatively straight-forward if the reward in question is one of the newly introduced ones. For instance, if a CSO has started to watch one of her partner's (IP's) favorite TV programs on those evenings when he does not smoke marijuana, then she would elect *not* to sit and watch the show with him if he had smoked that day. She would use her positive communication skills to convey this: "It looks like tonight isn't going to be a good night for us to watch TV together, because I can tell that you've been smoking. It has really been fun spending time with you in the evenings when you're not high. Let's try again tomorrow." The therapist helps the CSO identify additional reasonable rewards to withdraw at times of IP substance use as well, while always exploring the potential for a violent IP reaction, and adjusting accordingly.

The second manner in which negative consequences are introduced for drinking or drug use is by allowing the *natural* consequences of substance use to occur. Assume that a mother (CSO) typically cares for her adult child (IP) whenever he/she has a hangover by calling in sick for him/her. In all probability the CSO would be asked to consider letting the son/daughter deal with the consequences of nobody contacting his workplace at the time of his/her next hangover. Certainly, the negative ramifications of changing the CSO's normal behavior in these situations would be discussed at length, since both CSO and IP safety are of paramount importance. In the majority of cases CSOs elect to inform their IP in advance that this change in behavior will take place if drinking or drug use resumes.

Helping CSOs Improve their Own Lives

The Happiness Scale and Goals of Counseling forms are borrowed from CRA to help CSOs target different areas of their lives in which they would like to make changes. Since social isolation is quite common for CSOs, the "social life" category on the Happiness Scale is often a focus for goal-setting. For example, a goal for the CSO might be to reconnect with an old friend, or to take a class through Continuing Education in an effort to sample a new recreational activity. Potential problematic reactions from their IPs are always discussed in advance.

CONCLUSION 55

Inviting the IP to Sample Treatment

The procedures described thus far set the stage for treatment engagement to occur (as well as address other goals), but the final piece entails helping CSOs determine how and when to invite the IP to enter treatment. To articulate the request, positive communication skills are put into play again, but motivational "hooks" are added that stress IP-specific incentives. For example, if an IP has been struggling to find a job, the CSO might say, "I know you've been trying really hard to find work. The agency that I'm going to for my own therapy has counselors who can help people with a lot of things, including finding jobs. What do you think about giving that a try?" Reluctant IPs might also be encouraged to "sample" treatment for a session or two without making any long-term commitment. Another motivational hook is the idea that IPs can have their own therapist; they do not have to see their CSO's therapist.

Regarding the ideal time to extend the invitation, CSOs are taught to look for "windows of opportunity;" occasions representing a greater likelihood that the IP will agree to treatment. One common example is when an IP starts asking questions about what happens in the CSO's own therapy. CSOs are prepped to respond, "Why don't you come to a session with me and find out? I'd love to introduce you to my therapist." A somewhat different case is the IP who is unaware of the fact that the CSO is in therapy - and who asks the CSO why he/she has been acting differently toward the IP lately (i.e. the CSO has been using positive communication and rewards). The CSO might respond, "I've been in therapy to work on our relationship. We've been having our ups and downs, as you know. How would you feel about joining me for a session or two? It would mean a lot to me."

Although many IPs agree to treatment at this point in the CRAFT program, CSOs must be prepared for the possibility that the IP will still refuse at least temporarily. If this occurs, the CSO is encouraged to continue with the various CRAFT procedures. Given that most IPs *do* agree to attend treatment eventually, it is necessary to have an arrangement for a therapist to be available so that the IP does not get placed on a waiting list. Ideally the therapist should be behavioral or cognitive-behavioral so as to complement the CRAFT approach.

CRAFT SCIENTIFIC SUPPORT

CRAFT was first tested in a small study in the 1980s with the wives (CSOs) of treatment-refusing problem drinkers (IPs). The CSOs who received CRAFT were successful at getting their loved one to enter treatment in 86% of the cases, whereas none of the CSOs who

received the traditional (disease-based) treatment did. In subsequent years, the CRAFT program has been studied largely through the efforts of Meyers and Miller. CRAFT has continued to demonstrate high engagement rates, regardless of the type of relationship between the CSO and the IP (e.g. spouses, romantic partners, siblings, parents and their adult children). Some of the most compelling evidence comes from studies that contrasted CRAFT with the more traditional alcohol interventions. Specifically, the IP treatment engagement rates for CRAFT-trained CSOs (64%) were significantly better than those of CSOs in either one-on-one Al-Anon sessions (13%) or in the confrontational "intervention" (30%). Recently CRAFT was successfully conducted in a community treatment setting with CSOs of alcoholdependent IPs who had multiple other life problems.

The robust CRAFT findings have been similar for adult studies in which the treatment-refusing individual used illegal drugs. A recent meta-analysis by Roozen and colleagues supports these conclusions. And when CRAFT was applied to an adolescent sample, the parents (CSOs) demonstrated an engagement rate of 71% for their marijuana-abusing teens. One of the newest CRAFT studies was a test of the program in a group format. This format deserves further testing, both due to the cost-effectiveness of group therapy, and the potential benefits of learning from other CSOs in the group.

In addition to the high engagement rates, an important finding of the various CRAFT studies is that the CSOs typically experienced significant improvements in their own psychological functioning irrespective of whether their loved one entered treatment, and also regardless of the treatment they received. Importantly, CRAFT was successful in getting the resistant IP to enter treatment in an average of less than five CSO sessions. Finally, CRAFT has been shown to work equally well across ethnic groups, but since the main ethnic minority representation thus far has been Hispanic individuals, future testing should recruit a higher percent of African American, Asian, and Native American samples. Studies are already planned for testing CRAFT in the obesity and eating disorders area.

CONCLUSION

CRA and CRAFT are science-based treatments that use behavioral principles to facilitate change in alcohol or drug use, by working either directly with the substance abusing individual (CRA) or indirectly through the distraught family member (CRAFT). Both of these treatments have commonly been well received by therapists and clients alike, in all probability due to their highly supportive style and flexible application.

SEE ALSO

Cognitive Behavioral Therapies, Behavioral Treatments for Adolescents with Substance use Disorders, Disulfiram for Alcohol and Other Drug Use, Evidence-Based Treatment, Harm Reduction Approaches

List of Abbreviations

AA Alcoholics Anonymous
AFT Al-Anon facilitation therapy
CRA community reinforcement approach

CRAFT community reinforcement and family training

CSOs concerned significant others

IPs identified patients

JII Johnson Institute Intervention

Glossary of Terms

Alcoholics Anonymous this is an international organization that provides a support group for persons trying to overcome alcoholism that is characterized by its 12-step program.

Al-Anon the Al-Anon family groups are a fellowship of relatives and friends of alcoholics who share their experience, strength, and hope, in order to solve their common problems.

Behavior therapy this type of therapy uses basic learning principles to modify maladaptive behavior patterns.

Community Reinforcement Approach (CRA) CRA is an empirically supported behavioral treatment for individuals with substance use disorders that is based on the belief that one's "community" broadly defined plays a critical role in the recovery process. Relying heavily on operant principles, the main goal of CRA is to help clients achieve a clean and sober lifestyle that is more rewarding than a substance using one.

Community Reinforcement and Family Training (CRAFT) this empirically supported modification of CRA is designed to work through a family member or friend of a treatment-refusing drinker or drug user, with the goal of getting the resistant individual to enter treatment.

Concerned Significant Other (CSO) a CSO is a family member or friend of a treatment-refusing substance abuser who seeks treatment himself/herself in an effort to learn the techniques to get the treatment-refusing substance abuser to ultimately enter treatment.

Evidence-based treatment this term refers to mental and behavioral health interventions for which systematic empirical research has provided evidence of statistically significant effectiveness as treatments for specific problems (e.g. substance use disorders).

Functional analysis (FA) the functional analysis is a structured interview that outlines triggers and consequences (positive and negative) of substance-using behavior, thereby providing a framework for a conversation about the context within which the use occurs.

Identified patient (IP) the IP is a treatment-refusing substance user. **Johnson Institute Intervention (JII)** an intervention is an orchestrated attempt by a number of people (usually family and friends) to get

someone to seek professional help with an addiction problem. In many cases this involves the family members gathering to confront the substance abuser about the negative impact of his/her behavior on others.

Positive reinforcement positive reinforcement occurs when a behavior is followed by a stimulus that is rewarding, and which then increases the frequency of that behavior.

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Behavioral Couples Therapy for Alcoholism

Jeremiah A. Schumm*, Timothy J. O'Farrell\$

*Cincinnati VA Medical Center and University of Cincinnati, Fort Thomas, KY, USA

\$\frac{1}{2}\$ Harvard Medical School, Brockton, MA, USA

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INTRODUCTION

Alcoholism has historically been viewed and treated as individual conditions or disease processes. However, over the last 35 years, there has been growing recognition about the role of the family in understanding and treating alcoholism. Behavioral couples therapy (BCT) for alcoholism is one approach that has developed out of the recognition that significant others can play a substantial role in alcoholism and the recovery process. A goal of this chapter is to familiarize the reader with the BCT approach to treating alcoholism and to summarize empirical evidence supporting the application of this treatment. We begin by describing the rationale for this approach to treating alcoholism. Next we provide an overview of the major interventions that serve as components to this therapy. We then summarize the empirical findings in support of BCT as an efficacious treatment for individuals with a committed partner who does not have a substance abuse problem and who is willing to actively participate in the patient's alcoholism treatment.

We specifically describe the evidence showing that this treatment is related to reductions in alcohol-related problems, is related to improvements in intimate relationships, is shown to be cost effective, and is related to improvements in children's functioning. We also describe contraindications for the application of BCT, along with challenges that may be faced in implementing this treatment. Finally, we provide suggestions for future research and application of this therapy.

BI DIRECTIONAL ASSOCIATION BETWEEN ALCOHOLISM AND INTIMATE RELATIONSHIPS

A foundational assumption of BCT is that there exists a bi directional relationship between alcoholism and intimate relationships. According to this model, alcoholism not only creates problems for the individual with the condition, but these problems often have rippling effects that damage relationships with significant others

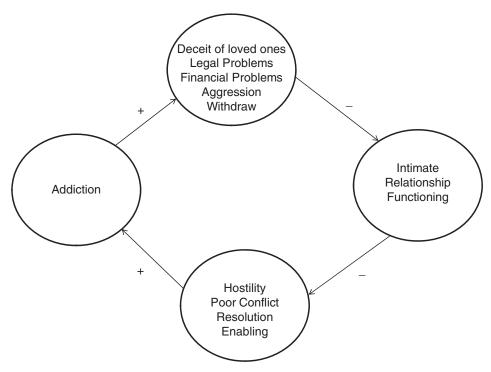


FIGURE 7.1 Bi directional association between addiction and intimate relationships.

(Fig. 7.1). It is unfortunately common for individuals with alcoholism to lie to their loved ones in order to try to cover up their drinking and its negative consequences. This, by itself, can undermine trust within relationships and lead to conflict and loved ones withdrawing support for the alcoholic individual who in turn drinks more in a vicious cycle. In addition, alcoholism contributes to problems, such as job loss or revocation of driving privileges, which impact not only the alcoholic individual but also their loved ones. These problems can be a substantial source of conflict and lead to ongoing resentments between individuals with alcoholism and their family members. Finally, research demonstrates that individuals with alcoholism and their significant others are at substantially elevated risk for experiencing intimate partner violence. Hence, alcoholism can undermine the basic safety and well-being of intimate relationships by contributing to circumstances in which individuals with alcoholism and their significant others resort to aggression toward one another.

In addition to the hypothesis that alcoholism damages intimate relationships, the BCT presumes that intimate relationship functioning can influence the progression or recovery from addictions. Individuals with alcoholism who are in critical and hostile family environments are at greater risk for relapsing to addictive behaviors (*see* Ketamine). Critical and hostile family systems may lead individuals with addictions to experience negative emotions, and it is common for individuals with addictions to revert to addictive behaviors as a method for

self-soothing difficult and painful emotional experiences. In addition, independent researchers have found that couples where one or both partners exhibit an addiction tend to have poorer conflict management styles versus couples where neither partner exhibits addictions. A lack of conflict management skills may exacerbate relationship distress and undermine the ability to collectively solve problems as they arise. Along with couples' conflict management deficits as an impeding factor to addiction recovery, it is common for significant others to unintentionally reinforce addictive behaviors. These enabling behaviors on the part of significant others can include obtaining alcohol or drugs for the person with the addiction or making excuses or covering up for the consequences of their addiction. These factors may, in turn, increase risk for relapse and reduce chances at recovery among individuals with addictions (see Fig. 7.1).

OVERVIEW OF BCT AND ITS MAJOR COMPONENTS

BCT is typically delivered in 12–20 therapy sessions. Published manuals by Timothy O'Farrell and by Barbara McCrady provide variations of the treatment approach. Typically these sessions are attended on a weekly basis by the couple. As will be described later in this chapter, BCT has undergone extensive empirical scrutiny supporting their application to the treatment of addictions.

BCT fits well into various addiction treatment settings in that it has been researched and employed in both group and single couple formats. In addition, BCT has been delivered and tested as a stand-alone intervention, as well as being delivered together with other individual and group-based addiction therapy. The treatment can be easily integrated into a variety of orientations to addiction treatment, including 12-step and cognitive behavioral addiction programs.

Given the bi directional cycle that occurs between addiction and relationship functioning, BCT provides interventions that target each of these domains. This therapy utilizes behavioral principles to help couples to work together in reducing addictive behaviors and their consequences, while also working to improve their relationship. The therapy has the specific goals of reinforcing behaviors that are consistent with addiction-related goals and helping couples to make positive behavioral changes within their relationship.

Interventions for Achieving Abstinence

The BCT approach has historically involved a primary goal of abstinence from addictive behaviors, since it is assumed that abstinence must first be obtained for the couple to be able to effectively work on relationship issues. The approach taken by Timothy O'Farrell and colleagues includes a behavioral recovery contract to help the couple to work jointly to achieve sobriety for the person with the addiction. A major component of the recovery contract is the daily "trust discussion." A goal of the daily trust discussion is to rebuild trust in the relationship around the issue of sobriety, which is often damaged as a result of attempts to cover up or minimize addictive behaviors and its consequences. In addition, it is often the case that the person with the addiction receives criticism for engaging in addictive behaviors with little positive reinforcement for the occasions during which sobriety is achieved. Therefore, another important goal of the trust discussion is to reinforce the addictive partner's sobriety behavior and the supporting partner's efforts to help in achieving sobriety.

When completing the trust discussion, couples are instructed to choose a specified time and place where they can talk without interruption. Couples are encouraged to try to make this as part of a daily routine; therefore, the trust discussion should be completed, if possible, during approximately the same time each day. The partner with the addiction issue is encouraged to take responsibility for his or her recovery by initiating the trust discussion. In the trust discussion, the patient states his or her intent not to drink or use drugs that day (in the tradition of 1 day at a time), the spouse expresses support for the patient's efforts to stay

abstinent, and the patient thanks the spouse for the encouragement and support. For patients taking a recovery-related medication (e.g. disulfiram, naltrexone), daily medication ingestion witnessed and verbally reinforced by the spouse also takes place during the trust discussion.

In addition to the daily trust discussion, the couple recovery contract includes several additional interventions to help the couple to work toward sobriety. One component is the commitment for both partners to focus on the present and future and not the past. This is meant to assist the couple in breaking away from the cycle of focusing on past addictive behaviors and relationship problems, which can escalate into arguments and negative feelings that contribute to relapse. The recovery contract also often includes commitment to self-help attendance by the person with the addiction (e.g. Alcoholics Anonymous), as well as self-help support for the partner (e.g. Al-Anon). Therefore, the treatment is quite complimentary to supporting self-help approaches to recovery. For individuals with drug addictions, the recovery contract typically includes weekly urine drug screens, with results being shared in the BCT sessions. These are used to help to reinforce sobriety from drugs and to help individuals with drug addictions rebuild trust with their partners.

Another BCT strategy is to check in at the beginning of the session about any engagement in addictive behaviors or thoughts, urges, or cravings to engage in these behaviors and implement strategies for coping with these. This is meant to emphasize the primary focus of the treatment on recovery from the addiction, and prioritize finding ways of stopping these behaviors. One approach that has been adopted by Barbara McCrady and colleagues in building couples skills in this area is to help each partner to engage in a detailed functional analysis of addictive thoughts and behaviors in order to better understand their patterns and ultimately be able to anticipate and better cope with them when they arise. Hence, McCrady and colleagues have integrated into their BCT approach that is often used in addressing addictive behaviors within individually oriented, cognitive behavioral treatment models for addiction.

It is common for partners to unintentionally enable ongoing addictive behaviors. For example, partners may try to assist the person with the addiction by helping to cover up for the consequences of their addictive behaviors or purchasing alcohol or drugs for the person with the addiction. Therefore, BCT seeks to help couples to recognize and stop partner enabling behaviors. This is done by educating couples on the common ways that enabling may occur and identify ways that enabling may be occurring within the couple's relationship. A plan for eliminating these enabling

behaviors is then developed, and therapists follow up throughout treatment to ensure that this plan is being effectively implemented.

Interventions for Improving the Relationship

BCT takes a stepwise approach to providing interventions for improving the relationship. The first set of interventions is meant to help the couple begin to increase the number of positive relationship behaviors. This follows the finding that couples who are dissatisfied with their relationship tend to display a relatively lower ratio of positive relationship behaviors and higher ratio of undesirable relationship behaviors versus those who are satisfied. It is often the cases that couples in which one or both partners have an addiction engage in a high degree of negative behavioral exchanges. This can contribute to these couples becoming dissatisfied with their relationship, thereby making it more difficult for them to work together to eliminate the addictive behaviors. Hence, the initial behavioral interventions are meant to help couples to begin to increase the number of positive exchanges within the relationship. It is thought that by improving the frequency of these relationship behaviors, couples' relationship satisfaction may increase, resulting in increased chances for obtaining and remaining abstinent from addictive behaviors.

One initial way that the treatment seeks to increase positive behavioral exchanges is to have the couple practice a daily ritual of noticing positive relationship behaviors. Addictions often lead couples to begin to notice and focus upon the undesirable behaviors within their relationship, while failing to notice many of the positive behaviors. Therefore, the "catch your partner doing something nice" exercise is meant to help couples to practice refocusing their attention to positive behaviors within the relationship. Once couples obtain practice noticing positive relationship behaviors, partners build upon this skill by sharing on a daily basis the noticed positive behaviors. Couples are taught that actively communicating and reinforcing these behaviors will help to improve relationship functioning and, in turn, improve chances at achieving sobriety.

Other BCT strategies for helping couples to increase positive behavioral exchanges include shared rewarding activities and planned caring days. Among couples with addiction, it is common to greatly decrease or cease activities that are mutually enjoyable and that do not involve engaging in the addictive behavior. Therefore, to address this tendency, shared rewarding activities help the couple to regularly plan and participate together in at least one mutually enjoyable sober activity per week. Some examples include going to the movies together, taking the kids to the park, or going on a walk together. Couples also practice engaging in "caring days" that involve planning

and engaging in a series of special surprises for one another. An example would be surprising one's partner by fixing his or her favorite breakfast, packing his or her lunch for work and including an "I love you" note in the lunch, and surprising him or her with a backrub that evening. The idea behind this intervention is that addictions often lead couples to reduce the frequencies in which they engage in unexpected signs of courtship and caring toward one another. This can also happen, independent of the effects of addiction, with couples naturally reducing the frequency of these behaviors the longer that they are in the relationship. Therefore, by reinvesting behavioral efforts into surprising signs of affecincrease couples will their relationship satisfaction. This increased relationship satisfaction will then serve as a resource for reducing the likelihood of ongoing addiction.

After introducing these basic behavioral strategies for improving positive couple exchanges, BCT helps couples to improve their communication. This is an important intervention for couples with addictions, since couples with addictions are shown to exhibit poorer communication strategies than those who do not have addictions. Poor communication and conflict resolution may decrease the likelihood that partners with addiction remain sober, while increasing the likelihood of engaging in ongoing cycles of addictive behaviors. Therefore, BCT teaches couples effective speaking and listening skills by providing in session instruction, modeling, and practice of these skills. Couples also practice applying these skills outside of the session, so that they learn to use these skills in their day-to-day lives. Once couples achieve basic competency of basic communication skills, they then learn effective advanced communication techniques to facilitate effective problem solving and to work together to identify and change areas that they would like to improve in their relationship.

Along with teaching general communication and problem-solving skills, BCT helps couples to improve their conflict resolution strategies. Unfortunately, partner violence is a common co-occurring issue for couples with addictions. Therefore, couples are taught ways to avoid conflicts escalating into violence. The "time out" intervention is one central component that Timothy O'Farrell and colleagues have built into their treatment. This strategy involves couples implementing a "time out" when arguments escalate to the point that the couple is at risk to engage in verbal or physical aggression. Partners learn to request a time out for a defined period of time. That way, it is clear how long the time out is expected to occur, and it helps the couple to avoid the common mistake of withdrawing and avoiding indefinitely without satisfactorily discussing the issue. During the time out, partners practice engaging in self-soothing behaviors (e.g. going on a walk) to help them to de-escalate anger and other negative emotions. The couple then reconvenes after the agreed upon period of time to further discuss the issue in a nonthreatening and calmer manner. In addition to the time out method, couples are taught to avoid engaging in arguments when one or both partners are under the influence of alcohol or drugs. This is done because it is highly common for arguments when either partner is under the influence to escalate to violence.

Interventions for Maintaining Treatment Gains and Addressing Relapse

Prior to ending BCT, therapists work with couples to develop a well-defined and mutually agreed upon continuing recovery plan for how they will continue to maintain their treatment gains. The philosophy is that recovery is a continuing process, and just because the couple ends BCT, this does not mean that the recovery process is finished. The continuing recovery plan provides a structured contract for what BCT interventions that the couple will continue to utilize following the end of the therapy. It also helps couples to identify strategies for maintaining sobriety and improvements in their relationship. An important focus during this final stage of treatment is to help couples to personalize their recovery plan so that they are selecting those interventions that they found to be most helpful. This will increase the likelihood that they will continue to engage in dyadic behaviors that were learned and practiced during the therapy.

Couples will often include follow-up visits with their BCT therapist as part of their continuing recovery plan. These visits typically occur every 2 months for a year following the end of the standard weekly therapy, but the schedule can be adjusted to fit the couple's needs. These sessions are used as an opportunity to check-in and ensure that the continuing recovery plan is being effectively sustained and as booster sessions to continue to work on developing dyadic recovery skills. Independent research by Timothy O'Farrell and Barbara McCrady demonstrated benefits of BCT booster sessions. Benefits of BCT booster sessions are especially evident for couples with more severe addiction problems. Hence, it is strongly encouraged for couples with more severe addiction problems to structure in followup sessions as part of the continuing recovery plan.

In addition to the interventions aimed at helping couples to maintain treatment gains, BCT therapists work with the couple to develop an action plan in the event that a relapse occurs. A fire evacuation plan is often used in presenting this to the couple by stating that having a relapse action plan is a good idea just like having a fire evacuation plan. Having such a plan

does not guarantee that you are going to experience a relapse (or fire), but it does make it safer and easier to deal with these circumstances if they were to arise. Therefore, BCT helps couples to identify upcoming situations that might increase the risk for relapse and develop a plan of action for addressing these. In addition, the treatment helps couples to identify early warning signs to relapse (e.g. stopping self-help attendance, changes in mood) and a plan for correcting these problems. Finally, BCT therapists help couples to identify sources of support for coping with relapses (e.g. AA sponsors, friends) and strategies for obtaining help from others during these events. Couples are encouraged to contact the BCT therapist if a relapse were to occur, so that the therapist can help the couple to navigate this issue and minimize the relapse.

EMPIRICAL SUPPORT FOR BCT

For those who have committed family members who are willing to be active participants in treatment, evidence supports the superiority of family-based treatment over individually based treatment for alcoholism. Of the couple-based approaches for treating alcoholism, BCT exhibits the strongest empirical support. In randomized clinical trials, the degree of difference favoring family-based over individually based alcoholism treatment is typically in the medium effect size range. In addition to multiple naturalistic studies, there have been at least 10 randomized clinical trials examining the efficacy of BCT. In nearly all of the randomized clinical trials, BCT is compared to another credible, individually focused alcoholism treatment, including indicognitive behavioral or 12-step-oriented treatment. Hence, among couples in which a committed partner is willing and able to actively participate in treatment, these studies provide information on the relative efficacy of BCT versus other well-established alcoholism treatments. Follow-up periods range from 6 months following treatment in initial studies to 12-24 months following treatment in more recent studies.

Primary Outcomes: Addictive Behaviors and Relationship Adjustment

In comparison to individually focused alcoholism treatment, BCT is shown to produce a higher number of abstinence days, lower days of heavy drinking, and lower negative consequences associated with use. The average effect size favoring BCT is in the medium range. It is noteworthy that studies normally do not show differences between BCT and individually oriented alcoholism treatment when these outcomes are assessed at posttreatment. Hence, individuals with alcohol use

disorders who receive BCT or individually focused treatment appear to gain similar benefits in showing reductions in substance-using behaviors immediately following treatment. However, during the extended follow-up period after treatment ends, studies tend to show BCT outperforming its active therapy comparators with regard to substance use outcomes. Typically, this is due to individuals who receive BCT sustaining their treatment gains better than those who receive individual alcoholism treatment, while those who receive individual treatment have more substantial deterioration with regard to alcohol-using behaviors.

Regarding relationship outcomes, BCT demonstrates an advantage over individual alcoholism treatment, with an effect size that is in the medium range. Couples who receive BCT tend to show fewer days separated, higher relationship satisfaction, higher agreement on important matters, and more positive communication behaviors versus those who receive individual alcoholism treatment. The general pattern of findings demonstrate that in comparison to those who receive individual treatment, couples who receive BCT show better functioning in this domain immediately following treatment and during the 6–24 months following treatment.

Researches on factors that may impact the responses to BCT are increasingly coming into focus. A recent study by Barbara McCrady and colleagues examined the efficacy of BCT among women with alcohol use disorder who had a committed male partner. In addition to the general finding that BCT led to greater reductions in alcohol use versus individual treatment, McCrady and colleagues also examined pretreatment factors that might influence responses to treatment. They found that BCT was especially efficacious for producing abstinence from alcohol among women who exhibited poorer relationship functioning upon entering treatment. Other findings showed that BCT was better than individual therapy in producing sobriety among women who exhibited mental health disorders that were co-occurring with the addiction. These results suggest that BCT may especially be beneficial in producing sobriety among women who have poorer relationship functioning and who exhibit mental health problems in addition to the addiction.

Intimate Partner Violence

Intimate partner violence is a common problem among couples with alcoholism and one that has been assessed in BCT outcome studies. Results from randomized clinical trials suggest that intimate partner violence is more substantially reduced with BCT versus individual alcoholism treatment. In addition, studies have examined the relative degree of partner violence among couples with alcoholism who receive BCT in comparison

to case-matched community couples where neither member exhibits a substance use problem. Results show clear and drastic declines in partner violence following BCT. During the year prior to BCT more than 60% of couples exhibit intimate partner violence, which is nearly five times higher than what is found in demographically similar couples without substance use problems. Following treatment, prevalence decreases to around one quarter to one third reporting partner violence. Further, studies of alcoholic couples who participate in BCT show that those who demonstrate remission of their drinking problems following treatment are similar to nonalcoholic community couples in rates of violence, while those who relapse have violence rates that are higher than community couples. This suggests that the ability of BCT to produce alcoholism remission following treatment may be particularly important in eliminating partner violence behaviors.

Child Functioning

Studies suggest that BCT results in better improvement in child functioning versus individually based alcoholism treatment. Although studies to date have exclusively focused upon heterosexual couples in which the father has an alcohol use disorder, results show better child functioning during the year following treatment for fathers who receive BCT versus those who receive individual treatment. These results are promising in suggesting that the benefits of BCT may generalize to the children of parents with alcoholism.

Cost Effectiveness and Cost–Benefit Outcomes

Several studies have examined the degree to which BCT is cost effective and results in reductions to societal costs. Regarding cost effectiveness, a study by Timothy O'Farrell and colleagues showed that BCT was more cost effective than interactional couples group therapy. In addition, there is clear evidence that BCT produces societal cost benefits in terms of reduction in addiction-related healthcare utilization, reduction in legal system involvement, and reduction in public assistance costs. Estimates indicate that BCT exhibits more than a 5:1 benefit-to-cost ratio. This means that for every dollar spent in providing BCT, there is a \$5 savings in societal costs.

CONTRAINDICATIONS AND CHALLENGES TO USING BCT

BCT is not appropriate for all couples with alcoholism, and it is necessary to consider circumstances

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where it is contraindicated. First, when either partner is actively suicidal or homicidal, the treatment is foregone, and the intervention shifts to ensuring safety. Second, if either partner is actively psychotic, BCT is unlikely to be beneficial, since individuals may be unable to fully engage in sessions or follow through in practicing the therapy skills. Third, the treatment cannot be implemented in situations where a restraining order exists between partners. In such cases, partners must wait to begin BCT until the courts remove this order.

BCT is also not appropriate for couples that exhibit a recent history of severe partner violence on days when they have not been using alcohol or drugs. By severe partner violence, we mean behaviors such as using a weapon or striking a partner in a manner that is, likely to result in serious injury. In these cases, the nature of the violence is often consistent with efforts to dominate and control one's partner, a violence pattern that is sometimes referred to as "domestic terrorism." We recommend in these cases a referral to a domestic violence program and working with the victim to ensure personal safety (e.g. referral to a shelter). In our clinical work and research, we have found this type of violence to be relatively rare among couples who present for BCT. Rather, it is common for couples to present with a history of less severe acts of violence (e.g. pushing or slapping) and violence typically occurring on days when one or both partners are using alcohol or drugs. As previously described, studies show that BCT can be beneficial for reducing violence among couples who do not exhibit severe levels of partner violence, which may be a function of reductions in addictive behaviors and improvements in relationship functioning and conflict resolution skills.

A challenge to implementing BCT is when couples are unclear with regard to their commitment to the relationship. We do not recommend pursuing BCT with couples who are unwilling to try to stay in the relationship long enough to attempt the program. This does not mean that they must promise to stay together permanently in order to try the treatment, but rather couples should be able to make a commitment to fully work with one another in trying the treatment and then see how the treatment impacts their situation. With these couples, therapists should consider meeting with couples to explore and establish a minimal level of commitment prior to proceeding with BCT.

Another challenge to implementing BCT involves the scenario in which both partners have an addiction issue. The efficacy of BCT with these couples has yet to be formally studied. However, we have clinically applied the treatment in such circumstances by making the necessary adaptations to focus on both partner's sobriety. For example, in these cases the recovery contract is modified to address each partner's plans for achieving sobriety.

Another challenge to implementing BCT is dealing with couples that become separated, either prior to or during treatment. If a couple is yet to start the treatment, it is good to establish what conditions must be met in order for the couple to reunite, and then work with the couple in addressing this prior to implementing BCT. Similarly, when couples separate during the course of treatment, therapists should discuss with the couple what conditions are necessary for them to get back together and the degree to which it is realistic to be able to continue with BCT under these circumstances.

A final challenge in the implementation of BCT is engaging couples in the treatment. It is sometimes difficult to obtain consent from individuals who are in addiction care to involve their partners due to concerns over what will be discussed or embarrassment. Therapists may also find that partners are holding resentments or are experiencing negative emotions toward the individual with the problem and may, therefore, have some reluctance to engage in treatment. To address these, we typically follow a series of steps that involve normalizing these feelings and asking for small commitments toward involving partners in care (e.g. start with an initial telephone call to the partner in the presence of the patient or ask for an initial joint meeting with both partners to explore various treatments options). In addition to reluctance to engage in therapy due to negative feelings, there is also the practical issue of scheduling couples when at least one of the partners may be working. To address this in our research studies and clinical practice of BCT, we have offered evening and weekend appointment times. Hence, it is ideal for clinics and treatment providers who are seeking to implement BCT to consider offering to patients some scheduling options that are outside of a standard nine to five workday. This will increase the likelihood that couples can realistically engage in the therapy and attend sessions regularly.

FUTURE DIRECTIONS

Although BCT is the most highly researched couple-based treatment for addictions, there is an additional need to expand research and the clinical application of BCT. The majority of studies conducted on BCT have involved heterosexual couples in which the male partner has a primary alcohol addiction. Although randomized clinical trials have supported the efficacy of BCT among heterosexual couples in which the female partner has an alcohol use disorder, the number of these studies is limited. Evidence also exists to suggest that BCT is efficacious for homosexual dyads, but this research requires replication. Finally, there are fewer studies where the primary addiction issue is something

other than alcohol. In fact, we are not aware of any randomized clinical trials examining the efficacy of BCT for the treatment of gambling addiction and know of relatively few examining the efficacy in treating various drug use disorders. Therefore, there is a need for more research on the efficacy of BCT in treating nonalcohol-related addictions.

Although BCT can be adapted to treat couples in which both partners exhibit a current addiction problem, the efficacy of the treatment for this population is yet to be formally researched. By treating both partners together, BCT may be a more efficient and effective method for addressing dually addicted couples in comparison to approaches that treat each partners' addiction on an individual basis. However, dually addicted couples may also be at higher risk for relapsing, since one partner's relapse may result in the other partner relapsing as well. Studies are needed to clarify if BCT produces better outcomes for these couples than competing addiction therapy approaches.

Another area of opportunity exists in the integration of BCT with interventions that address co-occurring mental health disorders. It is quite common for individuals with addictions to also exhibit co-occurring mental health problems, such as mood or anxiety disorders. This can create additional challenges for individuals to achieve sobriety, since negative affect is shown to be a common trigger for relapse. A study by McCrady and colleagues is promising in finding that when compared to individual therapy, BCT produced higher rates of sobriety among women alcoholism and with co-occurring mental health disorders. In addition, studies demonstrate that intimate partner relationships that involve higher degrees of hostility and criticism are risk factors for relapse to alcohol and drugs along with experiencing relapses with other mental health problems, such as depression or anxiety. Together, these findings suggest that treatment that integrates BCT with interventions that also address co-occurring emotional problems may be a promising approach to improving outcomes.

Finally, although BCT has a relatively strong evidence base in treating addiction, dissemination of BCT to clinical practice settings and training opportunities for clinicians in BCT are just beginning. An initial dissemination study by O'Farrell transported BCT to a community clinic in Calgary. Implementation of BCT was considered successful because BCT had better 6-month follow-up outcomes than the clinic's typical individual counseling program in a quasi-experimental evaluation, and because the BCT program in Calgary that began in 1998 continues to the present.

Training in BCT that is available consists mainly of isolated workshops, not a systematic, high quality, sustained training program or organization devoted to

teaching and fostering implementation of BCT. There are also other resources for training in BCT. The 2006 book on BCT by O'Farrell is a comprehensive clinician's guide book to BCT and includes a session-by-session BCT treatment manual. A web-based training course in BCT also is available. A link to this course is given in "Relevant Websites" section.

SUMMARY

BCT is a couple-based treatment for addictions that has been developed and researched over the past 35 years. The treatment conceptualizes addictions and intimate partner relationship functioning as having a bi directional association. According to this model, addictions deteriorate relationship functioning, while poor relationship functioning, in turn, increases engagement in addictive behaviors. Therefore, BCT seeks to reduce addictive behaviors, while simultaneously improving relationship functioning. Randomized controlled trials support the superiority of BCT versus individually oriented treatments for alcoholism for patients who have a nonaffected spouse willing to be engaged in the therapy process. Specifically, BCT is associated with greater sobriety, less addiction-related problems, and better relationship functioning following treatment. In addition, there is evidence that BCT is associated with significant reductions in intimate partner violence and improvements in child functioning. Evidence also shows that BCT has cost-benefit ratio of better than 5:1, suggesting significant societal cost savings for the delivery of this treatment. More studies are needed to understand the treatment's efficacy among those with nonalcohol-related disorders, couples where both partners exhibit addictions, and among nonheterosexual couples.

Glossary

Abstinence refraining entirely from addictive behaviors.

BCT behavioral couples therapy

Conflict management behavioral and communicative style in responding to arguments or disagreements.

Enabling behaviors that promote or unintentionally reinforce the continuation of a family member's addiction.

Functional analysis method of assessing the causal chain of events that leads to a specific behavior.

Intimate partner violence antagonistic verbal or physical behaviors toward a relationship partner.

Relapse returning to a prior pattern of addictive behaviors.

FURTHER READING 65

Further Reading

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Stanton, M.D., Shadish, W.R., 1997. Outcome, attrition, and family-couple treatment for drug abuse: A meta-analysis and review of the controlled, comparative studies. Psychological Bulletin 122, 170–191.

Relevant Websites

http://www.bhrm.org - Couples Therapy. http://www.healthquality.va.gov - Sustance Use Disorder. http://www.ireta.org - Web-based training course on BCT.

Network Support Treatment for Alcohol Dependence

Mark D. Litt

University of Connecticut Health Center, Farmington, CT, USA

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INTRODUCTION

Alcohol dependence is a serious and widespread addictive disorder. Based on results from the National Epidemiologic Survey on Alcohol and Related Conditions (NESARC), it is estimated that about 12% of American adults have had an alcohol dependence problem at some time in their life. In 2002 the US Department of Health and Human Services estimated that the cost of alcohol dependence to the US economy was

approximately 185 billion dollars per year. Despite being among the oldest of America's addictions, alcoholism remains one of its most pernicious, with few good treatment options available. The purpose of the present chapter is to provide an introduction to a treatment approach that may help some individuals reduce their dependence on alcohol. The approach is referred to here as Network Support treatment, and it is intended to help alcohol-dependent persons increase the number of nondrinking people in their social network. In the

course of introducing this approach, we will present background information to place Network Support treatment in perspective, and will discuss some of the results from treatment trials with this and similar approaches to alcohol-dependence treatment.

THE PROBLEM OF RELAPSE

Network Support treatment is not intended to get people to stop drinking. Rather it is designed to prevent relapse. Interestingly, the most significant problem related to treatment of alcohol dependence is not getting people to stop drinking. The real problem consists in getting people to stay abstinent once they have stopped. It has been estimated that fully one-third of treated individuals relapse in the first 90 days after completion of treatment. Furthermore, 1–2 years after treatment less than half of the patients who have been treated for alcohol dependence maintain sobriety. Despite increased attention to the problem of relapse in the last two decades, no treatments have been able to effectively counter the relapse phenomenon.

Many factors suggest that the cards are stacked against an alcohol-dependent person remaining abstinent after treatment. One conception of the processes involved in treatment and relapse suggests that individuals are rewarded for staying sober during treatment, but after leaving the treatment setting, the person once again encounters cues for drinking, and the old drinking pattern is reestablished. The evidence that this process occurs is persuasive. Several studies have concluded that drinking is increased when access to alternative rewards, such as nondrinking friends or activities, is constrained. Conversely, when access to alcohol is constrained, consumption is decreased. Even when treatment is conducted on an outpatient basis, the accessibility of alcohol is constrained (more or less voluntarily), thus reducing consumption, and making treatment-relevant activities more likely to be engaged in. When the person finishes treatment, however, access to alcohol is typically less constrained (e.g. the support for limiting alcohol use is gone) and the person often experiences few rewards for sobriety to compete with reinforcement from drinking.

According to this reinforcement model, to be effective against relapse, treatment needs to shift the source of reinforcement from the therapy setting to the person's home environment. That is, the nontreatment home environment must become as reinforcing of abstinence as the therapy setting was. This shifting of reinforcement would entail providing, or teaching the patient to provide for him/herself, alternative reinforcers for abstinence away from the treatment environment that will compete with the reinforcement from alcohol use.

ENCOURAGING PARTICIPATION IN NON-ALCOHOL-RELATED ACTIVITIES

The behavioral view of relapse discussed above pinpoints at least one difficulty with treatment, but also provides a possible answer. Since the rewards that keep people abstinent during treatment are not typically available when treatment is finished, perhaps it is possible to get the patient to develop new sources of reward for abstinence.

Studies by Martin Iguchi with drug abusers, and Nancy Petry with alcoholics, suggested that it may be possible to provide rewards for performance of activities that compete with drinking and that this may be a way to reduce drinking after treatment. In the Petry study, alcohol-dependent veterans presenting for alcoholism treatment at a Veterans' Administration Medical Center received a treatment in which patients earned the opportunity to win prizes by submitting negative breathalyzer samples and by completing steps toward treatment goals.

Treatment goals included developing participation in Alcoholics Anonymous (AA), improving relationships with family, improving health, and extending education. Steps toward these goals were defined in terms of specific behaviors that could be verified. For instance, developing participation in AA might entail attending three meetings per week or contacting an AA sponsor. Improving relationships with family members might include writing letters to loved ones or developing plans to do things together. The authors reported that 84% of these patients stayed in treatment throughout an 8-week period compared to 22% of standard treatment participants. By the end of the treatment period, 69% of those receiving the reward treatment were still abstinent, as compared to only 39% of those receiving the standard treatment alone. This study demonstrated that it was possible to devise a treatment that had the potential to help the patient change his/her own environment and lifestyle and to encourage the adoption of activities that might compete with drinking.

The most ambitious attempt to encourage the participation in nondrinking activities for alcohol-dependence treatment and relapse prevention is the Community Reinforcement Approach (CRA), first proposed in 1973, and since refined. CRA involves providing rewards for sobriety and encouraging the development of activities incompatible with alcohol use, such as participation in recreational and social activities and employment. CRA was intended as an all-encompassing effort to change both the physical and social environment of the patient. To achieve such change in the environment, CRA might include job counseling, assistance with finding housing, medical care, and legal help. Treatment might also incorporate pharmacological as

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well as psychosocial interventions, including the prescription of Antabuse or other drugs that can help reduce drinking. Although CRA is frequently cited as one of the most efficacious approaches to treatment, its use is not widespread, possibly because of the time, effort, and expense required to implement such a comprehensive program. Additionally, the complexity of the intervention makes it difficult to determine what features of CRA make it effective. Attention has thus turned to more limited ways of altering the environment so that it provides less encouragement for drinking.

THE SOCIAL NETWORK, AA, AND RELAPSE

Network Support for Drinking

One potent source of reinforcement for drinking is the drinker's social network, that group of people with whom a person spends the most time, or the most important time. The social milieu of an alcoholic serves to support the drinking of those in the network. Although this phenomenon has been recognized for some time, it has been difficult to quantify. General social support, for example, or simply the degree to which people support one another emotionally, has not been a particularly good determinant of how alcoholdependent people respond to treatment. Two researchers, Richard Longabaugh and Martha Beattie, recognized that a specific kind of support may help to determine whether patients continued to drink or not. They differentiated drinking-specific support from general support and coined the term network support for drinking. This network support construct, designating the amount of support an individual receives specifically for drinking, has been found to be a powerful indicator of poor outcomes in patients who go into treatment. Specifically, those who have social networks that are dominated by drinkers and that encourage drinking are much more likely to relapse back to drinking at a faster rate.

It follows that if a social network that reinforces drinking behavior leads to more drinking, then networks that reinforce sobriety should yield greater abstinence from alcohol. Evidence for this proposition has been scarce, and somewhat indirect. For example, researchers Andrew Gordon and Mark Zrull reported that some alcoholic patients who were treated and then contacted a year later reported that the active support (including participation in treatment) of nondrinking friends and coworkers was the most influential factor in their recovery. It seems that the best predictor of relapses was encouragement of drinking by coworkers, some of whom were members of the

patient's social network. As early as 1982, John Mallams conducted a study in which attendance by alcohol-dependent patients at a social group for recovering drinkers was planned. Those who attended the group drank significantly less than those who did not attend, experienced less behavioral impairment, and spent less time in heavy drinking.

The Influence of AA

Perhaps the clearest example of a social network that supports sobriety is AA. In many ways AA is a readymade sobriety-supporting network, and fulfills several of the conditions of a program that can compete with drinking. AA is conducted in groups, all members of which share the same goal and provide support. AA provides alternative activities to drinking, it constrains access to alcohol, and it rewards sober behavior. Certainly in the United States, AA has been credited with success in reducing alcohol use. It is frequently claimed that AA members achieve abstinence at a higher rate than do professionally treated alcoholics and that AA participants who are more active in the fellowship program do as well or better than less active participants. Studies of AA are difficult to conduct, however, because the members are usually devoted to one of the guiding principles of AA, anonymity, making it difficult to follow particular individuals over time. Those studies that have been conducted have produced results that are consistent with the idea that social support for sobriety can enhance treatment outcome.

From a scientific point of view, the studies that have been conducted of AA are troubling. A well-known difficulty with these studies is that patients who actually attend AA are self-selected. That is, these people go to AA on their own. Thus, it is not possible to know what the true effect of AA is. To put it another way, there is no way of knowing what would have happened to these individuals if they had not gone to AA. Perhaps many of those who choose to go to AA are people who would get better with any help, or with none. To get an understanding of the true value of AA, attendance at AA would have to be manipulated. Some people would have to get sent to AA while other people would not, and the choice of who gets AA or not would have to be random. To some extent this was done in Project MATCH, the largest psychotherapy study ever undertaken.

PROJECT MATCH

Project MATCH involved the collaboration of nine different treatment sites and over 1700 alcoholdependent patients. The purpose of the study was to

determine whether patients could be optimally matched to different kinds of treatments based on certain characteristics. It was believed, for example, that a cognitive-behavioral treatment might be a better match for patients who had psychiatric problems than would a treatment based on the twelve-step principles of AA (i.e. twelve-step facilitation treatment, or TSF). For the most part these matching hypotheses did not hold true.

Project MATCH has provided some of the most detailed information on social networks in alcoholics to date, however, and shown interesting results regarding people whose social networks were heavily populated with drinkers. Analyses of the Project MATCH data set indicated overall that patients whose social networks were supportive of drinking had worse outcomes than those whose social network did not support drinking. A high level of network support for drinking was also related to a decreased likelihood of involvement in AA. It was discovered, however, that among those with high network support for drinking, patients who had been assigned to the TSF treatment had better outcomes than patients assigned to another of the treatments (Motivational Enhancement Therapy or MET).

Further analysis revealed that exposure to TSF resulted in greater involvement in AA, even among those whose social networks were highly supportive of drinking. Thus, AA involvement by patients with high network support for drinking seemed to be at least partly responsible for the matching effect. Patients with both high network support for drinking and high AA involvement had more abstinence than those with network support for drinking who were not involved in AA (across all three treatments). In contrast, for patients whose social network did not support continued drinking, AA involvement had much less effect on outcome. The implication of these findings was that a treatment that encourages a change of social network, from one that is supportive of drinking to one that is supportive of sobriety, might be an effective way to prevent relapse.

THE UNITED KINGDOM ALCOHOL TREATMENT TRIAL SOCIAL BEHAVIOUR AND NETWORK THERAPY STUDY

Another significant large-scale effort to enhance the social network of drinkers was the United Kingdom Alcohol Treatment Trial Social Behaviour and Network Therapy study (UKATT SBNT). Over 700 patients at seven sites in the United Kingdom were assigned to either SBNT or to a three-session MET, a brief treatment intended to mobilize the patient to make changes on his/her own. As used in UKATT, SBNT consisted of

eight sessions conducted over a period of 12 weeks, covering three phases: Phase 1 was concerned with the identification of the social network; Phase 2 (sessions 2–7) focused on expanding or mobilizing the social network; and Phase 3, conducted in the last session, was used to consolidate the work carried out in previous sessions and preparing for the future. Unlike the TSF treatment in Project MATCH, there was very little emphasis placed on making use of AA, which tends to be less popular in Europe than it is in the United States.

At the end of the trial the research team reported that both MET and SBNT yielded significant decreases in drinking and in drinking-related problems at 12 months, but that there were no differences between treatment groups. Despite the measurement of network characteristics, the authors did not report whether SBNT did in fact act on the social network as planned, or whether changes in social network were related to drinking outcomes. It is not clear, therefore, whether UKATT provided support for a social network-based treatment for alcohol-dependent persons or not.

NETWORK SUPPORT TREATMENT

Guiding Philosophy

Like the UKATT SBNT, Network Support treatment was developed as an explicit attempt to change the patient's social network from one that is supportive of drinking to one that is supportive of sobriety. Unlike the SBNT, which hoped to use existing networks of friends and family, it was decided that Network Support would make use of the most extensive preexisting sober social network for drinkers in the United States, namely AA. To do this, Network Support was based on the TSF treatment developed in Project MATCH. Because the aim of TSF was to encourage AA attendance, it was considered a good basis for a treatment that could provide the patient with a new social network of nondrinkers.

Unlike TSF, AA is not the sole focus of Network Support treatment. Nor is the AA philosophy totally embraced in Network Support. Although AA attendance is encouraged, the exact means by which the social network is changed is determined by the individual patient. AA is presented as a tool, one among many, by which patients may develop a sober social network. For most patients, the spiritual aspects of AA are downplayed, and the disease and helplessness aspects are presented and challenged. Indeed, for most patients alcohol dependence is portrayed as something that can be managed. AA meetings are useful, however, and are portrayed in part as refuges: places where nondrinking is the norm. As such AA is a valuable resource.

STRUCTURE OF NETWORK SUPPORT TREATMENT

Overall Structure

Network Support treatment was originally designed to be a test treatment, a treatment used in research. As such it has a rather strict structure. Treatment involves 12 weekly, individual, outpatient sessions with a therapist. Each session lasts 60 min. Patients have up to 16 weeks to complete 12 sessions of treatment. Breathalyzer readings are collected at the beginning of each treatment session, and any patient with a blood alcohol reading above .05 is asked to wait until their blood level declines, or to return at a later date.

Abstinence Goal

Network Support treatment is intended for those who meet criteria for alcohol dependence. Generally these are individuals who have tried, sometimes many times, and failed to control their drinking. Therefore, the goal of Network Support treatment is to maintain abstinence from drinking. Patients are not dropped from treatment for occasional alcohol or other substance use, but if they do report drinking they are encouraged to commit to renewed abstinence during treatment, rather than to try controlled drinking. Patients who do not commit to abstinence are not disqualified from treatment, but the problems of continuing drinking are addressed by the therapist.

Session Structure

Network Support treatment is composed of several topics, one new topic for each weekly session of treatment. To help ensure adequate exposure to topic material, the 60-min session is divided into three phases. The first phase, about 20 min long, is focused on progress and past assignments. This phase involves obtaining a breath sample, reviewing the patient's progress since the last session, and reviewing the betweensession practice exercises assigned at the previous session. Review of patient progress includes an assessment of sober days versus drinking days, the presence of any withdrawal symptoms, and praise for adaptive skills used to promote abstinence. The patient's goals are discussed, and the patient's reactions to treatment and abstinence are also assessed.

The second phase of the session, about 30 min long, is devoted to providing the rationale and skill guidelines of the topic for that session. In addition to skills practice between sessions, patients are asked to practice skills during sessions as well. Therapists elicit patient reactions and individualized examples related to topic

material, and the therapist models specific skill components. Role-plays between patient and therapist may also occur during some sessions. The final phase of the session, about 10 min long, includes a summarization of session material, a brief discussion of how the patient might handle upcoming obstacles to sobriety, and the assignment of between-session skills practice for the upcoming week. Typically three between-session assignments are scheduled each week. The concept of between-session assignments (sometimes referred to as "homework") is sometimes unpopular with patients, but extremely important. The work of treatment takes place not in the office with the therapist, but when the patient is in his/her home environment, enacting the behavioral changes discussed.

SESSION TOPICS: CORE TOPICS AND ELECTIVES

Table 8.1 shows the topics covered in Network Support. The topics listed in bold type are core sessions and are intended to be discussed in the order listed by all patients. The remaining topics are electives and may be covered at the discretion of the therapist and patient. The set of topics to be covered is usually determined in the first few sessions, but may be subject to change. In particular, if a patient might benefit from additional conjoint sessions (sessions that include the presence of the patient's spouse or partner), those sessions may substitute for others that were originally planned.

Program Introduction

The program introduction presents the rationale for the program as well as the expectations for treatment. Patients are told specifically about the role of the social network in maintaining drinking, and the value of a new network to reinforce sobriety. The goal of abstinence is presented as the best approach for most people. The patient's confidentiality and its limits are discussed. The patient's drinking and treatment history are also reviewed, particularly his/her experience with AA. The patient is also introduced to the idea of ongoing between-session assignments. The importance of engaging in between-session assignments is stressed in the first session. After these introductory topics are addressed the therapist and patient discuss appropriate between-session assignments that can be reviewed the next week. These assignments may take the form of reading about AA, or attending a meeting, or completing an activities worksheet that may become the basis for developing activities that the patient can engage in with other nondrinking people.

TABLE 8.1 Network Support Session Topics

Core topics	Elective topics
Program introduction	Introduction to assertiveness
Need for support	Increasing pleasant activities
Getting active	Social skills identification
People, places and things	Social skills: Conversations
Termination	HALT
	Sober living
	Genogram
	Conjoint session — Enabling
	Conjoint sessions (multiple sessions possible)
	·

Need for Support

Certainly a key aspect of the AA philosophy is the idea that the alcohol-dependent individual is unable to control his/her drinking, and needs others, a fellowship, to help stay sober. In Network Support this topic material is based on the AA Step 1 idea of acceptance of oneself as unable to control drinking, but is modified slightly. Therapists discuss with patients the value of having a network of people who will support them in their efforts to stay abstinent, whether it is through AA or through other outlets. They also deal with the idea that drinking has become out of their control. The AA notion of "helplessness" is not stressed. Patients are not told that they are helpless in the face of drinking. But the need for assistance from others is stressed, and AA is presented as a tool to foster this assistance.

Getting Active

The third core session of the treatment program is entitled "Getting Active." The principle aim of this topic is to prepare the patient to get more active in AA. This entails familiarizing the person with some of the behavioral prescriptions embodied in AA slogans. Examples include "One Day at a Time," which is a key tenet of AA, but also expresses an adaptive way of dealing with the stress of stopping drinking. The AA concept of People, Places, and Things refers to identifying those stimuli in the person's environment that are cues for craving alcohol and drinking. The AA slogan "Easy Does It" reminds the client to avoid solving too many problems at once, and to "not bite off more than we can chew." "First Things First" emphasizes the importance of sobriety, making

sobriety the patient's top priority, and taking steps to promote sobriety. The therapist in this session also encourages the patient to talk things over with supportive family, friends, and AA peers to help set appropriate limits to drinking and other activities that have led to drinking in the past. Included in the session is a discussion of the advantages of AA attendance, encouragement to attend AA meetings, and to find an AA sponsor, a dedicated AA member on whom the patient can rely and contact in case of difficulty with drinking or cravings to drink.

People, Places, and Things

This topic is a key aspect of Network Support treatment. It encapsulates the theory on which Network Support was developed, namely that it is necessary to find ways to avoid or change the people, places, and things that cue and reinforce drinking. The need for the patient to learn to change his/her lifestyle, in particular the social network, to stay sober is stressed. The first step involves a discussion of the person's existing social network, particularly any drinking buddies or friends with whom the person frequently drinks. Discussion then turns to how the social network can be changed, what obstacles to change exist, and how they can be addressed. Between-session assignments take the form of scheduling attendance at AA meetings, searching for an AA sponsor, and finding nondrinking activities, preferably social activities, outside of treatment.

Increasing Pleasant Activities

Related to the idea of people, places, and things is the idea that pleasant (nondrinking) activities can serve as substitutes for those activities or situations that patients find stressful and that cue drinking. It is often not enough simply to have people eliminate activities that are not good for them. They need to substitute activities (people, places, things) that are good for them, in the sense that they are not linked to drinking, and can take the place of drinking activities. Not everyone needs help with this, but many people do. Patients in this session complete a leisure questionnaire designed to evaluate their interests and to provide a basis for discussion of alternative nondrinking activities. The therapist and patient review the questionnaire responses and discuss ways in which the patient might increase the number of such activities, while reducing the number of drinking-related activities. Between-session assignments include attending an AA meeting and scheduling a new nondrinking activity outside of AA.

Social Skills Identification

This is an elective topic, intended to help those who are having difficulty with the idea of changing their social networks, or who particularly reject AA. A key aspect of this topic is the idea that it is more important to add a nondrinking friend to one's network of close associates (i.e. those with whom one spends time at least once per week), than it is to drop drinking friends. A difficulty for some patients is that they have poor social skills, making it difficult for them to meet new people and maintain relationships even if they wanted to do so. Social skills are those behaviors that facilitate interaction and communication with others, making relationships possible. These include communication skills as well as nonverbal behaviors that people use to function in social situations. During this session the patient's social skills are assessed using the Social Functioning Interview, an interview-based survey developed by psychologist Alan Bellack, which also identifies those social situations that might be difficult for the patient to manage, and which might cue drinking. Having identified problematic situations, the therapist can help the patient work on ways to deal with them. Betweensession assignments after this session might include listing problematic social situations, working out ways to improve such situations, and practicing social skills discussed in the session, such as introducing oneself to a nondrinking person.

Social Skills: Conversations

Conversational skills are an important subset of more general social skills. Alcohol-dependent people who do not have well-developed conversational skills may drink in part to avoid the discomfort of social situations. Good conversational skills are critical for establishing friendships and other close relationships, as well as for getting along with coworkers in the workplace. Training in conversation skills focuses on increasing the frequency of interactions with others and improving the quality of those interactions. Good conversational skills require the ability to track and spontaneously respond to the other person, both verbally and nonverbally. In this session, patients complete a conversation skills assessment, in which patients rate themselves on their ability in different phases of a conversation, such as starting and maintaining a conversation. The therapist may work with the patient on different conversation skills using role-playing. Between-session assignments may include suggesting that the patient start a conversation with an unfamiliar person in a nondrinking enviand asking him/her to a conversation (minimum of 5 min) with someone at an AA meeting, or in another nondrinking environment.

Introduction to Assertiveness

Assertiveness refers to expressing oneself in a direct, nonaggressive way, particularly with respect to expressing one's needs or desires. Lack of assertiveness can lead to anxiety and frustration, which in turn may lead to drinking. Assertiveness training is frequently included as a component of more general social skills training. In Network Support treatment, assertiveness is evaluated in terms of how it may play a role in helping the patient meet new people and change the social network. Those who are too passive or too aggressive, for example, may be unable to make new acquaintances or maintain friendships. The session involves an assessment of assertiveness skills, a discussion of appropriate assertive responses in various situations, and roleplaying. Between-session assignments may include approaching a potential AA sponsor or practicing assertive skills in a nondrinking social activity outside of AA.

HALT

Another elective session concerns the AA-based acronym HALT, which stands for Hungry, Angry, Lonely, Tired. This is a shorthand term to refer to those situations in which relapse to drinking becomes more likely. Observational data and patient reports bear out the conventional wisdom that abstinent alcohol-dependent persons are more likely to drink if they are feeling vulnerable. This session, more than most of the others, focuses on self-care issues. The therapist discusses with the patient the need to get plenty of rest, and to eat appropriately, as being important to recovery. Other issues addressed include the need for sufficient sleep to be able to be refreshed enough in the day to cope with difficulties that may threaten sobriety. Other issues for discussion include instances of anger or loneliness, either of which may trigger urges to drink. The therapist briefly assesses these conditions, and the therapist and patient discuss potential solutions. Exercise, relaxation, hobbies, and other activities are all discussed as a means of managing mood. It is pointed out that a sober social network can help the patient with these issues. Between-session assignments usually include engaging in some new activity that addresses one of the HALT concerns, preferably in the company of nondrinking peers (e.g. playing basketball with a nondrinking friend; getting lunch with a nondrinker).

Sober Living (Nutrition, Exercise, and Hobbies)

It is sometimes the case that patients have very impoverished social lives. Over time alcohol dependence can "shrink" a person's lifestyle. As alcohol dependence develops, the client loses or abandons old

friends, old hobbies, and interests and activities. Life becomes increasingly centered around obtaining alcohol and maintaining access to alcohol. In early sobriety especially, emptiness and boredom can drive the person back toward drinking. This session content is designed to address this emptiness and boredom. The patient's nutrition, exercise, and hobbies are a specific focus of this session. This session differs from the HALT session in that HALT is focused primarily on finding ways to manage emergencies. This session is about changing significant parts of one's lifestyle. At the conclusion of the session, the patient is asked to commit to one way to improve his/her lifestyle in each of the three areas by the next session.

Genogram

The word genogram refers to a diagram illustrating a person's family members, how they are related, and their medical history. The genogram allows the patient to see hereditary patterns of behavior and medical and psychological factors that run through families. In Network Support treatment, the genogram helps the patient see the presence of alcohol dependence across generations, and can motivate the person to break the cycle of addiction by increasing his/her social support for abstinence. In the session the therapist diagrams two or three generations of the patient's family, starting with the patient's own generation. The patient is asked about drinking in his/her parents, and grandparents, as well as siblings and cousins. The patient is also asked about the possibility that his/her children might be affected by alcohol dependence. Patterns of inheritance are explored, and the patient is confronted with the possible implications of these patterns. At the conclusion of the session, the patient is asked to develop options to deal with facts exposed by the genogram, including finding ways to stay sober.

Conjoint Session – Enabling

An important aspect of Network Support treatment is securing support from those individuals already in the patient's close social network if possible. Typically the most important person in the network is the spouse or partner, if one is available. It is often the case, however, that the spouse or partner, rather than supporting abstinence, "enables" the patient to continue drinking. "Enabling" is the process whereby a close supporter of the patient may try to help the patient, but in reality makes it easier for the person to continue to drink. A common form of enabling is making excuses or lying for the person, for instance by providing to an employer an excuse for missing work. The support person may feel that providing the excuse can save the patient's

job, allowing him/her time to get things in order. Support persons may purchase alcohol for the patient, doing so in the belief that it is safer for the person to drink at home rather than drive to another location to purchase alcohol or to drink. The common effect of all forms of enabling, however, is to shield the patient from the natural consequences of his/her drinking problems.

This session topic is covered if a partner or spouse (supporter) is available and willing to help support the patient through treatment. In the session the supporter and the patient discuss behaviors by the supporter that might serve to enable the patient to drink. The discussion also deals with the possible motivations for the enabling behavior, the supporter's reactions to the patient's drinking, and possible ways for the supporter to cease the enabling. This might include the supporter attending Al-Anon meetings, intended to help the person accept the reality of alcohol dependence in someone close to him/her. Whether with or without the aid of Al-Anon, the emphasis in the session is for the supporter to take care of herself/himself, without regard for the patient; that is, the supporter must allow the patient to make the mistakes and face the consequences associated with heavy drinking. This is a means by which the supporter can become an important element of the patients' social network, reinforcing abstinence rather than drinking.

Additional Conjoint Sessions

Because of the importance of the spouse or partner in supporting abstinence in the patient, additional conjoint sessions may take the place of other elective sessions, depending on the desires and goals of the patient and the partner. Among the additional sessions that might be conducted with the spouse or partner are sessions on supporting and rewarding the patient's abstinence, and on detaching from the patient. Sessions focused on rewarding the patient's abstinence involve teaching the spouse or partner to get in the habit of noticing the improvements the patient is making in his/her drinking, and in other areas as well (e.g. mood, health). Partners are informed that slips may be a part of the recovery process and that together he/she and the patient can learn from them. Criticism should be avoided. The patient and partner are also asked to try to anticipate stressful periods or other circumstances that might test the patient and to plan on ways of dealing with those situations.

A session on partner detaching may be conducted if the spouse or partner has been unable to cope with the patient's treatment efforts, or difficulty with treatment. In such cases it may not be possible for the spouse to help the patient, but it is important that the treatment not harm the spouse or partner. In these situations the partner is counseled to "detach" from the situation. That is, he/she is encouraged to accept that the patient is dependent on alcohol and cannot necessarily help him/her. As in the session on enabling, the spouse or partner is encouraged to allow the patient to experience the negative consequences of his/her actions. The spouse is counseled to let go of anxiety, anger, and resentment.

Termination

The termination session is a core session of Network Support treatment. It is intended to provide closure to the first phase of a long and intensive process and to prepare the patient to maintain any gains made during the treatment. During this final session, the therapist and patient review the goals that were discussed and the patient's progress toward those goals. The purpose of the program is reiterated and the patient is urged to continue to make adaptive changes to his/her social network. The topics covered in treatment are summarized and the patient is asked about what topics were most and least useful. Additional treatment referrals are provided if necessary. The therapist ends by congratulating the patient on his/her achievements.

EFFICACY OF NETWORK SUPPORT TREATMENT

Network Support treatment has been tested in one major clinical trial, with results available for patients up to 2 years of follow-up. The complete reports of this trial have been published in the Journal of Consulting and Clinical Psychology. In this initial study 210 alcohol-dependent men and women were recruited from the community and received one of three outpatient treatments: Network Support (NS), Network Support + Contingency Management (NS + CM), in which patients were rewarded for completing between-session assignments, or Case Management (CaseM), a control condition in which no mention was made of changing social networks.

The results indicated that, in terms of drinking rates, both of the Network Support treatments led to better outcomes than the CaseM condition. Additional analyses indicated that the NS conditions did not reduce social support for drinking relative to the CaseM condition, but did increase social support for abstinence, as well as AA involvement. Furthermore, the increased support for abstinence and the increased AA attendance were partly responsible for the improved results. One important finding was that the addition of just one abstinent person to a social

network increased the probability of abstinence for the next year by 27%.

These findings indicate that drinkers' social networks can be changed by a treatment that is specifically designed to do so and that these changes contribute to improved drinking outcomes. After 2 years the decreases in drinking seen in the NS condition were maintained, with over 45% reporting total abstinence at the 2-year mark. In contrast, those patients who received the CaseM treatment, and those who received the NS + CM treatment, reported increasing drinking over the 2-year follow-up.

NETWORK SUPPORT: CONCLUSION

The development of Network Support treatment, and the clinical testing that has been conducted, has so far yielded the following conclusions: (1) Network Support interventions can help patients change their social networks. (2) The social networks of patients tend to become more supportive of abstinence, but support for drinking may not change. That is, patients may adopt new acquaintances but are reluctant to abandon their old friends. (3) If changes in the social network are made, the patient's chances for improvement increase. It is particularly important to add at least one nondrinking person to the social network.

Network Support treatment may hold promise for helping patients change their social networks and thereby lessen the chance of relapse. The current Network Support treatment has been enhanced with additional interpersonal skills training to improve patients' ability to develop more adaptive social networks. It is hoped that this enhanced treatment may further improve the chances of recovery for alcohol-dependent patients.

SEE ALSO

Improving the Quality of Addiction Treatment, Evaluating Treatment Efficacy, Evidence-Based Treatment, Cognitive Behavioral Therapies, Twelve-Step Facilitation Therapy, Community Reinforcement Approaches: CRA and CRAFT

List of Abbreviations

AA Alcoholics Anonymous
CaseM case management
CM contingency management
CRA Community Reinforcement Approach
HALT Hungry, Angry, Lonely, Tired
MET motivational enhancement therapy

NESARC National Epidemiologic Survey on Alcohol and

Related Conditions

NS network support
TSF twelve-step facilitation

UKATT SBNT United Kingdom Alcohol Treatment Trial Social

Behaviour and Network Therapy

Further Reading

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Multisystemic Therapy for Adolescent Substance Use

Ashli J. Sheidow*, Jaime L. Houston\$

*Family Services Research Center, Medical University of South Carolina, Charleston, SC, USA

\$Hempfield Behavioral Health, Inc., Harrisburg, PA, USA

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Multisystemic Therapy (MST) is an intensive familyand community-based treatment targeting youth at imminent risk for out-of-home placement, including juvenile offenders with substance abuse. Drs Scott Henggeler and Charles Borduin - the original developers of MST – and their collaborators have led most investigations on MST, with more recent investigations on MST effectiveness conducted by independent investigators. The empirical evidence for MST, including 20 published outcome studies (18 randomized trials and two quasi-experimental studies), has led the National Institute on Drug Abuse, the President's New Freedom Commission on Mental Health, and the US Surgeon General to recognize MST as one of the most extensively validated evidence-based psychosocial treatments for youth antisocial behavior, including substance abuse. The Surgeon General selected MST as one of only three empirically supported treatments for juvenile offenders, and the Substance Abuse and Mental Health Services Administration specified MST

as a model program for treating antisocial substanceabusing adolescents. Based on findings from over two decades of research, MST has become one of the most widely transported treatments for antisocial behavior in adolescents, including substance use. This chapter describes the application of MST for treating substance use in adolescent offenders, including an overview of the MST treatment model for adolescent substance use and a summary of the evidence for MST specifically with this population.

THEORETICAL BASES OF MST

The MST model draws from Bronfenbrenner's social–ecological and Minuchin's and Haley's family systems theories, viewing youth as embedded within multiple, interconnected systems (nuclear and extended family, peer, community, school). The reciprocal interplay of these systems influences behavior,

either directly (e.g. through parenting practices) or indirectly (e.g. through community factors that might influence parenting practices). Thus, behavior is viewed as multi-determined, with pertinent risk and protective factors identified in individual (e.g. cognitive biases), family (e.g. affective and instrumental relations), peer (e.g. prosocial versus antisocial nature of peers), school (e.g. academic performance), and community (e.g. criminal subculture) levels. Interventions used in MST pull from theoretical perspectives that complement the social-ecological models underlying MST. These include cognitive behavioral theory (e.g. problem-solving skills), behavioral theory (e.g. behavior plans), social learning theory (e.g. modeling and reinforcement influencing behavior), strategic formulations (e.g. understanding recursive sequences of behavior and family hierarchy), and Minuchin's structural formulations (e.g. attention to boundaries and repeated patterns of interactions that regulate family members' behaviors).

CHARACTERISTICS OF MST TREATMENT

Treatment is intensive, with a team of 2-4 full-time master's-level therapists each carrying caseloads of 4–6 families. Treatment includes an average of 60 direct contact hours over 3-5 months. The team is supervised by an advanced Master's- or doctoral-level supervisor. To remove barriers to participation, sessions occur at times (e.g. afterschool, evenings, weekends) and locations (e.g. home, school, community) that are convenient for the family. Further, therapists rotate being on-call, ensuring 24/7 availability for problem solving and emergencies. This model of service delivery allows flexibility in meeting families' needs while enabling rapid responses to crises that may threaten to disrupt treatment. Together, these elements support MST therapists in achieving high engagement and low treatment dropout rates.

In keeping with the systems approach, MST works with all pertinent systems in which the youth is involved, including peer group, school, neighborhood, immediate and extended family, and child welfare and juvenile justice agencies. Intervention protocols are relatively complex, however, given the multiple determinants of antisocial behavior and the need to target these determinants simultaneously across a complex and ever-changing ecology. To navigate these complexities, therapists and supervisors apply the nine core principles of MST within a standardized decision-making process that structures and guides treatment.

MST TREATMENT PRINCIPLES AND PROCESS

MST's fundamental goal is to empower caregivers to develop skills necessary for managing the problematic behaviors presented by their youth, both now and throughout their adolescence. The ability to individualize treatment and adapt to the family's changing needs is achieved through adherence to MST's nine core principles guiding the assessment process and structure planning, implementation, and evaluation of treatment. Treatment plans involve an MST therapist delivering a tailored set of evidence-based interventions targeted to each youth and family's unique strengths and struggles. This tailoring not only limits interventions to those that are necessary but also heightens the likelihood of achieving the family's buy-in to treatment and generalization of skill development. The nine core principles and treatment process are described next, accompanied by applications specific to adolescent substance use.

MST Principles

Principle 1. Finding the Fit – The primary purpose of assessment is to understand the "fit" between the identified problems and their broader systemic context.

MST relies heavily on a thorough, ecological conceptualization of youth antisocial behaviors. This conceptualization is the MST therapist's understanding of how the pieces "fit" together; that is, how is the behavior being sustained by variables in the youth's ecology? Accordingly, a "fit analysis" helps the MST provider make sense of the youth's problem behaviors in the context of his/her social ecology. Relying on what we know about the causes of youth problem behavior, MST providers investigate from an ecological and systemic perspective, identifying factors in the youth and his/her ecology that seem to be "driving" the youth to engage in problem behavior. These drivers become the "fit factors" for the fit analysis. To accomplish a thorough fit analysis, the MST therapist must be well informed about the most commonly observed youth (e.g. attitudes, cognitions, prenatal complications, drug exposure, cognitive functioning, biological processes, lack of prosocial activities, low academic functioning and involvement), family (e.g. ineffective parenting practices, low warmth and high conflict, caregiver psychopathology, substance use), community (e.g. poor housing quality, high crime, limited resources, easy access to drugs), and peer (e.g. access to drugs, modeling of substance use, beliefs, and norms) factors that drive antisocial behavior. The therapist's role is to assess what factors might be present for each youth and family, and prioritize which fit factors should be targeted in treatment planning. Further, the process is dynamic, as the conceptualization is updated in response to newly identified or appropriately resolved fit factors.

Consider the case of a 13-year-old boy, referred for engaging in various delinquent behaviors, who uses drugs after school with his neighbor. The boy's single mother returns from work around 06.00 p.m., leaving a 3-h window where he is unsupervised and has access to drugs at the neighbor's. Primary fit factors for this case appear to be low monitoring and parental supervision (i.e. youth can access drugs without the parent knowing) and negative peer associations (and corresponding lack of activities with prosocial peers). When he returns home, he is able to shower, brush his teeth, and change clothes before his mother returns from work, therefore disguising outward signs of use. Thus, another fit factor is that the parent cannot detect drug use when it has occurred and is not knowledgeable about how her teen conceals use. Because the mother is ignorant of his drug use, there is no consequence for the behavior, so he lacks motivation to stop using. A therapist might hypothesize that the main factors to target include low monitoring and supervision, negative peer involvement, lack of prosocial peer involvement, and lack of meaningful consequences.

Another example involves a 17-year-old girl; she is in a relationship with a 19-year-old who sells drugs and regularly offers her drugs. She spends all of her free time with him, and he ridicules her when she turns down his offers to use drugs. In the recent past, she had a warm relationship with her parents, and she still appears to want their approval and support. Her parents are aware of their daughter's relationship but have never met the boyfriend. They believe that she can make her own decisions and, though disappointed that she uses drugs, they feel they can do nothing about it given her age. The primary fit factors overlap those described in the previous example, but with some key distinctions. Like the first example, this 17-year-old's use appears to be driven, in part, by negative peer association (and corresponding lack of positive peer associations or prosocial activities). Her parents also exhibit low monitoring and supervision (e.g. they have not met the boyfriend; they do not know when or where she is using drugs). The reasons for low monitoring, however, are different. The girl's parents are aware of the drug use and can recognize signs of use, but they believe they are powerless to do anything about it due to her age. Further, the 17-year-old admits to having ineffective peer refusal skills to decline her boyfriend's offers, even if she wanted to quit using and improve her relationship with her parents.

Principle 2. Positive and Strength Focused – Therapist contacts emphasize the positive and use systemic strengths as levers for change.

A positive and strength-based approach has numerous advantages for successful outcomes and improved engagement and alignment in treatment. Focusing on family strengths can decrease negative effect, build hopefulness, create an environment of mutual problem solving (improving chances for generalization; see Principle #9), and enhance caregiver's confidence. This approach is communicated to the family throughout the entirety of treatment by emphasizing their strengths, as well as the strengths within the various ecological contexts (Principle #1). Providers actively investigate youth factors (e.g. competencies, altruism), caregiver factors attractiveness, resources, affective bonds, social support), peer factors (e.g. competencies, prosocial activities, inclusiveness), school factors (e.g. management practices, concern, prosocial activities), and neighborhood/community factors (e.g. law enforcement, business involvement, healthcare, neighbor concern), drawing upon strengths to develop individualized interventions.

A primary example of this principle is how therapists highlight any movement toward desired behaviors. Although eliminating substance use may be desired, any reduction in the behavior will be recognized; the therapist will attempt to understand the "fit" of the reduction, with the hope that the factors driving these reductions can be replicated or enhanced to further diminish/eliminate the behavior. Suppose that the 17-year-old girl described previously had two instant urine drug screens conducted over the past week by a parent: the first was negative (clean), but the second was positive (dirty). Although the youth has recently used drugs, the therapist will conduct a "positive fit analysis" to determine what factors drove drug abstinence earlier in the week versus drug use later in the week; perhaps the caregiver withheld cell phone usage earlier in the week, coincidentally eliminating the youth's ability to contact her boyfriend (i.e. a peer who promotes and provides drugs). This type of factor could be replicated to determine if it reduces the youth's drug use.

Another example of focusing on strengths involves MST clinicians (therapists, supervisors) avoiding blaming language. Even when faced with frustration resulting from a family not following through with the plan, the MST team attempts to see things from the family's perspective, identifying barriers the family may be experiencing that prevent them from following-through. Using the example of the 17-year-old, if a positive fit analysis indicates that limiting cell phone access might drive reduced drug use, the therapist could gain the parents' alignment to limit the youth's phone access. The therapist learns that the youth yielded positive drug screens and admitted to drug use later in the

month; after a fit analysis on the recent use, the therapist finds that the youth still had access to the cell phone. The therapist tries to identify barriers that prevented the parents from withholding the phone and finds that it is the primary means for the parents to communicate with their child, allowing them to know where she is and to coordinate transportation arrangements. Although the parents agreed to the plan of withholding the phone, they were unable to follow through due to practical barriers. Rather than expressing frustration or "giving up," the therapist acknowledges the barriers preventing the parents from following the plan and engages them in problem solving to overcome these practical barriers (e.g. develop communication plans that do not rely on the cell phone; limit what calls she can make through the phone company).

Principle 3. Increasing responsibility – Interventions are designed to promote responsible behavior and decrease irresponsible behavior among family members.

The fundamental goal of MST is to empower caregivers to effectively manage and resolve serious clinical problems presented by their youth both now and throughout their adolescence (see Principle #9: Generalization). MST views caregivers as the key to long-term positive youth outcomes and are therefore the strongest lever for change (i.e. the "change agent"). With this in mind, caregivers participate in every step of assessment and intervention, engaging other indigenous supports where needed. Therefore, rather than relying on individual therapy for the youth, providers align with the caregivers on treatment goals and provide them with the instruction and support needed to implement the intervention.

Consider the case of the 13-year-old boy who accesses drugs after school. The parent and therapist completed the fit assessment and are in agreement that primary "drivers" for the drug use are low monitoring and supervision, negative peer involvement, lack of prosocial peer involvement, and lack of meaningful consequences for drug use. Through the assessment, the therapist learns that the youth used to be involved in baseball but was ineligible for school athletics due to poor grades. The parent and therapist align on a treatment goal to reengage the youth in positive afterschool programs through the community until grades improve. It would be easy for the therapist to contact the local baseball league to inquire about eligibility requirements; however, the therapist would be taking the responsibility away from the parent and would lose a valuable opportunity for improving the mother's skills in accessing supports within her own ecology. A better approach is to train the parent on how to make the calls (e.g. guide her to create an agenda for the calls, role play the calls) and then support her as she makes the calls on her own. Principle 4. Present-focused, action-oriented, and well-defined — Interventions are present-focused and action-oriented, targeting specific and well-defined problems.

Clear treatment goals form the basis for MST interventions and are behaviorally defined so it is obvious what is being targeted and, therefore, assessed. A family with a nonspecific goal such as "youth needs to respect authority" would be guided to identify what disrespect for authority looks like for this youth (e.g. violating rules in the home, school, or community; physical and verbal aggression) and a behaviorally defined goal would be developed (e.g. youth will demonstrate improved respect for authority as evidenced by following household, school, and community rules, eliminating physical aggression, and reducing verbal aggression). This clear goal allows the treatment team and family to be action-oriented in developing plans for targeting these well-defined goals, closely tracking progress, and identifying transparent criteria for treatment termination. MST is an intensive treatment, so therapists develop weekly subgoals that target the prioritized fit factors (Principle #1). Given this action-oriented approach, rapid treatment change is expected. Further, emphasis is placed on the fit factors presently sustaining the behaviors, as opposed to those responsible for the initial development of the behaviors.

Imagine the 17-year-old girl who is using drugs with her older boyfriend. One driver the family identified was decline in the relationship between the youth and her parents, corresponding to lack of warmth in the home and increased conflict. With further assessment, we learn that the parent-child relationship began to wane after the parents divorced and the mother remarried. Currently, the biological father and stepfather are both actively involved in parenting, but the youth has struggled to adjust to the change in family structure. The divorce may have been the initial trigger, but other protective factors have since been lost that could have brought an end to the drug use, including adult supervision, prosocial peer involvement, and skills to manage distressing cognitions. As these latter factors are currently sustaining the youth's drug use, they are the fit factors that should be prioritized for intervention.

Principle 5. Targeting Sequences – Interventions target sequences of behavior within or between multiple systems that maintain the identified problems.

Problem behaviors are viewed from the socialecological framework as having a multisystemic set of causal and sustaining factors. Interventions are thus focused on changing family members' interactions with one another, as well as their interactions with the ecology (e.g. peer, school, community). While promoting responsible behavior of family members, this also extends the family's informal support systems (e.g. friends, clubs) rather than relying on formal support systems (e.g. probation, social services) to sustain positive changes.

Take the example of the 13-year-old boy who uses drugs after school with his neighbor. The therapist guided the parent through contacting the baseball league and preparing for tryouts to reengage the youth in prosocial activities. With this driver targeted, the mother and therapist now begin focusing on the remaining drivers (low monitoring after school; lack of meaningful consequences). To target these fit factors, the family and therapist developed a behavior plan including random drug screens with appropriate negative consequences for positive or refused drug screens. Following a positive screen, the mother implements the consequence - "grounding" him from going out with friends until he has a clean screen. Knowing that this means he cannot attend the football game that evening, the youth becomes agitated and tries to aggravate his mother with name-calling, following her around, cursing loudly, and punching a hole in the wall. Unable to effectively diffuse the button-pushing, she eventually gives in because she can no longer tolerate his disrespect. The mother contacts the therapist to report the incident. In reconstructing the sequence, it became evident that the consequence of grounding, while meaningful (as evidenced by the youth's intense displeasure), may not be enforceable at this time due to both the youth's problematic responses and the mother's ineffective management of button-pushing. To overcome this barrier, the mother and therapist align on a plan to utilize the youth's uncle, with whom the youth does not get aggressive, to temporarily provide support when a negative consequence must be implemented. Meanwhile, the mother can work with the therapist to improve skills for managing the youth on her own and identify negative consequences that are not as taxing on the mother (e.g. uncle confiscating the youth's gaming system/computer until the youth has clean screens).

Principle 6. Developmentally Appropriate – Interventions are developmentally appropriate and fit the developmental needs of the youth.

The MST therapist and supervisor review interventions to ensure they are well-matched to the youth's and family's developmental needs. Thus, the competencies youth typically develop during adolescence are emphasized (e.g. peer relations, academic planning). To illustrate, a comprehensive fit analysis for a 12-year-old's drug use identifies three primary fit factors: low supervision after school (his use only occurs after school when home alone), poor anger management skills (he is most likely to use when angry), and inconsistent

consequences for drug use (he is not always held accountable for drug use). When choosing intervention strategies, the family and therapist decide to initially target the low supervision and inconsistent consequences, as asking the youth to evaluate and modify his response to anger (e.g. cognitive interventions) may be more difficult given a preteen's limited developmental capacity to monitor internal dialogue and processes.

Principle 7. Continuous Effort – Interventions are designed to require daily or weekly effort by family members.

Youths referred for MST demonstrate high-risk behaviors that place them at imminent risk of out-of-home placement. Given this, the case conceptualization, intervention development, and intervention implementation must occur rapidly. By attaining daily or weekly effort by family members, the stage is set for rapid change in problematic behaviors. This, in turn, provides more opportunities for identifying barriers to intervention effectiveness, and more opportunities for families to feel empowered as they come to learn they are the "change agents" (Principle #3) for altering the youth's behavior. The intensity of MST, compounded with therapists' low caseloads, results in frequent in-person and phone contact, but homework assignments also ensure daily or weekly effort by family members.

In the example of the 17-year-old girl who uses drugs with her older boyfriend, the family and therapist hypothesize that a main driver for the youth's increased involvement with her boyfriend is due to discontinued involvement in afterschool activities (school musical, softball). Therefore, factors driving the youth's drug use include increased access to negative peers (with low parental knowledge of peers) and disengagement from prosocial activities. To begin reducing access to negative peers, the parents and therapist might agree to start a daily log of whom the youth is seen with, who she mentions, or who appears on the caller ID. This daily tracking allows the parents to rapidly collect information on members of the youth's peer group, providing means for contacting the peers' parents or limiting access to certain peers if needed.

Principle 8. Evaluation and Accountability – Intervention effectiveness is evaluated continuously from multiple perspectives, with providers assuming accountability for overcoming barriers to successful outcomes.

The MST assessment process is ongoing and follows a circular form (see MST Analytical Process) that guides treatment. Because goals are well defined (Principle #4) and interventions are devised to require continuous effort from the family (Principle #7), measurable outcomes can be monitored and evaluated frequently.

Data from multiple sources are gathered to ensure accurate evaluation. The MST therapist is responsible for monitoring outcomes, as well as for identifying and problem-solving barriers to treatment progress. Such an approach avoids blaming or negatively labeling individuals as "resistant"; instead, the therapist focuses on generating creative ways to overcome impediments to success and ensuring a "can-do" attitude (see the example for Principle #2).

Evaluating treatment progress continuously from multiple perspectives as applied to drug use in the example cases described here included youth self-reports and instant-report urine drug screens. The therapists also educate parents on scenarios in which substance use might not be detected reliably through these methods (e.g. deception, drugs with short detection times, huffing). To increase accuracy of their evaluations, the therapist helps the parents develop a plan for conducting random screens frequently enough, though randomly, to detect use. In addition, the therapist also teaches them to conduct room sweeps and other measures to detect drug paraphernalia, in addition to utilizing drug screens.

Principle 9. Generalization – Interventions are designed to promote treatment generalization and long-term maintenance of therapeutic change by empowering caregivers to address family member's needs across multiple systemic contexts.

Long-term therapeutic change is achieved by empowering caregivers to address the family and youth's needs across the multiple systems in which they participate. By leveraging strengths (Principle #2), increasing parental responsibility (Principle #3), and requiring presentfocused (Principle #4) continuous effort (Principle #7), caregivers can develop the skills necessary for achieving and continuing the progress made during treatment. As treatment continues, the role of an MST therapist rapidly changes from that of teacher/clinician to advisor/ consultant; meanwhile the family begins to rely more on themselves and indigenous supports (e.g. extended family, neighbors, friends) to sustain favorable outcomes long after termination of services. Consider again the 13-year-old who accessed drugs at his neighbor's while his mother was at work. The family and therapist determined that two primary factors driving the drug use were low monitoring and ineffective consequences. Working with the therapist, the parent develops a comprehensive monitoring plan, clear negative consequences for drug use, and rewards for clean screens. After 3 weeks of implementing the plan, the youth is no longer using drugs and has clean screens. To build on this success, the therapist guides the family in developing a plan to generalize the parent's improved monitoring, effective reward system, and consequence interventions to another problematic behavior: poor school performance. By building on the parent's developed skill set, the family is better positioned for continuing to apply their skills targeting the youth's substance use, in addition to any new problematic behaviors that might emerge as the youth ages.

MST Analytical Process

The MST Analytical Process (see Fig. 9.1) provides the framework for identifying youth and family problems, prioritizing drivers for change, designing interventions for implementation, and measuring successes and barriers to goal attainment. The MST team uses this framework to guide treatment while adhering to all nine MST principles. As denoted by the largest box in the figure, this process occurs within the environment of engagement and alignment, with the therapist taking full responsibility for obtaining and maintaining the family's and other key participants' engagement in treatment. Initially, the therapist must identify the referral behaviors and elicit the desired outcomes for treatment from key participants (e.g. immediate family, formal and informal supports). This information is then translated into well-defined overarching treatment goals, providing direction for the duration of treatment.

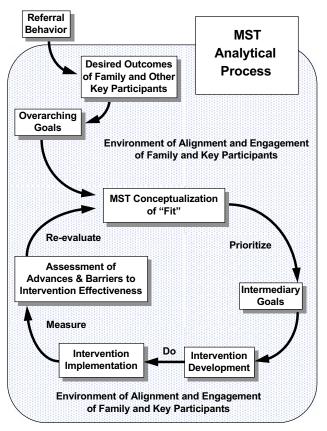


FIGURE 9.1 The MST Analytical Process guides treatment planning.

The therapist guides the family through fit analyses of the behaviors identified in the overarching goals, engaging key participants to identify multisystemic factors driving each of the behaviors. These factors are then prioritized based either on their potential for triggering antisocial behavior (including substance abuse) or on those that must be targeted prior to targeting the primary factors (i.e. prerequisite factors). The prioritized fit factors help the MST team generate working hypotheses the team uses to tailor interventions to the family. From this, the therapist and family determine the bestsuited interventions, attempt the interventions, and evaluate the effectiveness of the interventions. Based on the evaluation, the conceptualization (i.e. fit factors, hypotheses) may be revised and new or redesigned interventions are implemented. This iterative process continues until the behaviors are targeted successfully, at which point the factors driving the sustained improvements are identified (understanding the fit) and concrete plans are developed for the family to sustain those factors into the future.

To illustrate the MST analytical process, consider the case of a 16-year-old male referred by the juvenile probation department for running away, car theft, drug abuse, and physical aggression. The MST therapist begins by building definitions of the problematic referral behaviors, including their intensity and frequency, and how long the youth has exhibited these behaviors. The assessment indicates that the youth began seriously acting out when he entered high school. He started running away overnight and had at least two instances where he disappeared for several days. During one of these instances, he was found with a peer in a stolen car and was placed on probation for the incident. After the last incident, his parents found marijuana in his bedroom. When they confronted him about using drugs, he became verbally aggressive and threatened to leave or harm them if they searched his room again. When his parents tried to enter his room, he pushed his mother, resulting in his involvement with the police for assault and drug possession. At the time of intake into MST, the youth's parents and probation officer reported that he was physically aggressive every few weeks, left the house whenever he wanted, and was using marijuana.

The MST therapist then works with the family to identify outcomes they hope to see in the youth post-treatment. The family wants the youth to decrease the referral behaviors and to complete his chores. The probation officer, school guidance counselor, and aunt are identified as key participants in treatment and are invited to participate in MST. In addition to the existing desired outcomes, the key participants want the parents to establish age-appropriate rules for the youth. Next, overarching goals for treatment are developed, which

must relate to the referral behaviors, achieve the desired outcomes, guide the direction of treatment, and establish the discharge criteria. All subsequent interventions tie directly back to the overarching goals. For this youth, the overarching goals for treatment are to (1) eliminate physical aggression; (2) eliminate illegal drug use; and (3) follow household rules including chores, obtaining permission before leaving, and reporting whereabouts.

The therapist now begins the "fit" assessment by gathering detailed information from the family and key participants on recent sequences of aggression, rule-breaking, drug involvement, as well as factors that may drive the youth's behaviors. The therapist and family then prioritize fit factors. Specific to drug use, prioritized fit factors are: access to money to purchase drugs, no immediate negative consequences for drug use, few rewards for drug abstinence, low monitoring and supervision, negative peer association, and boredom. They are now equipped to develop interventions targeting these factors, while ensuring the interventions adhere to MST's nine principles.

First, the family limits the money they provide the youth and asks documentation on how he uses it (e.g. provide receipts from purchases). The therapist educates the family about behavior modification strategies (e.g. increased monitoring of youth, rewarding abstinence, enforcing consequences for use), and they collaboratively develop a tailored behavior plan, including monitoring the youth's whereabouts, conducting instant urine drug screens purchased from an online source, identifying and delivering meaningful and immediate negative consequences for drug use (as documented by positive drug screens), and identifying and delivering appropriate and immediate rewards for drug abstinence (as documented by negative drug screens). Before beginning, the therapist helps the family identify possible barriers to successful implementation of the behavior plan. Transportation issues and long work hours being potential barriers, the family agrees to invite one of their key participants, the boy's aunt, into treatment for support. She agrees to provide transportation to activities he earns as rewards in the plan and will help monitor by making surprise house visits during times the youth is home alone.

Simultaneously, the family also aligns on targeting fit factors of negative peer association and boredom. Though the youth is unwilling to provide information about his peers, the family and therapist utilize the ecology for assistance. The guidance counselor knows the youth's peers at school, and the probation officer provides contact information and common peer "hang outs" where drugs are often accessible. The therapist, family, and probation officer work together to restrict the youth's time with specific peers who are known drug users. The family and therapist then generate

a list of the youth's strengths, talents, and previous prosocial activities. Using this list, they contact people to inquire about getting him back into these activities and present these options to the youth, with incentives for him return to these activities. Once the plans are set in motion, the family and therapist assess the youth's progress each week, problem-solving barriers as they proceed. MST is concluded following sustained reduction in the targeted behaviors and development of a long-term sustainability plan.

EMPIRICAL BASES FOR MST

MST was developed to target adolescent antisocial behavior. Thus, most research on MST has focused on delinquency outcomes, as opposed to substance-use outcomes. This section gives an overview of MST's effectiveness for the primary target outcome (i.e. juvenile delinquency), the process by which MST started focusing on substance use, and a summary of empirical findings related to substance use treatment (of antisocial youth).

MST for Juvenile Delinquency

To date, 20 efficacy (i.e. testing a treatment delivered under optimal circumstances) and effectiveness (i.e. testing a treatment delivered under "real world" circumstances) investigations have established that MST can decrease rates of antisocial behavior and other serious clinical problems, improve family and school functioning, and reduce out-of-home placements (e.g. incarceration, residential treatment, hospitalization). As mentioned previously, the majority of these investigations have been conducted by the treatment developers (Drs Henggeler and Borduin and their colleagues), although a portion has been independent replications (i.e. conducted by investigators other than the treatment developers). Given the competitiveness of research funding and the complexity of implementing clinical trials, independent replications of adolescent treatments are atypical, especially for complex familybased treatments. The length of follow-up in MST research also is remarkable and nearly unparalleled, including an almost 14-year investigation.

Specific clinical trials of MST have focused on violent and chronic offenders, inner-city juvenile offenders, juvenile sexual offenders, and substance abusing/dependent juvenile offenders. Further, single trials have evaluated the use of MST for serious emotional and behavioral disturbances, psychiatric emergencies, and chronic health conditions. A recent review by Henggeler and Sheidow includes an overview of all extant MST research (in addition to investigations on Functional Family Therapy, Multidimensional Treatment

Foster Care, and Brief Strategic Family Therapy). As summarized in this review, findings across studies of offending youth routinely favor MST compared to control conditions. Positive outcomes in MST clinical trials include immediate and meaningful reductions in rates of rearrest (e.g. 24 and 72% reduction in recidivism) and conduct problems, as well as sustained decreases (e.g. 54% reduction in recidivism at 13.7-year follow-up). Effect sizes have been substantial (e.g. 0.50 for criminal behavior based on official records, 1.01 for arrest seriousness). Given the paucity of positive findings for juvenile justice interventions and the high cost of delinquency and common juvenile justice interventions (e.g. detention), these rates are particularly notable.

MST for Substance-Using Delinquents

Given the well-researched link between juvenile delinquency and adolescent substance use, Henggeler and colleagues first examined the substance-related outcomes for the violent and chronic juvenile offenders who participated in two of the early randomized clinical trials (RCTs) of MST. These substance-related outcomes were favorable for MST compared to controls. Notably, the follow-up investigation of arrest records nearly 14 years posttreatment demonstrated that MST participants continued to have fewer drug-related arrests than did their control counterparts.

The initial promising findings prompted focused research on MST for juvenile offenders who had substance abuse problems. A study of juvenile offenders meeting criteria for abuse or dependence randomized youth to MST or usual community services. This was a noticeably disordered sample, which sometimes is not the case in clinical research of adolescents. In addition to expected MST outcomes (e.g. 50% decrease in out-of-home placement compared to control), posttreatment findings favored MST for targeting substance use in a delinquent drug-involved sample (i.e. lower selfreported alcohol and marijuana use compared to control). In addition to the primary clinical outcome, MST was more successful than control at effectively engaging the substance abusing and substance dependent youths (and their families) in treatment (i.e. 100% of families in MST retained through 2 months of treatment with only one dropout pre-completion). This is particularly noteworthy, as low client retention rates traditionally plague substance abuse treatments. MST is also one of few treatments to have established cost savings, with a cost evaluation for this RCT showing that the incremental cost of MST was fully offset by reduced detention and treatment placement costs. Sustained treatment effects for marijuana use and violent crime were found at 4-year follow-up. Specific to substance use, urine drug screens collected from the youth showed appreciably higher rates of marijuana DISSEMINATION OF MST 85

abstinence for MST participants (55%) versus usual services participants (28%).

Following a surge in the number of US drug courts and the surprising absence of research investigating the effectiveness of such courts and their treatment services, a second randomized MST efficacy trial with substance-abusing juvenile offenders was conducted. Unlike a standard RCT that would compare MST to a control treatment, this study proposed to determine the effectiveness of (1) juvenile drug court, (2) integrating an evidence-based substance abuse treatment (MST) into juvenile drug court, and (3) adding a contingency management (CM) protocol into MST to further enhance substance-use outcomes (CM techniques and research are described elsewhere in Comprehensive Addictive Behaviors and Disorders). The trial demonstrated that juvenile drug court was generally more effective than standard family court services in decreasing substance use and criminal behavior. There was also support for using evidence-based interventions (i.e. MST or MST enhanced with CM) within drug court to improve substance-related outcomes for adolescents. Data from urine drug screens indicated that drug court with either MST or MST enhanced with CM reduced substance use compared to drug court with typical community treatment. Notably, however, the juvenile drug court had a significant impact on both criminal and placement outcomes compared to standard family court services, but MST did not further enhance these effects. Long-term follow-up from this study is forthcoming and will extend knowledge on juvenile drug courts and the treatments provided in those courts.

Independent research replication of MST for substance abusing/dependent delinquents has yet to be completed, although two additional RCTs of MST have contributed to the empirical bases of MST for substance use outcomes within regular delinquent samples. Timmons-Mitchell and colleagues' independent replication of MST for juvenile offenders found decreased substance use problems for the 6 months post-baseline within the group receiving MST. Further, Letourneau, Henggeler, Borduin, and colleagues' randomized effectiveness trial evaluating MST to treat juvenile sexual offenders found that the number of youth using substances decreased in the MST condition (by nearly 50%) while it increased in the treatment-as-usual condition (by 65%) at 12-month follow-up. Thus, the use of MST for treating substance use in a wide array of juvenile offenders is supported through numerous research investigations, including efficacy, effectiveness, and independent investigations. Not all of these trials focus specifically on substance use, and trials are limited to offender populations. Thus, one must look carefully within trials to identify the array of findings specific to substance use and must recognize that generalization is limited to the juvenile justice population. The empirical support for MST overall, which includes decades of efficacy and effectiveness randomized trials, and specifically the empirical support for MST in the treatment of substance use problems, makes the approach a preferred model for treating substance use in adolescent offenders.

DISSEMINATION OF MST

In general, large-scale transport of family-based treatments is difficult. That is, the extensive training required to prepare therapists (i.e. few graduate programs include adequate training in family therapy) combined with the practical demands for funding (i.e. groupbased treatments are often more lucrative) diminish the likelihood of family-based treatments being promoted by community-based agencies. Additional concerns specific to MST and many other family-based treatments for adolescents include the need for a team of therapists to be funded (i.e. as opposed to a single therapist), initial investment in training therapists and high rates of turnover, and comparatively protracted time until effects emerge (e.g. in comparison to residential or boot camp types of treatments). Even the proven financial advantages cannot always compete with the initial "sticker shock" over the required investment of starting an MST program. Regardless, the research findings and cost comparisons are powerful tools for convincing funders and stakeholders of the need for MST as compared to nonevidence-based, and potentially detrimental, treatments.

An important finding during the research studies was that the therapist adherence to MST treatment principles was related to more favorable youth outcomes; thus, dissemination of MST has had a strong emphasis on treatment fidelity. As demand grew for MST programs, the developers were unable to provide adequate training and support of fidelity for new MST programs across the country. In the mid-1990s, a purveyor organization (MST Services, see mstservices.com) was developed by Mr Strother and Drs Henggeler, Schoenwald, and Rowland to meet the growing demand. This organization, licensed by the Medical University of South Carolina to transport MST technology and intellectual property, provides the program start-up preparation and ongoing training and quality assurance that the developers would be unable to provide on such a large scale. In addition, MST Services trains network partners to be purveyor organizations for program development and ongoing quality assurance. Purveyor organizations provide manuals (treatment, supervisor, expert consultant, and program manuals), training (initial 5-day orientation, quarterly booster training, weekly case consultation, and supervisor and consultant training), organizational support (program operations manual, program development, program and agency leadership support), and implementation measurement and reporting (measures of therapist, supervisor, and consultant adherence, web-based system to track site performance and youth outcomes). Together, MST Services and their network partners provide support for the more than 480 MST programs in 30+ states and 12 countries.

CONCLUSION

Adolescent substance use represents a major public health problem. In particular, delinquent youth are at particularly high risk for substance abuse problems, and use is often associated with a range of negative outcomes (e.g. more severe delinquent behavior, continued offending into emerging adulthood, poor educational and occupational outcomes, elevated risk for HIV and other sexually transmitted infections) compared to nondelinquent youth. Thus, having effective treatments for juvenile offenders who abuse substances is of exceptional importance. MST is one such treatment that has been tested through a rigorous program of research and is widely disseminated in community-based practice across the United States and other countries. Existing texts provide details of MST as it applies to delinquent behaviors, but the present text provides an overview and examples of MST as it applies specifically to adolescent substance use.

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SEE ALSO

Behavioral Treatments for Adolescents with Substance use Disorders, Contingency Management

List of Abbreviations

CM contingency management MST Multisystemic Therapy RCTs randomized clinical trials

Further Reading

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Relevant Websites

http://www.mstservices.com – Multisystemic Therapy (MST) Services.

http://drugabuse.gov/nidahome.html - National Institute on Drug Abuse (NIDA).

http://www.mentalhealthcommission.gov/index.html - President's New Freedom Commission on Mental Health.

http://www.nrepp.samhsa.gov/ - SAMHSA's National Registry of Evidence-Based Programs and Practices (NREPP).

10

Multidimensional Family Therapy for Adolescent Substance Abuse: A Developmental Approach

Howard A. Liddle

Center for Treatment Research on Adolescent Drug Abuse, University of Miami Miller School of Medicine, FL, USA

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Treating adolescent substance abuse is challenging. The clinical profile of referred adolescents is complex. It can include the secretive and illegal aspects of drug use; involvement in criminal activities with antisocial or drug-using peers; despairing, stressed and poorly functioning families; involvement in multiple social agencies and services that may but typically do not meet the youth's and family's needs; disengagement from school and other prosocial contexts of development; and lack of intrinsic motivation to change. Many

contemporary developments in the drug abuse and delinquency specialties offer guidance for clinicians and hope for parents, adolescents, and families. The volume and, more critically, the quality of basic and treatment research in the adolescent treatment area have increased. At least until the recent economic downturn, an increased funding for specialized youth services could be noticed. And an expanded interest in the problems of youth from developmental psychopathology researchers, applied prevention and treatment scientists,

policy makers, clinicians and prevention programmers, professional and scientific societies, mass media and the arts, and critically, from the public at large, can be documented without difficulty. Greater consensus exists today than ever before about preferred conceptualizations and intervention strategies for youth problems in general, and adolescent substance abuse and delinquency in particular. Leading figures in the field now conclude that drug abuse results from both intraindividual and environmental factors. And, as the reasoning goes, unidimensional models of drug abuse are inadequate; making the support and continued development of more complex, multicomponent, and integrated research and intervention approaches are all the more important.

This contribution summarizes multidimensional family therapy (MDFT), an empirically supported family-focused therapy specializing in the treatment of youth drug abuse and delinquency. A developmental perspective and the basic science knowledge base about adolescent and family development inform and organize all aspects of the treatment. The knowledge base teaches therapists about the course of individual adaptation and dysfunction through the lens and tasks of normative development. Youth and family developmental milestones are benchmarks that guide assessment and interventions in terms of their framing and form. The developmental psychopathology knowledge base moves beyond consideration of symptoms only to understand a youth's and family's ability to cope with the developmental tasks at hand. It specifies the implications of stressful experiences and developmental failures in one developmental period for adaptation or problems in future periods. Because multiple pathways of adjustment and problem development may unfold from any given life cycle point, emphasis is placed equally on understanding competence and resilience in the face of risk. Adolescent substance abuse is conceptualized as a problem of development – a complex, multifaceted deviation from the normal developmental pathway. Substance abuse involves difficulties in facing developmental challenges and it is a set of behaviors that compromises capacities to achieve future developmental milestones.

The *risk and protective factor* knowledge base teaches clinicians about the empirically derived determinants of problem formation. Perhaps more critically given the clinician's responsibility, specific knowledge of risk and protection in the multiple realms that have been filled in by longitudinal studies empowers clinicians with knowledge of the diverse *promotive* processes that might be located and facilitated to fight against risk and negatively cascading developmental slides. It identifies factors from diverse domains of functioning (psychological, social, biological, and neighborhood/community) relevant to positive adaptation and threats

to development. Thinking in terms of risk and protection also helps therapists to identify key interactional or process terms about the intersecting and mutually influencing dimensions of the adolescent's and family's current life circumstances.

Another framework and body of knowledge, the ecological or contextual perspective, specify the interconnected web of influences forming the context of human development. Regarding the family as a principal developmental arena, ecological and contextual notions take a keen interest in how both intrapersonal and intrafamilial processes are affected by and affect extrafamilial systems (i.e. significant others involved with the youth and family, such as school, job, or juvenile justice personnel), and of course how these external to the family processes and events affect family development, parenting, and parent-adolescent relationships. Ecological and contextual ideas coincide with contemporary theorizing and empirical work about reciprocal effects (i.e. dynamic systems theory) in human relationships, and it underscores how, like all behavior, problems are manifest at different levels, and in different ways with different individuals, and how circumstances in one domain can affect other domains. Taken together, the ideas and still accumulating research about development, context, ecology, and risk and protection have had an enormous, transformative influence on the conceptualization of youth and family problems, the program theory in both treatment and prevention that is thought to be needed to impact multiple embedded problems, and the corresponding interventions that aim to resolve individual and family dysfunction and burden.

TEN GUIDING PRINCIPLES

- **1.** Adolescent drug abuse is a multidimensional phenomenon. Individual biological, social, cognitive, personality, interpersonal, familial, developmental, and social ecological aspects can all contribute to the development, continuation, worsening, and chronicity of drug problems.
- 2. Family functioning is instrumental in creating new, developmentally adaptive lifestyle alternatives for adolescents. The youth's relationships with parents, siblings, and other family members are fundamental areas of assessment and change. The adolescent's day-to-day family environment offers numerous, indeed essential opportunities to re-track developmental functioning.
- **3.** Problem situations provide information and opportunity. Symptoms and problem situations provide assessment information as well as essential intervention opportunities.

- 4. Change is multifaceted, multidetermined, and stageoriented. Behavioral change emerges from interaction among systems and levels of systems, people, domains of functioning, and intrapersonal and interpersonal processes. A multivariate conception of change commits the clinician to a coordinated, sequential use of multiple change methods, and working multiple change pathways.
- 5. Motivation is malleable but it is not assumed.

 Motivation to enter treatment or to change will not always be present with adolescents or their parents. Treatment receptivity and motivation vary in individual family members and relevant extrafamilial others. Treatment reluctance is not pathologized. Motivating teens and family members about treatment participation and change is a fundamental therapeutic task.
- **6.** Multiple therapeutic alliances are required and they create a foundation for change. Therapists create individual working relationships with the adolescent, individual parent(s) or caregiver(s), and individuals outside of the family who are or should be involved with the youth.
- 7. Individualized interventions foster developmental competencies. Interventions have generic or universal aspects. For instance, one always wants to create opportunities to build teen and parental competence during and between sessions, but all interventions must be personalized, tailored, or individualized to each person and situation. Interventions are customized according to the family's background, history, interactional style, culture, and experiences. Structure and flexibility are two sides of the same therapeutic coin.
- 8. Treatment occurs in stages: continuity is stressed. Core operations (e.g. adolescent or parent treatment engagement and theme formation), parts of a session, whole sessions, stages of therapy, and therapy overall, are conceived and organized in stages. Continuity linking pieces of therapeutic work together is critical. A session's components and the parts of treatment overall are woven together continuity across sessions creates change enabling circumstances.
- 9. Therapist responsibility is emphasized. Therapists (1) promote participation and enhance motivation of all relevant persons, (2) create a workable agenda and clinical focus, (3) provide thematic focus and consistency throughout treatment, (4) prompt behavior change, (5) evaluate, with the family and extrafamilial others, the ongoing success of interventions, and (6) per this feedback, collaboratively, revise interventions as needed.
- **10.** *Therapist attitude is fundamental to success.* They are neither "child savers" nor unidimensional "tough

love" proponents; they advocate for adolescents and parents. Therapists are optimistic but not naïve or Pollyannaish about change. Their sensitivity to contextual or societal influences stimulates intervention possibilities rather than reasons for how problems began or excuses for why change is not occurring. As instruments of change, a clinician's personal functioning enhances or handicaps one's work.

CHARACTERISTICS OF THE TREATMENT PROGRAM

Multidimensional Assessment

Assessment yields a dynamic and evolving therapeutic blueprint – an indication about where and how to intervene across multiple domains and settings of the teen's life. A comprehensive, multidimensional assessment process identifies risk and protective factors in relevant areas, and prioritizes and targets specific areas for change. Information about functioning in each target area comes from referral source information and dynamics, individual and family interviews, observations of spontaneous and instigated family interactions, and interchanges with influential others outside of the family. There are four overall targets: (1) adolescent, (2) parent, (3) family interaction, and (4) community social systems. Attending to deficits and hidden areas of strength, we obtain a clinical "moving" picture (transactional perspective) of the unique combination of weaknesses and assets in the adolescent, family, and social system. This contextualized portrait includes a multisystem formulation of how the current situation and behaviors are understandable, given the youth's and family's developmental history and current risk and resilience profile. Interventions decrease risk processes known to be related to dysfunction development or progression (e.g. disengaged or conflict heavy family relationships, parenting problems, strong and patterned affiliation with drug-using peers, disengagement from and poor outcomes in school), and enhance protection and develop problem solving, first within what the therapist finds to be the most accessible and malleable areas. An ongoing process rather than a single event, assessment continues throughout treatment as new information emerges and experience accumulates. Assessments and therapeutic planning overall are revised according to feedback from our interventions.

A home-based or clinic-based family session generally launches treatment. But before this meeting, clinicians try to have brief telephone conversations with a parent, and sometimes the youth. These talks can be important to relationship formation, ascertaining roadblocks to participation, and current crises. They begin the process of defining the treatment program, making it personal, and targeted to getting help to what can be a distressing set of immediate circumstances, given what can come with youth drug use and delinquent behavior. Motivation enhancement and assessment of the various corners of the youth's and family's life begins here. Even in the first session, therapists stimulate family interaction on important topics, noting to themselves how individuals contribute to the adolescent's life and current circumstances. We also meet alone with the youth, the parent(s), and other family members within the first session or two. These meetings reveal the unique perspective of each family member, how events have transpired (e.g. legal and drug problems, neighborhood and negative peer influences, and school and family relationship difficulties), what family members have done to address the problems, what they believe needs to change with the youth and family, as well as their own concerns and problems, perhaps unrelated to the adolescent.

Therapists elicit the adolescent's telling of his or her life story during early individual sessions. Sharing one's life experiences facilitates engagement. It also provides a necessarily detailed picture of the nature and severity of the youth's circumstances and drug use, individual beliefs and attitude about drugs, trajectory of drug use over time, family history, peer relationships, school and legal problems, any other social context factors, and important life events. Adolescents sketch out literally and in conversation an eco-map, a representation of one's current life space. This includes the neighborhood, indicating where the youth hangs out or buys and uses drugs, where friends live, and school or work locales. Per protocols, therapists inquire about health and lifestyle issues, including sexual behavior. Comorbid mental health problems are assessed by reviewing records and reports, the clinical interview process, and psychiatric evaluations. Adolescent substance abuse screening devices, including urine drug screens (used extensively in therapy), are invaluable in obtaining a comprehensive picture of the teen's and family's circumstances.

Parent(s)' assessment includes their functioning both as parents and as adults, with individual, unique histories and concerns. We assess strengths and weaknesses in terms of parenting knowledge, skills and parenting style, parenting attitudes and beliefs, and emotional connection to one's child. Inquiring in detail about parenting practices is essential, and this includes asking about available support for the parent, child care, other adults who help out or might be available for relationship or parenting help. Clinicians promote parentadolescent discussions, and in this process watch for relationship indicators such as supportiveness,

autonomy giving, problem solving, or the triggering of relationship conflict or emotional disengagement. Parents discuss their experiences of family life when they were growing up since these may be used to motivate or shape needed changes in current parenting style and beliefs, or the parent–adolescent relationship generally. Nothing is more vital to ascertain and facilitate than the parent's emotional connection to and investment in their child. Parent's mental health status and substance use are also appraised as potential challenges to improved parenting. On occasion we make referrals for a parent's adjunctive treatment of drug or alcohol abuse or serious mental health problems.

Information on extrafamilial influences is integrated with the adolescent's and family's reports to yield a comprehensive picture of individual and family functioning relative to external (to the family) systems, events, and circumstances. A new component of our approach provides on-site educational academic tutoring that meshes with core MDFT work. We assess school- and job-related issues thoroughly, and wellplanned parent-youth meetings with school personnel are frequent. Therapists cultivate relationships and work closely with juvenile court personnel, including probation officers who help to sort out the youth's charges and legal requirements. Facing juvenile justice and legal issues can be a complex and emotional matter for the entire family. Clinicians help parents understand the potential harm of continued negative or deepening legal outcomes. Using a nonpunitive tone, we help teens face and take needed compliance actions regarding their legal situation. Friendship network assessment encourages adolescents to talk forthrightly and in detail about peers, school, and neighborhoods. Friends may be asked to be a part of sessions. Frequently, they are met and included during sessions in the family's home. A driving force in MDFT is the creation of concrete alternatives that use family, community, or other resources to provide prosocial, development-enhancing day-to-day activities that become acceptable substitutes for drug and illegal activity involvement.

Adolescent Focus

Clinicians build a firm therapeutic foundation by establishing a working alliance with the teenager, a relationship that is distinct from, but related to, a working relationship with the parent. We present the program as a team process, following through on this proposition by collaboratively establishing therapeutic goals that are practical and personally meaningful to the adolescent. Goals become apparent as teens express their experience and evaluation of their life so far. Treatment attends to these "big picture" dimensions. Problem solving,

creating practical and reachable alternatives to a drugusing and delinquent lifestyle – all of these remediation efforts exist within an approach that addresses an adolescent's conception of his or her own life, values, life's direction, and meaning. Success in one's alliance with the teenager is noticed by parents. Parents expect and appreciate how clinicians reach out to and form a distinct relationship and therapeutic focus with their child. Individual sessions are indispensable and their purpose is defined in "both/and" terms. These sessions access and focus on individual and parent-teen and other relationship issues through methods that might be construed as an individual therapy (versus multiple systems) approach. Individual parent and teen meetings also prepare (i.e. motivate, coach, and rehearse) for joint sessions.

Parent Focus

A vital therapeutic task is to reach the parent or caregiver(s) as an adult with individual issues and needs, as well as a parent who may have declining motivation or faith in her or his ability to influence their child. Objectives with parents in every case include enhancing feelings of parental love and emotional connection, underscoring parents' past efforts, acknowledging difficult past and present circumstances, including the particular difficulties that their child brings them, generating hope, changing the parent-adolescent relationship, and of course, improving parenting practices. When parents enter into, think about, discuss and experience these processes, their emotional and behavioral investment in their adolescent deepens. This process, the expansion of parents' commitment to their child's welfare, has internal cognitive, emotional, and behavioral aspects is fundamental to the change model. Achieving these therapeutic tasks is instrumental to and sets the stage for later changes. Taking this first step in a parent's change, these interventions grow parents' motivation and, gradually, parents' willingness and capacity to address caring, reaching out (again), understanding the youth's point of view, and overall improvements in the parent-youth relationship and parenting strategies. Increasing positive parental involvement with one's adolescent (e.g. showing an interest, initiating conversations, creating a new interpersonal environment in day-to-day transactions) creates a new context for attitudinal shifts, enhanced behavioral and emotional repertoire, and behavioral changes in parenting. Parental competence is fostered by teaching and behavioral coaching about normative characteristics of parent-adolescent relationships, consistent and age-appropriate limit setting, monitoring, improved communication, and listening to one's child, and overt emotional support - all

research-established parental behaviors that enhance relationships, individual, and family development.

Cooperation is achieved and motivation is grown by discussing the serious, often life-threatening circumstances of the youth's life, and establishing an overt, discussable connection (i.e. a logic model) between that caregiver's involvement and creating, with the therapist's help, behavioral and relational alternatives for the adolescent. This follows the general procedure used with parents – promoting caring and connection through several means. First, through an intense focusing and detailing of the youth's difficult and sometimes dire circumstances, making sure that these realities are faced, discussed, and experienced deeply by the parent (although there is description of the youth's circumstances, the presumed mechanism of action here is experiential and not didactic or psychoeducational). This process, which is facilitated mostly in individual meetings with the parent and clinician seems to be ultimately a motivation for the parent. It is as if the parent concludes that they will not let their child continue to deteriorate, continue to get in trouble, or stay off track developmentally. Furthermore, parents moving through this process conclude that they can and should have a role in their child's change, and they begin, again with the partnership with the clinician, to craft a role and particular remedies that they can offer to help alter their child's current circumstance. The parent's re-engagement with their youth is seen not only as instrumental to the therapeutic process, but also something that evolves and emanates very much from the parent themselves, seemingly as a result of what some parents have called a soul searching about their child, their parenting, and most of all themselves.

Parent-Adolescent Interaction Focus

As discussed, some interventions begin with targeting and changing individual ideas, emotions, and behaviors (although these, eventually, have interactional aspects as well). But MDFT, as was the case with particular family therapy models over the years, also assess and change family transactions directly. Shaping changes in the interactions that are part of the parentadolescent relationship are made in sessions through the structural family therapy technique of enactment. A clinical method and a set of ideas about how change occurs, enactment involves elicitation and frank discussion in family sessions of important topics or relationship themes. These discussions reveal relationship strengths and problems. Expanding their repertoire of experience, perceptions, and behavioral alternatives, therapists assist family members to express, expand, discuss, and solve problems in new ways. As a behavioral activation strategy, this method also creates opportunities to search for behavioral alternatives as clinicians actively guide, coach, and shape increasingly positive and constructive family interactions. For discussions to involve problem solving and relationship healing, family members must be able to communicate without excessive blame, defensiveness, or recrimination. Therapists guide retreats from extreme stances since these actions undermine connection and problem solving, rekindle hurt feelings, and sap motivation and hope for change. Individual sessions review and process these important issues and prepare family members for family sessions where the topics can be discussed openly and expanded ways of relating attempted. The content focus of any given session is important. Skilled therapists focus in-session conversations on meaningful topics in a patient, sensitive way.

Focus on Social Systems External to the Family

Clinicians help the family and adolescent relate more effectively with extrafamilial systems. Families may be involved with multiple community agencies. Success or failure in negotiating these relationships affects short-term, and in some cases longer-term, outcomes. A give-and-take collaboration with school, legal, employment, mental health, and health systems influencing the youth's life is critical for engagement and durable change. An overwhelmed parent appreciates a clinician who can understand and coach or help negotiate directly with complex bureaucracies or obtain adjunctive services. Achieving these practical outcomes lessens parental stress and burden, enhances engagement, and bolsters parental efficacy. Therapists team with parents to organize meetings with school administrators, teachers, or probation officers. Since successful compliance with the legal supervision requirements is an instrumental therapeutic focus, therapists prepare the family for and attend the youth's disposition hearings. School or job placement outcomes are additional instrumental aspects of achieving an overall positive case outcome – they represent real world settings where youths can develop competence and build escape routes from deviant peers and drugs. In some cases, medical or immigration matters, or financial problems may be urgent areas of stress and need. We understand the interconnection and synergy of these life circumstances in improving family life, parenting, and a teen's reclaiming of his or her life from the perils of the street. Not all multisystem problems are solvable, nor are all or even most aspects of the youth's day-to-day social environment malleable. Nonetheless, in every case, our rule of thumb is to assess comprehensively, declare priorities, and as much as possible, work actively and directively to help the family achieve better day-to-day outcomes relative to the most consequential and changeable areas in the four target domains, and in their interactions.

DECISION RULES ABOUT INDIVIDUAL, FAMILY, OR EXTRAFAMILIAL SESSIONS

MDFT clinical interventions work from "parts" (subsystems) to larger "wholes" (systems) and then from these larger units (families/family relationships) back down to smaller units (individuals). Session composition is not random or at the discretion of the family or extrafamilial others, although sometimes this is unavoidable. Session goals and stage of treatment drive decisions about session participants. Session goals may be multiple, existing in one or more categories. Typically there are session-specific goals suggesting who should be present for all or part of an interview. For instance, first sessions, from strategic (i.e. relationship formation, giving a message about family involvement) and information-gathering (i.e. family interaction is a key part of what therapists access, assess, and ultimately attempt to change) perspectives, include all family members for a significant part of the session.

MDFT works in four interdependent and mutually influencing subsystems with each case. The rationale for this multiperson focus is theory-based and practical. Some family-based interventions might address parenting practices by working alone with the parent for most or all of treatment. Others might only conduct whole family sessions throughout (i.e. family interaction as the single or most important pathway of youth change). MDFT is unique in how it works with the parents alone and with the teen alone as well, apart from the parent and family sessions, in addition to targeting family level change in vivo, and multisystems change efforts (i.e. multiple pathways of change). Individual sessions have communicational relationshipbuilding and substantive value. They provide "point of view" information and reveal feeling states and historical events not always forthcoming in family sessions. We establish multiple therapeutic relationships rather than a single alliance as is the case in individual treatment. Success in those relationships connects to clinical success. A therapist's relationship with different people in the mosaic comprising the teen's and family's lives is the starting place for inviting and instigating change attempts. The strategic aspects of these actions are probably obvious by now. There is a leveraging, a shuttle diplomacy, that occurs in the individual sessions as they are worked to determine the most important focal content, and then grow motivation and readiness to address other family members in joint sessions.

MANUALS AND OTHER SUPPORTING MATERIALS

A previous but standard version of the manual is available online and a new version of the complete MDFT manual containing all core sessions (the basics of which are outlined and described above, in the sections of the four domains of work), clinical and supervision protocols is forthcoming. MDFT has an online training program, which includes a curriculum, worksheets, and therapy video segments for clinical sites training in the approach. A multistep certification procedure includes site readiness preparation, clinical and supervision training procedures including supervisor/ trainer preparation protocols, and adherence and quality assurance procedures. Independent MDFT training institutes have been established in the United States and Europe. Many clinical articles have been written over the years, and two MDFT DVDs are available.

Like the treatment, the training process is thought about in terms of stages and milestones to achieve in each stage. The methods of training and supervision are thought of in terms of what they are intended to achieve, and the goals of each stage have generic and idiosyncratic aspects. As with all therapies, there is content and knowledge at the outset that seems important. Certainly adolescent, parent, and family development are vital is content about how to think about the formation of problems that may be expressed primarily by individuals but can always be understood by pulling back the zoom lens and understanding surrounding rings of relationships and social settings. Training and supervision methods are multimodal; they involve case conceptualizations and presentations and discussion that focuse on making sense of symptomatic behavior and, above all, generating options for action and intervention, live supervision where sessions are observed and help offers during the session via phone, and videotape review, where the pressure of a live supervision context disappears, and one can reflect and disentangle a session or particular segment. Like the four corners of the MDFT system, the supervisor uses different methods to offer clinicians the needed opportunities to stretch their clinical range and build repertoire, to think on their feet and improvise, and eventually, to become their own "supervisor" in sessions - capable of being both "in" and "meta" to an interview so as to allow redirection or persistence if that is what is needed given the feedback from the interview.

EVIDENCE ON THE EFFECTS OF TREATMENT

MDFT has been developed and tested since 1985. In 2012, the 12th MDFT controlled trial will be completed. This research program has presented evidence supporting the intervention's effectiveness for adolescent substance abuse and delinquency. Four types of studies have been conducted efficacy/effectiveness randomized controlled trials (RCTs), process studies, cost studies, and implementation/dissemination studies. The projects have been conducted at sites across the United States with diverse samples of adolescents (African American, Hispanic, and Caucasian youth between the ages of 11 and 18) of varying socioeconomic backgrounds. Internationally, a multinational MDFT controlled trial with over 440 clinically referred adolescents in Germany, France, Switzerland, Belgium, and the Netherlands is complete. Study participants across studies met diagnostic criteria for adolescent substance abuse disorder and included teens with serious drug abuse and delinquency. MDFT has demonstrated efficacy in comparison to several other state-of-the-art, active treatments, including a psychoeducational multifamily group intervention, peer group treatment, individual cognitive behavioral therapy (CBT), and residential treatment.

SUBSTANCE ABUSE

MDFT participants' substance use is reduced significantly. Using an example from one study, MDFT youths reduced drug use between 41 and 66% from baseline to treatment completion. These outcomes remained consistent at 1 year follow-up. MDFT participants also have demonstrated abstinence from illicit drugs after treatment significantly more than youths in comparison treatments. For instance, in a recent study (at posttreatment and at 1 year follow-up) MDFT participants had 64% drug abstinence rates compared to 44% for CBT; in another study, MDFT achieved a 93% abstinence outcome compared to 67% for group treatment. MDFT has been effective as a community-based drug prevention program as well; and using a brief 12-session (over 3 months), in-clinic (community treatment setting) weekly protocol, MDFT has successfully treated clinically referred younger adolescents who recently initiated drug use.

SUBSTANCE ABUSE-RELATED PROBLEMS

Substance abuse-related problems (e.g. antisocial, delinquent, externalizing behaviors) were reduced

significantly in MDFT versus comparison interventions including manual-guided active treatments. Ninety-three percent of MDFT youth reported no substance related problems at 1 year follow-up.

SCHOOL FUNCTIONING

School functioning improves more dramatically in MDFT than comparison treatments. MDFT clients have been shown to return to school and receive passing grades at higher rates, and also show significantly greater increases in conduct grades than a comparison peer group treatment.

PSYCHIATRIC SYMPTOMS

Psychiatric symptoms show greater reductions during treatment in MDFT than comparison treatments (30–85% within-treatment reductions in behavior problems, including delinquent acts, and mental health problems such as anxiety and depression). Compared with individual CBT, MDFT had better drug abuse outcomes for teens with *co-occurring problems*, and decreased externalizing and internalizing symptoms, thus demonstrating superior and stable outcomes (1 year) with the more severely impaired adolescents.

DELINQUENT BEHAVIOR AND ASSOCIATION WITH DELINQUENT PEERS

MDFT-treated youths have shown decreased delinquent behavior and associations with delinquent peers, whereas peer group treatment comparisons reported increases in delinquency and affiliation with delinquent peers. These outcomes maintain at 1 year follow-up. Department of Juvenile Justice records indicate that compared to teens in usual services, MDFT participants were less likely to be arrested or placed on probation, and had fewer findings of wrongdoing during the study period. MDFT-treated youth have also required fewer out-of-home placements than comparison teens. Importantly, parents, teens, and collaborating professionals have found the approach acceptable and feasible to administer and participate in.

THEORY-RELATED CHANGE: FAMILY FUNCTIONING

MDFT youth report improvements in relationships with their parents. On behavioral ratings, family

functioning improves (e.g. reductions in family conflict, increases in family cohesion) to a greater extent in MDFT than family group therapy or peer group therapy (observational measures), and these gains are seen at 1 year follow-up. In another example, MDFT-treated youths report gains in individual, developmental functioning on self-esteem and social skill measures.

STUDIES ON THE THERAPEUTIC PROCESS AND CHANGE MECHANISMS

The MDFT studies have demonstrated how to improve family functioning by targeting in-session family interaction and how therapists build successful therapeutic alliances with teens and parents. Adolescents are more likely to complete treatment and decrease their drug taking when therapists have effective therapeutic relationships with their parents and with the teens as well. Strong therapeutic alliances with adolescents predict greater decreases in their drug use. Another process study found a linear adherence-outcome relation for drug use and externalizing symptoms. MDFT process studies found that parents' skills improve during therapy, and critically, these changes predict teen symptom reduction. Culturally responsive protocols have demonstrated increases in adolescent treatment participation. We are beginning to understand the relationship of particular kinds of interventions and key target outcomes. In one example, interventions focusing on actively shaping in-session family discussions and relationship issues change connected directly to differences in drug use, emotional and behavioral problems.

ECONOMIC ANALYSES

The average weekly costs of treatment are significantly less for MDFT (\$164) than standard treatment (\$365). An intensive version of MDFT has been designed as an alternative to residential treatment and provides superior clinical outcomes at significantly less cost (average weekly costs of \$384 versus \$1068).

IMPLEMENTATION RESEARCH

MDFT was integrated into a day treatment program for adolescent drug abusers. Key findings include following training, line staff therapists delivered MDFT with fidelity (e.g. broadened treatment focus post-training addressed more approach-specific content themes, focused more on adolescents' thoughts and feelings about themselves and community systems), and with model adherence at 1 year follow-up. Client

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outcomes in the program improved after MDFT was introduced, and these outcomes maintained at follow-up. For instance, youths' association with delinquent peers decreased more rapidly after therapists received MDFT training and drug use was decreased by 25% before and 50% after an MDFT training and organizational intervention (and the probability of out-of-home placements for non MDFT youth was significantly greater before MDFT was used in the program).

CONCLUSIONS

The MDFT is an extensively studied therapy for youth substance abuse and delinquency. Several characteristics can be noted. The MDFT is a flexible treatment system. Different versions of the approach have been implemented in diverse community settings by agency clinicians, with both male and female adolescents from varied ethnic, minority, and racial groups. Study participants were clinically referred, drug-using teenagers, and generally showed psychiatric comorbidity, delinquency, and juvenile justice involvement. Assessments included standardized measures, theory-related dimensions, and measures of import to the everyday functioning of target youth and families (in addition to substance use outcomes, school outcomes, family relationships, for instance). The MDFT has been tested against active treatments, including individual CBT and high-quality peer group and multifamily approaches, as well as services as usual. It has been varied on dimensions such as treatment intensity and demonstrated favorable outcomes in its different forms. An intensive version of MDFT was found to be a clinically effective alternative to residential treatment. MDFT has been effective as a prevention program with at-risk, nonclinically referred youths, and as an effective, short-term intervention for clinically referred young adolescents. The research program has used rigorous designs in conducting efficacy/effectiveness trials, followed CONSORT guidelines, used intent to treat analyses, and participated in multisite RCTs. We developed psychometrically sound adherence measures, and trained therapists, supervisors, and trainers in drug abuse and criminal justice settings nationally and internationally. MDFT process studies have clarified some of the approach's mechanisms of action, and economic analyses indicate MDFT to be an affordable alternative compared to standard outpatient or inpatient treatments. MDFT has favorable outcomes in reducing delinquency, externalizing, and internalizing symptoms. In recent work, HIV and sexually transmitted disease (STD) risks have decreased as well. Process studies show change in key components of the outcome equation (affiliation with drug-using peers, family and school functioning, as examples). The RCTs track outcomes with 1 year follow-ups, and outcomes retain at this assessment. A new study includes sustained positive outcomes at 4 years' post intake assessments. MDFT presents a well-defined clinical focus in how it establishes individual relationships with parent and youth, works with each alone in individual sessions, targets family interactional changes, and also works with individuals and parents vis-á-vis the teen's and family's social context.

List of Abbreviations

CBT cognitive behavioral therapyMDFT multidimensional family therapy

Glossary

Context adolescent development and treatment necessarily includes the multiple psychosocial social contexts of teens and their families. The context dimension reminds the clinician not to narrow his or her understanding to the individual or family level only. Interventions target many levels, aspects of functioning, and different individuals. Some of these pertain to adolescents' everyday functioning in social settings outside their families.

Multidimensional the dimensions of importance in MDFT include research (use of developmental theory and findings, different kinds of research in the MDFT research program), multiple levels or domains of human functioning (intrapersonal (cognitive, emotional, behavioral), and interpersonal (transactions and transactional patterns in family relationships and of individuals relative to extrafamilial individuals in relevant social systems and communities)), and multiple determinants of problem behaviors and multiple determinants, pathways, processes and methods used to create change (i.e. adolescent-focused sessions and interventions, and parent-focused sessions and interventions are important in and of themselves, and they also create opportunities to prepare for family sessions, and to process and review the family meetings).

Structural family therapy (Minuchin) the influences of SFT can be observed in MDFT's adoption of the enactment principles of change and intervention.

Strategic family therapy (Haley) emphasizes crafting a *strategy* for treatment, thinking in terms of *stages of therapy and of change*, and focusing on *out-of-session tasks* as a complement to in-session change enactments,

Treatment parameters refers to the organizational aspects of treatment. Sessions are held in clinical offices, home, school, juvenile court, or wherever the appropriate parties can be convened. Using the phone – to call the parent, adolescent, or other family members (e.g. to follow up after face-to-face contact, make more suggestions to follow the action plan set in the previous contact) – is common.

Further Reading

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Relevant Websites

http://www.cebc4cw.org/program/multidimensional-family-therapy/-CEBC.

http://www.youtube.com/watch?v=tu-r27w6mgg - MDFT In Practice Video

http://www.youtube.com/watch?v=FiOiOERc820 - Multidimensional Family Therapy, An Introduction (Part 1 of 2).

http://www.youtube.com/watch?v=YzjGqlPlU-g - Multidimensional Family Therapy, An Introduction (Part 2 of 2).

http://www.nrepp.samhsa.gov/ViewIntervention.aspx?id=16-NREPP.

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Brief Strategic Family Therapy for Adolescent Drug Abuse: Treatment and Implementation

José Szapocznik, Joan A. Muir, Seth J. Schwartz University of Miami, Miami, FL, USA

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Substance use represents an intractable problem for many adolescents. According to national statistics, nearly 60% of US adolescents have tried alcohol and more than one-third have tried marijuana by age 15. Although most adolescents who use substances do so in moderation and on a time-limited basis, a subset of those adolescents who use substances will continue to do so into their adult years. In general, adolescents who are most at risk for these substance abuse trajectories are those who initiate drug use at young ages (usually before age 14 or 15), whose involvement is especially severe, and who have experienced traumatic events or come from families with maladaptive interactional patterns.

Adolescent drug use is multi-determined, with both intrapersonal (e.g. deviant attitudes and impulsivity) and social-contextual (e.g. family problems, association

with deviant friends, and neighborhood crime and disorganization) processes serving as contributing factors. However, the family is perhaps the strongest influence on adolescent behavior and development. A cohesive family, positive parenting and involvement, effective parental leadership, and other adaptive family characteristics can offset the effects of deviant friends, neighborhood crime, and underperforming schools on adolescent drug use. There is also evidence that the family context helps to influence adolescents' attitudes, beliefs, and sense of self. A series of literature reviews strongly suggest that the family is the most promising and powerful target for interventions aimed at preventing or treating adolescent drug use and abuse.

Severe adolescent drug use is often associated with maladaptive family relationships. For example, family conflict, lack of parental involvement, and poor communication between and among family members predispose adolescents toward drug and alcohol abuse and related problems (such as delinquency, sexual risk taking, and dropping out of school). On the other hand, even when families are not maladaptive, when adolescents get into trouble (e.g. engage in more risky behavior compared to their peers), families can play a major role in bringing the adolescent back to a successful and adaptive developmental trajectory. As a result, family-based prevention and treatment interventions are among the most successful interventions for adolescent drug use/abuse. However, family intervention models differ in terms of how family relationships are conceptualized, in terms of the specific family processes that serve as targets for intervention activities, and in terms of the specificity with which family process interventions explicitly target adolescent drug use.

This chapter presents the Brief Strategic Family Therapy® (BSFT™) model, originally developed in the late 1970s. Empirically tested in a series of research studies, the BSFT model builds on the pioneering structural family systems work of Salvador Minuchin and the strategic approach of Jay Haley and Chloe Madanes. The *structural* dimension refers to the repetitive patterns of interactions among family members who are identified, and strengthened or transformed to better help the family achieve its goals; whereas the *strategic* dimension refers to interventions that are planned, problem focused, and intended to accomplish specific family goals such as reducing family conflict and adolescent drug use. Indeed, the integration of structural and strategic components is one of the innovations underlying BSFT.

BSFT PRINCIPLES

The BSFT model is guided by three primary principles. The first is that the family is a system, and thus family members are interdependent with one another. Therefore, what one family member says or does affects everyone else in the family. The second principle is that repetitive family patterns of interaction affect individual family members' development and behavior. As part of this principle, the BSFT model holds that improvements in family members' experience and behaviors require strengthening adaptive family interactions and transforming/restructuring maladaptive family interactions. The therapist brings the family together and may ask them to carry out an interactional task, such as discussing with each other what brings them to the therapist's office. As the family engages in its typical patterns of behavior, the therapist identifies those patterns that are adaptive and maladaptive. An example of the latter might be parent figures' inability to collaborate on parenting, which supports and maintains the adolescent's drug use. The third basic principle that BSFT reflects is strategic quality – that therapy is planned, problem focused, and practical (i.e. intended to achieve specific objectives). Hence, adaptive repetitive patterns of interactions (e.g. nurturing behavior) will be strengthened, while maladaptive repetitive patterns of behavior (e.g. inability of parents to speak with a single voice and support each other around parental functions) will be transformed specifically because they impact the adolescent's problem behaviors. For BSFT to be effective, yet brief, family interactions unrelated to the family's presenting problems are usually not directly targeted.

THE BSFT INTERVENTION

The goal of the BSFT model is to correct only those family dynamics that are *directly* connected to the adolescent's drug use. Other family problems, such as marital discord, could be addressed but, for the sake of brevity, are generally not addressed in BSFT therapy except to the extent that they impact the adolescent's drug use.

The BSFT program is usually implemented in 12–16 sessions over 4 months. A core principle of the BSFT service delivery approach is that where therapy is provided, it should never interfere with the delivery of the service. Consequently, BSFT can be delivered in office, home, or any other setting that is convenient to the family. Often for disorganized families, getting the family to treatment is a challenge, which home-based treatment can overcome.

Specific therapist strategies are organized into four domains. Although some domains are more likely to occur earlier or later, in general all intervention domains are used throughout therapy. Earlier sessions are characterized by joining interventions designed to establish a therapeutic alliance with each family member and with the family as a whole. This requires that the therapist accept and respect each individual family member and the way in which the family unit is organized as a whole. The early phases of therapy are also more likely to include tracking and diagnostic enactment to systematically identify adaptive and maladaptive family interactional patterns, which can then be used to formulate a treatment plan. A core feature of tracking and diagnostic enactment is that the therapist encourages the family to behave in their usual manner (e.g. as though the therapist was not present). Family members are encouraged to talk with each other about the issues that brought them to therapy, rather than directing comments to the therapist. By observing the family's patterns of interaction - the ways in which family members behave with each other repeatedly – the therapist can then formulate an initial treatment plan to THE BSFT INTERVENTION 99

transform family interactional patterns in specific ways that will reduce or eliminate the adolescent's drug use and related problem behaviors. As the family transforms or more candidly presents itself throughout treatment, the treatment plan is revised to keep abreast of the family's changes.

Over the course of treatment, therapists maintain an effective working relationship with family members through joining, facilitate within-family interactions through tracking, continuously assess evolving patterns of interactions through diagnostic enactment, and transform negative family interactions (while creating a motivational context for change) through reframing. However, during the later stages of treatment, the focus shifts to implementing restructuring strategies to transform family relations from problematic to effective and mutually supportive, and include (1) directing, redirecting, or blocking communication, (2) shifting family alliances, (3) promoting conflict resolution skills, (4) developing effective behavior management skills, and (5) fostering parenting and parental leadership skills. In illustrating the model, we will use the Lopez family, which consists of a mother, stepfather, and the mother's 15-year-old drug abusing son John. Other children in the family are married and live out of state or in the family's country of origin.

Diagnosis

In the BSFT model, therapists diagnose the family's repetitive patterns of interaction along six dimensions, each of which can be manifested in adaptive or maladaptive ways. These dimensions are organization, resonance, developmental stage, life context, identified patienthood, and conflict resolution. Organization refers to the hierarchies, alliances, and behavior control mechanisms within a family. For example, in a functional family with two parent figures, the parents must act with a united voice to reduce the likelihood of a youth "dividing and conquering" and becoming more powerful than his/her parents. In some families, however, one parent will form a cross-generational alliance with one or more of the children – such as Mrs Lopez and her son "bonding" against Mr Lopez. Such alliances are maladaptive because they place the teen in a position of power and responsibility for which he is not developmentally prepared – such as being burdened with Mrs Lopez's emotional needs. Moreover, it is difficult for Mrs Lopez to discipline John, with whom she is maladaptively allied. In such cases, Mrs Lopez is likely to undermine Mr Lopez's efforts to set limits for John. The parents' ability to work together as the leaders of the family is compromised. Indeed, an adolescent can occupy a position of power only if that power is granted – intentionally or otherwise – by one or both parents.

Resonance denotes the quality of the boundaries between family members, and between subsystems within the family (e.g. between the parents and the children). Ideally, these boundaries should be permeable enough such that family members can communicate effectively and can share emotional experiences with one another, but should be firm enough to prevent cross-generational alliances and to ensure that each family member is permitted to maintain her/his individuality as well as to play an age appropriate role within the family. Problems with resonance occur at the extremes of involvement, that is, with over- or under-involvement between family members. Mrs Lopez's very strong bond with John may have been appropriate when he was 2, but at age 15, his mother's over-involvement is preventing John from developing his own individuality. When family members are overinvolved, individual family members' development is often stifled. Typically, youth in John's position will feel stifled and will rebel. Hence, in addition to being in a maladaptive alliance with his mother and against his stepfather and thereby being triangulated in their disagreements, John is likely to rebel. In turn, his rebellion will increase Mr Lopez's anger toward him - and toward Mrs Lopez for enabling John's drug problem.

At the other extreme are under-involved relationships, such as Mr Lopez's weak affective bond with both Mrs Lopez and John. Mrs Lopez's alliance with John has prevented Mr Lopez from establishing a meaningful relationship with his stepson. Where family members are under-involved from one another, it is difficult for those family members to be empathic to one another's experiences. Under-involved family members are like ships passing in the night. For example, John and Mr Lopez may sit next to each other without speaking to each other. In other cases, no parent figure may have adequate involvement with an adolescent, in that case the youth has little guidance or support. This is often the case when a single, drugdependent parent finds drug seeking more urgent than caring for his/her child.

Perhaps more than any of the other dimensions, resonance must be considered within the family's cultural context. Many immigrant families, for example, come from regions of the world where familial closeness is especially valued. In more individualistic cultural contexts such as the United States, high levels of family closeness may be interpreted as over-involvement and may be experienced as suffocating and maladaptive, whereas in more collectivist and interdependent cultural contexts such as Latin America, Asia, and the Caribbean, high levels of closeness may not be viewed as problematic. The litmus test for whether a given degree of resonance is problematic is whether it is causing problems for the family or for a specific family member.

Developmental stage refers to the developmental appropriateness of family interactions. It is well known, for example, that parenting adolescents is a qualitatively different task than parenting young children. Adolescence is a time when young people begin to experiment with new behaviors, relationships, and identity choices – and adolescents require more autonomy than younger children do. When parents respond appropriately to the developmental needs of their children, the children are most likely to perform well in school, to associate with positive peers, to develop a positive sense of identity and purpose, and to have a more constructive relationship within the family. On the other hand, placing developmentally inappropriate expectations on a child - either by placing that child in a role intended for someone much older (e.g. the pressure on John to be his mother's companion) or for someone much younger (e.g. not allowing some independence and privacy for a 16-year-old) - places the youth at risk for rebellion, drug abuse, and related problems. Developmental transitions represent moments of increased risk for families and their children. A family may be going through a divorce or immigrating to a new country, or the child may be moving into high school. Each of these developmental transitions creates challenges that require the family and its members to adjust to new conditions. Flexibility to change patterns of interactions is critical at times of transition, or else the family and the vulnerable adolescent are likely to develop symptoms.

Life context refers to the situations in which the family and its members find themselves. For example, parents may have to work long hours and may come home stressed and tired, or adolescents may attend a school or live in neighborhoods with high crime and drug use rates. Regardless of the specific life context in which a family operates, the context needs to be considered when conducting therapy with a family. If Dad works 12 h per day and comes home at 09.00 at night, one way to ensure that Dad remains a vital member of the family is to set aside time to spend with him on a day when he is free, including eating meals together. If an adolescent is exposed to a large number of delinquent peers, parents may need to make extra efforts to engage the youth with prosocial and goal-oriented friends. In contrast, Mr Lopez often comes home after 12-h shifts as a floor manager, and his wife and stepson do not show any interest in spending time with him. Moreover, John attends school in a high-crime area, but his parents rarely know where he is or what he is doing after school or on weekends.

Identified patienthood – otherwise known as scape-goating – refers to family members blaming a single family member for most or all of the family's problems. For example, John is rebelling against Mr and Mrs Lopez, using drugs, and hanging out with the wrong

crowd – and both parents (especially Mr Lopez) have labeled him as "the problem." Parents often bring their troubled adolescent to therapy and instruct the therapist to "fix him." However, from a family-system's perspective, symptoms displayed by individual family members result from maladaptive family interactions, and the interactional or life context challenges facing the family must be addressed for the adolescent's behavior problems to improve.

For example, close examination of the Lopez family reveals that Mr Lopez feels isolated and Mrs Lopez feels overwhelmed and unappreciated. By attending to the each family member's experience (e.g. "Mr Lopez, you seem to be saying that you don't feel wanted"; "Mrs Lopez, I can see how overburdened you feel"; "John, you would like not to be yelled at all the time,"), the therapist can help the family redefine itself as facing multiple challenges, which reduces the emphasis on the adolescent as the only family problem, thereby creating a broader motivational context for change.

Conflict resolution – Families adopt a number of ways of addressing conflicts, some of which are effective and others that are ineffective in solving conflicts. Conflicts represent differences of opinion that often lead to emotionally and negatively charged situations. The conflict resolution strategies include denial, avoidance, diffusion, conflict emergence without resolution, and conflict emergence with resolution. Families may deny a conflict, such as cases where one parent is an alcoholic and no one is willing to address the problem openly. Avoidance occurs when a conflict begins to emerge but the family covers it up, minimizes it, or otherwise stops it from emerging (e.g. "Honey, you can see that your father had a rough day. Let's not bring that up now.") Diffusion, a frequently used conflict management tool in families with problem behavior youth, refers to attempts to change the topic of conversation when someone raises a contentious issue. Often diffusion takes the form of a personal attack against the family member who voiced the original complaint. For example, when John told Mr Lopez, "It really upsets me when you call me stupid," Mr Lopez changed the topic by attacking John: "You! You with your hoodlum friends – you need to grow up!" Mr Lopez changed the topic of discussion by taking the focus off of himself and placing it onto John. Conflict emergence without resolution refers to situations where the problem is brought up and discussed, but no resolution is reached. Take, for example, the following exchange between Mr Lopez and John:

Mr Lopez: "I don't like your friends!"

John: "Well, that's too bad because I like them!"

The conflict is clearly stated, but the family cannot move to resolution of the differences of opinion. In this case, family members may need help in coming to a better understanding of each other's needs to reach mutually agreeable solution (e.g. "I won't bug you about your friends as long as you do well in school, but you need to know what it is that worries me about your friends"). When the family becomes able to discuss and solve their conflicts, they have achieved conflict emergence with resolution. None of these approaches to conflict management are adaptive if overused. Effective conflict management requires families to use flexibly the whole range of conflict management styles. For example, it is essential that the family prioritize conflicts and determines which conflicts require resolution in the short-term, which must be delayed (diffused or avoided) in the short-term, to allow the family to focus on a single difference of opinion until resolution can be reached.

BSFT: THE INTERVENTION

To produce behavior change, the BSFT model increases motivation for behavior change, reduces concerns about change, identifies troubled family interactions, and corrects them. Four sets of techniques, joining, tracking and eliciting, reframing/creating a motivational context for change, and restructuring that comprise the BSFT intervention are used flexibly throughout the treatment process. As Fig. 11.1 indicates, there is a general sequence to their use, yet the sequence is used many times throughout the intervention; and some early interventions such as joining must be used often throughout the treatment process.

Joining

The strategic nature of BSFT becomes clear when the therapist embarks on the process of joining with the family. Joining is the process by which the therapist moves from being an outsider to becoming a member of the therapeutic team that includes the therapist and the family. The fundamental principle underlying

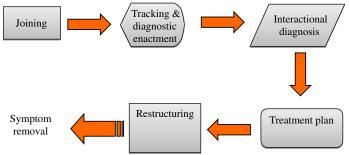


FIGURE 11.1 BSFT circular theory of change.

joining is that the therapist must empathize with each family member's wants and needs and must offer a tangible way to help each family member to reach her or his stated goals. For example, the therapist joined with John by suggesting that his participation in therapy would reduce Mr Lopez's screaming and criticism; with Mr and Mrs Lopez by suggesting that therapy can reduce or eliminate John's drug use; and with Mrs Lopez by saying that therapy would be able to reduce the tension at home. Therapists must be careful not to challenge the goals stated by any family member too early, because the whole family's co-operation is needed for change to occur.

Joining includes not only accepting, respecting, and initially following the family's unwritten rules and established power structure, but also behaving in ways that blend with the family. If family members use specific slang words, the therapist may use these same words when interacting with the family. Social-psychological research has demonstrated that groups have specific ways of behaving – that these patterns differentiate insiders from outsiders – and families are no different from other types of groups in this regard. Family members are most likely to trust the therapist when he/she behaves in ways that are familiar to the family.

Tracking and diagnostic enactment interventions are designed to systematically identify family interactional strengths and weaknesses that can be used to formulate a treatment plan. A core tactic of tracking and diagnostic enactment is encouraging the family to behave as they do when the counselor is not present. That is, encouraging family members to speak with each other about the concerns that bring them to therapy, rather than directing comment to the therapist. From these observations, the therapist is able to diagnose both family strengths and problematic relations. For example, Mr Lopez grumbled to his wife that "you let John get the best of you," and John interjects "Well, you never listen to me - only Mom does." The therapist is able to glean that Mr Lopez is irritated by Mrs Lopez's enabling of John's drug abuse, while John attempts to undermine any attempt by Mr Lopez to convince his wife to impose consequences on his stepson. In this way, John re-asserts his over-involvement with Mom and keeps Dad from undermining the comfortable alliance that he has with his mother. The therapist tracks or follows the interactional process. The therapist may also highlight the process: "Dad, is it always like this – that it is difficult to have a conversation with your wife about John, because John always responds when you talk to your wife about him?"

Diagnosis is the process by which the therapist identifies the interactional patterns within the family that are most closely related to the adolescent's symptoms.

Coming up with a diagnosis involves asking the family to interact and observing the specific interactions that involve the adolescent (either directly or indirectly) and that are most problematic. Families may interact spontaneously as is the case in the example above, or they may need to be asked to interact. One of the most straightforward ways to prompt an interaction is to redirect to the family communications that were initially directed toward the therapist. For example, when Mr Lopez told the therapist, "My wife is driving me crazy – she's so wrapped up with that kid and is always making excuses when he comes home high on drugs," the therapist can ask Mr Lopez, "Would you please say that to your wife?". When Mr Lopez tells Mrs Lopez, John is likely to respond, prompting a family interaction – an enactment of what might happen when the therapist is not present.

Reframing/Creating a Motivational Context for Change

Research shows that families are more likely to remain in treatment if their interactions are positive and constructive, particularly during the first therapy session. Negativity is one of the strongest predictors of early dropout from family therapy – but it is also one of the primary reasons why families seek help. One of the most effective ways to reduce negativity in an interaction is to reframe (change) the perspective through which the interaction is viewed, thereby creating a motivational context for change. Consider the following situation where Mr Lopez confronts John when he comes home high:

Mr Lopez (to John, angrily and harshly): If you come home high one more time, I am calling your probation officer.

Therapist (to Mr Lopez): I can see how much you worry that drugs can hurt John; that something could happen to John when he is out late at night with his friends.

Mr Lopez: I always think he is doing drugs and having sex with street girls. If he goes to jail or gets AIDS, it will destroy his mother.

Therapist (turns to John): Did you know that your parents worry about you?

John: I wish my stepdad would stop screaming at me. He's telling you he cares about me, but he really doesn't.

Therapist (to Mr Lopez): Dad, what do you think about what John just said?

Mr Lopez: I only yell at him because he frustrates me. I don't know how else to get through to him. But I worry about him.

Therapist (turns to John): Your dad worries because he cares. Did you know that?

John: I'm not sure I believe it. He's only here because of my mom.

Therapist (to Mr Lopez): Please tell John how much you care about him.

Mr Lopez: I do care about you, John. I am angry with you, but you're the closest thing to a son I've ever had. I don't want to see anything bad happen to you.

Through this interactional sequence, the therapist transforms a negative interaction to one where concern is expressed positively, thereby creating a different context that leads to greater openness and a motivational context for change. When properly carried out, reframing, i.e. changing the meaning of interactions, is the technique that can best reduce negative affect and set the stage for change without eroding the alliance between the therapist and any family member.

BSFT ENGAGEMENT

The same intervention techniques – joining, tracking and diagnostic enactment, and reframing – are utilized to engage families into treatment. Family therapists face the daunting challenge of engaging multiple family members into treatment. Our research demonstrates that, if a family is characterized by maladaptive interactional patterns that prevent it from achieving its goals of eliminating a youth's drug use and related problem behaviors, typically the same maladaptive interactional patterns serve as an obstacle to bringing the whole family into treatment. BSFT-specialized engagement strategies capitalize on the same basic principles (i.e. identifying patterns of interaction) and techniques used in the therapy model itself. Often one essential family member, such as the drug abusing youth or an alienated father figure, may not want to come to treatment. With the approval of the caller, the therapist will contact this family member directly and join with him in an effort to convey that she or he has something to gain from coming into treatment. Essentially, the therapist tries to get "around" the problematic interactional patterns of behavior by inserting himself/herself into the engagement process. When a family member, usually a mother, calls and asks for help, the therapist uses this first call as an opportunity to begin to explore the family interactions. Specifically, the therapist will give the caller a task - "bring all the members of the family into the first session." The organizational structure of the family will become apparent when the caller either responds that "my son won't come to treatment," or "my husband won't come to treatment," or "it is best if just my son and I come – it is not necessary to bring my husband." In the first and second cases, the caller lacks the influence needed to bring that family member into treatment. In the third case, the caller either prefers not to bring her spouse, or is at best ambivalent about bringing him. In each case, and with the caller's approval, the therapist will reach directly to the family member: (1) who does not want to come to treatment or (2) whom the caller is not eager to bring to treatment. These specialized engagement strategies have resulted in much higher rates of full-family treatment engagement and treatment completion compared to standard engagement strategies.

In our research on how BSFT therapists achieve treatment engagement and retention, we have found that: (1) negativity among family members is a strong predictor of dropout; (2) the most effective way to reduce negativity is through reframing; and (3) an imbalanced relationship between therapist–father alliance and therapist–adolescent alliance increases the likelihood that the adolescent will drop out of treatment. Hence, reducing negativity through reframing and maintaining a balanced father figure-therapist to teen—therapistalliance increases engagement and retention in treatment.

BSFT RESTRUCTURING TECHNIQUES

Once the therapist has been accepted as a temporary member of the family, and maladaptive family patterns of interactions associated with the adolescent's problem behaviors have been identified, a treatment plan can be formulated (i.e. which patterns of interactions need changing). Once this plan is in place, the therapist is ready to restructure or change the targeted maladaptive family interactional patterns. Like all the BSFT interventions, restructuring interventions work in the present. Often family members may hold deep resentments toward one another and spend years fighting about old wounds. If family members begin to tell stories about the past, the therapist will ask them to direct their statements toward the family members involved in the story (e.g. "Tell, Dad how you feel"; "Dad, I hate that you are always working and never have time for me"). This direct communication between son and father becomes an enactment in the present. Such direct communication in the present provides an opportunity for the therapist to create a motivational context for change (Dad, I hear your son say that he cares about you and wants to spend more time with you. Is that what you hear also?), creating an opportunity for Dad to respond to the son's positive message "that I want to spend more time with you," rather than to the anger that he more typically experiences.

Reframing is perhaps the most commonly used restructuring technique in the BSFT. We have already

described reframing as a technique that creates a motivational context for change. As the therapist recasts a negative interaction or feeling in a more positive or tender way - so that the negativity is reduced reframing is used as a springboard for encouraging family members to behave differently with each other. Anger can be recast as hurt or concern – for example, when Mrs Lopez yelled at John and called him a "disgrace to our family" because he had been arrested several times for drug possession, the therapist might say to Mrs Lopez, "I can see how upset you are. You had such dreams for your son and now.... Now you are afraid that those dreams are impossible. The idea that your son may not be able to achieve your dreams for him ... is breaking your heart." In turn, as the mother's emotions turn from anger to sadness and grief, John's defiance may soften. Once more tender emotions are expressed, the therapist can use them to build positive family interactions. For example, the therapist may ask John to ask his mother what makes her so sad. Because having a conversation about sadness, regret, and hurt is more productive than trading accusations, the interactional pattern of accusations and conflict diffusion is transformed into a conversation about "what binds us together." In turn, this shift in emphasis may help to elicit new ways of interacting between mother and son.

Shifting boundaries and alliances is another restructuring technique. For example, because John and his mother were allied against his stepfather, John was often triangulated into conflicts between his parents - that is, he became the punching bag in the fight. In therapy, the therapist began to redirect communication so that it occurred directly between Mr and Mrs Lopez, thereby "de-triangulating" John. One way to restructure this kind of maladaptive pattern of interactions is for the therapist to sit the parents facing each other and for the therapist and John sit to a side, next to each other. The therapist will then have the parents talk about a parenting issue. When John responds to Mr Lopez's accusations that Mrs Lopez has been protecting John, the therapist will warmly put his hand on John's shoulder and say "not now, let them talk"; and will turn to the parents and ask them to go on with their conversation. The therapist must do more than remove John from the triangle; he must also facilitate a more constructive discussion between the parents. For example, "Mr Lopez, it looks like you worry a great deal about John. Tell your wife what worries you!" which will typically lead to some agreement about what worries the parents about John. In this way, the therapist provides the parents with the opportunity to practice communicating directly with one another even when the adolescent is attempting to triangulate himself into their interaction. Later in therapy, the therapist will ask the parents to practice keeping John out of their conversation.

Depending on the specific form that the triangulation takes, other strategies may be implemented as well. In triangles, in which there is usually a parent–teen alliance, with the other parent under-involved. The marginalized parent may be asked to carry out a task (e.g. spend leisure time with the adolescent – such as enjoying hobbies together) as a way of increasing the marginalized parent's involvement with the teen. The goal of this task is to balance each parent figure's alliance with the youth.

Tasks are an essential component of the BSFT. The first task given to a family is to "come to treatment as a complete family." All other tasks are first assigned insession to allow the therapist to help the family to carry out the task before assigning it outside the session. For example, an adolescent and an under-involved father may be given an in-session task to discuss an activity that the adolescent enjoys. The adolescent and father will be instructed to spend leisure time together (e.g. go bowling together) only after their in-session conversation has gone well. Other common tasks include asking parent figures to discuss rules and consequences, for the adolescent to practice explaining to the parent what makes friends so important (e.g. they validate me) or what makes school so aversive (e.g. I get picked on; I never do well in school; teachers don't like me).

BSFT AND CULTURE

The BSFT model was originally developed in Miami, and the initial series of empirical evaluations were conducted using primarily Hispanic families with conduct problem, delinquent, or drug abusing adolescents. However, the BSFT intervention principles and interventions are culture-independent. For example, concepts such as systems, structure (interactional patterns), and problem focus can be used across cultures. However, the specific application of a concept may vary considerably by culture. Joining may vary according to the family's cultural context, with some highly patriarchal cultures requiring much stronger father-therapist alliances than mother-therapist or son-therapist alliances. Developmental appropriateness may also differ across cultures, with some cultures allowing older adolescents and young adults considerable independence - such as an expectation that children move out of the house when they finish college, whereas other cultures require adolescents and young adults to obey their parents and live at home until they marry.

As noted, the "normative" distance between family members, or the strength of family bonds, vary across cultures. In many traditional cultures, family members are typically closer and have stronger bonds with each other, as compared to the increased autonomy that characterizes more individualistic Western cultures. Families' cultural backgrounds must be respected, and therapists must possess sufficient knowledge of the culture to be able to ascertain how far they can move the family away from cultural customs to change family interactions. Indeed, the BSFT approach has been implemented with Hispanic Americans, with White Americans, with African Americans, with some Asian immigrant groups, and in a number of European countries. Cultural content can be used to make the BSFT strategies relevant for a given cultural group – such as discussing the roles that mothers and fathers typically play in a specific cultural context – but the strategies themselves are applicable across cultural groups. One notable exception is when the culture is extremely hierarchical and teens are supposed to obey parents, but are not supposed to verbally respond to them (i.e. "seen but not heard"). Because the BSFT model encourages conversations between parents and their children, in families who have migrated to the United States from extremely hierarchical cultures, we have found it useful to include a brief psycho-educational component that teaches parents and children the differences between the parents' culture of origin and the American culture to which the child may be acculturating. Such an understanding may create the motivational context for parents to be willing to discuss with their children the habits, mores, and challenges they confront in the new culture, recognizing that such challenges are outside of their culture of origin.

The BSFT model is well suited for families immersed in cultural change and where intergenerational and/or cultural conflicts occur between parents and adolescents. In many immigrant families, children, and adolescents adapt quickly to the new cultural context, whereas parents often do not. Perhaps more problematically, some children and adolescents in immigrant families relinquish their cultural heritage, which many parents find disrespectful – and among adolescents from immigrant families, research shows that those who relinquish their cultural heritage are at risk for drug abuse. For example, some Hispanic adolescents in the United States do not wish to speak Spanish, listen to American rap and hip-hop music, and prefer to spend time with their peers than with their parents. In these situations, intergenerational conflicts are compounded with cultural conflicts, and resolving the usual parent-teen intergenerational conflicts also involves addressing cultural conflicts within the family. Parents may feel hurt and disrespected because their adolescents have abandoned the family's heritage, and adolescents may feel that their parents are old-fashioned and are nagging or overburdening them. Fortunately, the BSFT approach is well suited to address this classic conflict between the traditional ways of parents and the modern and individualistic ways of adolescents.

BSFT RESEARCH: THERAPY PROCESS STUDIES AND OUTCOME EVALUATIONS

The BSFT model has been evaluated in a number of randomized clinical trials. The first generation of evaluations focused on: (1) the efficacy of BSFT treatment in reducing behavior problems and substance use, and (2) the efficacy of BSFT Engagement in bringing families into treatment. These studies demonstrated the usefulness of the BSFT model and led the US Department of Health and Human Services to label the BSFT approach as one of its "model programs" and to be included in the National Registry of Evidence-based Programs and Practices (NREPP). More recent evaluations of the BSFT approach have taken the form of effectiveness trials, where community providers are trained to implement the model in "real-world" settings. These more recent evaluations have also been conducted at multiple sites across the United States.

BSFT Efficacy

The efficacy of the BSFT model in reducing behavior problems and drug abuse has been tested in two randomized clinical trials. The first trial focused on younger children with behavior problems that can lead to drug abuse in adolescence. José Szapocznik and colleagues randomized maladjusted 6-11-year-old Cuban boys to BSFT, individual psychodynamic child therapy, or a recreational placebo control condition. Both treatment conditions were implemented by highly experienced therapists - and both were found to be equally efficacious, and more efficacious than recreational control, in reducing children's behavioral and emotional problems and in maintaining these reductions at 1-year post-termination. However, at 1-year followup, the BSFT condition was associated with a significant improvement in observer-rated family functioning, whereas individual psychodynamic child therapy was associated with a significant deterioration in observerrated family functioning.

In a second study, Daniel Santisteban and colleagues randomly assigned Hispanic (half Cuban and half from other Hispanic countries) behavior problem and marijuana using adolescents to receive either BSFT or group counseling. The BSFT condition was significantly more efficacious than group counseling in reducing conduct problems, associations with antisocial peers, and marijuana use, and in improving observer-rated family functioning. In contrast, group counseling was associated with increases in adolescent marijuana use.

BSFT Engagement

The efficacy of BSFT Engagement was tested in three separate studies with Hispanic adolescents with behavior and drug problems and their families. In the first study, Hispanic (mostly Cuban) families with drug abusing adolescents were randomly assigned to BSFT + Engagement as Usual (i.e. the control condition) and BSFT + BSFT Engagement (i.e. the experimental condition). The Engagement as Usual condition was modeled after community-based adolescent outpatient programs' approaches to engagement in the Miami area.

The efficacy of BSFT Engagement was measured using two criteria, first engaging client-families to attend the intake session and, second, retaining the client-families to the completion of treatment. Retention in treatment was measured because it is the ultimate goal of engagement interventions and reflects whether or not the family received an adequate dose of therapy. The results of the study revealed that 93% of the families in the BSFT Engagement condition, compared with only 42% of the families in the Engagement as Usual condition, were engaged into treatment. Moreover, 75% of families in the BSFT Engagement condition completed treatment, compared with only 25% of families in the treatment as usual (TAU) condition.

In a second study by Daniel Santisteban and colleagues, we found that the efficacy of BSFT Engagement procedures was moderated by Hispanic nationality. Among the non-Cuban Hispanics (composed primarily of Nicaraguan, Colombian, and Puerto Rican families) assigned to the BSFT Engagement condition, the rate of engagement was high (93%) compared to the lower rate for Cubans assigned to this same condition (64%). There is evidence that, in Hispanic families, acculturation to American values and behaviors is associated with decreased familism. As a result, it is possible that the lower engagement rate found for Cubans was due to higher rates of Americanization in the Cuban families, in which the parents had been in the United States for many years and the adolescents were primarily US-born. It is possible that such families perceive less need for family involvement in adolescent drug abuse treatment. On the basis of this finding, specific reconnection strategies have been incorporated into the current version of BSFT Engagement.

A third study tested the ability of BSFT + BSFT Engagement to engage and retain adolescents and their families in comparison to a *community* control condition. An important aspect of this study was that the control condition was implemented by a community treatment

agency and, as such, was less subject to the influence of the investigators. The Hispanic adolescents and families in this study were primarily Cuban or Nicaraguan. Findings in this study showed that BSFT Engagement had an 81% engagement rate, significantly higher than the 61% rate in the community control condition. Likewise, among families who were successfully engaged, 71% of BSFT cases, compared to 42% in the community control condition, were retained to treatment completion.

BSFT EFFECTIVENESS

In real world implementation of evidence-based family therapy models, groups of therapists are assigned to administer only the evidence-based family therapy intervention (i.e. they have no other caseload). By practicing only BSFT and working with a team of therapists who all practice BSFT, fidelity to the model is fortified.

An effectiveness trial of the BSFT approach was conducted within the National Institute on Drug Abuse's Clinical Trials Network (CTN). Due to constraints imposed by the CTN's approach to clinical trials, both therapists and participants were randomized to condition within each site. This is in contrast to the way in which BSFT and other similar family-based interventions are implemented in real-world settings (i.e. by creating therapist teams dedicated to the conduct of BSFT). The CTN randomization approach represents a limitation of the study that likely affected our ability to obtain optimum results.

The study compared BSFT and treatment as usual (TAU) (which was allowed to vary to be specific to whatever treatment the agency typically provided for drugusing adolescents) by randomizing 480 adolescents and their families (213 Hispanic, 148 White, and 110 Black; 377 male, 103 female) referred to 8 community drug abuse treatment agencies around the United States. 72% of the adolescents had been referred for treatment by the juvenile justice system. Services in both conditions were delivered by therapists in community agencies.

Compared to BSFT families, families in TAU were 2.33 times (11.4% BSFT; 26.8% TAU) more likely to fail to engage (defined as not completing at least two sessions) and 1.41 times (40.0% BSFT; 56.6% TAU), more likely to fail to retain (defined as completing less than eight sessions) compared to families in BSFT. These differences were statistically significant and generalized across ethnicity. Whereas the usual expectation is that BSFT therapy should last approximately 4 months, the median length of treatment for those participants who were retained in treatment was 8 months in both conditions.

Drug use was operationalized as the number of self-reported drug using days within each 28-day period during the year prior to assessment. The median number of self-reported drug use days per month at the 12-month (final) follow-up was significantly higher in the TAU condition (3.5 days) than in the BSFT condition (2 days). The low number of drug using days may have been a result of the overwhelming majority of adolescents having been referred from residential treatment or from the juvenile justice system – where adolescents are subjected to continued surveillance.

There were significantly greater improvements in the BSFT condition, relative to TAU, in *parent-reported* family functioning (positive parenting, parental monitoring, effectiveness of parental discipline, parental willingness to discipline adolescents when necessary, family cohesion, and absence of family conflict). However, *adolescents* in both conditions reported significant improvements in family functioning, with no statistically significant differences by treatment condition. In addition, BSFT was effective in reducing alcohol use in *parents*, and this effect was mediated by parental reports of family functioning. In addition, BSFT had its strongest effect in reducing adolescent drug use among youth whose parents used drugs.

To measure the extent to which BSFT therapists adhered to the treatment protocol, adherence items were developed to index joining, tracking and eliciting enactments, reframing, and restructuring. These items were completed by trained independent raters who watched videos of therapy sessions and rated each therapist on these BSFT behaviors. Restructuring and Reframing (reducing negativity) were associated with engagement (defined as family attending a second treatment session). The impact of adherence on Retention (family attending at least eight sessions - a minimal dose of BSFT) was evaluated using adherence ratings for sessions 2–7. Higher levels of all four-therapist behaviors predicted significantly higher rates of retention. Additional findings indicated that joining was related to improvements in observer-reported family functioning, and that the effects of therapist behaviors on adolescent drug use varied across the course of treatment. Across time, as would be expected, joining tended to decrease and restructuring tended to increase. Smaller declines in joining and larger increases in restructuring predicted significantly less adolescent drug use at the 12-month follow-up; and therapists whose attempts to restructure maladaptive family interactions increased most during the course of treatment were also associated with "better" adolescent drug use outcomes. These results indicate that, within a sample of therapists from community agencies, therapists' clinical interventions follow a pattern that is consistent with the theory behind the BSFT model.

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BSFT IMPLEMENTATION

Although treatment researchers know how to successfully treat drug abuse, they have not been successful in achieving widespread adoption of evidence-based treatments in the front lines of practice. The most important lesson in implementing the BSFT model is that three types of interventions are required. One is the evidence-based intervention, in our case Brief Strategic Family Therapy® (BSFT $^{\text{TM}}$), which we have described above. The two other interventions needed are not in realm of treatment, but rather in the realm of BSFT implementation. One of these interventions involves the training of therapists to fidelity in conducting the BSFT model. The other is a systemic intervention involving the treatment agency.

To conceptualize the need for an additional intervention focusing on the BSFT implementation, it is useful to refer back to our systems orientation: there is an inevitable relationship between changes in the behavior of the system and changes desired in a target unit. In the BSFT model, the system is the family and the target unit is the adolescent. However, in implementing an evidence-based intervention, the system is the agency that must change to support the adoption and sustainability of the BSFT model and the target unit is the team of therapists trained to implement the BSFT approach with fidelity. To promote adoption and sustainability, the agency must also target funders, judges, and legislators whose support is needed to facilitate the use of the BSFT in the community.

The BSFT implementation begins with a site readiness assessment. Site readiness refers to the process of engaging organizational leaders, agency staff, and community stakeholders in preparing them to adopt the BSFT program. The goal of the site readiness process is for agency staff at all levels, from therapists to agency leaders, to obtain a full understanding of the requirements (including changes in therapist behavior and organizational structure) that must be met to implement the BSFT program. Site readiness activities begin with joining strategies to ensure that the BSFT trainer is viewed as a member of the "agency team" working to produce better adolescent treatment results and continued funding for the program. Once this is achieved, it is possible to discuss therapist eligibility, select the BSFT team, and explain and discuss training and supervision issues. Because the vast majority of agencies implementing the BSFT program are adopting an evidence-based program for the first time, changes in their standard practices are required to successfully implement the BSFT model.

The next phase of BSFT implementation is the training phase, which includes 3-day workshops and 2 h of weekly group supervision of videotaped sessions for approximately 1 year. Workshops cover the research evidence supporting the BSFT model, the philosophy of the model, and the theoretical principles such as understanding the family as a system; that patterns of interaction in a family are repetitive and predictable; and that lasting change can be created by carefully planning interventions targeting those patterns of interaction that are directly linked to the adolescent's problem behavior. Ultimately, BSFT trainers must demonstrate to therapists that the BSFT approach will better help them to reach their own clinical goals. Each workshop is conducted at the agency site by a BSFT trainer and includes interactive lectures, taped demonstrations of family therapy sessions, live case consultations, and interactive class exercises. Weekly supervision helps therapists integrate the didactic information into their behaviors in therapy. A critical step toward an agency's BSFT sustainability is the selection of the BSFT on-site supervisor. In weekly supervision during the first year, an especially competent BSFT therapist will emerge and will be nominated as a supervisor whose role is to lead weekly group supervision sessions. The BSFT on-site supervisor is selected and trained during the second year of BSFT implementation. The BSFT on-site supervisor is selected jointly by the BSFT Trainer and the agency leadership. The primary responsibility of the BSFT on-site supervisor is to ensure fidelity to the model – which is crucial given our research linking BSFT adherence to good clinical outcomes. The BSFT on-site supervisor is guided and supported through weekly supervision meetings with the BSFT trainer. During these weekly meetings, the BSFT trainer provides guidance and coaching on how to supervise and maintain fidelity to the BSFT model, offers techniques to implement when therapists "drift away" from the model, presents guidelines for successful case closures, and supports the BSFT on-site supervisor in monthly meetings with agency leaders.

The next step in the BSFT sustainability plan is officially licensing the agency's BSFT unit. Agencies are granted a license to practice the BSFT model once staff have been trained and once the agency possesses the necessary resources to implement the model. In the second year of licensure and beyond, agencies are required to participate in an annual 2-day booster workshop and an annual 2-day advanced training visit. Booster workshops address areas in which the therapists may have drifted away from the model. Live consultation occurs wherever therapy is being delivered (usually at the clinic office or in clients' homes).

A final aspect of sustainability is supporting agency leadership with funders and other stakeholders by presenting the model and the research evidence. As we stated above, joining with funders and stakeholders is essential because their support is needed to facilitate therapist training and good clinical outcomes for adolescents and families.

CONCLUSIONS

Nearly four decades of research has shaped the BSFT model as it is disseminated today. The model was originally developed to address conflicted parentadolescent relationships in immigrant families and has evolved into a broadly applicable treatment approach. Indeed, the model has evolved in response to specific clinical needs - engagement interventions were added to bring reluctant family members into treatment; reframing became increasingly prominent as a way to reduce negativity and to increase engagement and retention; and in response to the frustration of being unable to sustain programs in community agencies, we established the BSFT Implementation program and a BSFT Institute to carry it out. Achieving the three core goals of implementation - adoption, fidelity, and sustainability – in community-based practices involves a great deal more than just the BSFT model. In fact, successful implementation involves three layers of intervention: (1) the BSFT model that the therapist uses to treat the family; (2) the BSFT training program used by the trainer to help therapists to achieve high fidelity to the program; and (3) an organizational intervention conducted by the BSFT consultant that ensures adoption and long-term sustainability.

SEE ALSO

Ethical Issues in the Treatment of Drug Dependence

List of Abbreviations

BSFT brief strategic family therapy CTN Clinical Trials Network TAU treatment as usual

Glossary

Avoidance a conflict emerges, but the family does not discuss it. For example, if a mother yells at her son, the father might say, "Let's not do this now – Juan has a big game coming up tomorrow."

Conflict resolution style a family's typical ways of handling disagreements between or among family members.

Denial a family's refusal to acknowledge conflicts when they appear. For example, "Your mother is not really angry with you. She just had a rough day at work."

Developmental stage family members behave in ways, or are placed in roles, that are appropriate for their age and stage in life. For example, asking a child to spend most weekends with the family is appropriate for a 6-year-old, but not for a 16-year-old.

Directing/redirecting therapists' attempts to change family interactions by encouraging a family member to behave in new ways; or to block a family member from interacting in her/his usual way.

Drug abuse any use of illicit drugs.

Family alliances the pattern of close and distant emotional or instrumental relationships between and among family members.

Identified patienthood blaming all of the family's problems on one family member, often the drug-abusing adolescent.

Joining the process of accepting (e.g. through validation) and being accepted by the family and its members.

Life context the circumstances in which the family and its members live. For example, poverty, immigration, normative (e.g. births, deaths), and nonnormative (e.g. bullying, homelessness) life events that must be considered when evaluating family interactions.

Maladaptive interactional patterns patterns of family interactions that are not successful in achieving the family's own goals (e.g. preventing or stopping adolescent drug use).

Organization the internal structure of the family – including who is most closely allied with whom and who has authority in the family.

Reframing creating a motivational context for change by redefining a situation or interaction in a way that creates new opportunities for interactions. For example, a mother's anger at a son being arrested for drug possession might be reframed as "I can see how much you care for your son. You are so worried that your dreams for him will not happen."

Resonance emotional closeness or distance between and among family members.

Restructuring interventions used to change patterns of family interactions. Restructuring techniques include reframing, directing/redirecting, and shifting family alliances.

Tracking and diagnostic enactment creating the opportunity for diagnosing a family's repetitive pattern of interactions by encouraging family members to behave as they would if the therapist was not present. For example, when the mother begins to tell the therapist about how her daughter makes her angry, the therapist asks the mother to tell the daughter (rather than telling the therapist).

Triangulation when two family members in conflict with each other place a third, less powerful person into the midst of their conflict.

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Relevant Websites

http://archives.drugabuse.gov/TXManuals/BSFT/BSFT2.html Archives – National Institute on Drug Abuse. http://bsft.org/ – Brief Strategic Family Therapy official website.

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Functional Family Therapy for Adolescent Substance Use Disorders

Holly Barrett Waldron^{\$}, Janet L. Brody^{*}, Michael S. Robbins^{\$}, James F. Alexander^{**}

*Center for Family and Adolescent Research, Albuquerque, NM, USA *Oregon Research Institute, Eugene, OR, USA **Functional Family Therapy, Salt Lake City, UT, USA

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OVERVIEW

The influence of a family on the development and maintenance of substance use problems has long been recognized. Parental and sibling use, family members' attitudes toward use, poor family management practices, and disturbed marital and family functioning have been linked to adolescent substance abuse. The family has also been a major resource in the treatment of adolescents with substance abuse or dependence disorders. Treatment outcome research has shown that family-based interventions are associated with higher rates of treatment engagement and retention, significant reductions in substance use,

and improved functioning in other behavioral domains.

The focus of this chapter is the functional family therapy (FFT) approach for adolescents with addictive behaviors and their families. FFT is a widely disseminated evidence-based treatment developed for youth with conduct disorder, delinquency, and other disruptive behaviors. FFT has also been implemented with families of alcohol- and drug-using adolescents and has emerged as a well-established treatment for this population. The purpose of this chapter is to provide an introduction to FFT for clinicians who treat adolescents with alcohol and drug use or related problem behaviors. The philosophy and core

intervention components of the FFT model are presented, including examples of intervention strategies that can be integrated into FFT with families of adolescents referred for treatment of alcohol and drug use problems. A summary of the evidence supporting FFT for alcohol- and drug-using adolescents is provided.

THE FUNCTIONAL FAMILY THERAPY MODEL

Conceptual Overview

The FFT model conceptualizes alcohol and drug abuse as problem behaviors that develop and are maintained in the context of maladaptive family relationships. Thus, changing family interactions and improving relationship functioning are the keys to reducing adolescents' involvement with alcohol and other drugs. The essential core and distinguishing feature of family system models, relative to other treatment models, is that the locus of problem behavior is relational, transcending the individual, and therefore the focus of treatment should also be relational. The FFT model goes beyond systems theory, integrating and conceptually linking behavioral and cognitive intervention strategies to the ecological formulation of the family disturbance.

The treatment goals are threefold: (1) reduce adolescent substance use and other problem behaviors, (2) improve family relationships, and (3) increase adolescents' productive use of time. Underlying these goals is the emphasis on changing interaction patterns in the family such that the functions served by drinking or taking drugs are met through other, more adaptive, behaviors. The specific methods used to achieve treatment goals are accomplished in five distinct phases: motivation, relational engagement, assessment, behavior change, and generalization. Each of these phases has associated goals, intervention strategies and techniques, and therapist skills.

FFT usually involves 12–16 sessions of 60–75 min, often with sessions scheduled twice weekly at the beginning of the treatment to potentiate the initial change process. This is followed by a period of weekly sessions to space learning and allow time between sessions for practice, concluding with sessions that occur several weeks apart, as families are able to maintain new behaviors independently. Homework is an integral part of treatment. FFT is designed to include all family members who are living together and any other extended family members or significant others who are central to family functioning. With such an inclusive focus, getting the whole family to become involved in

therapy may be the therapist's first greatest challenge and initial target of intervention.

Engagement

Engagement includes activities that maximize family members' initial expectations about treatment. As such, these interventions begin the process of preparing family members for treatment and are meant to elicit a positive reaction to the therapist. This phase also involves high levels of responsiveness to referral systems and family members. Activities can include superficial aspects, such as wearing appropriate clothes, as well as matching (if possible) to families concerning ethnicity and gender, and being sensitive to issues of gender and culture.

A host of variables can influence treatment expectancies including characteristics of the service delivery system (e.g. reputation, location, and friendliness of staff), family attitudes and beliefs, and therapist characteristics (e.g. age, gender, ethnicity, cultural sensitivity, education, and interpersonal warmth). Adopting the language system used by the family, normalizing problems, and expressing confidence are only a few of the many ways therapists can influence family expectations for change.

Motivation

Families with substance use problems frequently enter treatment with an established pattern of interaction involving intense negative affect and malevolent attributions. These patterns and behaviors represent a major impediment to change at the onset of treatment. However, confrontation is associated with family resistance. Maintaining a nonblaming, nonjudgmental tone lowers family defensiveness and hostility and opens the way for change to occur without forcing family members to admit their fault for previous failures. The primary objective of the motivation phase of intervention is to create a motivational context within which change can occur. This objective is facilitated by interventions that help family members experience a reduction in negativity (anger, blame, and hopelessness). Decrease in negativity is essential in this early phase of intervention prior to initiating formal behavior change techniques because family members' intense negative emotions can preclude them from making a realistic commitment to change.

Two major classes of intervention are used to create a working context: change focus and change meaning.

Change focus techniques disrupt family conflict by redirecting, diverting, or interrupting escalating negative interactions. Therapists "divert" when they intercept a negative speech act made by a family member, thereby inserting themselves into potentially escalating blame or

anger. Therapists "interrupt" when they insert a comment, as respectfully as possible, before a family member can complete a negative statement. Often this takes the form of a clarifying question, but one that focuses on something other than the negativity itself. Therapists can also disrupt conflict by commenting on the process of how family members relate to each other in a nonblaming, strength-based manner. By "pointing process," therapists are able to shift the focus from adolescent or other family member problem behavior to relational aspects that underlie patterns but are hidden from the family. Another technique, "sequencing/ circular questioning," is used to create depth of knowledge about a problem sequence including the actions each person took and their meaning. Finally, "strengthbased relational statements" ascribe a positive attribution about one person's efforts toward another. This includes seeing the positive side of apparently negative relational patterns, as in "at least we don't have to guess about your anger.... You are quite open about it, which gives us something to work from."

Change meaning techniques disrupt family conflict by changing the meaning of how family members understand themselves, each other, and their histories. The goal is not to create cognitive change by challenging "maladaptive" cognitions or providing interpretations. Rather, the focus is to provide a nonblaming and potentially more hopeful viewpoint as a basis or context for change.

"Relabeling" interventions are reflections that use similar but less harmful explanations. Relabeling often involves using a "softer" relational focus (e.g. concern versus nagging) to create a less negative tone in the family. Reframing involves introduction of a new perspective that changes the conceptual, attributional, or motivational viewpoint of family members. Reframes include an acknowledgment of the negativity to establish that the therapist understands the relevance of the problem but to go beyond this reflection to offer an alternative and possibly benign motive for the behavior.

In FFT, therapists also work to create new themes (explanatory frames) for understanding family interactions differently, and if possible more benignly. "Behavioral themes" involve identifying sequences of problem interactions in which all the negative elements are identified but reframed in a more positive way. "Relational themes" switch the focus to relationships rather than behaviors. Relational themes maintain the basic elements of reframes but provide new perspectives on the relational meaning of events or behaviors.

Substance Use-Specific Motivation Strategies

The FFT therapist will encounter many different types of family dynamics, and there is no single approach that will be effective for all families. This section identifies some of the common therapeutic challenges encountered when working with these families.

Establish the "Meaning" of Substance Use in the Family

Therapists should attempt to identify current or prior experiences that may be exacerbating views about substance use. Substance use often "means" different things to different members of the family, and the differences in meaning lead to difficulty in communication within the family. For example, suppose mom had a brother who died of a drug overdose. She sees her son using drugs and is very frightened that he will escalate his drug use like her brother. For mom, the son's drug use is perceived as potentially life threatening. Dad, on the other hand, was a drug user in high school, just like his son, and stopped using over time. For dad, drug use is a "normal" teenage activity that elicits little concern. In a family dynamic like this, mom will tend to address the drug use as zealously as dad minimizes it, leaving her feeling increasingly unsupported and frustrated. The son will receive a mixed message from his parents, hearing tacit approval from dad while engaging in heated exchanges with mom as she exerts pressure on him to stop using drugs. By examining differences in meaning, the therapist can focus the intervention on providing reframes that highlight the relational nature of the problem: "Mom's reaction is so strong because her life experience leads her to be much more worried about what might happen to you with the drug use. Dad isn't as worried because he didn't suffer the same loss as your mom. The bottom line for mom is: this is about making sure nothing bad happens to the son she loves so much. The drug use brings up the pain your mom feels over the loss of her brother and it's a regular reminder of how vulnerable she feels. That's why she tries so hard to control what you're doing. So when mom yells, that's her way of saying 'I'm really frightened'."

When parents disagree about the importance of drug use as a problem, the therapist should not directly challenge positive beliefs about drug use. Instead, the therapist should point out how the difference of opinion limits the ability of the parents to work together as a team, creating bad feelings with the more concerned parent, who ends up feeling less supported. It also sends the message to the adolescent that the more the parents disagree, the more he or she will probably be able to get away with continuing the problem behavior.

Punitive Stance toward Drug Use

Some families adopt a rigid, punitive parenting approach in response to drug use. The adolescent is viewed primarily in terms of his problem with drugs. There is limited attention to other aspects of the

relationship. Many times these families tend to get stuck in a cycle of escalating negative consequences. Rules are set for the adolescent, the rules are broken, and then increasing punishments are applied. The adolescent often becomes defiant under this punitive interaction style, with the result of escalating conflict and confrontation in the family. While this pattern is also common in families facing other adolescent disruptive behaviors, the unique issue with substance-abusing families is that a substance use "lapse" is a normative occurrence in the recovery process. Recovery is rarely an "all-ornothing" phenomenon and the event of a lapse can provide a useful opportunity to evaluate what went wrong with the recovery plan and how to avoid the same pitfall in the future. Thus, parents who define any evidence of recurring substance use as a rule violation and failure will likely set the stage for crises that disrupt treatment and interfere with the expected process of recovery. While providing relational reframes for these families, the therapist should specifically work to eliminate the threat of removal from the home. The adolescent's absence from home limits the ability of the family to heal wounds, constructively resolve problems, and provide basic support. It sends the message that the parent's love is conditional to a set of behaviors, the parents will worry about the safety and well-being of the adolescent even more, and it will further damage the relationship without solving the problem the parent is most concerned about. One particularly effective reframe is to offer a longer term perspective for the family, "As Johnny moves toward adulthood, one of the goals of the family is to help him launch into being an independent and successful adult. It might be time for Johnny to move toward independence and living on his own, but we want that to happen as constructively as possible. So he knows he has your support to be successful when he leaves home, and he's not moving out in anger."

A second key intervention is to expand the focus of parent–youth relationship beyond the negativity that currently defines the relationship (e.g. emphasis on rules) to re-establish a strong positive bond. Strengthening the bond is a critical component because it will provide the motivation to change behavior.

Parental Substance Abuse

A particularly challenging situation occurs when one parent is a chronic alcoholic or drug user, and the family enters therapy with the united belief that the parent's use is responsible for the adolescent's drug use problem. The parent's acceptance of blame and regular apology for both his own drinking or drug use, as well as for the adolescent's drug use, allows all the drug use to continue. Rather than accepting the families' interpretation of the problem, the therapist must reframe the

parent's drinking or drug use behavior to provide an alternative relational focus for the problem. "It sounds like it has been really important to the family to have someone who takes responsibility for all the problems, and that's clearly your role, but I'm wondering whether the family has really done everything they can to communicate to you how important it is to have you available for the other aspects of family life. I'm talking about the fun parts of being a member of this family, like being together for dinner, or coming home early so everyone can see a movie together. And, I'm curious, are you responsible for Sally's talent in art too, or is mom the one who gets credit for the good stuff?" The intent of this type of reframe is to help the family think about the "roles" in a different way. In this scenario, we have a "good parent, bad parent" dynamic that actually reinforces the current behavioral patterns and allows the dysfunctional behavior patterns to continue. By challenging the rigid roles defined by the family, the therapist helps everyone take responsibility for the dysfunctional behavior.

Talking about Drug Use in Sessions: Individual Problem versus Relational Focus

In substance-abusing families where the substance use is a direct component of the relationship (as when family members use drugs together), it is important to highlight the connection between use and relationship contact. However, the therapist needs to avoid allowing the family to focus on drug use content alone and maintain an emphasis on clarifying the meaning of drug use for the relationship. The therapist will also have to negotiate situations where the parent views his/her own drug use as acceptable but the adolescent's use as a problem behavior. Because parental drug use is one of the strongest risk factors for adolescent use, the best outcomes will occur when parents are motivated to reduce or eliminate their own use. Again, focus on the relational nature of the drug use is a key approach to take. One effective technique in this situation is to use reframing in conjunction with questions about the circumstances and behavioral sequences associated with conjoint substance-using behavior. This is followed by a reframe that emphasizes the positive or negative role the drug use is playing in the relationship and points to a relational motivation for reducing the use.

Relational Assessment

Relational assessment takes place at two levels: (1) what change is needed (i.e. the behavioral targets of change) and (2) how the behavior change needs to occur to maintain the functions served by the behavior. The concept of the interpersonal function of behavior is unique to the FFT model and is an essential element in

determining how behavior change techniques should be implemented in the family.

Relational functions are defined in terms of the interpersonal relatedness or interdependency they allow each family member to achieve with each other. Each family member has a relational function, closeness, distance, or midpointing, with each other member of the family. The essence of understanding the interpersonal function of behaviors between members of each dyad is to look at the outcome of the behavior. If a behavior is associated with repeated interaction patterns that result in family members experiencing significant physical or psychological separation from one another, then the outcome, or function, of the behavior is distance. By contrast, if the outcome of behavior is that family members experience greater connection or interdependency, then the function of the behavior is closeness. Some relationships are characterized by marked distance and closeness, with the blending referred to as midpointing.

While certain behaviors more commonly produce certain functions (e.g. drunkenness produces distance), a particular behavior must never be assumed to create a specific function. For example, an adolescent's drug use could create considerable distance in that the youth spends the majority of free time with other drug-abusing peers. Alternatively, drug use may cue a repeated behavioral sequence in the family that routinely results in increased closeness when the mother and father rally around the adolescent. Drug use could also involve a mix of both closeness and distance when the youth alternates messages that cry for help with messages that reject parental attempts to help. Also, functions are unique to each relationship and any given behavior may simultaneously produce one function in one dyad and another in a different dyad (e.g. son's drug use elicits nurturance and concern from mom and simultaneously increases distance between son and dad, and husband and wife).

Although our society typically views closeness or intimacy as desirable in relationships and distance as undesirable, FFT functions are not conceptualized as inherently good or bad. In addition to healthy forms of closeness, "smothering" or enmeshed relationships represent maladaptive forms. While some forms of distance or autonomy are unhealthy (e.g. isolating oneself from other family members, being nonresponsive), maintaining distance from other people may facilitate the development of independent thinking and a sense of autonomy and competence. Midpointing can also be expressed in either adaptive or maladaptive ways. For example, a young adult with a drug problem may at times use his/her addiction as a way of escaping from the family and at other times use it as a way of connecting with them (e.g. "I lost my license, so you need to drive me to work."). There can also be nonpathological expressions of midpointing, such as the teenager who remains active in the family's affairs but also participates extensively in the extracurricular school activities and spends prosocial time with friends. The critical concept is that while the behaviors by which functions are achieved can be maladaptive and may need to change, the functions themselves are simply descriptive of family relationships and are preserved rather than targeted for change. The identification of the functions for each dyad in the family allows the therapist to develop a change plan that will address maladaptive behaviors while ensuring that each family member's functions with others are maintained.

Behavior Change

The behavior change phase focuses on establishing and maintaining behavior change both at the individual level and for the family as a whole. The primary goal of the behavior change phase is to establish new behaviors and patterns of interaction that will replace old ones, preventing maladaptive patterns from reappearing and producing long-term change in the family.

In this phase, therapists draw from a menu of treatment strategies, such as communication training, contingency management, negative mood regulation, and increasing rewarding shared activities, to achieve the objectives for change of each target behavior in the treatment plan. In addition, therapists will need to be familiar with specialized evidence-based cognitive behavioral interventions for substance abusers. The particular selections and applications of techniques, however, depend on several considerations. An understanding of interpersonal functions is key; intervention attempts can lead to rapid change or resistance depending on how well the intervention strategy has been fitted to each family member's interpersonal function with each other family member. Even when the behavior change strategy is technically correct and well developed, resistance will arise if the intervention implemented is inconsistent with one or more of the family members' interpersonal functions. For example, a son using methamphetamine may achieve considerable distance from his parents, while at the same time creating a context for his father's merging function with his mother. That is, the son's substance use allows the couple to draw closer, discussing their concerns and attempting to solve the problem of how best they can help their son. Attempts to move the son into more interdependent interactions with his parents would be incompatible with the family's relational functions and resistance to therapy would likely result.

An early goal in the behavior change phase is to enhance the family's experience of positive change by increasing positive activities and interactions. By maximizing the success experiences of families, the positive momentum and family motivation established in the engagement phase will continue.

The specific techniques introduced by the therapist can include any strategies capable of changing behavior. The FFT model has not created a new set of techniques for changing behavior. Rather, clinicians are directed to the broader literature on evidence-based cognitive and behavioral treatments to integrate change strategies into FFT as needed. Communication and problemsolving skills training are considered core strategies and are implemented in some form with virtually all families. Other topics may or may not be used and are presented as a menu of options. In addition, there are a host of technical aids that can be integrated into behavior change sessions to support families' change efforts.

Substance Use-Specific Behavior Change Strategies

There are specific behavior change techniques to address the unique problems associated with substance abuse. However, as with the FFT intervention more generally, the behavior change program selected for families will be based on the specific problems that are associated with each family.

When both the adolescent and the parent are involved in substance use, conducting a functional analysis of their use behavior (i.e. identifying antecedents and consequences of use, as well as the quantity, frequency, and circumstances surrounding use) can help reinforce the relational nature of the substance use and identify specific ways in which the adolescent and parent can support each other in reducing use. This technique can be effective in motivating parents to address their own use and can be introduced as an exercise for parents who resist changing their own behavior.

Drug use reduction can be hampered by difficulties coping with the urges and cravings. Several techniques exist for identifying and coping with urges and cravings. One strategy that can be implemented when the adolescent has a contact or midpointing function with one or both parents is to have the adolescent seek support from the parent(s) to help monitor and cope with urges to use. Similarly, relapse prevention techniques can be discussed with the entire family, and specific responsibilities can be assigned to family members to help support the adolescent's sobriety.

Helping individuals regulate negative moods and emotions (e.g. anger management, coping with negative thoughts) can be effective in helping families break their established patterns of escalating conflict. The process involves examining and challenging automatic and irrational thoughts associated with a particular situation, and then demonstrating the link between these thoughts, negative moods, and poor family communication.

Generalization

The final phase of FFT is designed to facilitate maintenance of behavior change and generalization of treatment gains to the natural environment. As family members experience short-term changes, they are helped to consider alternative ways to continue positive change. A key goal of the generalization phase is for families to apply their newly acquired behavioral skills to novel situations outside the therapy room. For families with substance-abusing adolescents, this will include ongoing practice of both general and substance abuse-related strategies. Families tend to be more successful using the behavior change strategies over time when they are able to identify situations where they failed to use them outside the therapy room and examine the barriers they experienced putting them in place. Even one successful experience using the behavior change strategies outside the therapy room can have a very powerful impact on the families' motivation for change.

Finally, families are connected in a web of social, legal, cultural, economic, and community systems. In the generalization phase, the FFT model incorporates specific principles that govern the inclusion of these systems in the treatment process. Unlike generic treatment planning, which at times wraps services around the family with little consideration of family dynamics, FFT focuses on each family's interpersonal needs when considering adjunctive support services. Before an intervention is implemented, it is necessary to establish the validity of the intervention for the family and tailor the intervention to the family's relational needs. For example, job training for a 16-year-old may be valuable in providing necessary skill building. However, the mom may not support participation in such a program if it replaces the father's role and enables the father to further disengage from the family. By facilitating appropriate links to adjunctive services, treatment effects can be generalized to new contexts and sustained over time.

Therapy moves toward termination when (1) drug and alcohol use and other problem behaviors are reduced or eliminated, (2) adaptive interaction patterns and problem-solving styles have been developed and occur independent of the therapist, and (3) the family appears to have the necessary motivation, skills, and

resources to maintain a positive clinical trajectory without the support of ongoing services.

EVIDENCE FOR THE EFFECTS OF TREATMENT

In the early 1970s, FFT was initially developed for crisis intervention with juvenile offenders and their families. Over time, however, the effectiveness of FFT has been replicated across sites and settings for substance use problems and a wide range of other problem behaviors. Moreover, FFT can be implemented by professionals with diverse background and training, and it demonstrated effectiveness across cultural groups. In addition, evidence has been found for the preventive effects of FFT for siblings of problem youth and for the long-term effectiveness of the intervention.

With respect to drug use, one of the initial studies examining the effectiveness of FFT compared FFT to a parenting skills group intervention. Both the FFT and parent training groups showed significant reductions in substance use of more than 50% at follow-up. Although no differences were found between the two treatment groups for treated families, engagement rates differed dramatically (93% in FFT versus 67% in the parenting condition). In a reanalysis of this study, it was found that FFT had greater substance use reductions than the comparison condition.

Findings for FFT with families of adolescents with a substance use disorder have been replicated in a series of three randomized trials we have conducted comparing FFT to group and/or individual cognitive behavioral therapy (CBT). In the first study, FFT was evaluated alone and in combination with CBT (FFT-CBT). Adolescents in both of the FFT conditions showed significant reductions in marijuana use from pretreatment to 4 months following initiation of treatment and over time (up to 19 months). However, over time, the other interventions evaluated in this study were also effective. As such, these results provide support for the short-term benefit of FFT for substance-abusing youth. Support was also found for family relationship functioning improvement as a causal mechanism of change in the FFT conditions, but not in the group condition, suggesting that mechanisms underlying positive change in group treatment are distinct from those in FFT.

In a second study of youth referred for the treatment of alcohol-related problems, FFT (with and without CBT) was compared to individual and group CBT approaches. All four conditions were associated with significant mean reductions in alcohol use from pre-to posttreatment. Significant reductions in marijuana use, not the prime intervention target, were also shown in

the FFT only and with CBT conditions. The integrated FFT-CBT condition was the least effective in reducing marijuana use.

A third randomized trial evaluated the efficacy of an integrated FFT + CBT intervention to CBT alone for Anglo and Hispanic drug-abusing adolescents across two project sites, one in New Mexico and the other in Oregon. Results of the analysis revealed that the Hispanic participants in FFT experienced significant reductions in drug use at each posttreatment assessment point as compared to the pretreatment point, supporting the efficacy of FFT. Differences between the post and follow-up conditions for the CBT condition were not significant. Anglo youth in FFT and in CBT showed significant reductions in drug use at each posttreatment assessment point, but there were no differences between conditions.

TRAINING AND SUPERVISION

Training in FFT for adolescent drug abusers is a three-phase process. During phase I, the initial goal is to impact the service delivery context to build a lasting infrastructure that supports therapists to implement FFT with the highest integrity. By the end of phase I, the training objective is for therapists to demonstrate strong adherence and high competence in FFT. Training includes several on-site workshops as well as weekly consultations over the course of the first year. Assessment of therapist adherence and competence is based on data gathered through a webor PC-based Client Services System (CSS). Phase I is designed to be completed in 1 year and, at most, not extend beyond 18 months.

The goal of the second phase of implementation is to foster increased self-sufficiency at the site, while also maintaining and enhancing site adherence and competence in the delivery of FFT. During phase II, a member of the local team is identified to receive specialized training as a site supervisor. This individual participates in an externship that involves 9 days of live supervision and case consultation over a 3-month period at the end of phase I or beginning of phase II. This person also attends two 2-day supervisor trainings, and is then supported by regular monthly phone consultations as well as one on-site training. In addition, training involves regular review of the site's database to monitor site/ therapist adherence, service delivery trends, and outcomes and to develop and implement quality improvement plans in collaboration with the local site supervisor. Phase II is a 1-year process.

The goal of the third phase of training is to further enhance the self-sufficiency of a site in ensuring model fidelity, staff development, interagency linking, and program expansion. During this phase, the local site supervisor takes increased responsibility for monitoring outcomes using the CSS database. The on-site supervisor continues to participate in regular consultation calls, but these occur less frequently than during phase II. A one-day on-site training is provided for continuing education in FFT. Phase III is an ongoing process.

SUMMARY AND CURRENT DIRECTIONS

FFT is an integrated systemic and cognitive behavioral intervention that produces change through a phase-based process. Each phase has its own unique goals, tasks, and interventions. FFT therapists are trained to be clear on the overall principles and perspectives that guide the integrative process, with a default mode that is relational and respectful but is accommodating enough to utilize other perspectives as long as they are consistent with the FFT model and to help intervene with this particular family, effectively, at this particular time.

Research on the efficacy and effectiveness of FFT has led to the widespread dissemination of the model into community settings including drug use, juvenile justice, mental health, and child welfare settings. To date, FFT Inc., the dissemination organization charged with training and monitoring the quality of implementation of FFT in community settings, has trained more than a thousand therapists from nearly 300 agencies/systems in nine countries. Information about training in FFT can be found at www.fftinc.com.

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SEE ALSO

Dissemination of Evidence-Based Treatment into Practice, Treatment for Co-occurring Substance Abuse and Mental Health Disorders, Multisystemic Therapy for Adolescent Substance Use, Multidimensional Family Therapy for Adolescent Substance Abuse: A Developmental Approach, Brief Strategic Family Therapy for Adolescent Drug Abuse: Treatment and Implementation, Criminal Justice Interventions

List of Abbreviations

CBT cognitive behavioral therapy CSS Client Services System FFT functional family therapy

Glossary

Behavioral themes therapist interventions that identify sequences of several problem and family member interactions in which all the negative elements are included but are reframed or at least relabeled (see descriptions for reframing and relabeling below) to reduce family blame, negativity, and hopelessness.

Divert therapist interrupts blaming or angry interactions by intercepting negative statements made by a family member toward another family member.

Interrupt therapist inserts a comment, as respectfully as possible, before a family member can complete a negative statement.

Pointing process therapist shifts the focus from the adolescent's or other family member's problem behaviors to relational aspects that underlie relational patterns that are hidden from the family.

Reframing therapist introduces a new perspective that changes the negative conceptual, attributional, or motivational viewpoint that family members have toward one another to a more positive (or at least neutral) or workable set of attributions and emotions.

Relabeling therapist reflections that use similar, but less harmful, explanations for family members' behaviors by introducing a "softer" relational focus (e.g. concern versus nagging) to create a less negative tone in the family.

Relational functions the interpersonal relatedness needs of individual family members, ranging from closeness/connection to distance/autonomous, that are inferred from family members' behaviors, verbalizations, and emotional reactions as well as the patterns of interaction in the family.

Relational hierarchy the pattern of relative influence that parents and youth have over each other in terms of "controlling" each others' behavior.

Relational themes therapist interventions that switch the focus to relationships rather than behaviors. Specific behaviors may be noted, but relational patterns become the major focus. These interventions maintain the basic elements of reframes but often seem more like "stories" and even "myths" rather than specific sequences of negative behaviors.

Sequencing/circular questioning therapist interventions that are used to create depth of knowledge about a problem sequence including the actions each person took and their meaning.

Strength-based relational statements therapist interventions that ascribe a positive attribution about one family member's efforts toward another.

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Relevant Website

www.fftinc.com – Functional Family Therapy Training and Dissemination.

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Individual and Group Counseling for Substance Use Disorders

Delinda Mercer

Behavioral Health Unit, Scottsbluff, NE, USA

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Addiction counseling has been one of the most widely used treatments for substance use disorders (SUDs), and research has shown addiction counseling to be very effective for cessation of substance use. Sometimes, counseling comprises the entire treatment program for a patient. However, the introduction of new medications and other new types of interventions have led to a more multimodality treatment approach, which usually includes counseling as one component. Such multimodality approaches can usually provide greater intensity of treatment and can simultaneously address biochemical, psychological, and behavioral aspects of SUDs.

Individual Drug Counseling (IDC) and the parallel group model Group Drug Counseling (GDC) were developed as a treatment approach based on what competent, conventional drug counseling typically involved. In developing these models, numerous expert drug counselors were interviewed, and they shared their treatment philosophy, themes in counseling, and interventions or other tools they used in drug counseling. This led to the development of a drug counseling model that basically relied on the conventional interventions but was very well organized and manualized. Counselors were carefully trained in the model, and ongoing supervision was provided. The reason this

model set out to be fairly conventional was that it was designed for use in research protocols that wanted to compare more novel treatments with an approach that approximated drug counseling "treatment as usual" or what drug counselors typically do. Sometimes this model has been used in research as the basic counseling program to which different treatments being studied can be added.

These manuals for individual and group counseling were designed to be components in a more comprehensive treatment program. In the research for which they were designed, these counseling models were combined with initial medical and psychosocial assessments, detoxification and stabilization, family involvement, and ongoing participation in a mutual support program. However, these treatments can be used individually, by a counselor in outpatient practice, who can draw upon additional resources as needed. Also, these counseling models may be used in conjunction with pharmacotherapy, other medical therapies (e.g. acupuncture), family or couples therapy, or professional psychotherapy.

This model of addiction counseling does not focus much attention on the role of family members in treatment, not because it is not important in treatment but because this model was not intended to provide an all-inclusive treatment. When this model was used in the cocaine collaborative study, in addition to the group and individual counseling, a multifamily psychoeducational group was provided. This was found to be very beneficial for patients and families.

OVERVIEW OF THE IDC AND GDC MODELS

The primary goal of drug counseling is to help the client achieve and maintain abstinence from addictive chemicals and behaviors. The secondary goal is to help the client recover from the damage the addiction has done to the client's life. The following are the most important elements in the IDC/GDC approach. In counseling, these elements are not independent of one another; the concepts are related, and there is a fair amount of overlap.

- Based on the disease model
- Focus on behavioral change
- Mutual support program participation
- Family involvement
- Drug testing
- Preventing relapse
- Lifestyle changes
- Spirituality

BASED ON THE DISEASE MODEL

Drug dependence is believed to be a multidetermined, maladaptive way of coping with life problems that often becomes habitual and leads to a progressive deterioration in life circumstances. Habituation of drug use is dependence, which is a disease in its own right that damages the addict physically, mentally, and spiritually. The disease model conceptualizes alcohol and drug addiction as a biopsychosocial illness that affects the social, psychological, spiritual, and physical dimensions of an individual. This disease is said to be progressive in nature, and there is no cure, but it can be arrested through treatment and abstinence. Recovery requires changes that reflect a lifelong commitment to abstinence and recommends a more balanced and spiritual way of living, with the aid of ongoing mutual support participation.

FOCUS ON BEHAVIORAL CHANGE

Addiction counseling is usually primarily present oriented, fairly directive, and focused on behavioral change. Counseling involves a combination of (1) psychoeducation, which teaches the client strategies and provides information important to recovery; (2) monitoring, which makes the client more aware of and holds them accountable for their drug use or related behaviors; and (3) support, which provides the client with an ally in the process. Addiction counseling emphasizes specific behavioral change with the primary goal of achieving and maintaining abstinence from all substances. It is important to establish clear goals related to cessation of drug use early in treatment and keep abreast of the patient's success with abstinence and with compliance in other aspects of the treatment.

Addiction counseling focuses primarily on drug use or close calls, triggers, urges to use substances, social pressures to use substances, impact of SUDs on family and other relationships, building a recovery support system, identifying and managing relapse warning signs or risk factors, and addressing other addictions. Using active coping skills and monitoring any movement toward relapse are also emphasized in addiction counseling. Other issues may be discussed in counseling but only as they relate to drug use and recovery. This is in contrast to some psychotherapy models that may devote time to analyze past experiences or significant relationships. Treatment programs that provide a multimodality approach may offer other behavioral treatments in addition to addiction counseling, and these treatments may address issues such as family recovery or psychiatric needs, but these should always be in PREVENTING RELAPSE 119

addition to, and never instead of, counseling that focuses on the drug use and desired abstinence.

MUTUAL SUPPORT PROGRAM PARTICIPATION

This philosophy of the 12-step program is integrated into the counseling, and ongoing participation in a 12-step or other mutual support programs is strongly encouraged. Active participation in 12-step programs such as Alcoholics Anonymous (AA) or Narcotics Anonymous (NA) is generally associated with improved outcomes. AA, NA, and other 12-step programs are abstinence oriented and foster a network of healthy social support for individuals in recovery. Key aspects of the 12-step philosophy for therapists treating SUDs are (1) the belief that addiction is a disease rather than a bad behavior; (2) the belief that addiction damages the whole person physically, mentally, and spiritually and that recovery must address all these domains; (3) the belief that healing or recovery comes from connecting to something larger than oneself, referred to as "higher power" in AA or NA; (4) the paradox of surrendering power in order to ultimately be empowered to attain sobriety; (5) the idea that interpersonal support is critical for recovery; and (6) the belief that recovery is a lifelong process that encompasses sobriety as well as continued personal growth.

Introducing the client to the idea that ongoing mutual support program participation is an important factor in recovery, during formal treatment, can promote continued participation after treatment has ended. Ongoing participation in 12-step or other mutual support programs is thought to be helpful in preventing relapse. There are other models of self-help programs, such as Rational Recovery, SMART Recovery, Women for Sobriety, and Men for Sobriety, that are also useful, but these tend to be less widely available than the 12-step programs. However, they also foster continued recovery, and they may be a better "fit" for some people than the 12-step programs. Self-help programs such as Dual Recovery Anonymous or Double Trouble are also available for individuals with substance use and psychiatric disorders.

FAMILY INVOLVEMENT

Significant family member involvement is associated with more successful addiction recovery. Increasingly, treatment programs try to involve family members in their addicted member's treatment. This may be through individual family therapy, a multifamily group, or occasional family workshops, which are

psychoeducational in nature. Through these interventions, the counselor can teach family members about the nature and consequences of addiction and the treatment, recovery, and relapse processes. This enables families to more effectively support their addicted member through the process of recovery as well as determine what they may need in terms of help and support for themselves since addiction has many adverse effects on family members. Also, family involvement allows the counselor to explore historical and relationship factors in the family that can undermine treatment.

DRUG TESTING

In addiction treatment programs, clients are usually tested for drug use to help promote abstinence and honesty. Drug testing most often involves Breathalyzer to test for alcohol and urinalysis to test for other drugs. Other methods that are less frequently used include testing of blood, saliva, or hair, and each method has its pros and cons. The therapeutic aspects of drug testing are that the client is aware that drug use will be monitored so there is less likelihood of deception. Also, regular monitoring gives the therapist repeated opportunities to reinforce abstinence and address any lapses almost immediately. It is valuable to pair drug testing with self-report of any drug use. In each counseling session, the therapist and client will review any recent drug use or near use. Drug testing encourages honesty, and it helps hold the patient accountable for his or her behavior. Prompt results and feedback on drug tests assures the patient that the therapist is knowledgeable and concerned with his or her progress in recovery.

PREVENTING RELAPSE

Relapse prevention is a set of treatment strategies taught to the client in addiction counseling to help the client avoid a relapse to substance use. Relapse prevention is also a cognitive behavioral model in itself, but the basic concepts are widely used in addiction counseling. These strategies help the client by identifying and managing high-risk situations, including negative emotional states, and interpersonal situations, such as social pressures to use. Treatment involves helping the client reduce relapse risk by examining which emotions or interpersonal situations are perceived to be high risk for relapse, and then, specific strategies are taught to reduce risk in these situations.

Clients are given the skills to identify and manage relapse warning signs, including changes in attitudes, thoughts, feelings, and behaviors. Counseling assists clients to manage lapses and relapses to substance use by developing a plan to interrupt a relapse ahead of time, before one's thoughts are clouded by the urge to use substances. Clients are also taught to challenge addictive thinking that would promote relapse.

LIFESTYLE CHANGES

The IDC/GDC model promotes living a healthy lifestyle. It takes a holistic view of the person and promotes improved health and wellness in a variety of areas, including physically, mentally, and spiritually. Counseling holds that recovery must address all these domains. Making lifestyle changes is encouraged as a part of the process of recovery, and engaging in new healthy activities is an important part of establishing alternative behavioral routines.

It is not unusual for addicts in their active addiction to neglect aspects of their health, including not eating nutritious meals, not getting regular sleep, not getting healthy exercise and recreation, and in cases of severe addiction, possibly not maintaining good hygiene. Also, substance dependence requires a lot of time, so there is a narrowing of the addict's behavioral repertoire to the point where they are no longer seeing the friends or doing the activities once they enjoyed. Addiction counseling will address and promote eating nutritious food, establishing a healthy sleep routine, and getting appropriate exercise through healthy recreational activities. This may involve a significant amount of education or just a little reminder depending on the client's level of knowledge in this area.

SPIRITUALITY

Spirituality is a significant aspect of addiction counseling. In IDC and GDC, spirituality is defined in a manner consistent with how it is viewed in the 12-step approach, which is acknowledgment of some form of higher power, a sense of connection to something larger than the individual, and a need for honesty with oneself and importance of others in one's life. Spirituality is viewed broadly and not in association with any specific religion or belief. Addiction is assumed to damage the addict's spirituality, and recovery involves the process of reconnecting to one's spiritual nature. For many patients, spirituality is an important and useful concept in recovery from addictions as well as other mental illnesses. Despite that the concept is somewhat nebulous and the meaning is different for different individuals, based on their prior exposure to religion, spirituality gives us a way of assisting clients to grapple with deep emotional needs to feel connected to the universe and connected to one's self. For many clients, it reinvigorates a sense of purpose and that can be very healing.

STAGES OF RECOVERY

In this model, treatment is conceptualized as occurring in stages, although the stages are flexible and clients can move back and forth between stages in their process of recovery. The first stage of treatment is about acknowledging a problem and committing to treatment. Much of this stage may take place before the patient even gets to treatment. The second stage is establishing abstinence, and the third stage is maintaining abstinence. Most of the information in the IDC and GDC manuals focuses on the establishment and maintenance of abstinence stages. The last stage is advanced recovery, and this is considered to be a long-term, if not lifelong, process that occurs after the active treatment phase, which was 6 months in this model.

- Acknowledging the problem
- Establishing abstinence
- Maintaining abstinence
- Advanced recovery

THEMES IN TREATMENT BY STAGE OF RECOVERY

These topics are to be discussed within the individual counseling sessions, and many are also addressed in the psychoeducational group. The individual counselor chooses the theme or themes relevant to the client's current needs or point in recovery and introduces that topic. The counselor considers the client's stage in recovery and tries to review the topics appropriate to one stage before moving to the next. However, the counselor has flexibility in determining what theme is most appropriate for the client at the time. The manual provides background information on each topic in recovery that will guide the counselor in a discussion of the topic. Approximately half of these topics come from a relapse prevention approach and the other half comes from the 12-step model. The IDC and GDC manuals provide more detailed suggestions and guidelines for each topic.

- Acknowledging the problem
 - 1. Acknowledging one's use is a problem
 - 2. Confronting denial
 - 3. Motivation for treatment
- Establishing abstinence
 - 4. Addiction and associated symptoms
 - 5. People, places, and things

- 6. Structure of personal time
- 7. Craving
- 8. High-risk situations
- 9. Social pressures to use
- 10. Compulsive sexual behavior
- 11. Postacute withdrawal symptoms
- 12. Use of other drugs (other than the primary addiction)
- 13. Mutual support participation (12-step or other programs)
- Maintaining abstinence
 - 14. The relapse process and tools for preventing it
 - 15. Relationships in recovery
 - 16. Development of a drug-free lifestyle
 - 17. Spirituality
 - 18. Shame and guilt
 - 19. Personal inventory
 - 20. Character defects
 - 21. Identification and fulfillment of needs
 - 22. Anger management
 - 23. Relaxation and leisure time
 - 24. Employment and finances
 - 25. Transference of addictive behaviors
- Advanced recovery

Advanced recovery presumes that the client is stable in abstinence and is working on the bigger issues of creating a meaningful and satisfying sober life, while continuing to attend to the personal program of recovery. This stage of treatment is not specifically addressed in the manuals, which focus on the active phase of treatment, which precedes advanced recovery. However, many of the themes are the same, and the client returns to process them from a different point in recovery. Themes that are usually prominent in advanced recovery include maintaining a healthy lifestyle, healing relationships or establishing healthy relationships, life goals, and personal responsibility. Some of the topics in the maintaining abstinence stage, particularly relationships in recovery, identification and fulfillment of needs, and relaxation and leisure time, set the stage for the client to move into advanced recovery. In advanced recovery, the client may choose whether he or she wants to continue in regular counseling, although it is strongly recommended that a mutual support program is continued.

LOGISTICS OF THE INDIVIDUAL COUNSELING SESSION

Sessions typically run about 45 min in an outpatient setting; however, 30 min may be adequate for some clients. In the original research, clients began with two individual sessions, and then reduced to one session

per week, after 12 weeks. It was hoped that this would coincide with the clients' increasing stability and abstinence. Within each session, the counselor follows a structure that adheres to the following format:

- **1.** Inquiring as to the last time the patient used substances
- 2. Discussing recent substance use or close calls
- 3. Addressing any urgent problems the patient has
- 4. Providing feedback about drug screens
- 5. Discussing relevant recovery-related topics

The discussion topics refer to the themes listed above.

COMBINING GROUP AND INDIVIDUAL THERAPY

A combination of GDC and IDC seems to work best for many clients. Some clients feel more comfortable sharing personal information with an individual counselor, while others benefit greatly from the connection and mutual support of the group. In this model, IDC and GDC present very similar information and teach the same strategies, but in a different format. Each format offers some unique treatment elements that are beneficial to the therapeutic process. Both individual and group sessions have a clear structure. However, within the framework of the structure, the content of the discussion is largely up to the client(s). An effort is made to effectively address the client's individual needs at any point in treatment while also recognizing the commonality of many issues in addiction and recovery.

GROUP DRUG COUNSELING

Group counseling is considered a very important and necessary part of most drug counseling programs because there are some aspects of recovery that groups can tackle particularly well. Groups provide a forum for peer feedback and support among individuals recovering from substance dependence. Through groups, individuals can hear other people's experiences and learn ways to change behaviors. This creates a feeling of connection and support, which hopefully fosters the optimistic belief that "together we will accomplish this." Also, peer feedback about someone's behavior is often more powerful and may be more easily "heard" and accepted than feedback from professionals whom patients sometimes view as different from them.

In the groups, as in individual counseling, recovery is conceptualized as occurring in stages. The GDC model focuses on the stages of establishing abstinence, which correlates with phase I group, and maintaining abstinence, which correlates with phase II group. Each group phase lasted 12 weeks, with one group per week, in the original research protocol.

During phase I, group members meet weekly for 12 weeks for a psychoeducational group session, in which they receive information about addiction and recovery. During the psychoeducational group sessions, patients receive information and participate in discussions about various topics on recovery (addiction, recovery, cravings, people, places and things, relationships, mutual support programs, support systems, managing feelings, warning signs of relapse, coping with high-risk situations, and maintaining recovery). These topics are basically the same as those addressed in the individual counseling sessions, but in the group session, there is a different format for their presentation. Each topic presented has a lecture and discussion along with handouts and written assignments to facilitate learning. Group members are encouraged to interact with each other and share experiences regarding the topics. In this way they can develop relationships and give and receive encouragement and support.

The second phase of treatment is called the problemsolving group. Clients continue to meet weekly for 12 more weeks. This phase is a less-structured group where members solve problems of various life issues without resorting to substance use. Group members are encouraged to discuss current problems or concerns for the group to process. The group leader will facilitate feedback, encouragement, confrontation, or any other form of interaction among group members to help with these problems. Our experience was that many clients liked the accomplishment inferred by graduating from one group phase and moving to the next. They received certificates and recognition from their counselors and fellow members for abstinence and for graduating from each group phase, and many appreciated this.

LOGISTICS OF THE GROUP COUNSELING SESSION

Groups typically run about 75–90 min, depending on the number of members present and the specific setting. Our groups had rolling admissions, so each session might have some new members. When new members were present, the group counselor would go over the group ground rules during the introduction/check-in portion of the group. Groups are led by a group drug counselor or sometimes coled by two counselors, if possible. Group sessions have the following format:

1. Group members submit a urine sample and take a Breathalyzer test.

- **2.** Members introduce themselves, admit to their addiction, and state their date of last use of any type of drug or alcohol.
- **3.** Members are encouraged to talk briefly about how they are doing and about any cravings or temptations experienced since the previous group meeting.
- **4.** If any members have used since the last session, the group will help them process the event and develop a plan to prevent further relapse.
- 5. If there is a topic, the group leader will introduce it and encourage members to discuss how it relates to their recovery. (In the more advanced problemsolving group, members are encouraged to describe a current problem or concern and get feedback from one another.)
- **6.** In the final 10 min, members are asked to state their plans for the next few days in an effort to help them structure their time. Members are also encouraged to mention the self-help meetings that they are attending and perhaps invite others to attend with them.
- 7. The session ends with members reciting the Serenity Prayer aloud.

This group structure and program worked very well. Clients liked it; usually attended, shared, and learned things in the group; respected the process; liked the group leaders; and supported each other in recovery. These groups are structured, while still providing opportunities for clients to express themselves openly and get needs appropriately met by the group and the counselor.

STRATEGIES FOR DEALING WITH COMMON PROBLEMS IN THE IDC/GDC MODEL

Not Attending Sessions

Clients are repeatedly urged to arrive for all sessions promptly, to call if they are going to be late, and to call at least 24 h in advance if they must cancel a session. If they fail to fulfill these obligations, the counselor will confront them about it in the session.

If a client arrives late for a session, the consequence is a shorter session because the counselor should end the session on time. Repeated missed sessions without appropriate cancellations and rescheduling will eventually result in dismissal from the program, but clients in the original research protocol were given many chances before termination from treatment for nonattendance.

Being Sober for Counseling Sessions

Clients are requested to arrive sober for all visits. If a client arrives obviously intoxicated, the counselor will remind the individual of the responsibility to come clean and will reschedule the session. If a client arrives for a group or an individual session mildly under the influence but not intoxicated it is at the counselor's discretion whether to continue with or reschedule the session.

When a Crisis Occurs

If the client presents with an urgent, addiction-related problem such as marital dissolution or financial problems as a result of the addiction, the counselor should try to address these problems in the session, with an emphasis on how they are related to the addiction or addictive behavior. The counselor should then help the client develop strategies for dealing with the problems in a manner consistent with recovery, including identifying how to obtain appropriate assistance from social services. If the client presents with a true crisis (e.g. becoming suicidal after spending all of his or her money on a cocaine binge), the counselor should organize a team effort among the appropriate treatment staff to provide any medical or psychiatric services that the client requires in order to remain safe.

Slips and Relapses

If a relapse occurs, the counselor and client should use the session immediately following the relapse to identify and process the events, thoughts, and feelings that precipitated the relapse. Relapse to drug use is a common occurrence that can be devastating to the client. The counselor must communicate to the client that relapse to drug use does not mean that the entire treatment program has been a failure. The counselor should educate the client about relapse and about how important it is to take corrective action rather than be overcome by feelings of depression or failure. Some episodes of drug use can be managed without seriously interrupting the treatment program and can be used in a positive and educative way to strengthen the recovery process. In dealing with a relapse, the counselor should use the general principle that relapse is caused by failure to follow one's recovery program. Thus, the counselor should identify where the client deviated from his or her recovery plan and help the individual do all that is reasonable to prevent such a deviation from recurring.

Relapse can be viewed as having differing levels of severity that determine the appropriate therapeutic response. The counselor must understand the appropriate interventions to be used in each case. The least severe type of relapse is a slip. A slip is a common occurrence involving a very brief episode of drug use that is associated with no recurrence of symptoms of dependence. Such an episode can serve to strengthen the client's recovery if it is used to identify areas of

weakness in the recovery plan and point out solutions and alternative behaviors that can help prevent future drug use from occurring.

The next most severe type of relapse is when the client resumes drug use for several days, and the use is associated with some of the signs and symptoms of addiction. In such a case, clinically the counselor might want to intensify treatment temporarily, although this was not done in the original research protocol. Intensified contact may help reinstitute abstinence. The client should be encouraged to think about what was done and learn from the experience how to avoid relapse in the future. The client should also be encouraged to recommit to his or her recovery program.

The most serious form of relapse is a sustained period of drug use during which the client fully relapses to addiction. Often a client who relapses to this extent will also drop out of treatment, at least temporarily. In this case, if the client returns to treatment, he or she should most likely be detoxified again, either in an inpatient or outpatient setting. The decision to detoxify a client as an inpatient or outpatient should be made conjointly by the treatment staff involved. The decision should be based on the severity of the relapse, availability of social support, and presence of unstable medical or psychiatric conditions.

RESEARCH ON THE IDC/GDC MODELS

These treatment manuals were developed for use in the National Institute on Drug Abuse (NIDA) Cocaine Collaborative Study. This was a multicenter investigation examining the efficacy of four psychosocial treatments for cocaine-dependent patients. Four hundred and eighty-seven patients were randomly assigned to one of four manual-guided treatments: IDC plus GDC, cognitive therapy plus GDC, supportive-expressive therapy plus GDC, or GDC alone. Treatment was intensive, including 36 possible individual sessions and 24 group sessions for 6 months. Primary outcome measures were the Addiction Severity Index–Drug Use Composite score and the number of days of cocaine use in the past month. Compared with the two psychotherapies and with GDC alone, IDC plus GDC showed the greatest improvement on the Addiction Severity Index-Drug Use Composite score and on number of days of cocaine use in the last month. Overall, compared with professional psychotherapy, IDC was more effective at reducing cocaine use in this study.

Another study attempted to make the IDC and GDC models more "community friendly" in order to facilitate the dissemination of evidence-based treatments to the community setting and to support effectiveness testing. Revised versions of IDC and GDC treatment manuals

for cocaine dependence were developed, and a preliminary study of their effectiveness was conducted. It was concluded that counselors were able to implement the new treatment manuals with acceptable levels of adherence and competence. Results found that substantial change in drug use was evident, but the amount of abstinence obtained was limited.

CONCLUSIONS

IDC and the parallel group model GDC were developed as a treatment approach based on what competent, conventional drug counseling or "treatment as usual" typically involves. The models were initially developed for use in the NIDA Cocaine Collaborative Study and found to be efficacious in that protocol. These manuals for individual and group counseling can be used as a stand-alone treatment, but they were originally designed to be components in a more comprehensive treatment program. Combined with detoxification, initial medical and psychosocial assessments, and ongoing participation in a self-help program, individual and group addiction counseling makes a complete treatment package.

The primary goal of IDC/GDC is to help the client achieve and maintain abstinence from addictive chemicals and behaviors. The secondary goal is to help the client recover from the damage the addiction has done to his or her life.

The IDC/GDC approach is based on the disease model. The disease model conceptualizes SUDs as a biopsychosocial illness that affects social, psychological, spiritual, and physical dimensions of the individual. There is no cure for the disease, but it can be arrested through treatment and abstinence. Recovery requires changes that reflect a lifelong commitment to abstinence and recommends a more balanced and spiritual way of living. This philosophy of the 12-step program is integrated into the counseling, and ongoing participation in a 12-step or other mutual support program is strongly encouraged. IDC and GDC address addiction and related behaviors in a straightforward, present-oriented manner. This model helps the client by setting presentoriented, behavioral goals and focusing directly on ceasing the substance use. Relapse prevention is incorporated in the model, in that the client is helped to develop behavioral tools and basic cognitive coping strategies to abstain from drug use and then maintain abstinence. Drug use is monitored via testing with frequent feedback given for abstinence or drug use. Family involvement is encouraged.

IDC and GDC present very similar information and teach the same strategies, but in a different format. Each format offers some unique treatment elements that are beneficial to the therapeutic process, and clients do seem to benefit from a combination of GDC and IDC.

SEE ALSO

Evidence-Based Treatment, Cognitive Behavioral Therapies, Twelve-Step Facilitation Therapy, Treatment-as-Usual for Substance Abuse in Community Settings, Self-help Groups

List of Abbreviations

AA alcoholics anonymous
GDC group drug counseling
IDC individual drug counseling
NA Narcotics Anonymous
NIDA National Institute on Drug Abuse
SUD substance use disorder

Glossary

Behavioral model of counseling or therapy relating to or emphasizing behavior.

Biopsychosocial concerned with the biological, psychological, and social aspects of a disorder, rather than only the medical aspects. **Cognitive** model of counseling or therapy relating to or emphasizing thinking.

Mutual support program programs, like AA and SMART recovery, through which one can access information and support.

Psychoeducational relating to psychological aspects of education. **Relapse** return to substance use following a period of abstinence.

Further Reading

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Relevant Websites

www.nida.nih.gov - National Institute on Drug Abuse. www.samhsa.gov - Substance Abuse and Mental Health Service Administration.

14

Self-Help Groups

Ann Dadich

University of Western Sydney, Sydney, NSW, Australia

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SELF-HELP PARADIGM

Self-help groups (SHGs) operate within the self-help paradigm alongside sociopolitical movements, community development initiatives, and peer mentoring schemes, and they share the following ten principles:

1. The peer principle

The egalitarian spirit of the groups is fostered by the social homogeneity of group participants.

2. Self-determination and new forms of participation

Self-governance is exercised to direct the group and the degree of involvement for each individual. 3. Helper therapy and the restructuring of help

Group participants are helped most by being helpful to others, and thus engage in reciprocal support.

4. The consumer as producer and consumer capital

Group participants are no longer mere recipients of help; they are also the providers of support.

5. Strength versus pathology

Groups emphasize the fundamental role of inner strengths, be they of the individual, group, or community. This is opposed to a focus on pathologies, problems, or afflictions.

6. Noncommodification

The support inherent in SHGs is not a commodity that can be bought or sold. This lies in contrast to service provision, which includes human services and self-help materials that can usually be purchased for a profit.

7. Social support

This type of support enables group participants to reinterpret their personal situation more positively and helps them develop a resiliency to stress.

8. Ethos

Ethos is said to encompass a group's behaviors, practices, and values. These values are typically characterized by anti-dependency, antielitism, antibureaucracy, sharing community, informality, anti-addiction, a spiritual bias, and participatory democracy, particularly when it comes to helping others.

9. The self-help solution

Given the indigenous leadership of SHGs, they offer a solution to some of the limitations associated with human services.

10. Internality

Self-reliance (be it on the group or the self) offers an alternative to reliance on conventional treatments. It also offers healing or recovery whereby group participants are able to resolve a problem of the body, mind, or spirit. This differs to curing, which is typically imposed by a human service provider.

Together, these principles illuminate the underlying values of SHGs. Although there is much variety in their operationalization, management, and governance, they help to transform problems into manageable issues.

Definitional Issues

Although the self-help paradigm offers a useful tool for understanding SHGs, there is currently no single definition of these groups. This is largely due to the following factors:

1. Various labels

Various terms are used to refer to these groups, both by the groups themselves and those who research the area. In addition to SHG, other terms include support group, self-help organization, mutual help group, as well as the relatively more encompassing terms of mutual aid self-help and self-help support group, both of which capture both the autonomous and supportive components of these groups. With regard to addiction, examples include Alcoholics Anonymous (AA), a 12-step fellowship for individuals who identify as an alcoholic, Secular Organizations for Sobriety or Save Our Selves (SOS), the Mental Illness Addiction Support Group (MASG), and the Calix Society.

2. Various definitions

Some definitions indicate that SHGs bring together individuals with a shared problem or an affliction. Others assert that group participants are drawn together by common experience and/or attributes. For example, Narcotics Anonymous (NA), a nonprofit fellowship for individuals who experience drug problems, is tailored to individuals "who feel they may have a problem with drugs," while Birds of a Feather supports "troubled airmen toward sobriety." However, Moderation Management "empowers individuals to accept personal responsibility for choosing and maintaining their own path, whether moderation or abstinence."

3. Operational variation

At a functional level, SHGs typically perform two major roles: support and education. Some, however, are also involved in advocacy. Advocacy can occur at a personal level on behalf of individual group participants or a sociopolitical level on behalf of the constituency group participants are part of. However, at an operational level, there is greater heterogeneity between and within SHGs, even when groups share a common label. Differences emerge between group aims, the principles adopted to achieve these aims, the nature of participant involvement, the involvement of human service providers, degrees of group membership, and so forth. For instance, within AA, meetings are typically chaired by a member, while Women For Sobriety (WFS) groups are "run by a WFS Certified Moderator." Such diversity contributes to a lack of consistency among SHGs. It is therefore unlikely that one operational definition can be developed. It is also unlikely that research into the area can be readily generalized to all SHGs. However, such diversity promotes access to appropriate support among individuals who may otherwise remain isolated and disengaged.

4. Involvement of human service providers

There is a lack of consensus about the degree of involvement from human service providers, particularly those who do not share the experience(s) of group participants. Although some groups operate in isolation from human service providers, either by choice or because they lacked credibility among human service providers, most groups have established links with human service providers, who serve as an advisor, a consultant, guest speaker, or provider of in-kind support (like a venue at which to meet) and/or

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administrative support. For instance, some AA chapters convene within public hospitals and public mental health services.

5. Confusion with other support systems

Given their similarities, SHGs are often considered part of other support systems, either naturally occurring or part of the human services paradigm. All systems, be they formal or informal, may involve groups of people who demonstrate support and understanding, as well as learning through the experiences of others. However, SHGs retain a uniqueness that has perhaps accounted for their appeal among group participants. For instance, all 12-step fellowships offer solidarity with individuals who share similar experiences.

These factors help to explain why understandings of the SHG remain clouded. Despite this, these groups operate within a shared self-help paradigm. They bring together individuals with common experiences and operate at the discretion of group participants.

SIGNIFICANCE

The popularity of SHGs is evident when attempting to locate support for almost any health or mental health issue, including substance use. One Australian directory includes over 700 different bodies within that nation alone. In the United States, their presence is even greater with an SHG for every illness identified by the World Health Organization. The popularity of these groups in the United States is matched by the support of political structures and human services. This is evident in the prevalence of self-help clearinghouses across the United States, each established to support new and existing groups, as well as refer interested individuals to appropriate groups. This compares with the few Australian self-help centers, each of which differs in structure and function. For every Australian self-help center, there are approximately 10 self-help clearing houses in the United States.

Perhaps partly because of difficulties in defining SHGs, there is limited information about the number of individuals accessing these groups. Similarly, there is also limited information about who is using these groups, and how they are using them. There is some information about particular SHG organizations, like AA. Although official statistics are not available, there are estimated to be over 2 million members in over 150 countries, internationally. Similarly, NA convenes over 58 000 meetings per week, in approximately 131 countries. GROW, a community of individuals who progress toward recovery using 12-step program, is said to attract approximately 10 000 Australians.

However, collated information from a range of SHGs is lacking.

International literature might provide some direction. Epidemiological research suggests that within a 12-month period, approximately 3–7% of Americans, potentially representing over 15 million individuals, frequent a SHG of some kind, and lifetime participation rates are estimated at about 25 million.

The popularity of SHGs in Western societies has been attributed to several factors. These include the dissatisfaction experienced by users of human services, the decline of supportive institutions, and the sociopolitical climate. This popularity exists within a climate of capitalism and its push for individualism.

SHGs have proven to be quite cost-effective. Historically, the United States and Britain have demonstrated the viable existence of SHGs within both a free enterprise health system, and under a centralized national health service. European countries have demonstrated this viability with systems that lie somewhere in between.

Group Participants

SHGs may not be suitable for everyone. Research concerning groups that meet around mental health and/or substance use issues appear to paint a portrait of the typical participant. Despite discrepancies concerning sex, level of education, and class, research suggests that group participants tend to be female, Caucasian, aged between 30 and 50 years, and of middle class. These demographic details reflect research findings concerning self-care practices. In the management of health and mental health, middle-age and middle-class females have been found to have the most success.

Membership surveys within 12-step fellowships portray a slightly different image of the typical member. For instance, a 2007 survey of over 8000 AA members in the United States and Canada indicated that the average age was 47 years and 67% were male. Similarly, a 2009 survey of over 11 000 NA members revealed an average age of 43.5 years, that most members were in full-time employment (61%), and 58% of all members were male.

Research about SHGs suggests that group participants, particularly those with serious mental health and/or substance use issues, tend to be socially isolated. They have markedly reduced social networks, are typically unemployed, and usually not married. This was partly reflected in the aforesaid survey of NA members. A large proportion of respondents indicated that participation had helped to improve family relationships (92%) and/or social connectedness (88%). However, social isolation alone is unlikely to

predict group involvement. Rather, it is likely to be influenced by a combination of factors, including (but not limited to) personal issues, individual attributes, and cultural norms. This was affirmed in the aforesaid surveys of AA members, which suggested that the largest proportion of respondents were married (35%) and employed (65%).

Well-being has also been implicated in the depiction of the typical group participant. Group participants are believed to have experienced very poor mental health, if not a crisis point, a rock bottom, during which they realize change is needed. And most participants come to realize that the change they desire can only result with the help of others. However, some research suggests that group participants participate in a SHG following a period of recovery. This research suggests that group participation necessitates a degree of self-manageability and sociability.

Although group participants may experience poor mental health, if not a crisis, their ill health should not serve to immobilize them. Research suggests that participants need to be somewhat functional, as well as sociable in order to participate effectively. This is partly affirmed in the aforesaid survey of NA members, with the largest proportion indicating their capacities to manage their own affairs, prior to membership (45%). These include employability, ability to retain their own residence, ability to support a family, and the ability to maintain relationships.

From this literature stems three propositions. First, it suggests that the people who experience very poor mental health may not be appropriate candidates for SHGs. Second, it suggests that group participants typically have an extended experience with the issue that brought them to the group, whereby they have reached a low point, or have somewhat progressed. Third, there is a select population of people that may reap the benefits of group involvement. This population predominately includes those who are between 30 and 50 years of age and who are relatively functional and sociable, despite poor well-being.

REASONS FOR GROUP PARTICIPATION

Most individuals who come to SHGs want change in their personal circumstances. They would like to experience change at a personal level (that is, their well-being and emotional state) and/or at a social level (that is, their connections with support networks). Although SHGs encourage group participants to help each other, group involvement appears to be motivated by an identified need for help, which is not being met elsewhere.

Group participants have often accessed conventional human services to address this need, prior to group involvement. This finding pertains to groups that specifically meet around substance use issues. This suggests some inadequacies in conventional sources of support.

BENEFITS

Participation in SHGs, particularly in groups that address mental health and/or substance use issues, is associated with several benefits. Beneficiaries include not only the individual participant, but also the group, and the wider community. Although these benefits collectively speak of change, for clarity, they are presented at the personal, social, and structural levels.

Personal Level

Supported by people who share common experiences, group participants have been found to experience behavioral, cognitive, and spiritual transformation. This is made possible through several group processes. For instance, within the group, participants are exposed to others with similar issues. This can normalize, if not promote, the experience, which may be particularly important for those who experience the effects of stigma. Personal issues that were once shameful are transformed into a qualification for group membership. Furthermore, fellow group participants, particularly those who have experienced greater personal growth, also make for positive role models.

Group participants also learn new information and hear an array of opinion. This can improve self-understanding, particularly in relation to the predicament that brought them to the group (for instance, possible external manifestations and/or causes). This serves as a cognitive antidote to personal issues.

In learning new information, group participants become aware of suitable coping strategies and treatments that might be of benefit. They also have a forum in which to discuss fears and concerns about treatments they are ambivalent about. The information shared in SHGs holds particular relevance for group participants, as much of it is born from the experiential knowledge of fellow participants who have had comparable experiences. They are able to compare their personal situation and monitor any progress.

The inherent processes of SHGs can give rise to many personal benefits for group participants. They can develop greater communicative skills, experience an improved ability to control undesirable behaviors, and/or adapt to the issue that initially brought them to the group. Mental health benefits also abound, for group participants are thought to experience a greater

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sense of hope, improved self-image and personal identity, and an enhanced self-esteem.

If nothing else, SHGs can offer increased access to helpful support that might otherwise be limited from conventional sources. This advantage becomes apparent when the cessation of undesirable behaviors, like addiction, leaves an individual with excessive time on their hands.

Other noted benefits include the encouragement given to participants to become more active in the management of their own affairs. Exposure to diverse information not only increases appreciation for the diverse views and experiences of others, but also encourages the group participant to self-determine the opinions and/or practices they incorporate into their own knowledge base.

The practice of reciprocal support is an important part of SHGs, whereby group participants support each other. Because the support is offered by people who share similar experiences, it is more likely to meet the needs of the recipient. Yet, more importantly, this process is of benefit to both the helper and the helpee. The importance of reciprocity is demonstrated by the suggested benefits experienced by participants, regardless of whether they adopt a passive or active role in the group. For instance, while the listening audience learns from the insights offered by more verbal group participants, those who share their personal narrative are believed to benefit from the cathartic experience.

Social Level

SHGs are said to offer an environmental antidote to the social isolation often experienced by individuals with substance use issues. They facilitate the development of support networks and a subsequent sense of belonging. This is especially because group participants share similar experiences and (at times) common identities. These networks can serve to increase not only the number of friendships, but also the types of relationships.

The networks developed by group participants have been regarded as particularly beneficial to mental health. It is widely believed that social support acts as a buffer to stress and is thus implicated in the promotion of health. The support offered by SHGs can be both emotional (through affirmation and encouragement) as well as practical (aiding with daily affairs). Yet of particular benefit is the long-term nature of this support and the fact that it can be tapped into when it is most needed.

Changes to support networks can extend beyond the group context. SHGS can play an important role in improving relationships with significant others, either directly or indirectly. In a direct way, some groups encourage the involvement of family members, friends, and human service providers. This is aptly demonstrated by 12-step fellowships like Al-Anon and Co-Anon, which are specifically for relatives and friends of people with an addiction. This serves to raise awareness of the particular issues faced by the different parties and improve communication channels. In an indirect way, the communicative skills and coping strategies developed in the group can be used to enhance relationships with those outside of the group. This includes family members and friends as well as human service providers. SHGs can provide greater insight into personal issues and available treatments. They can also demystify the jargon typically used by service providers. Armed with this knowledge, group participants become better able to communicate their needs and preferences to others. This demonstrates the relationship between SHGs and other life domains.

Structural Level

SHGs have also been discussed as part of a recovery program. Through their emphasis on empowerment, self-reliance, and reciprocal support, they can efficiently address long-standing problems with conventional human services. SHGs allow the ratio of helper to helpee to be dramatically altered. Furthermore, with improved social functioning, group participants are able to make greater contributions to the wider community. This includes partaking in education and/or employment.

Critical Success Factors

Several factors appear to increase one's propensity to continue involvement in, and derive benefit from a SHG. These include best-fit, structure, the sharing of narratives, reciprocal support, as well as active and prolonged involvement.

Best-Fit

Best-fit between the SHG and the participant appears to be crucial. Continued involvement in a SHG is more likely if an individual believes they share similarities with fellow group participants and is thus compatible. This includes demographic characteristics, personal attributes, and ideology.

Structure

Some SHGs, like 12-step fellowships and GROW, adopt an explicit structure, which directs the group ethos. Such structure is thought to be particularly beneficial for people who have limited social skills or lack of confidence. It provides these individuals with direction

about the way they should engage with the group. It also promotes a framework for learning and subsequent personal development through the use of explanation, repetition, and uniformity.

Narrative Sharing

The disclosure of personal narratives is deemed an essential practice of SHGs, fostering both group intimacy and personal development. This is especially true of groups like 12-step fellowships and GROW, where group participants are encouraged to identify with the successful efforts of fellow participants as they share their own story.

Reciprocal Support

Opportunities for group participants to help each other can benefit both the helper and the helpee. In fact, the benefits of group involvement can diminish when group participants are primarily involved in only one of these roles.

Active and Prolonged Involvement

Active involvement and affiliation are said to influence the perceived usefulness of SHGs. Active participation has several meanings and can refer to efforts both within and beyond the group context. Active participation can include speaking at group meetings, welcoming newcomers, organizing social and/or political events, or performing administrative tasks. It can also refer to the extent to which group philosophies and practices are incorporated into daily life.

GROUP TYPES

12-Step Fellowships

Of all the SHGs that meet around mental health and/ or substance use issues, 12-step fellowships are arguably the most well-known. For this reason, they are described in further detail.

Twelve-step fellowships were born with the advent of AA in 1935, when an alcoholic from New York, Bill W, was introduced to Dr Robert S who shared a similar view about recovery. By sharing their personal narratives with each other, they came to recognize the spiritual support they received and the personal strength they developed to work toward sobriety. These experiences helped them to conceive a path for others who are affected by addiction.

Twelve-step fellowships are highly structured, encouraging participants to adhere to a 12-step program. This provides instruction for a manageable lifestyle, particularly for those who experience an addiction, a compulsion, or other behavioral problems. In fact,

there is a 12-step fellowship for a wide array of issues (see Table 14.1), each of which adapts the 12-step program accordingly. For instance, the 12 steps of Cocaine Anonymous are as follows:

- **1.** We admitted we were powerless over cocaine and all other mind-altering substances that our lives had become unmanageable.
- **2.** Came to believe that a Power greater than ourselves could restore us to sanity.
- **3.** Made a decision to turn our will and our lives over to the care of God as we understood Him.
- **4.** Made a searching and fearless moral inventory of ourselves.
- **5.** Admitted to God, to ourselves, and to another human being the exact nature of our wrongs.
- **6.** Were entirely ready to have God remove all these defects of character.
- 7. Humbly asked Him to remove our shortcomings.
- **8.** Made a list of all persons we had harmed and became willing to make amends to them all.
- Made direct amends to such people wherever possible, except when to do so would injure them or others.
- **10.** Continued to take personal inventory, and when we were wrong promptly admitted it.
- 11. Sought through prayer and meditation to improve our conscious contact with God as we understood Him, praying only for knowledge of His will for us and the power to carry that out.
- **12.** Having had a spiritual awakening as the result of these steps, we tried to carry this message to addicts, and to practice these principles in all our affairs" (Cocaine Anonymous® World Services, 2011).

Twelve traditions guide the meetings stipulating accepted practices and ideology (see Table 14.2 for an example). These offer all subgroups a degree of consistency and means that almost anyone could establish a group or facilitate a meeting with the regular rotation of the facilitator role, or chairperson.

A key belief within the 12-step approach views problem behaviors, like addictions and compulsions, as a disease, rather than a learnt behavior or a symptom of other issues. This disease is believed to manifest psychologically, physically, and spiritually. It is also thought to have an enormous impact on significant others. For this reason, 12-step fellowships also encompass groups for family members and friends of individuals with the disease (see Table 14.3).

Within groups (or chapters), diversity is typically rich with respect to age, cultural background, and socioeconomic status. However, some chapters attempt to target particular populations, like young people, to narrow this diversity. Most groups convene weekly for approximately 90 min. A community agency or religious facility

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TABLE 14.1 12-step Fellowships for People Who Experience an Unmanageable Life*

AA	Alcoholics Anonymous	N/A or NAIL	Neurotics Anonymous
CA	Cocaine Anonymous	NicA	Nicotine Anonymous
CLA	Clutterers Anonymous	OA	Overeaters Anonymous
CMA	Crystal Meth Anonymous	OLGA	Online Gamers Anonymous
DA	Debtors Anonymous	PA	Pills Anonymous
EA/EHA	Emotions Anonymous/ Emotional Health Anonymous	RA	Reentry Anonymous
FA	Food Addicts in Recovery Anonymous	SA	Sexaholics Anonymous
FAA	Food Addicts Anonymous	SA	Smokers Anonymous
GA	Gamblers Anonymous	SAA	Sex Addicts Anonymous
НА	Heroin Anonymous	SCA	Sexual Compulsives Anonymous
LBA	Lip Balm Anonymous	SIA	Survivors of Incest Anonymous
MA	Marijuana Anonymous	SLAA	Sex and Love Addicts Anonymous
NA	Narcotics Anonymous	WA	Workaholics Anonymous

^{*} Given the absence of a universal and comprehensive database of SHGs, this information is likely to be incomplete.

(like a church hall) is the usual meeting place. However, some meet in a public setting, like a café.

Chapter diversity is also apparent in their foci. For instance, some are "closed" to individuals who identify as having an addiction, while others are open. Some chapters are speaker meetings, at which members share their personal narrative, while other chapters offer greater time for discussion. Furthermore, some chapters (or some of the meetings within a chapter) are devoted to studying the 12 steps and traditions of AA, or the Big Book of AA, a 164-page publication that documents a guide to recovery. To optimize access, 12-step fellowships are also available in alternative (non-face-to-face) forms. This includes the Loners International Meeting, which provides AA in print-form.

Following an opening rite, the chairperson typically acknowledges the need to observe confidentiality and anonymity. The chairperson then invites individual group participants to share their experiences and thoughts, and usually extends this invitation to a different gender consecutively. In accepting this invitation, a group participant will share without interruption or feedback from others, as cross talk is discouraged.

Halfway during the meeting, participants are typically invited to I.D – or identify themselves. They state their first name, the attribute that brought them to the group, and the number of days they have experienced

a manageable life (or, in the case of those with substance use issues, sobriety or clean time). Another identification rite involves marking birthdays, not of biological birth, but birth into recovery. These birthdays are typically recognized at the end of the meeting.

In closing the meeting, the chairperson invites participants to stand and recite a prayer. Despite references to God (also evident in the 12 steps and traditions), participants are encouraged to adopt a personalized understanding of a Higher Power, which can take any desired form. Following the prayer, participants are then encouraged to stay for the second part of the meeting to meet each other informally, and in a more personal way. Group participants also meet at the social activities and annual conventions that are organized within some fellowships. Regular newsletters also serve as a network tool. Funding for these and other expenses come solely from group participants who donate money at the end of meetings.

The 12-step approach advises that the act of helping others aids personal recovery. It is a repeated theme in meetings and manifests in various ways. One key example is that of sponsorship. Senior group participants become mentors to newcomers, offering personalized guidance as they attempt to understand and adhere to the 12-step program. One 12-step fellowship, Alateen, an SHG for young relatives and friends of alcoholics,

SELF-HELP GROUPS

1 Each member of Alcoholics Anonymous is but a small part of a great whole. AA must continue to live or most of us will surely die. Hence our common welfare comes first. But individual welfare follows close afterward.

- 2 For our group purpose there is but one ultimate authority a loving God as He may 8 express Himself in our group conscience.
- 3 Our membership ought to include all who suffer from alcoholism. Hence we may refuse none who wish to recover. Nor ought AA membership ever depend upon money or conformity. Any two or three alcoholics gathered together for sobriety may call themselves an AA group, provided that, as a group, they have no other affiliation.

- With respect to its own affairs, each AA group should be responsible to no other authority than its own conscience. But when its plans concern the welfare of neighboring groups also, those groups ought to be consulted. And no group, regional committee, or individual should ever take any action that might greatly affect AA as a whole without conferring with the trustees of the General Service Board. On such issues our common welfare is paramount.
- 5 Each Alcoholics Anonymous group ought to be a spiritual entity having but one primary purpose — that of carrying its message to the alcoholic who still suffers.
- 6 Problems of money, property, and authority may easily divert us from our primary spiritual aim. We think, therefore, that any considerable property of genuine use to AA should be separately incorporated and managed, thus dividing the material from the spiritual. An AA group, as such, should never go into business. Secondary aids to AA, such as clubs or hospitals which require much property or administration, ought to be incorporated and so set apart that, if necessary, they can be freely discarded by the groups. Hence such facilities ought not to use the AA name. Their management should be the sole responsibility of those people who financially support them. For clubs, AA managers are usually preferred. But hospitals, as well as other places of recuperation, ought to be well outside AA and medically supervised. While an AA group may cooperate with anyone, such cooperation ought never to go so far as affiliation or endorsement, actual or implied. An AA group can bind itself to no one.

- The AA groups themselves ought to be fully supported by the voluntary contributions of their own members. We think that each group should soon achieve this ideal; that any public solicitation of funds using the name of Alcoholics Anonymous is highly dangerous, whether by groups, clubs, hospitals, or other outside agencies; that acceptance of large gifts from any source, or of contributions carrying any obligations whatever, is unwise. Then, too, we view with much concern those AA treasuries which continue, beyond prudent reserves, to accumulate funds for no stated AA purpose. Experience has often warned us that nothing can so surely destroy our spiritual heritage as futile disputes over property, money, and authority.
- Alcoholics Anonymous should remain forever nonprofessional. We define professionalism as the occupation of counseling alcoholics for fees or hire. But we may employ alcoholics where they are going to perform those services for which we might otherwise have to engage nonalcoholics. Such special services may be well recompensed. But our usual AA Twelfth Step work is never to be paid for.
- Each AA group needs the least possible organization. Rotating leadership is the best. The small group may elect its secretary, the large group its rotating committee, and the groups of a large metropolitan area their central or intergroup committee, which often employs a full-time secretary. The trustees of the General Service Board are, in effect, our AA General Service Committee. They are the custodians of our AA Tradition and the receivers of voluntary AA contributions by which we maintain our AA AA's General Service Office at New York. They are authorized by the groups to handle our overall public relations and guarantee the integrity of our principal newspaper, the AA Grapevine. All such representatives are to be guided in the spirit of service, for true leaders in AA are but trusted and experienced servants of the whole. They derive no real authority from their titles; they do not govern. Universal respect is the key to their usefulness.
- No AA group or member should ever, in such a way as to implicate AA, express any opinion on outside controversial issues particularly those of politics, alcohol reform, or sectarian religion. The Alcoholics Anonymous groups oppose no one. Concerning such matters they can express no views whatever.
- Our relations with the general public should be characterized by personal anonymity. We think AA ought to avoid sensational advertising. Our names and pictures as AA members ought not be broadcast, filmed, or publicly printed. Our public relations should be guided by the principle of attraction rather than promotion. There is never need to praise ourselves. We feel it better to let our friends recommend us.
- 12 And finally, we of Alcoholics Anonymous believe that the principle of anonymity has an immense spiritual significance. It reminds us that we are to place principles before personalities; that we are actually to practice a genuine humility. This to the end that our great blessings may never spoil us; that we shall forever live in thankful contemplation of Him who presides over us all.

^{*} Sourced from AA Australia 2011, The twelve traditions of Alcoholics Anonymous, National Office AA (GSO), viewed 1st May 2011, http://www.aa.org.au/members/twelve-traditions.php.

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TABLE 14.3 12-step Fellowships for Relatives and Friends*

ACA	Adult Children Alcoholics	COSLAA	Codependents of sex and/ or love addicts
Al-Anon	For relatives and friends of alcoholics	FA	Families Anonymous for relatives and friends of addicts
Alateen	For young relatives and friends	Gam-Anon	For relatives and friends of gamblers
Co-Anon	For relatives and friends of addicts	Gam-A-Teen	For young relatives and friends of gamblers
CoDA	Codependents Anonymous, for people wanting to develop healthy relationships	Nar-Anon	For relatives and friends of addicts
COSA	Codependents of sex addicts	S-Anon	For relatives and friends of sex addicts

^{*} Given the absence of a universal and comprehensive database of SHGs, this information is likely to be incomplete.

includes examples of a different form of sponsorship. Given that group participants include minors, a participant of an equivalent adult fellowship, like Al-Anon, sponsors the group as a whole. The role of this person is to ensure that young participants understand and adhere to the steps and traditions of the fellowship. The structure in this group tends to have greater flexibility, allowing for discussion during the meetings.

The popularity of 12-step fellowships should not detract from the range of SHGs worldwide that aim to facilitate well-being through peer-driven support. To demonstrate this array, several examples are briefly described.

Other SHGs

Birds of a Feather

Commencing in 1975, this international organization is premised on the principles of AA, offering peer support to active or inactive pilots and cockpit crew members who experience addiction to alcohol and/or other drugs. Group participants convene at individual nests. That is, local groups that gather to work through the 12 steps of recovery.

Calix Society

Founded in 1942, the Calix Society brings together individuals who identify as Catholic and who maintain recovery through affiliation with and participation in AA. As such, it offers a community of faith to individuals working the 12-step program.

GROW

Starting in Australia in 1957, GROW offers a peerdriven community in which mutual support and friendship are fostered among people who experience mental health issues, including addiction. Reflecting a 12-step fellowship, GROW is premised on a recovery program that encourages individuals to actively address personal issues within a safe and nonthreatening group meeting, this includes the assignment of practical tasks that help to translate the group discussion into daily life.

Moderation Management

Moderation Management is a behavioral change program complemented by a support network for individuals who have a desire to address their use of alcohol and live a healthier lifestyle. This is supported by a ninestep program that offers practical guidance on matters such as ways to monitor alcohol consumption as well as self-management strategies.

Save Our Selves

Commencing with an article in 1985, the SOS provides a nonreligious and nonspiritual alternative to 12-step fellowships. It aims to support individuals who may be uncomfortable with the spiritual components of 12-step fellowships, by encouraging individuals to assume active responsibility for their recovery. This is further reflected in the organization's recognition of science to understand and address addiction.

Self Management and Recovery Training

SMART (Self Management and Recovery Training) Recovery brings together individuals with a shared experience to offer a unique type of support. Although it integrates elements of cognitive behavior therapy and motivational interviewing and espouses seven stages of change, it is situated in the self-help paradigm, valuing non-commodified experiential wisdom.

Women for Sobriety

Since 1976, WFS has provided peer support to women who aim to remain abstinent from alcohol and other drugs. This is demonstrated through its SHGs, during which women work through a 13-step program that espouses positivity and personal growth. This program is said to enable women to form a personalized journey toward long-term recovery.

CRITICISMS

Some groups, like 12-step fellowships, have been criticized for their practices. This includes the practice of self-labeling. Group participants are encouraged to identify (at least within the group) with the issue that initially brought them to the fellowship, for instance, as an alcoholic and/or addict. These issues are considered life-long diseases, for group participants are never recovered, but are always in recovery. This concern is not isolated to 12-step fellowships, but also extends to other SHGs.

Furthermore, it is believed that the life-long disease of group participants cannot be managed independently. It requires life-long involvement in a 12-step fellowship. This has been criticized as transferring one's addiction to another form of dependency, that of group membership. This can serve to absorb the individual into one particular lifestyle, much to the exclusion of all other activity, thus limiting personal growth and re-engagement with family or broader social networks.

The quest for abstinence, as opposed to moderation, is also questioned in the literature. Twelve step fellowships endorse complete sobriety from substance use for those who identify with an addiction (bar nicotine and prescribed medications). Yet this somewhat conflicts with harm minimization practices. Although recent research suggests that the two approaches can be complementary, many argue that the aim of harm minimization is to reduce drug-related harm, and abstinence is but one method toward this.

Furthermore, if one does not agree with 12-step beliefs and practices, the dissenter is typically considered not ready for the fellowship, akin to the notion of denial. This view tends to regard the nonconformist as unenlightened and perhaps inferior to group participants.

Literature highlights additional drawbacks associated with SHGs. However, most are born from the concerns of authors, human service providers, or potential group participants, not empirical research with current group participants. Some authors for instance, argue that SHGs are mere examples of the blind leading the blind. Group participants are thought to be provided

with false or misleading information from peers who lack academic credentials. This is further compounded by the lack of accountability often found in SHGs.

It is also thought that associating with people in similar situations may actually propagate undesirable behaviors and encourage the acquisition of stigmatized identities. This is a particular concern for young people who are thought to be impressionable. However, recent research suggests that this is not necessarily the case.

There are concerns that SHGs deter group participants from conventional human services, and that this may justify funding reductions to the human services sector. In contrast to this, others suggest that negative group experiences will leave service providers with a greater workload in having to pick up the pieces. This view is firmly juxtaposed by recent research, which found SHGs served to re-engage individuals with conventional human services.

There are also concerns about the practices of particular groups. Some practices are thought to be too lax, too structured, or suspect in their effectiveness. This includes the use of peer pressure to encourage conformity among group participants. An additional matter is the stigma often associated with substance use issues. This can serve to deter potential participants. Furthermore, it is argued that some SHGs, like 12-step fellowships, do nothing to address the problem of stigma. They simply medicalize the issue to increase social acceptability.

Despite the aforementioned concerns about SHGs, research suggests that the concerns of those actually involved in these groups are far more moderate. Collectively, the studies speak of problems associated with the operational structures of a group or its processes. In reference to the structures, some individuals have found the 12-step approach limiting. They believe that it fails to appreciate the complexities of their personal situation. This problem becomes particularly evident when individuals concurrently access human service providers who operate from a different paradigm.

A number of other problems in SHGs have been identified. These include a lack of strong leadership, a leadership role that is not shared among group participants, disorganized agendas, and groups that are stagnant.

The processes and dynamics that unfold within the group can also be problematic. For some individuals, this includes the presence of those who behave inappropriately, fail to demonstrate empathy, or breach confidentiality. Others have found their group experiences to diminish personal well-being, leaving them feeling overwhelmed or less efficacious. This is particularly the case when there is sole focus on the problems associated with substance use issues.

Further to this is the negativity of fellow group participants, which can even lead to the termination of group

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involvement. This is a possible concern of all SHGs, particularly those that meet around chronic conditions, like substance use issues. However, some researchers argue that group participants cannot be sheltered from reality forever, but the truth must be delivered in a timely fashion. For if this truth falls on unprepared ears, the group experience may be discouraging and unhelpful.

These aforesaid problems are not exclusive to SHGs. They hold relevance to other group environments. Nevertheless, ideal group conditions are still no guarantee that experiences with a SHG will be favorable.

Without wanting to detract from the possible weaknesses of SHGs, the aforesaid problems might simply reflect limited fit between the group and the individual. However, some researchers advise that the complexities of this relationship should not be used to justify negative research findings.

Like formal treatments, SHGs may not be appropriate for all individuals who experience substance use issues. However, like formal treatments, the potential value of SHGs may be optimized when complemented by other resources and support systems, like human services. This is supported by current literature.

SUMMARY

SHGs can form an important part of recovery for people who experience substance use issues. Through the provision of noncommodified peer support, they can facilitate personal, social, and structural change. Furthermore, given their relative accessibility, SHGs can help to sustain such change. More specifically, they are economically accessible, as no fees are required. Typically, they are geographically accessible, given the number of established groups and chapters. They are also cognitively accessible, as group participants can self-determine their degree of involvement.

Caution is warranted before becoming overly optimistic about the preponderance of positive findings. There are inherent methodological issues in many studies to date, these include the reliance on self-reports from group participants, the use of retrospective data, the lack of comparison groups, and the use of cross-sectional designs. Notwithstanding some methodological exceptions, a systematic review of 12-step fellowships for alcohol dependence identified a need for more efficacy studies (Ferri et al., 2006).

Although SHGs may not be the panacea for everyone with substance use issues, several factors appear to increase their perceived value. These include best fit between the group and the participant, a structure that guides group processes, the sharing of personal narratives, the reciprocity of support, as well as active and prolonged group involvement. Some of these factors

appear to reflect those associated with successful treatments.

Given the complex and chronic nature of substance use issues, SHGs may be best perceived as a supplement to a suite of strategies toward recovery. This is because SHGs can offer a unique type of support (be it psychological or practical) and can be accessed if, and when deemed appropriate by the individual.

SEE ALSO

Therapeutic Communities®, Twelve-Step Facilitation Therapy, Network Support Treatment for Alcohol Dependence, Individual and Group Counseling for Substance Use Disorders, Faith-Based Substance Abuse Programs

List of Abbreviations

AA Alcoholics Anonymous

NA Narcotics Anonymous

SOS Secular Organizations for Sobriety or Save Our Selves

SHG self-help group

WFS Women For Sobriety

Glossary

Disease concept although not officially promulgated by 12-step fellowships, this term conceives addiction as a ailment with psychological, physical, and spiritual dimensions.

Higher power a belief in a greater entity that helps to relinquish control over perceived willpower and embrace hope for personal growth and recovery.

Powerlessness a belief that individuals who experience an addiction largely lack the capacity to control their destructive behaviors.

Sponsor a member of a 12-step fellowship who mentors newcomers by providing guidance to work the 12-steps, sharing personal experiences, and provides support toward recovery.

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Lavoie, F., Borkman, T., Gidron, B. (Eds.), 1994. Self-help and Mutual Aid Groups: International and Multicultural Perspectives. Haworth Press, New York.

Powell, T.J. (Ed.), 1994. Understanding the Self-help Organization Frameworks and Findings. Sage Publications, Newbury Park, CA.

Self-Help Clearing House

Australia

www.coshg.org.au - Collective of Self Help Groups (VIC).

www.mentalhealth.asn.au/our-programs/mental-health-informationservice.html – Mental Health Association NSW.

www.selfhelpqld.org.au - Self Help Queensland.

www.shout.org.au - SHOUT (ACT).

www.connectgroups.org.au - WISH (WA).

Canada

www.selfhelp.on.ca - SelfHelp Resource Centre.

Israel

www.selfhelp.org.il - Israel Self Help Centre.

Japan

www.t-oka.net - omofumi Oka.

HK

www.selfhelp.org.uk - Self Help Nottingham.

USA

www.mentalhelp.net/selfhelp – American Self Help Clearing House. www.selfhelpgroups.org – American Self Help Clearing House, New Jersey.

Self-Help Groups

www.grow.net.au – GROW. http://lifering.org/ – LifeRing Secular Recovery. www.moderation.org – Moderation Management. http://pagansinrecovery.com/ - Pagans In Recovery (PIR).

www.smartrecovery.org - SMART Recovery.

www.cfiwest.org/sos/index.htm - SOS (Secular Organizations for Sobriety or Save Our Selves).

12-step Fellowships

www.aa.org - Alcoholics Anonymous.

http://sites.google.com/site/clutterersanonymous/Home-Clutterers Anonymous.

www.ca.org - Cocaine Anonymous.

www.crystalmeth.org - Crystal Meth Anonymous.

www.debtorsanonymous.org - Debtors Anonymous.

www.emotionsanonymous.org – Emotions Anonymous / Emotional Health Anonymous.

www.foodaddictsanonymous.org - Food Addicts Anonymous.

www.foodaddicts.org - Food Addicts in Recovery Anonymous.

www.gamblersanonymous.org - Gamblers Anonymous.

http://heroin-anonymous.org/haws/index.html-Heroin Anonymous.

www.lipbalmanonymous.com - Lip Balm Anonymous.

http://marijuana-anonymous.com/ - Marijuana Anonymous.

www.na.org - Narcotics Anonymous.

www.neuroticsanonymous.org - Neurotics Anonymous.

www.nicotine-anonymous.org - Nicotine Anonymous.

www.olganon.org - Online Gamers Anonymous.

www.oa.org - Overeaters Anonymous.

www.pillsanonymous.org - Pills Anonymous.

www.reanon.org - Reentry Anonymous.

www.sexaa.org - Sex Addicts Anonymous.

www.slaaonline.org - Sex and Love Addicts Anonymous.

www.sa.org - Sexaholics Anonymous.

www.sca-recovery.org - Sexual Compulsives Anonymous.

www.realfriendsandfamily.org/sa.html - Smokers Anonymous.

www.siawso.org - Survivors of Incest Anonymous.

 $www.workaholics-anonymous.org-Workaholics\ Anonymous.$

www.womenforsobriety.org - Women For Sobriety (WFS).

15

Twelve-Step Facilitation Therapy

Jeffrey B. Kingree Clemson University, Clemson, SC, USA

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WHAT IS TWELVE-STEP FACILITATION THERAPY?

In the literature on the treatment of substance dependence, authors typically refer to Twelve-Step Facilitation (TSF) Therapy as a specific, structured, and manual-based intervention that is delivered by professionals to persons with alcohol and/or other drug dependence. TSF Therapy has multiple objectives that support two overarching goals: (1) to increase abstinence from alcohol and other non-medically indicated psychoactive drugs and (2) to increase participation in Twelve-Step Organizations (TSOs) such as Alcoholics Anonymous (AA) and/or Narcotics Anonymous (NA).

The first goal of TSF Therapy is based on a conception of substance dependence as a chronic, incurable disease that is characterized by an inability to control the amount of a specific substance that is consumed. The goal of abstinence and the conception that undergirds it have generated much controversy and debate over the years. Nevertheless, they are endorsed generally

by the American public and leading health organizations in the United States and many countries worldwide. The goal and conception are supported by most relevant research. Whereas some studies suggest that controlled drinking may be possible for persons with less severe alcohol problems, most indicate that it is not a practical goal for persons with alcohol dependence. There is considerable evidence that the etiology of substance dependence is influenced by genetic or other physiological factors that lessen the capacity of certain people to control their level of consumption. Moreover, people who abstain from alcohol and drugs following substance-dependence treatment experience significant physical, psychological, and social improvements relative to those who use varying amounts of these substances in the posttreatment period.

The second goal of TSF Therapy is based on a conception that TSOs are uniquely suited to assist substance-dependent persons in achieving abstinence. Evaluating this conception empirically has been challenging as ethical and practical constraints have precluded using

randomized clinical trials (RCTs) to examine the relative effectiveness of participating in these organizations. Nonetheless, observational studies have consistently shown that participation in TSOs following substance-dependence treatment is associated with higher levels of abstinence and psychosocial functioning. These findings have emerged from studies that used objective measures of TSO participation and substance use, included long-term follow-up assessments, and controlled statistically for motivational and other potentially confounding factors.

As has been stated often by others, participating in TSF Therapy and TSOs are separate experiences. Whereas TSF Therapy is a professionally delivered and time-limited intervention designed to prepare substance-dependent persons to achieve abstinence, TSOs provide interventions that are delivered by peers in the community and designed to provide assistance for sober living on an ongoing or continuous basis. On the other hand, the two interventions share common conceptions about substance dependence and the most effective ways to address it. Because TSF Therapy is based on principles and practices of TSOs, it cannot be fully understood without adequate knowledge of the nature of these organizations.

WHAT ARE TSOs?

TSOs primarily serve people who are dependent on a psychoactive substance or who engage in some other compulsive behavior such as gambling or excessive eating. AA is the original TSO and the one on which all the others are based. It took shape in the mid-1930s in two cities (Akron and New York) in the northeastern United States. NA was established a decade or two later in Los Angeles. TSOs also exist for persons who are concerned about a family member or a friend who has a substance-dependence problem and/or who engages in some other compulsive behavior. Ala-Anon was the first TSO for significant others, founded in the early 1950s for the purpose of assisting family and friends of alcoholics.

The TSOs that target persons with substance dependence tend to be international in scope and are governed by a set of 12 traditions and a highly democratic structure. They are decentralized entities, with a central office serving a coordinating role and relatively autonomous, individual chapters located in communities throughout the world. Leadership is provided largely by participants on a voluntary, nonpaid, and rotating basis. With their emphasis on anonymity, TSOs maintain no rosters or lists of members. Moreover, they do not charge fees or require a written or verbal commitment to join. These organizations do not take public positions on controversial issues,

including those related to substance use. They have rules that prevent individuals or entities from exercising inordinate influence on any of their policies or practices.

The 12-step approach for addressing addictive behaviors advocated by these organizations has remained remarkably consistent over time. As with TSF Therapy, the 12-step approach conceptualizes substance dependence as an incurable disease or a condition that has physical, emotional, and spiritual concomitants. The approach is not preoccupied with whether the concomitants are causes or consequences of substance dependence; it is also not preoccupied with whether or not substance dependence satisfies criteria of a true disease. The approach does maintain that the continued use of substances by dependent persons will inevitably lead to more physical, emotional, and spiritual problems. The 12-step approach also holds that the best, if not the only, way that dependent persons can avoid substance use and associated problems is through ongoing participation in TSOs.

The 12 steps for AA are listed in Table 15.1. They are ordered sequentially to reflect the process of recovery. In the parlance of influential, subsequently developed psychological theories that have shaped understanding of behavioral change, Steps 1-3 are concerned with preparation, Steps 4–9 are concerned with action, and Steps 10-12 are concerned with maintenance. However, most experienced participants in TSOs report using many if not all of the 12 steps on a regular basis. The steps place a heavy emphasis on spirituality that is absent from most empirically validated theories of behavioral change. Honesty, humility, atonement, service to others, and reliance on God or a higher power are specified as ingredients for recovery. Nonetheless, participants are granted considerable latitude in interpreting the meaning of each step as well as the strategies they may use to work it. Most notably, they are allowed or even encouraged to conceptualize God or a higher power in whatever way they choose. Whereas the majority of participants in TSOs conceptualize a personal, forgiving God that is consistent with Christian precepts, others conceptualize specific worldly forces (e.g. nature, a TSO) as their higher power.

People can participate in TSOs in a variety of ways, including working the 12 steps, attending mutual help group meetings, reading organizational literature, using a sponsor, and eventually sponsoring another member. Among these different activities, meeting attendance and sponsorship have received the most emphasis by clinicians and researchers.

The meetings of TSOs are normally held in public settings such as churches, treatment centers, or hospitals. They are led by temporary chairpersons, who typically begin them by reciting a nonsectarian prayer and reading the organization's guidelines. The meetings are then

- 1. We admitted that we were powerless over alcohol that our lives had become unmanageable.
- Came to believe that a power greater than ourselves could restore us to sanity.
- 3. Made a decision to turn our will and our lives over to God as we understood Him.
- 4. Made a searching and fearless moral inventory of ourselves.
- 5. Admitted to God, to ourselves, and to another human being the exact nature of our wrongs.
- Were entirely ready to have God remove all these defects of character.
- 7. Humbly asked Him to remove our shortcomings.
- 8. Made a list of all persons we had harmed and became willing to make amends to all of them
- 9. Made direct amends to such persons wherever possible, except when to do so would injure them or others.
- 10. Continued to take personal inventory and when we were wrong promptly admitted it.
- 11. Sought through prayer and meditation to improve our conscious contact with God, as we understood Him, praying only for knowledge of His will for us and the power to carry that out.
- 12. Having had a spiritual awakening as a result of these steps, we tried to carry this message to alcoholics and to practice these principles in all our affairs.

conducted generally according to one of two formats. In the speaker format, one or two participants share their story, talking at length about their experiences with substance dependence and the TSO. In the discussion format, participants take turns talking about various topics related to substance dependence and recovery.

A sponsor is an experienced member of a TSO who provides guidance and support to another member with a typically shorter period of abstinence. The nature of this guidance and support can vary considerably depending on the expectations of members who are sponsoring or being sponsored. A sponsor serves as a resource for a member to call for advice or consultation and often provides guidance on working the 12 steps.

Several multi-item survey instruments have been developed to tap involvement in specific TSO activities. These instruments have been used in research on predictors and outcomes of TSO participation. Studies of predictors have found that persons with more severe substance dependency, higher network support for substance use, and who perceive more benefits than barriers to participating in TSOs subsequently have higher levels of participation. Studies on outcomes have found that attending meetings and using a sponsor are positively associated with subsequent levels of abstinence and psychosocial functioning.

TSOs AND PROFESSIONAL TREATMENT

AA emerged in the midst of the Great Depression and in the aftermath of the Prohibition Period in the United States. Alcoholism and other forms of substance dependence were highly stigmatized conditions that generated limited public sympathy. Most hospitals in urban areas did not welcome alcoholics for treatment but were compelled to serve those who presented acute medical issues. Treatment resources were devoted mostly to detoxification and alcoholic-related morbidity, with limited attention given to assisting alcoholics to maintain abstinence following detoxification. With its focus on maintaining sobriety, AA led to a shift in treatment emphasis from managing acute aspects of substance dependence to facilitating long-term sobriety in the community.

With its early success, the AA organization gave consideration to operating treatment programs for alcoholics. However, a policy of independence was soon adopted that declared that the organization would not become involved directly in treatment endeavors. Be that as it may, AA and other TSOs have never precluded participants from establishing or working in alcohol treatment programs. Early participants in AA were instrumental in the development of new programs that were established as separate units in general hospitals in Akron and New York City. Physicians and nurses supervised the detoxification process and attended to other medical needs that were presented by the patients. Volunteer and paid staff members who were also AA participants provided an intensive indoctrination to the AA approach through educational classes as well as individual and group counseling sessions. Patients read AA literature, attended AA meetings held in the hospital or surrounding community, and worked on the 12 steps. Sponsorship was emphasized heavily: some programs required patients to have a sponsor at the time of admission and/or would discharge patients only in the presence of their sponsors.

The 12-step approach of AA provided a treatment model that could be adopted by other programs. As news about AA spread and chapters formed in more cities, additional 12-step-based treatment programs surfaced in general hospitals and other settings (e.g. private, free-standing facilities, public psychiatric hospitals, and prisons). The additional programs tended to extend and expand on the original model established in Akron and New York City, delivering more services through a longer length of stay.

A program that was developed in Minnesota, initially at Willmar State Psychiatric Hospital and later at the private Hazelden Foundation, evolved to represent the exemplary 12-Step Model of substance-dependence treatment. As with TSF Therapy, the Minnesota/Hazelden or

12-Step Model aimed to motivate patients to accept substance dependence as an illness, abstinence as the only viable solution, and AA or other TSOs as the vehicle to achieve the solution. The program was designed for a 28-day stay, which became the standard duration of 12-step—based treatment programs. It was distinguished by a philosophy of genuine respect toward patients. Treatment was administered in a voluntary and noncoercive manner, with patients housed generally in unlocked units and not prevented or unduly pressured from discharging themselves against medical advice. Moreover, the 12-Step Model bolstered the status and potential usefulness of alcoholics by maintaining that they were uniquely qualified to help others to recover from alcoholism.

Although counselors who were active in AA or other TSOs became the cornerstones of 12-step-based programs, other recovering and non-recovering professionals were hired to assist with the emotional, spiritual, and physical concomitants of substance dependence. Many programs used family therapists to assist spouses, parents, children, and siblings who may have been affected adversely by a patient's substance use but in a position to influence his/her recovery. Other professional staff included clergy members who helped patients with spiritual aspects of the TSO approach and recreational therapists who aided patients to develop new interests and activities as alternatives to using substances.

The Minnesota/Hazelden or 12-Step Model has been evaluated empirically in diverse populations. The model has been compared to other forms of treatment in quasi-experimental and randomized experimental designs. These studies mostly have found higher rates of abstinence, psychosocial functioning, and participation in TSOs among those who received 12-step-oriented treatment.

THE STRUCTURE AND COMPONENTS OF TSF THERAPY

TSF Therapy was manualized for implementation in a large, multisite RCT known as Project MATCH, or Matching Alcoholism Treatments to Client Heterogenity. Funded by the National Institute on Alcohol Abuse and Alcoholism, Project MATCH was conducted in the early to mid-1990s for the primary purpose of determining whether specific client characteristics moderated the effects of TSF and two other treatments for alcohol dependence.

The TSF Therapy Manual developed for Project MATCH specifies that therapists deliver 12 weekly individualized sessions. Table 15.2 presents the topic, purpose, and one sample activity for each of the

sessions. Project MATCH was delivered to persons who were dependent on alcohol but not on cocaine, stimulants, or opiates and thus AA was presumed to be the most appropriate TSO for them to participate. Since the TSF Manual refers specifically to AA and not other TSOs, this description of the TSF intervention also refers only to AA. However, as described below, the TSF Manual has been used as a guiding framework in interventions with persons with other types of substance dependence who were encouraged to participate in TSOs more broadly.

The TSF Manual includes additional guidelines for therapists that are informative about the nature of the TSF intervention. The guidelines refer to therapists as "facilitators," "resources," and "advocates" of the 12-step approach. Therapists are instructed to adhere to 12-step conceptions and philosophy as well as to advocate continuously for the TSF goals of abstinence and AA participation. Therapists are advised to perceive any resistance to these goals as acts of denial and as justification for using "nonjudgmental confrontation" with the patients. That is, when perceiving resistance from patients, therapists are expected to express concerns in a direct, honest, caring, and noncritical manner. At the same time, therapists are cautioned against using heavy-handed or controlling tactics. The guidelines state that therapists do not need to be personally recovering from alcohol dependence but they do need to be knowledgeable of AA philosophy, literature, and vernacular. To be qualified to deliver the TSF intervention, therapists are expected to have attended at least 20 AA meetings and to be able to refer patients to specific meetings and potential sponsors.

Session 1

The first session provides an introduction to the TSF intervention. It has a unique format consisting of two parts. In the first part, patients are asked about their alcohol use, alcohol-related consequences, and prior attempts to decrease or discontinue drinking. It is designed to conclude with the patients being informed that their responses indicate they have developed tolerance and loss of control in relation to drinking and that these consequences are indicative of alcohol dependence. In the second part of the introductory session, patients are presented a descriptive overview of TSF Therapy with its dual goals of abstinence and AA participation.

The abstinence goal is straightforward. The manual instructs therapists that it applies to alcohol and other psychoactive substances that are not medically necessary. In contrast, the second goal is more ambiguous given the different ways and amounts that patients can participate in TSOs. The TSF Manual provides some specificity for this goal by instructing therapists to give

TABLE 15.2 Structure of TSF Therapy as Specified for Project MATCH

Session Number and Topic	Purpose	Sample Activities
1. Introduction	Stimulate clients' interest in participating in AA	Clients document their history of alcohol use and consequences
2. Acceptance	Facilitate clients' acceptance of their alcohol dependence	Clients interpret and discuss Step 1
3. Surrender	Facilitate clients' commitment to attend AA meetings	Clients interpret and discuss Steps 2 and 3
4. Getting Active	Encourage clients' involvement in different AA activities	Clients identify three desirable characteristics in a sponsor
5. Genogram	Depict intergenerational nature of alcohol dependency and its implications for clients	Clients construct a family history of alcohol dependence across three generations
6. Enabling	Increase clients' commitment to address enabling relationships	Clients are encouraged to address three enabling relationships
7. People, Places, and Things	Illuminate common risk factors for relapse in clients' lives	Clients complete a lifestyle contract detailing actions they will take to reduce relapse risk
8. Hungry, Angry, Lonely, and Tired	Continued focus on risk factors for relapse in clients' lives	Clients write a goodbye letter to alcohol
9. Moral Inventory	Promote honest self-appraisal and release guilt among clients	Clients identify their character defects and assets
10. Sober Living	Promote lifestyle changes	Clients are encouraged to set goals for nutrition and exercise
11. Conjoint Therapy	Garner partner support for clients' recovery	Partners are asked about their alcohol use and informed about AA
12. Termination	Promote continued abstinence and participation in AA	Clients are asked to make commitments to continue to participate in AA

 $Note: TSOs = Twelve ext{-step}\ organizations$

patients a list of meetings in their geographical areas of residence and to ask the patients to indicate the number of meetings they plan to attend over the ensuing week. Patients are also asked at this time to commit to read specific AA literature over the ensuing week. Therapists are instructed not to require patients to attend a specific number of meetings or to read a specific amount of literature. However, they are expected to encourage patients to attend an average of one meeting per day over a 90day period, which is consistent with recommendations made within AA itself. At a later point of the intervention, additional specificity is provided for the second goal when patients are strongly encouraged to obtain a sponsor. The TSF Manual specifies criteria for sponsors, which include being of the same sex as well as having maintained continuous abstinence for at least the preceding 12 months.

The structure of the first session conforms to value expectancy theoretical frameworks like the Health Belief Model and the Theory of Planned Behavior that have guided the implementation and delivery of numerous interventions to reduce unhealthy behaviors. TSF assumes that people who are alcohol dependent will value or favor abstinence when they are presented

with a clear, readily implemented behavioral alternative to alcohol use. Thus, the first session is structured first to sensitize alcohol-dependent patients to the need to abstain and then to present AA as a suitable or appealing mechanism through which this change can be readily achieved.

Sessions 2-11

Among the 10 interim sessions, three cover core or essential topics that are intended to be delivered to all patients immediately following the introductory session. The remaining seven sessions can cover various elective topics or repeat core topics. Additional information about the intervention is provided in the following descriptions of the sessions.

Three-Part Format

The interim sessions follow a standard three-part format. For the first part, the manual instructs therapists to conduct a review of the patients' experiences with drinking and AA participation since the prior session. Patients may be asked to share any feelings or thoughts in relation to these goals that have been recorded in journals that they are expected to use. Therapists are advised

to extend congratulations for nondrinking days and to react in nonjudgmental ways to any "slips" that may have occurred, interpreting instances of the latter as direct manifestations of the disease of alcoholism. Patients are also asked about their AA participation since the prior session, including the number of meetings attended and specific literature read. To the extent patients have participated, they can be asked about their reactions to these activities. Any patients who report negative reactions to specific meetings and/or literature should be referred to alternative meetings and readings. Any patients who report that they have not participated in AA should be queried about their reasons for this in a firm but noncoercive manner.

In the second part of these sessions, therapists present new material and activities corresponding to one of the core or elective topics. They are allowed some flexibility when presenting new material in the second part "so long as the presentation remains consistent with the AA view of alcoholism." The manual designates therapeutic activities that can be used during this part to facilitate progress toward the TSF goals.

In the third part, therapists suggest recovery tasks and activities that patients can implement in the ensuing week to reinforce the topical material and activities that are covered in each session. The recovery tasks and activities may touch on specific core or elective topics but concentrate on promoting engagement in AA. Consistent with AA practice, the manual advises therapists to present the tasks or activities as suggestions and not assignments. Patients are asked to indicate a specific number of AA meetings they will attend and specific literature they will read following each session.

Brief Description of Interim Sessions

As indicated above, Table 15.2 depicts the topic, purpose, and one sample activity for each of the interim sessions. Session 2 deals with Step 1 of AA and is designed to help patients accept that they are dependent on alcohol and need to receive external help for the condition. The manual advises therapists that acceptance often occurs in stages and encourages them to exercise patience with clients who are working through the process.

Session 3 focuses on Steps 2 and 3 of AA. It aims to facilitate surrender of self-reliance and acceptance of the AA approach. Patients are asked questions for the purposes of reminding them how they have lost control over alcohol and prompting them to contemplate the benefits of abstinence, spirituality, and the social support of AA participants.

Session 4 aims to enhance the patients' motivation to participate in AA. Therapists explain the greatest benefits accrue to those who participate fully in AA activities. Patients are encouraged to develop a supportive social network by asking participants for phone numbers and permission to call them. Many AA participants seek support, advice, and understanding through telephone conversations with other members. However, the use of the telephone for such conversations has been understudied.

Session 5, the first to cover an elective topic, leads patients through the process of developing a genogram for family alcoholism. The manual states that a genogram is intended "to reinforce the concept of alcoholism as a disease and to motivate the patient to break the cycle of addiction by working the AA program." Though producing a genogram for family alcoholism would be expected to increase patients' acceptance of their alcoholism and increase their motivation to change, it is unclear whether or not this notion has been confirmed through empirical methods. Among patients with a limited family history, the genogram exercise may serve instead to reduce acceptance of an alcohol problem and motivation to change.

Sessions 6, 7, and 8 are intended to facilitate continued abstinence and AA participation by attending to malleable risk factors for drinking that may operate in the patients' lives. Accordingly, Session 6 covers ways that significant others may have intentionally or unintentionally encouraged the patients' drinking behaviors. It may be conducted only with the patients or conjointly with their significant others. Session 7 illuminates how patients need to make changes in relation to certain people, places, and things that have contributed to their drinking. Session 8 emphasizes the importance of avoiding or minimizing adverse physical and emotional states such as hunger, anger, loneliness, and feeling tired.

Session 9 examines Steps 4 and 5 of AA, which, respectively, calls for constructing a moral inventory and sharing its contents with another person. The act of constructing a moral inventory of one's strengths and limitations is presumed to produce more self-awareness and a balanced self-concept. The act of sharing the inventory is believed to relieve guilt and to promote trust in others. However, as with the genogram, the discrete effects of performing Steps 4 and 5 have not been carefully evaluated through empirical studies.

Session 10 is aimed toward assisting patients to develop a healthy lifestyle. Patients are asked to discuss how their alcohol use harmed their diet and restricted their involvement in exercise and hobbies. Patients are also asked to set goals for proper nutrition, exercise, and hobbies.

Session 11 is used for conjoint therapy or to repeat a core or an elective topic. If conducted as conjoint therapy with a significant other, the session may focus on the need for appropriate detachment. The manual indicates that significant others can appropriately detach by allowing the alcoholic-dependent persons in their lives to experience and manage the negative consequences of their drinking. Al-Anon is described as a resource that significant others can use to cope effectively with instances of alcohol dependence among family members and friends.

Session 12

The last session provides a termination for the therapeutic intervention. Through a series of questions, patients are asked to evaluate the intervention and to reflect on how it has influenced or affected them. They are queried about ways that the experience has altered their views toward alcoholism and AA, which can illustrate specific changes that have occurred. Patients are encouraged to set goals for AA participation in the post-treatment period, which can improve the likelihood that the changes will be maintained or enhanced over time.

EVALUATIONS OF TSF THERAPY DELIVERED IN PROJECT MATCH

The TSF intervention has been rigorously evaluated through at least six RCTs. Project MATCH generated the first and most exemplary evaluation. The sample for this project included 1724 alcohol-dependent individuals who were enrolled in either outpatient (n = 772) or aftercare (n = 952) programs located in geographically diverse areas across the United States. Within each type of program, the study participants were randomly assigned to receive TSF, CBT, or Motivational Enhancement Therapy (MET) for a 3-month period. CBT was designed primarily to teach or instill skills to avoid relapse and to enhance general coping. MET was designed primarily to help patients recognize the need for change and assist them to channel their internal motivational resources for the purpose of addressing their alcohol problems.

The therapists who delivered the treatments in Project MATCH were selected to be representative of the types of therapists who would deliver these treatments in settings across the country. This feature resulted in a few systematic differences in therapist characteristics between the three conditions. Compared to therapists delivering CBT and MET, those delivering TSF were less educated and more likely to have participated in AA.

Although Project MATCH was intended primarily to test hypotheses related to treatment matching, the rigor with which it was conducted has provided the strongest test to date on the relative effectiveness of TSF in relation to its goals of promoting abstinence and AA participation. The sample was large and geographically diverse, albeit more stable socially than the population of persons who receive treatment for alcohol dependence in the United States. The therapists who worked on

the project received extensive training, supervision, and monitoring to ensure fidelity to the treatment protocols. Biological and collateral data were used along with self-reported data to assess substance-use outcomes among all participants at 3-month intervals for 1 year following treatment completion and for participants in outpatient programs at 3 years following treatment completion. Follow-up rates were excellent, with more than 90% of the participants being retained at each assessment over the first 12 months of follow-up and roughly 85% of the outpatient sample retained at the 36-month follow-up.

Effects of TSF Therapy on AA Participation

The effects of TSF Therapy on participation in AA have been investigated extensively with data from Project MATCH. The findings have shown higher levels of AA participation among patients assigned to TSF than patients assigned to the other treatments. These findings were expected given that TSF was the only one of the three treatments that advocated strongly for such participation. Notably, however, substantial proportions of the patients who received CBT and MET also participated in AA in varying degrees over the follow-up period.

Effects of TSF Therapy on Abstinence

Project MATCH compared the effects of the three treatments on two alcohol consumption variables: (1) percentage of days abstinent (PDA) and (2) drinks per drinking day (DDD). Analyses of these variables revealed no robust or consistent differences between CBT, MET, and TSF. However, when reviewing findings on these variables at specific assessment points, TSF performed somewhat better than the other treatments in the analyses of PDA scores. Accordingly, participants who received TSF had significantly higher PDA scores than those who received CBT or MET in the aftercare sample at the 15-month follow-up as well as in the outpatient sample at the 36-month follow-up. The effects of TSF Therapy on abstinence at these assessment points were found to be at least partly mediated by AA participation (i.e. participants in TSF had higher rates of abstinence as a result of participating more in AA).

The relative benefits of TSF on PDA as opposed to DDD are sensible when considering the emphasis placed by TSF and AA on total abstinence as an essential goal. Discussions that occur in the TSF sessions as well as AA meetings and literature focus on strategies to avoid the first use of alcohol. Controlled use of alcohol is antithetical to AA precepts, and participants are discouraged from considering it as a viable possibility. The delayed effect of TSF on abstinence also seems sensible when considering that TSF was the only one of the three interventions that promoted continued use

of an abstinence-oriented, community-based resource following treatment completion.

Patient Characteristics as Moderators of TSF Therapy

Project MATCH assessed numerous patient characteristics as potential matching variables, or moderators of treatment effects, on PDA and DDD. Ten of the matching variables were designated as primary and 11 as secondary. Two reliable patient characteristic × treatment interactions involving the TSF outpatient sample have emerged in reported analyses of the primary matching variables. First, among patients with low psychiatric severity, PDA scores at the 15-month follow-up were higher for TSF than for CBT. Second, among patients who had social networks that were highly supportive of drinking at baseline, PDA scores were higher at the 15- and 36-month follow-up in TSF than in MET, and higher in TSF than CBT at the 36month follow-up. Among the different patient characteristics examined as secondary matching variables, only one (i.e. degree of alcohol dependence) was found to moderate the effects of TSF aftercare treatment on PDA and DDD. More specifically, aftercare patients with high alcohol dependence had better outcomes when treated with TSF than CBT; conversely, aftercare participants who were relatively low in alcohol dependence had better outcomes with CBT than TSF.

In terms of outpatient treatment, the findings indicated that TSF was more effective than the other treatments for persons who had low levels of psychiatric severity, high levels of alcohol dependence, and social networks characterized by high levels of alcohol use. These findings are logical when considering the nature of alcohol dependence and TSF's emphasis on total abstinence and participation in TSOs. Accordingly, alcohol dependence is a chronic condition that is remitted by practicing abstinence. People who are in remission from alcohol dependence continue to face the threat of relapse to drinking. The threat of relapse is larger among persons who are more severely dependent. Participation in TSOs includes activities that promote continuous vigilance to this threat. These activities provide opportunities to interact in an alternative social environment, but they may contribute to anxiety among persons with high psychiatric severity.

EVALUATIONS OF TSF THERAPY IN OTHER RCTs

Since the outcome data were disseminated from Project MATCH, results have been published from at least five other RCTs that compared TSF with CBT or a related form of psychotherapy as treatments for substance dependence. The subsequent RCTs have differed methodologically from Project MATCH in significant ways. First, the subsequent RCTs have been conducted with smaller samples and have experienced more attrition, thereby resulting in less statistical power than in Project MATCH. Second, the subsequent RCTs have recruited samples from specific geographic areas and thus have been less geographically representative than the one in Project MATCH. Third, the patients in the subsequent RCTs have possessed a comorbid condition (e.g. major depression, opiate dependence, cocaine dependence, domestic violence perpetration) that was one exclusion criteria in Project MATCH. Fourth, the subsequent RCTs have addressed the comorbid conditions with various interventions (e.g. antidepressant medications, methadone maintenance (MM), exercises to control violent tendencies) that were not provided in Project MATCH. Fifth, the treatments delivered in three of the subsequent RCTs have varied in intensity and length from Project MATCH, with one including 10 weekly sessions and two including more than 12 sessions delivered over periods longer than 12 weeks. Sixth, the level of training of therapists has varied across the subsequent RCTs as well as systematically between conditions in the same RCT, with the latter introducing a potential confound that was not present in Project MATCH. Seventh, the format for delivery of TSF and comparison therapies also has differed across the subsequent RCTs: two trials used individual sessions exclusively as was done in Project MATCH, two used therapeutic groups alone, and one combined therapeutic groups and individual sessions. Eighth, the assessment strategies in the subsequent trials have diverged from Project MATCH as well as among themselves, with some reporting posttest but no follow-up results, some not reporting any results for biological measures of substance use, and some not reporting if TSF had any effect on participation in TSOs. Even though these methodological variations constrain comparisons of results between the subsequent RCTs and Project MATCH, as well as among the subsequent RCTs themselves, they have expanded knowledge regarding the effectiveness of slightly varied forms of TSF for persons with different types of substance-dependence and comorbid conditions.

The first of the subsequent RCTs to publish results was conducted in New Haven, Connecticut. It included a sample of 122 patients who were diagnosed with cocaine dependence as well as alcohol dependence or abuse. This RCT had five conditions: (1) TSF with disulfiram, (2) TSF without disulfiram, (3) CBT with disulfiram, (4) CBT without disulfiram, and (5) disulfiram with clinical management (CM). Disulfiram, which is a medication that has been prescribed for alcoholism for more than 50 years, produces adverse physical

reactions (e.g. nausea, headache) in persons who consume alcohol. The CM condition provided nonspecific psychotherapy primarily for the purpose of promoting adherence to disulfiram. Post-baseline assessments of PDA for cocaine and alcohol occurred at the end of treatment (i.e. 3-month posttest) and at a 12-month follow-up assessment. Patients who received TSF reported longer periods of sustained abstinence from cocaine, but not from alcohol, at posttest relative to those who received CM. On the other hand, patients who received TSF did not differ from those who received CM on abstinence from cocaine or alcohol at the 12-month follow-up. Moreover, patients who received TSF did not differ from those who received CBT on abstinence at any of the assessments. Although the published findings did not include any data related to participation in TSOs at posttest, results did indicate no significant differences in meeting attendance between the three conditions at the follow-up assessment.

Another RCT conducted in New Haven compared TSF and CBT among 75 alcohol-dependent individuals who had been arrested for domestic violence in the preceding year. The content of these interventions was based largely on the manuals used in Project MATCH, with some modifications made for addressing issues related to domestic violence. Data on substance use and physical violence were collected from the patients during treatment as well as at 12 and 24 weeks posttreatment. Analyses revealed that patients who received CBT reported more PDA from alcohol during treatment relative to those who received TSF. However, participants in the two conditions did not differ on PDA or biological measures of drug use collected during treatment and also did not differ on the PDA measures of alcohol use or drug use collected in the posttreatment assessments. Similarly, the analyses of measures of physical violence revealed no differences between the conditions during or following treatment. No comparative data on participation in TSOs have been published from this project.

A third RCT to publish findings after Project MATCH compared TSF and relapse prevention (RP) as aftercare interventions in a sample of 131 patients who had completed an intensive residential or outpatient treatment program for substance dependence in Montreal. The RP intervention was designed to provide patients with cognitive and behavioral skills that they could use to refrain from using substances in risky settings. Both the TSF and RP interventions were delivered in 10 weekly sessions, each lasting 90 min, to small groups comprising four to eight patients. The primary analyses examined the extent to which patients were working the 12 steps and abstaining from alcohol at a follow-up assessment, which occurred 4 months after the patients had completed one of the aftercare interventions. The

results revealed no significant differences in working the 12 steps or in abstinence rates between patients in the TSF and RP interventions. Secondary analyses showed that patients with elevated levels of psychological distress had higher rates of abstinence when treated in TSF than in RP, which conflicted with the findings of Project MATCH.

A fourth RCT following Project MATCH compared TSF and Integrated CBT (ICBT) in a predominately male sample of 148 patients recruited from an outpatient psychiatric program operated by the Veterans Administration in San Diego. In addition to being randomly assigned to either TSF or ICBT for treatment of substance dependence, each patient was administered psychotropic medication for the treatment of major depression. The TSF and ICBT treatments were delivered to small groups over a 24-week period in two phases of equal length. The first phase included 24 sessions that were delivered twice weekly. The second phase included 12 weekly sessions that were largely designed to review and reinforce topics covered in the first phase. The primary outcome variables were assessed with relatively low attrition at the midpoint and the end of the 24-week treatment period. The analyses found that clients who received TSF had higher levels of PDA and participation in TSOs, and lower levels of depression, at mid-treatment and posttreatment relative to clients who received ICBT. The results for depression may have been tied directly to the higher levels of PDA for clients in the TSF condition, but this has not been reported in the literature. Whether these findings endured into the posttreatment period also does not seem to have been reported.

A fifth RCT to publish findings subsequent to Project MATCH compared the effectiveness of TSF and Acceptance and Commitment Therapy (ACT) in 138 opiatedependent patients in Reno, Nevada. Each of the patients was receiving clinic-administered methadone, which is a synthetic opiate that blocks cravings and other effects of withdrawal without producing the intense euphoria of other opiates. Both the TSF and ACT interventions were composed of 32 individualized sessions and 16 group sessions that were delivered over 16 weeks, with 16 of the individual sessions in TSF being delivered by the patients' sponsors. The study design allowed for comparing the two interventions against a randomly determined, control condition of patients that was provided only MM. Biological and selfreported outcome measures of drug use, as well as self-reported outcome measures of psychosocial functioning, were assessed at a 24-week follow-up, or 8 weeks following the conclusion of treatment. Analyses of the outcome variables revealed that participants in TSF and ACT had less drug use than those who received MM only but did not differ between themselves. On the other hand, analyses of the self-reported drug use, psychological distress, and social adjustment measures found that the two interventions did not differ in effects from MM or themselves at the follow-up assessment. Findings related to participation in TSOs appear not to have been reported.

CONCLUSIONS

Although the manual for TSF Therapy was created for Project MATCH in the early 1990s, the guiding principles and practices included in it have been exerting a leading influence on the delivery of substance-dependence treatment at least since the 1950s. This chapter describes these principles and practices, highlights their origins in AA, and reviews findings from projects that have examined the effects of TSF Therapy on one or both of its primary goals of promoting abstinence and participation in TSOs.

Among the six projects reviewed in the chapter, Project MATCH used the most rigorous methodology. Increased participation in AA occurred across the three therapeutic interventions, even though this outcome was not an explicit goal of CBT or MET. Because recipients of different types of substance-dependence treatment are apt to increase their participation in AA or other TSOs, and because such participation is strongly associated with abstinence, it is difficult to detect unique effects for TSF in relation to its primary goals. Nonetheless, at least some superior outcomes for TSF were reported in three of the six projects that examined abstinence and three of the four projects that examined participation in TSOs. In contrast, only one of the projects found more improvement in abstinence in CBT than TSF, and this advantage did not persist into the posttreatment period. Unsurprisingly, none of the four projects that examined participation in TSOs found benefits for the CBT-related treatments relative to TSF.

Abstinence appears to be the most appropriate goal for substance-dependence treatment as it is associated with marked improvements in physical, social, and psychological functioning. Participation in TSOs also appears to be an appropriate goal for substancedependence treatment as it is associated consistently with higher levels of abstinence. The Project MATCH Manual for TSF Therapy outlines specific strategies for increasing such participation, and these were generally found to be effective for this purpose in the evaluations reviewed in this chapter. However, there are practical obstacles to the widespread use of these strategies in treatment programs, primarily in terms of costs. With recognition of this, several researchers recently have developed brief TSF interventions that reinforce the need for abstinence and participation in TSOs. Evaluations of these efforts have illuminated the value of linking clients directly with active members who can provide assistance, while also suggesting that sustained participation probably cannot be achieved through a single-session intervention.

List of Abbreviations

AA Alcoholics Anonymous

ACT Acceptance and Commitment Therapy

CBT Cognitive Behavioral Therapy

CM clinical management

DDD drinks per drinking day

ICBT Integrated CBT

MET Motivational Enhancement Therapy

MM methadone maintenance

NA Narcotics Anonymous

PDA percentage of days abstinent

RCTs randomized clinical trials

RP relapse prevention

TSF Twelve-Step Facilitation

TSOs Twelve-Step Organizations

Glossary

Discussion format one of the two general formats used in support group meetings of TSOs, whereby participants take turns talking about issues associated with substance dependence.

Disease concept the notion of substance dependence as a disease with physical, emotional, and spiritual symptoms that is progressive unless arrested through abstinence.

Genogram an exercise used in TSF Therapy, whereby patients identify cases of substance dependence among family members for the stated purpose of reinforcing the notion that substance dependence is a disease.

Higher power a term used by participants in TSOs to refer to God or other potentially healing force that operates in the universe.

Minnesota Model/12-Step Model an approach to substancedependence treatment that prescribes abstinence from alcohol and other drugs through continuous participation in TSOs.

Moral inventory a specific exercise used in TSOs, TSF Therapy, and 12-Step Model Programs, whereby persons identify their strengths and weaknesses (Step 4) and disclose them to another person (Step 5).

Speaker format one of the two general formats used in support group meetings of TSOs, whereby one or two participants talk at length about their experiences with substance dependence and TSOs.

Sponsor an experienced participant in TSOs who provides support and guidance to less experienced participants.

Further Reading

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Faith-Based Substance Abuse Programs

Geoffrey C.B. Lyons, Frank P. Deane, Peter J. Kelly Illawarra Institute for Mental Health, University of Wollongong, Wollongong, NSW, Australia

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Faith-based organizations have historically played an important role in supporting people, and their families, experiencing substance use problems. As governments increase their outsourcing of substance abuse resources to non-government agencies, the role of these faithbased organizations is becoming increasingly important. In conjunction with this, outsourcing is a growing demand for faith-based organizations to be economically accountable and adopt evidence-based practices. Thus, there is an increasing need to understand the mechanisms and importance of religious or spiritual components of treatment in relation to recovery outcomes. However, there is great diversity in the way faith-based organizations express and utilize their faith in the provision of substance abuse treatment. These differences complicate attempts to define what constitutes a "faith-based" program and understand how relevant "faith" is to treatment.

Faith-based programs can generally be understood to lie on a continuum. At one end of the continuum are

treatment services that are essentially "faith-based" in name only, using secular treatment approaches and only being linked to faith through administrative relationships with a larger religious organization. On the other end of the continuum are the more religiously driven service providers, using treatments that are based only on religious material. Overall, the ways in which faith-based organizations integrate "faith" into their services can be generalized into the following categories: (1) religious affiliated providers whose treatment content is completely religious, (2) religious affiliated providers who amalgamate religious and non-religious treatment content, (3) religious affiliated providers whose treatment is secular but whose organization's values are religious, and (4) treatment providers who are affiliated with a religious organization but use secular treatment components and are minimally influenced by the affiliated religious organization. A broad range of religions provide faith-based treatment services (e.g. Islamic and Native American), but there is very little empirical work written outside of Christian-based services. Subsequently, Christian substance abuse agencies are by far the most common and are the focus of this chapter.

THE STRUCTURE OF FAITH-BASED TREATMENT PROGRAMS

Christian faith-based programs can be distinguished from secular services primarily by a unique Christian theory of addiction. This theory acknowledges the role of biological, environmental, and psychological determinants but fundamentally views substance abuse as a sin that both results from and maintains a person's separation from God. Christianity teaches that sin is overcome through an acceptance of Jesus Christ and a subsequent process of sanctification. Sanctification is broadly considered to be a progressive growth in holiness that occurs as one commits to the Christian faith and connects with God, Christ, and the Holy Spirit. Hence a relationship with Christ as the driving force in the recovery process is central to the Christian theory of addiction. Thus, both patients and providers of faithbased programs often passionately emphasize that it is the salutary role of Christ in the treatment process that ultimately differentiates their program from other secular approaches.

A limited number of studies have attempted to contrast faith-based substance abuse treatment programs with secular programs. These studies have generally found that the structure of faith-based programs is often common to secular programs. Dimensions of treatment that are common to both secular and faith-based programs include the provision of detoxification services, group therapy, the provision of work opportunities, and referrals to health-care providers and social support services. Additionally, as with secular programs, faith-based programs may be residential or outpatient based, and participants are usually free to discharge whenever they please. Faith-based service fees are often minimal, if any, so they often service individuals from lower socioeconomic backgrounds. Though the majority of faith-based programs are Christian, they usually also provide treatment to individuals with non-Christian views. Faith-based programs can be differentiated from secular programs by their use of spiritual activities that are designed to cultivate a relationship with the divine. These can include chapel or religious services, group and private prayer sessions, pastoral counseling, and bible study. These activities are also used to foster cohesion within the therapeutic community, which plays an important role in the faithbased recovery process.

One of the major treatment approaches that blurs the lines between faith-based and secular programs are the Twelve Steps of Alcoholics Anonymous (AA).

THE TWELVE STEPS OF AA AND FAITH-BASED ORGANIZATIONS

The Twelve Steps of AA are one of the primary frameworks of substance abuse treatment used today. Much of the empirical research about spirituality and recovery is related to Twelve Step-treatment approaches, so an overview of this theory is highly relevant to any discussion of faith-based treatment approaches. The founders of the Twelve Steps were members of the Christian-based Oxford Group, so there are many similarities between the Christian and Twelve Step theories of substance abuse. In particular, as with the Christian theory, Twelve Steps approaches acknowledge the role of biological, psychological, and sociological determinants in substance abuse, but conceptualize substance abuse as a spiritual disorder. Specifically, the Twelve Steps theorize that dependence occurs when a person's inherent relationship with God (also known in AA as a "Higher Power") has been replaced by substance use. The concept of "character flaws," such as resentment, pride, and laziness - which were based on the seven deadly sins of Christianity – are theorized to both result from this spiritual void and contribute to it by inhibiting treatment engagement and maintaining substance abuse. Thus, Twelve Step programs focus on reconnecting a substance abuser with their Higher Power and, through the experience of a spiritual awakening, transcend the character flaws that maintain the addiction. Hence, just as the Christian approach focuses on acceptance and sanctification through Christ, the Twelve Steps focus on spiritual surrender and transformation through a Higher Power.

Though spirituality is central to the Twelve Steps, AA fellowships are not affiliated with religious institutions. There is also a great deal of variation in the way they use spirituality in their treatment. For example, some AA fellowships are essentially secular, even substituting the Higher Power for a secular conceptualization such as the group itself, while others maintain the theistic conceptualization of the Higher Power. Thus, some AA fellowships lean more heavily toward a faith-based definition while others are closer to being secular programs. Overall, there is a trend within the empirical literature to consider AA fellowships as being more closely aligned with faith-based services than secular, though in reality they do not neatly fit either distinction.

AA fellowships can often be confused with other treatment approaches that are not specifically affiliated with AA but incorporate the Twelve Steps into treatment. In

particular, Twelve Step Facilitation programs and "Twelve Step-based" treatments are frequently mistaken as AA fellowships. Twelve Step Facilitation is a manualized intervention designed to facilitate AA involvement while Twelve Step-based treatments generally combine the Twelve Steps with other treatment approaches. Often, these Twelve Step-based treatment programs may use the Twelve Steps as a foundation to treatment while also integrating secular (e.g. empirical psychotherapies) or religious (e.g. Christian theology) theories and components. Because of the similarities between the Christian and Twelve Step theories of substance abuse, many Christian faith-based treatment programs are able to combine the Twelve Step framework with their Christian values (e.g. promoting Jesus Christ as the Higher Power of the Twelve Steps). Empirical research has shown the Twelve Steps to be an effective treatment approach and so this integrative approach helps legitimize the inclusion of spirituality within treatment. The integration of faith-based approaches (such as Twelve Steps) into secular programs and the use of secular approaches in faith-based treatment programs, makes clarifying the relative treatment effectiveness of faith-based programs and their elements a challenge.

EMPIRICAL RESEARCH AND FAITH-BASED SUBSTANCE ABUSE PROGRAMS

Research on spirituality and substance use disorders is generally considered to be limited in scope. Though there is probably more research on the topic than is generally acknowledged, several issues do hinder the progress in this area. Firstly, and possibly most importantly, research is generally inhibited by the lack of guiding theories - so systematic research is rare. Rather, studies often investigate isolated hypotheses or take broad exploratory approaches. Results are rarely tied together in the context of a unified theory. As a result, research is fragmented and not as progressive as it otherwise might be. Secondly, both "spirituality" and "recovery" are difficult constructs to define and their many dimensions may interact in a variety of complex ways. Thirdly, empirically trained scholars interested in the mechanisms of behavior change often hold secular attitudes and overlook or minimize the potential influence of spirituality and religiosity in the recovery process. Matters of spirituality or religion are rarely a part of undergraduate or postgraduate behavioral science curricula and are often seen as being more suited to philosophy or theology. Thus, scholars whose primary interest is religion or spirituality rarely publish in the substance abuse field. Fourthly, substance abusers participating in research may also be suffering withdrawal symptoms and have long histories of abuse and potential cognitive impairments. These factors may impair their ability to reliably participate in research. Finally, it can be difficult to differentiate the effects of spiritual development from the effects of program participation and commitment. Despite these barriers research is progressing in the field across three broad fronts. Firstly, early research focused on establishing a negative relationship between religiosity and substance use behaviors. Secondly, research has explored the effectiveness of faith-based programs. Thirdly, research has begun to explore how religiosity and spirituality may operate on recovery-based outcomes. Each of these will be briefly discussed.

Religion and Spirituality as "Buffers" against Substance Abuse

Religion is associated with numerous positive physical and psychological health benefits, including decreased rates of cardiovascular disease, hypertension, depression, suicidality, and mortality rates. Religion and spiritual beliefs and practices are also negatively related to substance use. Though alcohol and other substances can be used in some religious services (e.g. the use of wine in the Christian Eucharist), the majority of religions denounce intoxication. Individuals who are very religious or spiritual may more frequently engage in practices that support their spirituality, such as church service attendance, prayer, meditation, scripture reading, and bible study. Ideally, the very nature of these activities requires the individual to be calm, open to experience, cognitively alert, and selfdisciplined. While intoxication can certainly calm an individual it also inhibits the cognitive abilities and affective states required for serious spiritual practices. Thus, individuals who are more religious or spiritual often have lower rates of substance use and so, within the empirical literature, religion and spirituality are generally considered to protect an individual from substance abuse. This in turn has provided further rationale for research into the role of religion and spirituality in the treatment of substance abuse.

The Effectiveness of Faith-Based Programs

Researchers have explored whether faith-based programs (usually Twelve Step programs) are effective treatment options. A limited number of multisite clinical trials exploring the outcomes of Twelve Step Facilitated, Cognitive Behavioral, or Motivational Enhancement residential programs have been conducted. Results suggest that clients generally have significant improvements in their substance use

behaviors and psychosocial functioning after discharge, irrespective of program structure. However, it has also been demonstrated that patients from the Twelve Step programs can have significantly higher levels of post-treatment abstinence. This is possibly a result of the Twelve Step philosophy which emphasizes complete abstinence, as opposed to the controlled drinking/usage philosophy adopted by many secular programs.

The use of post-discharge social support systems also plays an important role in maintaining recovery. Participation in outpatient self-help groups after discharge can help validate and normalize the difficulties associated with maintained abstinence. Clients who engage with Twelve Step fellowships after discharge not only have significantly greater chances of long-term abstinence, but are also significantly less likely to utilize professional services (e.g. counselors or psychologists) after treatment in comparison to those who participate in Cognitive Behavioral programs. Furthermore, though they use less professional services, Twelve Step clients have been shown to still maintain the same level of psychological wellbeing as seen in those who do rely heavily on health professionals. This may be because the support provided from participation in Twelve Step self-help fellowships after discharge substitutes the support that is otherwise obtained from professional health services. As a result, the total cost of care for Twelve Step programs can be significantly less than Cognitive Behavioral programs.

Thus, research currently suggests that Twelve Step programs can be as effective as secular programs and potentially more cost effective. Whether this research applies to Christian faith-based programs that are not Twelve Step-based remains unclear.

Mechanisms of the Spirituality–Recovery Relationship

In addition to explorations of effectiveness, research has also investigated the mechanisms by which religious participation and spirituality may affect recovery. Particularly relevant themes include the role of spiritual development, spiritual maturity, and spiritual experiences on recovery outcomes; religious coping in substance abuse treatment; the relationship between purpose in life and recovery outcomes; and psychological well-being and recovery.

Spiritual Development and Spiritual Awakenings in Substance Abuse Treatment

The Twelve Step and Christian theories of addiction theorize that an absence of God is central to a substance use disorder. Therefore, faith-based programs often focus on developing a relationship with the divine. Central to this aim is the assumption that spirituality can change during participation in substance abuse treatment programs. In support of this, scholars have highlighted the role of spiritual development and spiritual awakenings in the recovery process. Longitudinal research has shown that though not all faith-based clients experience a spiritual awakening, those who do have a significantly higher chance of prolonged abstinence. Furthermore, other dimensions of spirituality, such as spiritual beliefs, spiritual practices, spiritual maturity, and the day-to-day experiences of a spiritual life (e.g. feeling a loving connection with God, feeling supported by God, drawing inner strength from one's faith) have all been shown to increase after participation in faith-based treatment and be associated with improved recovery outcomes. Additionally, individuals who relapse after treatment also tend to experience significantly greater decreases in spirituality constructs, such as spiritual experiences and maturity. This suggests that research and faithbased treatments may need to focus not just on cultivating spirituality and spiritual awakenings, but also teaching strategies for maintaining spiritual gains post-treatment.

Religious Coping and Faith-Based Treatment

Trauma, psychopathology, unemployment, degradation of family and social systems, and inefficient stress management strategies are all positively associated with substance use disorders. In fact, substance abuse itself is often an ineffective coping strategy for stress and adversity. Faith-based programs invite clients to replace dysfunctional substance use coping strategies with religious ones. There are a variety of ways that a person's religion may help them cope with distress, both functional and non-functional. For example, positive ways of coping via religion may include viewing God as loving and forgiving, seeing adversity as part of God's plan, trusting that God will provide support and guidance, drawing support from religious communities, or using prayer to sooth affective arousal. Negative coping strategies may include seeing God as negative and punishing; blaming the devil for adversities; pleading with God for miracles; arguing with others about faith, God, and religion; or abandoning religion and spirituality altogether. Research has shown that use of negative coping strategies is associated with poorer psychological health and psychopathology. Individuals who adopt negative religious coping strategies may also manage stress and adversity less effectively. In contrast, positive religious coping is associated with improved physical and psychological health. In the context of substance abuse treatment, research exploring the role of religious coping is in its infancy. It has been found that participation in faith-based programs increases the adoption of positive religious coping strategies. It has also been demonstrated that individuals who use positive religious coping strategies also have longer histories and higher frequencies of attendance at AA self-help groups. This implies that participation in Twelve Step fellowships increases one's use of positive religious coping – potentially through the spiritual transformation process. Religious coping is also positively correlated with abstinence self-efficacy and negatively associated with cravings and post-treatment substance use. Subsequently, the increase in religious coping that occurs via participation in faith-based programs may operate on substance use behaviors by increasing abstinence self-efficacy and reducing cravings. However, because the research is limited it is difficult to draw any definitive conclusions. For example, some researchers have failed to find associations between religious coping strategies and reduced substance use behaviors. Research also shows that religious coping strategies are not always negative or positive; often their functionality is dependent on the situation at hand. Thus, research findings must be treated as preliminary. The adoption of religious coping strategies in faith-based substance abuse treatment, which strategies are most effective for which issues, and how they operate on substance abuse is still a relatively unexplored area of research.

Meaning and Purpose in Life in Substance Abuse Treatment

The theologies and philosophies underlying religious traditions shape peoples' beliefs and ways of understanding the world. Thus, religion and spirituality have a profound impact on peoples' values, purpose in life, and behaviors. It is not surprising then that the experience of being in a faith-based program can dramatically affect how substance abusers understand their life history and current life circumstances. For example, Christian theology has many explanations for why suffering exists and its function in a person's life. Suffering exists because the person lives in a "fallen world" (a world corrupted at every level by sin) and because God is absent in their lives. Suffering also acts as an invitation to reconnect with God and his divine purpose, which in turn results in personal growth. Thus, an introduction to Christian theology can help validate and explain the sufferings associated with a life of substance abuse (e.g. loss of relationships, career, finances, health, and self-respect), potentially allowing the substance abusers to accept and appreciate the struggles associated with their addiction. (The process of coming to an acceptance and appreciation of suffering through an exploration of Christian theology is based on anecdotal evidence and needs to be empirically validated.)

Because of the centrality of meaning and purpose in life in religion, research has begun to explore their role in the spiritual-recovery relationship. Less purpose and meaning in life has been associated with alcohol use, cocaine use, heroine use, depression, resentment, and suicidal ideation. Purpose in life is significantly lower in alcoholics compared to non-alcoholics. Purpose in life is also negatively associated with post-treatment drinking and drug use and mediates a relationship between depression and alcohol use. Research has also shown that purpose in life can significantly increase after participation in residential treatment programs and is predicted by an individual's daily spiritual experiences and feelings. This implies that the day-to-day experiences associated with a person's spirituality (e.g. feeling loved by God) can promote greater levels of purpose in life and through this less substance use. This provides some support for the underlying theology and theories used in faith-based substance abuse programs: that a reconnection with God fills the spiritual void inherent in substance abuse and reduces substance use behaviors by giving the person purpose in life. However, it is important to note that purpose in life alone may be insufficient for producing sustained recovery. Research has also demonstrated that purpose is ineffective if the individual does not have the skills to manage or attain the desired goal. In these cases, a sudden growth in purpose in life has the potential to merely produce over confidence and set the individual up for failure and future hardships. Treatment providers must therefore be aware of the need to establish appropriate skill sets alongside religious/spiritual education if they are to maximize the benefits drawn from a spiritually based purpose in life. The cultivation of meaning and purpose in life in substance abusers via the religious conversion/spiritual awakening process is one of the growing areas for future research.

Spirituality and Psychological Well-Being in Substance Abuse Treatment

Among substance abusers, religious faith and spirituality are positively associated with indicators of psychological well-being, including optimism, social support, hardiness to stress, and life satisfaction. They are also negatively correlated with indicators of poor psychological well-being and psychopathology including trait anxiety, depression, resentment, and stress. Correlations between religion, spirituality, and psychological well-being indicators, such as these, tend to be in the low to moderate strength range, suggesting there is some degree of variability in the degree to which they may affect (or be effected by) psychological well-being.

Forgiveness is also an indicator of psychological well-being, being negatively associated with anger,

resentment, and depression, and also central to Christianity and the Twelve Steps. Hence, interest in how or if forgiveness is associated with a spirituality-recovery relationship has greatly increased. There are several types of forgiveness, including forgiveness of others, self-forgiveness, receiving forgiveness from others, and receiving forgiveness from God, but at their core they all involve the purposeful releasing of anger and resentment (whether it be directed at others or self). Currently, there is little research on the role that feeling forgiven by others or God has on a recovery from substance abuse. What is known is that a client's spirituality can predict the degree to which they feel forgiven and that feeling forgiven in turn predicts lower levels of resentment and greater purpose in life. How this directly contributes to substance use behaviors after treatment is unclear.

Research has predominately explored forgiveness of others and forgiveness of self. What is supported by current research is that forgiveness of others and forgiveness of self can be predicted by a person's level of spirituality, can increase during participation in faith-based treatment, and are negatively associated with resentment. This suggests that as people in treatment explore their faith and become more religious or spiritual they may also become more forgiving of others and themselves. Furthermore, forgiveness of self and forgiveness of others are associated with a reduction in the negative consequences of drinking, prolonged abstinence, and improved mental health. Generally, forgiveness of others is more strongly associated with anger and hostility, whereas forgiveness of self is more consistently associated with anxietybased symptomatology (e.g. anxiety, somatization, obsessive compulsive measures). In particular, selfforgiveness has emerged as being at least as influential on recovery outcomes as forgiveness of others (which has traditionally been the emphasized type of forgiveness).

Substance abusers are highly stigmatized and it has been theorized that the anger, resentment, and pride that often hinders engagement in treatment and degrades social systems may actually be a defense against the shame associated with stigmatization. Thus, treatment that focuses on reducing shame and low self-esteem via increasing self-forgiveness may help promote recovery.

SUMMARY OF THE EMPIRICAL LITERATURE ON FAITH-BASED PROGRAMS AND SPIRITUALITY

Spiritual-based treatment programs can be as effective, and potentially more cost effective, than secular

programs. Furthermore, the empirical evidence suggests that spirituality can develop during brief treatment periods and that the development of spirituality, the experience of a spiritual awakening, spiritual maturity, and daily spiritual experiences can all be positively associated with recovery outcomes. Because spirituality and recovery are multidimensional constructs there are likely to be many ways in which the two are associated. This complicates the task of determining how spirituality within a faithbased program operates on recovery. What has been empirically demonstrated is that spirituality may operate through purpose in life, forgiveness, optimism, self-worth, social support, resilience to stress and anxiety, as a comforter in time of distress, and through improved self-efficacy. However, it is important to note that the majority of the findings supporting these mechanisms have not been replicated and should be considered preliminary. Furthermore, correlations and predictive relationships tend to be reliable but at a low to moderate strength. Additionally, though Christian faith-based programs are one of the most common treatment options for substance misuse, most of the research available relates to Twelve Step programs. There is a real need to research spirituality within the context of Christian faith-based programs and to determine if the psychological benefits of religion and spirituality are unique to clients of these programs or common to all individuals recovering from substance abuse. Nevertheless, faith-based programs appear to be a valid treatment option for individuals with substance use disorders and produce psychological well-being and reduced substance use behaviors that are equivalent to secular approaches.

SEE ALSO

Health Care Reforms and Treatment for Substance Use Disorders, Improving the Quality of Addiction Treatment, Evaluating Treatment Efficacy, Evidence-Based Treatment, Motivational Enhancement Approaches, Cognitive Behavioral Therapies, Twelve-Step Facilitation Therapy

Glossary

AA Alcoholics Anonymous

Abstinence self-efficacy the degree to which a person believes that they will be able to abstain from substance use even in the face of adversity.

Cognitive behavioral therapy a psychological treatment approach that aims to improve functionality by addressing a person's thought processes and behaviors.

FURTHER READING 153

- **Daily spiritual experiences** the day-to-day experiences and feelings associated with a person's religious faith or spirituality.
- **Motivational enhancement therapy** a therapeutic treatment that aims to facilitate behavior change by resolving ambivalence and increasing motivation.
- **Recovery** a reduction in the symptoms of substance use disorders and an improvement in psychological and physiological well-being that results in a return to functional normality.
- **Religion** a formalized and institutionalized method of cultivating spirituality.
- **Sanctification** a growth in holiness that occurs in conjunction with a deepening of the Christian faith.
- **Spirituality** the thoughts, feelings, experiences, and behaviors that develop from a search for and connection with the sacred.
- **Spiritual awakening** a sudden or gradual transformation of character that results from an individual's spiritual exploration and/or experiences.
- **Spiritual maturity** often resulting from a dedication to spiritual growth or exploration, spiritual maturity is characterized by an ability to draw support and security from one's faith while also being open and accepting of another's faith.
- **Twelve Steps** the Twelve Steps of Alcoholic Anonymous is one of the most prolific models of substance abuse treatment. It proposes that substance abuse can be overcome by following 12 sequential steps, commencing with a spiritual surrender to God.
- **Twelve step facilitated** a manualized therapeutic intervention that is designed to facilitate involvement in the Alcoholic Anonymous treatment approach.

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Behavioral Treatments for Smoking

Sheila M. Alessi*, David M. Ledgerwood\$

*Calhoun Cardiology Center – Behavioral Health, University of Connecticut Health Center, Farmington, CT, USA

\$Wayne State University School of Medicine, Detroit, MI, USA

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INTRODUCTION

Cigarette smoking is a leading preventable cause of morbidity and premature mortality around the world. In the United States, the smoking prevalence rate in adults is estimated from 20 to 22% and one in five smokers die from smoking-related illness. Worldwide, about a third of adults smoke and 1 in 10 smokers die from related illness. Illnesses causally linked to smoking include cardiovascular disease, lung disease, many cancers, reproductive effects, and other adverse health consequences. Moreover, the increased smoking-related morbidity and mortality extends to nonsmokers regularly exposed to secondhand smoke. For instance, there are approximately 50 000 deaths related to secondhand

smoke each year in the United States. Infants and children living in homes where parents smoke experience increased risk of respiratory illnesses, asthma, and sudden infant death syndrome. The annual economic cost of smoking is approximately \$96 billion in healthcare costs and \$97 billion in lost productivity in the United States; clearly, a global perspective magnifies costs substantially. Over a lifetime of smoking, the financial toll is an estimated US \$33 per pack for the smoker, \$5.56 per pack for the smoker's family, and \$1.44 per pack for the society. Undeniably, cigarette smoking remains a widespread and an extremely serious public health problem.

Fortunately, about 70% of smokers express at least some interest in quitting. About a third of smokers in

the United States make a serious attempt to quit each year. Most people quit "cold-turkey" or with self-help materials and without formal treatment; about a third seek formal treatment. This chapter focuses on effective behavioral interventions for cigarette smoking, which can be used alongside pharmacotherapies, or in combination, which is the recommended and most effective choice when intensive treatment is appropriate. The information presented is drawn from the scientific research literature and a leading clinical practice guideline published by the US Department of Health and Human Services.

BRIEF CLINICAL INTERVENTIONS

There is a dose–response relationship between treatment intensity and efficacy, with more intense interventions generally producing relatively increased quit rates. However, not all smokers require intensive interventions. Further, intensive treatment is not always feasible or practical. In hospitals and many clinical settings, a premium is on maximizing the extent to which all smokers receive at least some intervention for their smoking. There are substantial opportunities to reach smokers via clinical healthcare settings. For example, an estimated 70% of smokers have contact with a primary care physician each year. This potential capacity for a wide reach has driven the call for the routine identification and assessment of smokers in clinical care. While identification and assessment are necessary elements to address smoking with all patients, they have not yet translated into increased quit rates. Lack of resources devoted to smoking cessation services and the need to develop organization and systems support have been offered as likely explanations. One meaningful and relatively obtainable goal is the brief (<3 min) clinical intervention delivered by healthcare practitioners to all smokers regardless of the reason for presenting for care. Brief clinical interventions are effective when provided by a variety of healthcare professionals and can relatively easily conform to the constraints of the typical busy clinical practice. Two models for such interventions are briefly presented below, and the practice guideline should be consulted for more information.

The 5 A's

One model for the brief clinical intervention is presented in the practice guidelines and is referred to as the 5 A's: ask, advise, assess, assist, and arrange. The first step is to *Ask* about tobacco use and document smoking status for every patient. To that end, there has been a systems-level push to add smoking status as

the "5th vital sign." Second, for current smokers, clearly and strongly *Advise* about the importance of quitting in a manner that considers health circumstances, costs related to smoking, and effects on relationships. Third, *Assess* the individual's motivation to quit on a scale of 0–10. Fourth, for persons willing to try to quit, *Assist* with the development of a quit plan, with elements like setting a quit date, creating a plan to tell family and friends, planning for risky situations, removing smoking-related products from the environment, and recommending pharmacotherapy, if appropriate. The fifth step is to *Arrange* for follow-up after the target quit date to reassess smoking status and provide support. Inclusion of at least one follow-up visit is beneficial and recommended.

The 5 R's

For smokers not willing to try to quit, motivational interviewing techniques are recommended, and the model recommended is referred to as the 5 R's: relevance, risks, rewards, roadblocks, and repetition. That is, focus on the personal *Relevance* of quitting smoking by emphasizing specific factors important by the patient (e.g. health problems, family history). Identify the *Risks* of continued smoking to short- and long-term health. Discuss *Rewards* of quitting, including proximal and distal benefits (e.g. improved health, saving money). Identify *Roadblocks* to quitting (e.g. nicotine withdrawal, concern about weight gain, low self-efficacy to quit) and create a plan to deal with them if the situation arises. Finally, motivational counseling is *Repeated* as needed.

Several factors are known to affect outcomes from brief clinical interventions. For example, the involvement of more than one type of healthcare professional in the delivery of the intervention, not necessarily at the same time, is associated with improved abstinence rates, as are the inclusion of practical counseling and intratreatment social support. Practical counseling involves reviewing past quit efforts for relevant information including strategies that helped and/or did not help, risky situations, and challenges related to other smokers (e.g. spouses), and developing strategies to deal with such situations are developed. Intratreatment social support refers to providing support and encouragement as part of an empathetic therapeutic process.

INTENSIVE INTERVENTIONS

The availability of effective brief clinical interventions is crucial to casting a wide net over addressing smoking with all smokers. However, there is a dose–response relationship between treatment intensity and effectiveness,

and practice guidelines recommend providing intensive behavioral interventions to any smoker interested.

Framework and Specific Interventions

Smoking interventions are most often multicomponent, deriving from and invoking a number of cognitive frameworks and models. As such, it is difficult to parse effects to specific treatment components, but there is some evidence in the literature including a few recent meta-analyses that allows some conclusions to be drawn. In general, cognitive-behavioral and social learning theory frameworks inform some of the predominant behavioral treatment components including cognitive-behavioral therapy, motivational interviewing, and relapse prevention.

Cognitive-Behavioral Framework

A central premise of cognitive-behavioral models of addiction is that substance use is a learned behavior that is largely established through modeling, operant conditioning, and classical conditioning processes. Factors that are considered to play crucial roles in substance use are positive expectancies associated with use; the behaviors, beliefs, and norms exhibited by one's social network; and the role of stress and the coping skills and self-efficacy for dealing with it. Consequently, interventions that have cognitive-behavioral roots involve anticipating and planning for situations that place one at risk for relapse. The antecedents and consequences (cognitive, emotional, environmental, physical, and social) of smoking are explored, strategies to deal effectively with triggers and risky situations are modeled and role-played to master new skills, and meaningful alternative reinforcers are identified to strengthen commitment and rewards from not smoking.

Stemming directly from this framework is cognitivebehavioral therapy, which takes a goal-oriented, directive, and systematic approach to changing dysfunctional cognitions, behaviors, and emotions. A functional analysis is used to identify triggers or antecedents of smoking behavior, cognitions, and emotions that are contributing to the maintenance of smoking, and positive and negative consequences of smoking and abstinence. Once functional analysis is complete, coping skills and support systems can be brought to bear on establishing and maintaining abstinence. Most studies in the research literature find that cognitive-behavioral therapy improves abstinence compared to no-treatment control groups. When compared to other active treatment conditions, outcomes tend to be comparable, as with other effective treatments. In addition, there is limited evidence that cognitive-behavioral therapy

may be associated with reduced weight gain following quitting under some conditions.

Motivational Interviewing

Motivational interviewing is a client-centered counseling style focused on developing motivation to change. The therapist's role is to uncover and help build rapport, resolve ambivalence, provide normative feedback, and evoke commitment to change in an empathetic and collaborative manner. The principles of motivational interviewing are to express empathy, develop discrepancy, roll with resistance to change, and support self-efficacy to make changes. Content covered includes personalized relevance of change, risks and rewards of change, roadblocks to change, and the need for repetition in these efforts. The overall goal is to evoke the client's own intrinsic motivation and to empower the client to make decisions rather than having decisions imposed by others. Conceptually, this therapeutic style should be most effective in persons who demonstrate low motivation to change, although the research literature is mixed in that regard. A recent meta-analysis by the Cochrane Collaboration found that motivational interviewing was associated with increased abstinence at 6-month follow-up compared to brief advice or usual care, and counseling contact longer than 20 min was especially effective. Findings of increased odds of smoking cessation with motivational interviewing are further supported by two additional meta-analyses to date. Beneficial effects may be less substantial in pregnant women compared to nonpregnant women. In general, though, improvements in outcomes with motivational interviewing seem on par with benefits with other effective psychosocial therapies.

Relapse Prevention

Even with effective treatment, rates of relapse to smoking are high. In general, counseling strategies consistent with Marlatt and Gordon's relapse prevention model seem to decrease the likelihood of relapse compared to usual care conditions, at least in the relative near term. Developed in the context of alcohol abuse and dependence, the relapse prevention model has been extended to other substance use disorders including tobacco use and dependence. The model is based on social-cognitive theory and involves behavioral and cognitive strategies for identifying, dealing with, and preventing situations that place the individual at high risk for relapse. Several cognitive processes are considered key to understanding why relapse occurs, including self-efficacy or a belief in one's ability to abstain from substance use, outcome expectancies or beliefs about the positive/negative consequences of use and/or abstinence, and abstinence violation effects,

when initial lapses are perceived as recovery failures that increase the chances of a full-blown relapse. Relapse is considered a process that can theoretically be prevented and interrupted by addressing these cognitive processes as they occur. The immediate antecedents and consequences of use are identified and coping strategies developed to monitor for and deal with such situations. The process involves use of specific strategies for improving coping skills and self-efficacy, correcting endorsed myths about substance use, and dealing with lifestyle factors that increase the likelihood of relapse, like stress. While effective, a meta-analysis by Irvin et al. found that the effect size of relapse prevention interventions for smoking were significantly smaller than those for alcohol and polysubstance abuse, and all effect sizes were the strongest when assessed immediately posttreatment relative to 1-year follow-up, suggesting the need to develop programs that more adequately address the needs of ex-smokers. While motivational interviewing components are associated with improved abstinence, there are no specific interventions that reliably prevent relapse following treatment. There is some evidence that self-help materials can decrease long-term relapse in individuals who quit without formal treatment. In the absence of reliable evidence-based interventions for relapse prevention at the time of the last practice guideline in 2008, the authors report a consensus that for some smokers, use of intensive evidence-based behavioral and pharmacological treatments are likely needed to produce the best outcomes including preventing relapse but does not make further recommendations. More recently, a number of studies have examined the use of extended therapies to maintain abstinence or prevent relapse. Results suggest that cognitive-behavioral therapy for an extended duration (i.e. 40 weeks) following intensive pharmacotherapy combined with behavioral therapy produces high long-term abstinence rates (i.e. 2-years follow-up).

There is a large literature on self-efficacy and its predictive relation to relapse or the maintenance of abstinence. A meta-analysis by Gwaltney et al., however, suggests that relationships between self-efficacy and relapse largely reflect smoking status at the time that self-efficacy is measured and that controlling for smoking status at the time of assessment substantially reduces its predictive value, although it does remain a significant predictor and its assessment may be useful for treatment development.

Transtheoretical Model

According to the transtheoretical model, individuals progress through a series of stages of readiness to intentionally change a problem behavior, like smoking. Individuals who do not yet recognize the need to quit

smoking or have no immediate intention to quit are said to be in the precontemplation stage. Those thinking about quitting in the relatively near future and considering the pros and cons are in the contemplation stage. In the preparation stage, people are taking steps toward quitting, like collecting information on effective treatments. People actively engaged in trying to quit are said to be in the action stage. Finally, those who have quit and for whom relapse prevention is the focus are in the maintenance stage. The transtheoretical model has intuitive and clinical appeal and is widely applied. However, it is not without criticism including that the model oversimplifies how individuals plan for change, and that it neglects the role of reward and punishment in the formation of entrenched habits. A recent metaanalysis by the Cochrane Collaboration calls into question the utility of using a stage-based approach to adjust counseling. Results found that stage-based counseling interventions were no more or less effective at producing long-term (at least 6 months) abstinence compared to their nonstage-based counterparts. The authors do note that it is possible that future research will uncover benefits of using a staged approach with interventions that could not be included in analyses because the literature was too small (e.g. telephonebased counseling). By contrast to findings in adults, there is some evidence for the efficacy of treatments that have stage-based components relative to control conditions in youth (less than 20 years old).

Format and Modality

Counseling and Self-Help

Group counseling and individual counseling of comparable durations and intensities typically produce similar quit rates. Counseling is especially effective when it is proactive and includes practical counseling and intratreatment social support, as noted above. A meta-analysis by Fiore et al. found that counseling alone (i.e. no pharmacotherapy) increases the odds of smoking cessation by a factor of 1.49–1.76. Use of multiple formats (e.g. proactive telephone counseling, individual counseling) seems to confer improved effectiveness over the use of a single format. Proactive counseling (telephone or face-to-face), group and individual counseling are more effective than self-help materials but do not have as broad a reach. As a stand-alone intervention, self-help materials do not improve outcomes over no-treatment control conditions but there is evidence of marginal effectiveness when used as an adjunct to face-to-face counseling. Nevertheless, from a publichealth perspective, self-help materials play an important role in increasing awareness of the consequences of smoking, importance of quitting, availability of support services, and the range of evidence-based treatment options available.

Personalized Interventions

Individualization of treatment can occur at the outset and during the course of treatment. Treatment can be customized based on personal characteristics of the smoker like quit attempt history or some dimensional variable like readiness to quit, although no specific method of tailoring has consistently improved outcomes. Another example of customization is stepped care, a process of starting with a minimal intensity intervention and incrementally increasing treatment intensity for nonresponders. Stepped care is cost-effective in that expensive resources are reserved for those who demonstrate a need for them. There is some evidence for improved outcomes with this approach in hospitalized patients while benefits for others are as of yet unclear. Throughout the treatment, personalization can occur via ongoing adjustments in emphasized coping skills, strategies, and other elements based on success-attaining goals. In regard to effects of ongoing personalization on outcomes, dynamic feedback in particular (i.e., collecting data and using it to produce tailored feedback via human or computer-based algorithmic computation) is associated with improved short-term and long-term quit rates compared to standard (static) self-help materials and no treatment. Examples of customized written materials include those produced via printed feedback forms and interactive websites.

Technology

Telehealth refers to the use of telecommunication technology and electronic information to deliver health-related care, information, and other services and support educational and administrative activities. Telehealth interventions for smoking are increasingly prevalent and popular. Advantages include increased access to care, decreased time to care, potentially lower costs, and improved efficiencies. These can be standalone options or adjuvant treatments, provided via human resources, automated or interactive systems, or some combination thereof.

A large-scale example of a teleheath initiative for smoking is the US National Network of Quitlines. Quitlines can provide proactive follow-up calls, mailed self-help and informational materials, assistance obtaining pharmacotherapy, and referral and triaging of callers to other services, and some have associated websites with additional resources. Trained staff can provide reactive and/or proactive counseling if available. Most quitlines target the general population but some target specific groups like pregnant women, adolescents, and low-income smokers. Proactive telephone counseling is especially effective, and there may be a dose–response

relationship with three or more calls more likely to produce benefits. Importantly, there is empirical evidence that proactive counseling (telephone-based or otherwise) increases quit rates compared to minimal or no counseling and that proactive counseling plus medication are more effective than medication alone.

Fax-to-quit services are proactive programs designed to identify smokers in primary care settings and link smokers to smoking cessation treatment. Typically, a smoker completes a form in the physician's office and it is faxed to a designated quitline call center. The call center then attempts to contact the individual usually within 48 h to engage him/her in a quit plan, which can include one or several counseling sessions. The effectiveness of fax-to-quit programs has only been investigated in a small number of studies but with positive results compared to control conditions. The focus on proactive outreach and telephone counseling makes fax-to-quit approaches particularly likely to engage smokers who have not sought services independently.

Mobile phones are another technology being increasingly used to deliver interventions and monitor and manage smoking. Mobile technology is integrated into daily life for most people, with an estimated >70% of the world's population currently subscribing to mobile phone service. It is a potential means to reach audiences who do not access traditional treatment services, and it allows for individualization, interactivity, and immediacy. Mobile phone technology includes voice service, applications ("apps"), e-mail, short message service and multimedia service, and Internet access. The literature on smoking interventions that include mobile phone-based elements is currently small. There is some evidence for improved short-term (6-month) quit rates with text messaging-based interventions, as reported in a meta-analysis of four studies by Whittaker et al. Overall, the popularity of and growing access to mobile phone technology suggest that a rise in the number of interventions that have phone-based components is likely. Mobile phone-based applications and programs that are consistent with evidence-based guidelines are needed along with accompanying outcomes-based research.

Advances in computer-based technology and exponential growth in computing have led to an increase in their application to smoking cessation. The first generation of computer-based interventions involved computer-generated feedback forms subsequently mailed to individuals. Currently, interventions delivered on a single computer or via the Internet can include specific quit plans, multiple feedback opportunities, e-mail reminders or other information, Flash technology, interactivity (e.g. chat rooms, social networks), and audio-video streaming. Computer-based interventions offered to individuals in medical care settings (e.g. using

the 5A's/5R's approach) have demonstrated acceptability and a small number of studies thus far suggest these interventions can be effective at reducing smoking. Web-based interventions are potentially even more desirable because of features like increased accessibility but there is limited research supporting the use of the Internet as a smoking treatment access point. Some research suggests benefits of sites that are tailored, interactive, and used frequently and in conjunction with a more intensive intervention relative to less intensive or static or control conditions. Overall, Internet-based interventions combined with evidence-based treatment may improve quit rates, but there are few studies to date and the results are mixed.

Treatment Intensity

Treatment intensity is defined in the practice guideline as (1) minimal intensity (3 min or less), (2) low intensity (3-10 min), and (3) higher intensity (10 min or more). For all these intensities, consistency with practice guidelines is important to treatment effects. Even brief advice to quit smoking that is consistent with practice guidelines is effective when delivered by physicians, and possibly other healthcare professionals, increasing quit rates by 1–7% above quit rates of about 2–3% in untreated smokers, with some evidence of benefits remaining long-term (e.g. 12 months). For high intensity interventions, a total of 30-90 min of total contact time spread out over at least four sessions is especially effective, with further increases not seeming to produce additional benefits. In terms of the types of providers, in general, interventions delivered by trained physicians and nonphysician clinicians produce comparably increased abstinence rates compared to control conditions, but effects by the type of provider have not been examined taking treatment intensity into account. Practice guidelines recommend that intensive treatment be provided to all interested smokers.

SPECIFIC POPULATIONS

Separate attention is given to some populations of smokers because of particular vulnerabilities, disproportionate smoking-related morbidity and mortality burden, and other considerations. Behavioral interventions that are effective in the general population of smokers tend to be effective in specific populations, although treatment effect sizes can differ.

Women Versus Men

Recent evidence suggests that women are at greater risk than men for smoking-related illnesses, including lung cancer, which is second next only to breast cancer in cancer prevalence among women. Women smokers also have elevated rates of diseases related to pregnancy, oral contraceptive use, and menstrual function, as well as increased cervical cancer rates. Several studies have revealed that women may have more difficulty in quitting smoking than do men. Specifically, while women and men are equally likely to initiate quit attempts, women appear to have greater difficulty maintaining abstinence. This gender discrepancy has been found in studies of self-directed quit attempts as well as behavioral and nicotine replacement treatments. Some work suggests that women are more likely to use smoking to manage negative affect and prevent weight gain than men. Research is needed on underlying mechanisms and effective treatments to address gender disparities (also see the Exercise section below).

Racial and Ethnic Minorities

There is evidence for racial and ethnic differences in smoking and smoking-related health outcomes. Compared to Caucasians, African Americans are less likely to have ever been smokers, although rates of current smoking appear similar. These data may reflect that African American smokers have greater difficulty in quitting smoking. African American smokers are as likely as Caucasians to want to quit smoking, but they are less likely to utilize smoking cessation treatment. A similar scenario is evident with Hispanic smokers. Lower utilization may be related to lower income and lower likelihood of health insurance coverage. Receipt of healthcare advice to quit smoking is positively associated with utilization of smoking cessation treatment among these groups, suggesting that improving access to healthcare has the potential to improve outcomes. The availability of culturally appropriate treatment options may improve outcomes for some as it does in other areas related to health.

Employees

Several natural aspects of the workplace lend themselves to promote smoking cessation including regular long-term opportunities to provide access to services and monitor progress, and the potential for various forms of social support throughout the organizational structure. Treatments that are effective outside the workplace are similarly effective when offered within the work setting. Incentives (distinct from contingency management interventions; see below) and competitions that target the workforce of smokers increase participation in quit smoking programs but the literature is mixed in terms of effects on actual quit rates. SPECIFIC POPULATIONS 161

Hospitalized Patients

Hospitalization presents a unique opportunity to identify and connect smokers with evidence-based smoking cessation treatments due to indoor smoking restrictions, Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accreditation requirements, and the negative impact of smoking on recovery from illness, which can drive motivation to quit. Intensive smoking cessation treatment with at least one contact and a minimum follow-up of 1 month postdischarge increases the odds of quitting in all hospitalized smokers and in specific subgroups like coronary heart disease patients. There is limited evidence of improved quit rates with longer duration treatment or with pharmacotherapy added to less intensive behavioral therapy.

Pregnant and Postpartum Women

About 12% of women report smoking cigarettes during pregnancy. The most commonly recognized health consequences of smoking when pregnant are increased risk of premature birth, low birth weight, and sudden infant death syndrome. Less well publicized is the substantial increased risk of having a baby born with malformations like deformed limbs. Effective behavioral interventions of moderate or high intensity are effective in pregnant women who want to quit but as with other populations, a significant proportion of those treated do not quit. Further, amongst those who do quit, an estimated 70% relapse within 6 months postpartum. Strategies to improve quit rates and prevent relapse in this population are needed urgently.

Smokers with Other Substance Use Disorders

The prevalence of smoking in individuals with other substance use disorders is an estimated 67 to more than 90%, depending on substance of abuse. Substance abusers who smoke experience more smoking-related morbidity and mortality than nonsubstance abusers. Most substance abuse treatment patients express some interest in quitting smoking but few treatment programs address smoking. Of those who do, most address smoking within the context of counseling generally; few offer pharmacotherapy and formal smoking cessation counseling is rare. Organizational barriers to integrate smoking into substance abuse treatment include difficulty with reimbursement; belief that smoking is not important in treating other substance abuse; concerns that quitting smoking will jeopardize other treatment outcomes; lack of staff and organizational support, training and resources, lack of smoke-free policies and grounds, and a smoking staff culture. Importantly, there is now strong research evidence that

treating smoking does not jeopardize and by contrast may benefit substance abuse treatment outcomes. For example, individuals who continue to smoke are at higher risk of relapse to other substance use. Several leading organizations now advocate for treating smoking along with other substance use disorders, and initiatives like the 1999 New Jersey decision to make licensure contingent on the provision of smoke-free grounds, ban use of tobacco by staff during work hours, and make assessment and treatment of tobacco use available to all substance abuse treatment patients are making headway. In general, treatments that are effective for the general population are effective in substance abusing smokers, but relatively less so. Quit rates tend to be lower, but what constitutes a clinically significant effect is also likely lower given the very high rates of smokingrelated morbidity and mortality in this population. Overall, more research on strategies to improve long-term smoking cessation outcomes in this population is needed as are continued efforts to integrate smoking into treatment for other substance use disorders.

Other Psychiatric Diagnoses

Rates of nicotine dependence among individuals with mental health diagnoses are substantially higher than smokers without mental health problems across most Axis I and Axis II disorders, with resulting increased burden on these populations in terms of smoking-related morbidity and mortality. Complicating treatment of smoking in people with mental health problems is that dependence may be entangled with psychiatric symptoms. For example, among smokers with schizophrenia, who are far more likely to smoke than nonpsychiatric individuals, it has been proposed that nicotine may play a role in regulating negative symptoms (e.g. apathy, avolition), possibly through its ability to raise dopamine levels in the nucleus accumbens and prefrontal cortex. Nicotine may also improve cognitive deficits via improved sensory gating. Thus, for individuals with schizophrenia, smoking may provide a self-medication role that is difficult to counteract with behavioral interventions. There is some evidence that contingency management, a systematic application of positive reinforcement to promote behavior change like quitting or reduced smoking, may reduce smoking in people with schizophrenia but larger trials are needed.

Depression symptoms and nicotine dependence also seem to be highly associated. Smokers are more likely to report depressive symptoms and more likely to meet diagnostic criteria for major depression than are nonsmokers. Depressed smokers have higher nicotine dependence scores and smoke more cigarettes than non-depression smokers. Further, depressed smokers are

more likely to relapse to smoking during times of high stress and experience more protracted withdrawal effects. However, there is evidence that history of depression is not an independent predictor of smoking cessation failure.

Relatively few studies have examined the efficacy of smoking cessation interventions for individuals with serious mental illness like psychotic disorders. Treatment does not appear to worsen mental state when applied to patients with stabilized psychiatric conditions. However, long-term abstinence is rare. It has been suggested that behavioral interventions may best be utilized as adjunctive treatments to assist individuals with mental illness to establish coping skills to maintain abstinence, but more research is needed.

Adolescents

Adolescence is a time of particular vulnerability to developing nicotine dependence. Monitoring the future data from 2010, for example, suggest that about 3% of 8th graders and nearly 11% of 12th graders are daily cigarette smokers. Behavioral therapies are the treatment of choice for adolescent smokers as there is insufficient evidence to support the use of pharmacotherapy in this cohort, although this is an active area of research. Effects of behavioral interventions such as motivational interviewing or structured brief advice tend to be modest. Additional findings suggest that adolescent smoking and quit attempts are significantly associated with parental smoking and cessation. Specifically, teens of parents who quit smoking are less likely to become smokers and more likely to quit if already a smoker than teens with a parent who currently smokes, suggesting that family-based smoking interventions may be useful, but more research is needed. A group that has received less attention in the research literature is young adults (e.g. age 18–24), in whom the smoking prevalence rate is about 22%. A recent review of the few published studies to date concluded that the extent of methodological heterogeneity and lack of scientific rigor in the current literature largely preclude conclusions.

ALTERNATIVE STRATEGIES

Hypnosis

Hypnotherapy is proposed to help individuals quit smoking by weakening the desire to smoke and increase motivation to quit. Relatively few controlled trials have been conducted comparing hypnosis to no treatment, brief advice, or counseling and that literature does not show clear effects of hypnosis on smoking outcomes.

Acupuncture

The empirical evidence on acupuncture for smoking cessation including two meta-analyses does not support improved outcomes with active compared to sham acupuncture (i.e. acupuncture at sites not expected to affect smoking). There is limited evidence of improved short-term outcomes with acupuncture compared to no-acupuncture control conditions. Larger and more rigorous trials are needed to improve understanding of possible effects of acupuncture on smoking treatment outcomes.

Exercise and Physical Activity

Physical activity and exercise are associated with lower levels of cigarette smoking in several crosssectional studies. Proposed possible mechanisms of action include reduced cravings to smoke, reduced withdrawal effects, a rising of self-esteem, and slowing of postquitting weight gain. However, there is limited evidence of direct effects of exercise on smoking outcomes in the empirical literature to date. Most promising are observations of some benefits of exercise on psychological outcomes including reduced tension, anxiety, stress, irritability, and restlessness, even in the absence of differential smoking reduction between exercise and nonexercise treatments. Another approach may be to apply exercise-based interventions to moderate weight gain during a quit attempt or following cessation but research results are thus far equivocal. For example, exercise has been found not to be associated with reduced postcessation weight gain at the end of treatment but there is some support for reduced weight gain long-term (i.e. at 12 months). There are also no clear benefits of exercise for smoking cessation in specific populations (e.g. women, problem drinkers, postacute myocardial infarction patients). It is important to note that several methodological issues complicate the current literature including small sample sizes, poor adherence to exercise regimens, and lack of objective outcomes. For example, research suggests possible differential efficacy with vigorous versus moderate activity levels, but poor adherence to exercise regimens is associated with worse outcomes and adherence appears to be worse with vigorous exercise. Overall, more research is needed to directly compare moderate versus vigorous activity, to examine strategies for improving adherence to all exercise levels, and to address methodological issues that complicate interpretation of research results.

Contingency Management

Contingency management is primarily a process of systematically using positive reinforcement to promote CHALLENGES 163

clinically relevant behaviors that has demonstrated efficacy for improving abstinence in a diverse range of substance abuse treatment populations and settings (see Contingency Management). Briefly, contingency management is based on the behavioral principles of operant conditioning that predict that behaviors (e.g. smoking abstinence) that are reinforced or rewarded are more likely to recur. With this procedure, a target behavior is identified, like abstinence, and defined objectively (e.g. drug-negative urinalysis). It is monitored often to maximize chances for reinforcement and minimize failing to detect competing behaviors (e.g. drug use). When the target behavior occurs, tangible incentives or rewards (e.g. voucher) are provided, and incentives are not provided when the target behavior does not occur. A large body of research demonstrates that substance use can be modified by changing environmental consequences of use like the availability of alternative (nondrug) reinforcers, thus supporting the use of contingency management to treat substance abuse.

Most research on contingency management for smoking has been conducted under tightly controlled experimental conditions and in samples not seeking treatment. Results generally indicate substantial short-term reductions in smoking when procedures include elements essential to the efficacy of this intervention. Contingency management may be particularly helpful for individuals trying to quit smoking for whom pharmacotherapy is not appropriate and for those disproportionately affected by smoking but not commensurately aided by standard treatment options. One such group is pregnant smokers, for whom the general consensus is that pharmacotherapy is contraindicated. Research on contingency management for smoking in this population indicates significant smoking reductions that, for many, endured throughout the postpartum period. Another group for whom contingency management may be helpful is adolescents. About 20-25% of adolescents who try smoking progress to daily smoking and nicotine dependence but there is insufficient evidence to support pharmacotherapy for this group. Notably, contingency management alone or in conjunction with other therapy (e.g. cognitive-behavioral therapy) can substantially reduce smoking among adolescents. Contingency management might also be helpful for individuals with co-occurring substance use disorders, who are at elevated risk of smoking-related morbidity and mortality. Research in residential treatment patients, methadone-maintained opiate-dependent patients, and in the Veteran's Administration hospital population demonstrates that contingency management can reduce smoking and promote abstinence in this group. Results from a few small trials in individuals with schizophrenia are also promising. Application of this intervention to improve adherence with smoking cessation medications is another area of interest. Despite promising results, this literature remains relatively small, in part because of technological limitations on detecting smoking via breath or urine tests in the context of contingency management (*see* Contingency Management for a more detailed discussion).

CHALLENGES

Effective behavioral interventions for smoking exist but there are challenges and limitations to overcome to optimize outcomes for many smokers. Some issues relate to access to and utilization of effective treatments. On the side of the smoker, limited knowledge about the harmful effects of smoking and effective treatments; lack of desire, motivation, or self-efficacy to quit; the potential stigma associated with receiving treatment, for the first time or after already having attempts to quit; and the costs of treatment can limit demand. Public health campaigns and policies are two means through which information dissemination occurs. For some groups of smokers, information presented in a culturally specific manner may improve the impact of outreach efforts. The availability of affordable healthcare and health insurance coverage for smoking treatment is also crucial to widespread utilization of services. On the healthcare setting side, limited training on how to counsel patients who smoke and on the availability of evidence-based treatments and related community resources can negatively impact treatment referrals. Myriad other demands, insufficient resources, and limited incentives to address smoking with patients remain serious barriers. The need for specialized training on how to counsel patients who smoke and on treatment options are now widely recognized and such training is being incorporated into medical school curriculum and continuing medical education programs. Many hospitals now require that smoking status be documented for all patients, a practice sometimes referred to as the fifth vital sign. This practice improves the extent to which smokers are identified but organizational support, resources, and other attendant issues need to be addressed to improve translation of assessment into delivery and utilization of services, including delivery of the most effective treatment strategy - combine behavioral and pharmacological treatment.

Of those who do use formal treatment, a substantial gap exists between the number of smokers who seek treatment and the number who achieve initial abstinence. Larger still is the gap between the number who quit and those who successfully remain quit long-term. There is a pressing need for methods to maximize treatment efficacy for the general population of smokers and for specific subgroups like those

discussed above. To develop these methods will likely require innovative strategies and an improved understanding of the moderators and mediators that impinge on treatment effects. Further, even with current best practices and with knowledge of situational, environmental, and other factors that increase relapse risk, relapse rates are high and strategies to prevent relapse reliably are forthcoming. Relatively highly intensive interventions are associated with improved short-term and long-term outcomes but also sometimes with higher attrition.

Another challenge includes the identification of the active components of efficacious interventions. Discussions of effective behavioral therapies for smoking in the scientific literature and in practice guidelines largely consist of generalizations about intensity, contact time, and other structural and content elements that impact treatment effectiveness. Motivational interviewing and cognitive-behavioral therapy are widely used in practice and examined empirically but several factors complicate evaluation of these and other specific methods. Examples include the often composite nature of counseling without clear distinctions between therapeutic approaches, confounding of counseling and noncounseling components, individualization of counseling based on clients' needs which can lead to heterogeneity within and across studies, and the use of comparison conditions that are brief advice or treatment as usual and not consistently matched in intensity and duration. Further, there are differences between studies in patient characteristics, treatment fidelity, and other elements that make cross-study comparison, systematic replication, and meta-analytic assessment problematic.

CONCLUSIONS

Cigarette smoking remains a leading preventable cause of morbidity and mortality around the world with disastrous health and economic costs. Effective behavioral interventions for smoking exist, and effect sizes overall are in the range reported for approved smoking cessation pharmacotherapies. Improvements in access to and utilization of evidence-based treatments, the systematic integration of smoking treatment into healthcare and other settings, and innovative strategies and scientifically vetted methods to improve treatment effectiveness and prevent relapse are needed to more fully realize the potential individual and public health benefits of treating smoking.

SEE ALSO

Contingency Management, Medications to Treat Addictions: Nicotine Replacement, Non-nicotine Medications

Glossary

Classical conditioning a behavioral learning process whereby an individual responds in a particular way to a (conditioned) stimulus that was previously neutral but has been repeatedly paired with a (unconditioned) stimulus that occurs naturally with the desired response.

Effect size a standardized measure of the strength of an effect of an independent variable (e.g. type of treatment) on a dependent variable (e.g. percent who quit smoking). It represents the change (measured in standard deviations) in an average person's outcome (the dependent variable), if given the treatment (the independent variable).

Lapse after some period of abstinence, a brief return to some smoking (e.g. a few cigarettes) that does not progress to regular prolonged smoking and is followed by a return to abstinence.

Modeling learning through observing others.

Operant conditioning a learning process whereby behaviors that are reinforced tend to occur more frequently while those that are not reinforced (or are punished) occur less frequently.

Reinforcement in behavioral science, a response or behavior is followed by the presentation of a desirable stimulus and the frequency or likelihood of subsequent responses is increased.

Relapse a return to regular smoking after some period of abstinence.

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Relevant Websites

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Behavioral Treatments for Adolescents with Substance Use Disorders

Susan H. Godley, Mark D. Godley

Chestnut Health Systems, Chicago, IL, USA

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INTRODUCTION

Adolescent Treatment

Survey data from 2009 suggest that 4.6% of adolescents in the United States meet DSM-IV criteria for alcohol abuse or dependence and 4.5% meet criteria for illicit drug abuse or dependence. These prevalence rates translate into large numbers of adolescents who need treatment for one or more substance use disorders. It is important that effective treatments are available because research has shown early initiation of substance use and its associated problems often results in more severe and longer lasting alcohol and other drug problems. Fortunately, for those adolescents entering treatment there are several empirically supported behavioral treatments available. These treatments began to be systematically adapted for adolescents with substance use disorders and studied through randomized clinical trials in the 1990s. Most of the treatments

have been evaluated in outpatient settings; however, brief treatments also have been evaluated in hospital emergency rooms (ERs) and school settings.

In this chapter, we review theories of change that support behavioral treatments for adolescents, common features of these approaches, specific approaches that have been supported in randomized clinical trials including brief and combination treatments, research related to the effectiveness for gender and racial groups, and future research needs.

Theories Underlying Behavioral Treatments

There are three different theories that serve as the basis for behavioral treatments. Classical conditioning theory was articulated after Ivan Pavlov noticed that hungry dogs would salivate at the sight of assistants who were associated with their feeding. The major concept underlying this theory is that given repeated

pairings over time, a given stimulus elicits a certain response. This theory suggests that alcohol and substance use are a response to stimuli that could be any number of people, places, or things that have been associated with an individual's use. The goal of treatment is to help an individual avoid certain stimuli that elicit substance using behavior.

Operant or "Skinnerian" conditioning outlines rules for increasing and decreasing behavior based on the consequences of that behavior. A behavior increases when it is positively reinforced, so for example, alcohol or drug use increases when an individual finds that using substances has pleasurable consequences. A clinician will help the individual identify alternative reinforcers to compete with substance use. These reinforcers are most effective when they are individualized and can range from verbal praise from a therapist or parents for efforts of an adolescent to decrease alcohol or substance use to a tangible reinforcer like money or prizes.

Social learning theory was developed by Albert Bandura and explains behavior based on the interaction of cognitions with behavioral and environmental influences. Modeling and observing the behavior of others plays a large role in learning new behavior. So, for example, an individual might learn to use alcohol or drugs in response to stress or happy occasions in life due to observing this behavior by a significant adult. An adolescent might learn better communication skills by observing other adolescents model these skills in a group. Regardless of the theory underlying the particular behavioral approach, they share several common features.

Common Features of Behavioral Treatments

Behavioral treatments are rooted in the scientific method and rely on methods of training clinicians that include specifying the desired clinical behaviors, observation of the clinician providing the treatment, and feedback to shape desired behaviors. It is generally understood that the rationale for the rigorous monitoring of therapists' in-session behavior helps maintain fidelity to the model and will result in therapeutic outcomes similar to those in clinical trials that established the intervention as an evidence-supported treatment. Treatment manuals provide background on a particular approach and break down aspects of the treatment into smaller steps and decision rules to help the clinician determine when it is appropriate to use different treatment components. Usually, video or audio recordings of simulated or real sessions are reviewed in order to provide clinicians feedback to learn to deliver an approach competently. The feedback is typically based on rating guidelines used to evaluate the quality of a clinician's in-session behavior. Even after clinicians have demonstrated the ability to implement the approach well, there may continue to be periodic reviews of their work to assess ongoing fidelity to the established intervention. In research studies, the use of these approaches is typically time-limited based on a fixed treatment period, but in practice, lengths of treatment vary based on the level of care, need, and available financial resources to pay for treatment. Next, we provide descriptions of several specific behavioral approaches.

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Cognitive-Behavioral Therapy

One behavioral approach that is widely used for adolescents with alcohol and substance use problems is cognitive-behavioral therapy (CBT). As noted by Yifrah Kaminer and Holly B. Waldron, this approach draws from all three behavioral theories. It is important to note that the content of CBT sessions varies greatly across the different research studies that have evaluated it and in practice settings.

CBT techniques that are based on classical conditioning help adolescents identify stimuli that lead to their alcohol or substance use and teach them how to interrupt a chain of events or "triggers" so that the end result is not substance use. Stimuli can be places, people, things, or even emotions like sadness or boredom. Thus, avoiding a friend's house where drugs are typically available and used would interrupt the antecedents that lead to alcohol or drug use. Learning to substitute a positive thought for a negative one might help avoid substance use for an individual who uses alcohol or drugs to help forget about bad feelings.

Operant conditioning principles suggest that repeated alcohol or drug use can be at least partially explained by the reinforcing effects adolescents experience from their alcohol and drug use. A therapist may help adolescents find alternative reinforcing activities that provide opportunities to experience socially positive outcomes that will compete with their substance using behavior. One of the most common features of CBT is teaching individuals several different coping skills. Consistent with Albert Bandura's theory of self-efficacy, if individuals learn to use coping skills to decrease stressful situations in their lives, confidence in their ability to control situational outcomes will increase, and they will be less likely to use alcohol or drugs to relieve stress.

Typical skills that are the focus of CBT sessions are problem solving, communication skills, anger management, coping with cravings or urges to use, and alcohol APPROACHES 169

or drug refusal skills. However, the number of coping skills taught can be quite expansive and might include topics like improving social support or depression management. A CBT session will generally include a brief discussion of the adolescent's status since the last session and any significant events that have occurred, a review of the homework that was agreed upon in the prior session, the rationale for the coping skill being presented, didactic instruction related to the topic, modeling or demonstrating the desired skill, an opportunity for the adolescent to practice or rehearse the behavior with feedback, and discussion of homework to be completed prior to the next session so that the individual has the opportunity to "try out" the coping skill in his or her natural environment. A critical aspect of the approach is reviewing the homework assignment when an individual returns for the next session. If the homework was completed, the therapist praises the adolescent's efforts and discusses what was learned from the experience. If the homework assignment was not completed, the therapist discusses with the adolescent why it was not completed and helps the individual overcome any obstacles or discomfort so that he or she is more successful the next time.

In keeping with the principles of social learning theory, a therapist may help the adolescent identify positive adult or peer models whose behavior he or she might want to imitate. These could be individuals who have had problems with alcohol or drugs themselves and are now active in recovery or individuals that have never had problems, but live their lives in a way that the adolescent feels is successful. Social learning theory also supports the use of CBT in groups, and research suggests that it can be quite successful in group delivery. There has been some research to suggest that peer influence in groups for delinquent youth can have a negative impact on group members, but this research has not been validated in groups for alcohol or drug use treatment. On the contrary, meta-analyses by Holly B. Waldron and Charles W. Turner indicate that group delivery of CBT can be as or more effective than individual CBT approaches. The next approach described shares several aspects of CBT.

Adolescent Community Reinforcement Approach

The Adolescent Community Reinforcement Approach (A-CRA) is adapted from an adult treatment approach, the Community Reinforcement Approach (CRA) that was first developed and tested in the 1970s. It was modified for adolescents and evaluated as part of a multisite study of treatment approaches for adolescents who presented with cannabis abuse or dependence, and later evaluated with young people who were homeless and

who had other types of alcohol or drug abuse and dependence diagnoses. The approach has been widely disseminated in the United States through special federal grant mechanisms to treatment organizations and is spreading to Canada and Brazil. In the earliest CRA studies for adults, there were a number of different treatment procedures that were used, including "reinforcer access counseling," "social/leisure counseling," "job finding counseling," and "problem prevention." Over time, these procedures have been described in more detail in books and manuals, and additional procedures have been added. A-CRA incorporates several CBT procedures, and this treatment approach illustrates how a package of different treatment components can be grouped in a treatment manual that therapists can draw upon to individualize treatment.

One of the identifying features of A-CRA, which has its basis in operant conditioning theory, is the emphasis placed on determining each individual's reinforcers, which might be used to motivate behavior change. For example, a young person might want to please a girlfriend who wants him to be substance free, finish high school, participate on an athletic team, or complete juvenile justice probation requirements. The approach also acknowledges that alcohol and other drugs have taken on reinforcing properties for the young person, so it is important to find alternative, healthy behaviors that can replace the using behavior so that the individual learns to have an enjoyable life without the use of alcohol or drugs. A-CRA procedures can be grouped into (1) assessment and planning procedures (e.g. functional analyses of substance use and pro-social behavior, the Happiness Scale, and Goals of Counseling), (2) skill building procedures (e.g. communication, problem solving, relapse prevention, and job finding), and (3) a miscellaneous group that helps promote pro-social reinforcer access (e.g. systematic encouragement) or sobriety (e.g. sobriety sampling). There are a total of 18 different procedures that a therapist can choose from based on discussion during a treatment session. Important additions for adolescents are the sessions that involve parents or other important caregivers in adolescents' lives. The overall goal of the family sessions is to improve the home environment for both adolescents and their parents by teaching them better communication and problem-solving skills. Once learned, these skills also help facilitate changes in areas assessed as needing improvement via the Relationship Happiness

A-CRA has been evaluated as a relatively short (12–14 sessions) intervention. The procedures can all be used in individual therapy sessions, and many also are appropriate for use with groups (e.g. communication skills, problem solving, and relapse prevention). In a continuing care application known as Assertive Continuing Care

(ACC), clinicians deliver A-CRA procedures in the home along with case management.

Results of clinical trials of A-CRA as a primary outpatient treatment and when used as a part of ACC have been favorable when compared to treatment as usual conditions. When compared to two other evidence-and manual-based treatments, A-CRA was found to be the most cost-effective.

Family Behavior Therapy

Family Behavior Therapy (FBT) was developed by Nathan Azrin and Bradley Donohue over a 20-plus-year period and also is based on CRA. Its developers conceived substance use as a strong reinforcer, and the eight components described for this approach target (1) building skills that are incompatible with drug use, (2) modifying the environment so that there is reinforcement available for engaging in activities incompatible with drug use, and (3) setting up a "level" system of tiered awards for achievement of goals related to actions incompatible with drug use. Like A-CRA, it has primarily been tested in outpatient settings. It is designed to be delivered in up to 16 sessions that are 60–90 min in length over 4–6 months. It is not surprising that, since it has the same lineage as A-CRA, there are several similarities between the two approaches. Both are designed to increase positive interactions between the clinician and treatment participants, as well as between adolescents and others in their lives. Both are youth and parent centered in that clinicians are trained to seek input and direction for treatment goals from participants. They have some similar components, including communication and job getting skill training. The most striking differences between the two approaches are the FBT expectation that a primary significant other attend every session, the contingency contracting-based level system, and the steps of the self-control component.

Clinicians are expected to work on specific tasks with parents or other appropriate significant others during treatment planning, different aspects of communication training, environmental restructuring, and the development of the level system. Basically, the level system provides a structure so that adolescents earn rewards from their parents for staying substance free and not getting into trouble at home, school, or with the criminal justice system. First, the clinician works with adolescents to identify potential daily and bonus rewards. These might include items that adolescents already have access to noncontingently like money, transportation, or the use of a cell phone, or something they might like access to like a certain video game. Next, the clinician works with the parent to develop three levels of goals in specified areas (e.g. chores, curfew, and school) and assesses what parents feel are acceptable daily awards for each of the three levels of goals and bonus awards that could be given if the adolescent accomplishes specific goals on consecutive days. Finally, the parent and adolescent meet together with the clinician and review what is basically a contract that outlines which behaviors would result in rewards for the adolescent. Each day at home, the contract is reviewed and parents provide rewards as per the agreement.

The urge control or self-control component was developed to provide adolescents with the skills to identify their thoughts related to substance use and redirect those thoughts so that they do not end up using. This component involves seven distinct steps, beginning with thinking or saying "Stop!", thinking of negative consequences of substance use, relaxation, thinking of pro-social alternatives, choosing an alternative behavior, telling an important other person in the adolescents' lives how they avoided the substance use behavior, and thinking about positive consequences that are likely to result from avoiding substance use. These steps are practiced during sessions in what is called a "trial," while the clinician provides the adolescent specific praise and help so that they execute the steps correctly.

As of 2012, the developers have made available a manual and materials to support the dissemination of FBT. These materials include a detailed guide to the approach, checklists to guide clinicians in the delivery of each component, and a method for assessing treatment integrity.

Contingency Management

Another behavioral intervention that first showed promise in the treatment of both adult and adolescent substance disorders is contingency management (CM), also known as Motivational Incentives. This approach is based on the central operant learning principle: behavior is a function of its consequences. Behavior that produces a positive, pleasurable consequence will increase the likelihood of future occurrence; similarly, behavior that results in avoiding or escaping a negative consequence may also serve to increase the frequency of that behavior. CM is an intervention for reinforcing positive behavior (e.g. no drug use) while associating negative behavior (e.g. drug use) with an absence of reinforcement in an attempt to have the individual begin linking abstinence with desirable pro-social goods or services.

There are two main types of CM that have been used in the treatment of substance use disorders: voucher-based reinforcement therapy and the "fishbowl," or the variable magnitude of reinforcement procedure. Both procedures offer rewards for negative urine/breath tests, but the method of reward differs. Developed by Stephen Higgins and colleagues, vouchers for goods or

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services are given in an attempt to re-establish positive behaviors that occurred prior to drug use. For example, if an adolescent enjoyed rollerblading prior to becoming addicted to alcohol and/or other drugs, vouchers earned through treatment could be used to purchase equipment or admission to an indoor skate park. If drug/alcohol screens indicate recent use, no vouchers are given. This particular approach has been shown to result in clinically significant periods of abstinence.

Some CM interventions for drug-free behavior also have been supplemented with contingent reinforcement to increase pro-social behaviors that compete with drug use. This dual reinforcement approach is consistent with the proposed change mechanism in CRA, namely, to increase the density of positive reinforcement by increasing desirable social, recreational, and leisure activities in the adolescents' environment such that relapse or return to use results in time-out from positive reinforcement. Thus, instead of or in addition to earning a reward for providing a negative urine or breath sample, an adolescent could earn one for participating in an agreed upon social or recreational behavior while drug-free between therapy sessions.

The fishbowl, or variable magnitude reinforcement procedure, was developed by Nancy Petry and her colleagues and it has been used to reward participants for negative urine/breath screens and for increasing pro-social behaviors. For each negative screen, participants receive a certain number of "draws" from a fishbowl or similar container. Each draw has a chance of winning a prize. Typically, the majority (half) of slips of paper in the bowl have "good job" written on them, while the other half are associated with prizes. The majority of prizes are small, consisting of items that typically cost \$1. A smaller amount of prizes are large, and are worth approximately \$20. There is a much smaller chance of drawing a jumbo prize, which is typically worth up to \$100. Consecutive negative urine screens earn escalating bonus prize drawings. Thus, if an individual is drug-free on three consecutive urine tests, he or she would earn a drawing plus three bonus draws. At any time that a urine screen indicates drug use, bonus draws would start over or reset to one with the next negative urine test result. Initial research suggests that results of the variable magnitude reinforcement procedure are comparable to and less costly than the voucher method.

When the fishbowl method is used to increase prosocial activities, an individual is required to produce verification that an activity was completed to earn the prize drawings. Using this approach, Godley and colleagues helped adolescents with substance use disorders select from activities including 12-step meeting attendance, movies with friends, and doing activities with parents. So, in this study, adolescents had the opportunity to earn prize drawings for negative urine screens, and

also when they presented verification (e.g. movie theater ticket stub; signed attendance sheet by 12-step meeting chairperson) for participation in pro-social activities.

Several scientists have studied whether monetary reinforcement could be used to increase abstinence from cigarette smoking in adolescents. During these experiments, youth were given monetary rewards or gift certificates based on providing breath samples that showed carbon monoxide levels related to abstinence. Samples were taken daily, and reinforcements were provided for each sample that indicated abstinence, and in one study, additional rewards were provided for consecutive readings indicating abstinence. These studies revealed much higher rates of abstinence for those receiving the rewards for abstinence readings than for those in the comparison group.

One study examined the effectiveness of variable magnitude reinforcement procedures. Participants were adolescents in a substance abuse intensive outpatient program that involved CBT and family systems therapy. Participants submitted once weekly biological samples and received draws for negative samples. No draws were received if the adolescent tested positive for any substance. A bowl containing tokens was used for the draws. Approximately half of the tokens were labeled "good job." A smaller amount were labeled "small," which entitled the participant to a small prize, such as a candy bar or drink. Approximately 8% of the tokens were labeled "large," and could be used to obtain a \$10 gift certificate. Another 0.2% of the tokens were labeled "jumbo," and could be exchanged for a \$60 gift certificate. Participants earned two draws the first time they submitted a negative sample. For every subsequent negative sample, the number of draws increased by two. If at any time a participant tested positive, his/her number of draws was reset to two. The results of this study again showed that adolescents in the test group were three times as likely to remain abstinent as adolescents in the same treatment program who did not receive incentives.

Researchers have provided a rationale why CM might be easier to implement with adolescents and some guidelines for its use. John M. Roll and Donnie Watson suggest that since adolescents typically live with their parents, they could be taught to administer a CM protocol in the home environment and thus the nature of their environment could be more susceptible/ malleable to the reinforcement/punishment regime of CM. Yifrah Kaminer also has summarized seven steps/tips to use when adapting CM specifically for adolescents: (1) target the most important behavior to be changed; (2) pick rewards that adolescents would find desirable; (3) provide rewards either at a fixed rate or use a progressive scale in which each consecutive positive behavior (e.g. negative urine screen) results in an increase in reward; (4) be specific about the procedures to be used; (5) provide rewards immediately once the positive behavior is observed; (6) make use of priming, which involves giving a reward prior to beginning implementation; and (7) follow an evidence-supported approach to implementing CM.

BRIEF TREATMENTS

To improve the accessibility of behavioral treatments for adolescents, researchers have developed and studied brief interventions in locations that are thought to be more conducive to engaging young people than specialty substance use clinics. This is important because even though several adolescent alcohol or other drug (AOD) treatments have been found effective, less than one out of 19 adolescents with a substance use disorder actually receives treatment. Adolescents appear to be slow to acknowledge they have an alcohol or drug problem and rarely seek treatment on their own. Most are required to attend treatment by juvenile justice authorities, their parents, or due to requests from school administrators. Barriers to treatment attendance include transportation, parent work schedules, or parents who are occupied with the care of other children. The possibility of intervening with adolescents, particularly those whose substance use has not involved external agencies and authorities, has been studied in brief, school-based, and hospital ER interventions using motivational interviewing (MI) and CBT.

School-Based Interventions

Many schools in the United States offer some type of school-based services. Eric F. Wagner and his colleagues developed the Teen Intervention Program (TIP) for delivery in schools to address multiple factors they theorized influence the development of substance problems. In 10 weekly sessions, the intervention includes exercises that explore environmental influences, beliefs, and expectancies, and learned behaviors associated with AOD problems. Central to the TIP model is the theory that giving adolescents the ability to make choices about their treatment will help them move toward a decision to change their behavior. The intervention also incorporates components that allow adolescents to determine their readiness to change and to set goals related to changing their substance use and other aspects of their lives. The didactic material, discussion topics, and exercises have the following objectives: (1) educate adolescents about their use; (2) raise awareness about the reasons for their use; (3) help the participant understand the "antecedents, consequences, and patterns associated with their personal use habits"; (4) help the adolescent set and meet goals for reducing or

ceasing use; and (5) develop coping skills to manage stress and other factors related to use. Clinicians who provide TIP are chosen based on their experience providing adolescent group treatment and are not school employees. In a randomized trial, both the TIP and the control conditions resulted in initial improvement in substance use, but the response to TIP was significantly greater and longer lasting.

Another school-based intervention is a brief motivational and cognitive behavioral intervention developed and evaluated by Ken Winters and his colleagues. The investigators compared a two-session intervention for the adolescent only with a three-session intervention that included the same two adolescent sessions with an additional session for parents. The two adolescent sessions were 1 h in length, used an MI approach (nonconfrontational and supportive), and were identical for both conditions. The focus for Session 1 was obtaining information about substance use and consequences for use, discussing the participant's willingness to change and the benefits of change, and discussing what goals for change the participant would like to set. In Session 2, progress toward goals was discussed, including discussion of barriers and whether the participant wanted to continue previously agreed upon goals or set new ones. In the condition that included the parent, the third session consisted of using the same MI style to discuss the adolescent's substance use problem, parental attitudes/behaviors toward the substance use, parental monitoring to promote the participant's goal progress, and healthy drug use behaviors and attitudes by the parent. In a randomized trial, both groups performed well relative to an assessment and referral only control group, but the brief intervention that included parents demonstrated greater reductions in alcohol use than the adolescent-only version of the brief intervention.

Hospital ER Interventions

Adolescents who are taken to a hospital ER for an alcohol-related event may be more receptive to an intervention provided in that setting. Due to the large number of adolescents who use and abuse alcohol, Peter Monti and colleagues created a one-session MI intervention that targets adolescents in hospital ERs. The focus of the MI was the alcohol consumption and risky behavior related to alcohol use, especially driving after drinking. The session typically lasted between 30 and 45 min after potential participants were given a small mental status exam to ensure that they were able to understand and participate in the intervention. The basic components of the MI included an introduction, participant assessment, exploration of motivation, enhancement of motivation, and establishment of a plan to help reduce additional problems related to drinking. A randomized

trial of this MI approach compared to standard care for adolescents in the ER for alcohol-related events revealed significantly better outcomes for reported drinking and driving, subsequent moving violations, alcohol-related injuries, and alcohol-related problems.

COMBINATION BEHAVIORAL TREATMENTS

Researchers have examined the effectiveness of various combinations of behavioral interventions. The theory that underlies combination treatments is that they will be more effective than one treatment component by itself. So, for example, if an effective treatment that focuses on enhancing motivation is paired with CBT, then the adolescent will be more motivated to practice new CBT techniques to change their behavior, thus improving overall treatment effectiveness. Additionally, if the intervention includes the family, and targets family communication, for example, then this might also increase treatment effectiveness. The studies below illustrate, however, that it is not always true that higher dose interventions or ones with more components are more effective or maintain desired changes for a longer period of time.

Motivational Enhancement and CBT

One example of the combination of two treatments is Motivational Enhancement Treatment (MET) with CBT. MET is a variation of MI, and the goal is to increase the adolescent's motivation to change. It is based on the premise that change is more likely to occur if the decision to change is the adolescent's rather than an external requirement (i.e. the justice system or parents). MET draws from five core principles: (1) empathic listening, (2) highlighting discrepancies between what an adolescent wants out of life and their behaviors, (3) avoiding argumentation, (4) what is called "rolling with resistance," which involves responding to resistant statements with empathy rather than confrontation, and (5) reinforcing self-efficacy statements or statements that suggest an individual believes he or she can change. In the multisite Cannabis Youth Treatment study, there were three interventions evaluated that included this approach. All three had two sessions of MET. One condition included the addition of three group CBT sessions that targeted refusal skills, enhancing social support, and planning for relapse (MET/CBT5). The second condition, MET/CBT12, added seven more CBT sessions (problem solving, anger management, communication, coping options for cravings and urges, managing depressed feelings, and managing thoughts about substance use). The third combination treatment also added family therapy and education sessions to MET/CBT12 and was called the family support network (FSN). One of the surprising results from the comparison of these treatments was that the brief five-session treatment was as effective as the 12-session version of MET/CBT and the multicomponent FSN model. The research design did not allow examination of whether the combined treatment was more effective than the MET or CBT intervention alone.

MET/CBT and CM

Catherine Stanger and her associates compared the combination of MET/CBT12, a voucher-based reinforcement therapy, and a family management curriculum developed by Thomas J. Dishion and colleagues. The voucher schedule allowed adolescents to earn escalating vouchers worth up to \$570 for testing negative (both urine and breath) for all substances, provided these tests were corroborated by parents' reports. The family management curriculum was augmented by a fishbowl variable magnitude CM approach. Parents earned up to six fishbowl draws per week by (1) attending therapy, (2) attending mid-week urine testing appointments, (3) implementing substance monitoring contracts with their adolescent twice per week, (4) completing homework, and (5) administering breathalyzer tests.

The control condition received MET/CBT12 and a structured psychoeducational parent curriculum, which had little overlap with the family management curriculum provided in the experimental condition. Control participants also earned \$5.00 vouchers twice per week for attending scheduled counseling and urine testing appointments. Both groups were offered 12 more weeks of once weekly substance testing following the 14-week active treatment phase to reinforce parent monitoring of their adolescent's substance use or nonuse.

The results indicated that both conditions reduced marijuana use, with significantly more consecutive weeks of marijuana abstinence for the experimental condition during the treatment phase. These results compare favorably to other outpatient adolescent studies; however, there was considerable erosion of treatment effect over the follow-up period. This study also found that regardless of treatment condition, reduced negative/inconsistent parental discipline and improved parental monitoring were important predictors of posttreatment marijuana use.

EFFECTIVENESS OF BEHAVIORAL APPROACHES BY GENDER AND CULTURE

Epidemiological data suggest that problems associated with substance use can vary by gender. There is also a widespread concern that treatments must be

culturally appropriate, as behavioral and other evidence-based approaches are implemented in countries that have great cultural diversity and are exported from developers in one country to another. Thus, a logical question is whether the effectiveness of behavioral approaches for adolescent substance use disorders generalizes across gender and cultural groups. There are a number of problems inherent in addressing this question, and paramount among them is the scarcity of studies with sufficient sample size, gender and racial diversity, quality implementation, and process and outcome measures. Danielle Barry and colleagues combined data from three different adult CM studies and found that ethnicity was not related to treatment outcome. Susan H. Godley and colleagues examined several process (e.g. engagement and satisfaction) and outcome measures (e.g. days abstinent) for more than 2000 adolescents participating in a large federally funded A-CRA dissemination and implementation effort. Results indicated that the intervention was equally well implemented across gender and racial groups and equally effective across racial groups, with males having equivalent gains in abstinence and recovery compared to females despite males having greater intake severity and differential outcomes at 6 months. There is an obvious need for more studies to examine this important topic, especially when transporting treatments developed and tested in one group to another group.

SUMMARY

Behavioral treatments for adolescent substance use disorders have an impressive record of controlled research with strong comparative effectiveness data. As with other evidence-based treatments, there are limitations related to treatment effectiveness and in understanding the mechanisms related to the underlying theory of change for each therapeutic approach. For example, CBT has improved substance use outcomes for adolescents in some controlled trials. Researchers have hypothesized that the reason for these changes is an improvement in self-efficacy (i.e. a belief in one's ability to change). However, more research is needed to determine whether improvement in self-efficacy is a result of specific improvements in coping skills or nonspecific factors, such as therapeutic alliance or treatment engagement. Similarly, A-CRA has demonstrated improvement in substance use outcomes. However, more research is necessary to better examine the extent to which improvements in drug-free pro-social activities improved coping skills, or both mediate clinical outcomes compared to other variables, including nonspecific treatment factors. The CM intervention change mechanism appears much more straightforward due to the clear specification of reinforcement contingencies and reliance on biological measures to verify drug use/nonuse. Adolescent studies with posttreatment follow-up suggest that after the withdrawal of reinforcement, drug use behavior begins to increase again. While this finding is not unique to CM, it may receive more attention because of the well-specified, time-limited nature of reinforcement used in these studies. CM research with adults has shown that the achievement of at least 12 consecutive weeks of abstinence dramatically increases the odds of abstinence 1 year later. Research is needed with adolescents to test for this effect, as it would provide useful information for the design and conduct of future CM protocols. For example, protocols that start with high magnitude reinforcement for a 12-week period may prove helpful in studying whether CM can achieve 12 or more weeks of consecutive abstinence with sufficiently high numbers of adolescents to predict sustained abstinence during a subsequent 9-month posttreatment phase.

All the behavioral approaches described above, while effective, would benefit from additional research explicitly designed to provide continued assistance (for poor responders) or to maintain therapeutic gains made during the active treatment phase. Such approaches are beginning to be studied in both adults and adolescents and involve various continuing care strategies that require ongoing monitoring of behaviors such as substance use, relapse antecedents (e.g. internal feeling states such as boredom or loneliness, substance using friends, etc.), and competing pro-social activities. Goal setting and negotiated assignments to deal with problems in any of these areas can be implemented with appropriate follow-up by the clinician, including reintervening to provide more intensive treatment in the event of a sustained relapse. Early signs of promise in this line of continuing care research have been demonstrated in the work of Kaminer and his colleagues as well as Godley and colleagues, but it is very early yet, and more tests with greatly expanded monitoring periods (e.g. 4 years or more) are needed. Relatively brief behavioral interventions in schools and ERs have proven to be useful in expanding both access to treatment and improving substance use outcomes/reducing harm for adolescents whose substance use problems are less severe or at least have not precipitated problems with the juvenile justice or other social systems that remand them to treatment. These approaches are noteworthy in that they can be relatively easily imbedded within settings where youth are found and do not require additional, often complicated, steps to initiate treatment in specialty clinics. However, while available, these brief interventions still are rarely implemented in schools, hospital ERs, or other youth-serving FURTHER READING 175

organizations in the community. Future research is needed to learn how to expand implementation of the existing brief approaches in these settings and to develop and evaluate other brief models of monitoring, support, and re-intervention.

Addiction is increasingly recognized as a disorder beginning in adolescence, and research in behavioral treatments for adolescents has grown in volume and acceptance over the past decade. This trend is expected to continue. Researchers will continue their efforts to understand underlying change mechanisms and improve outcomes during active treatment. Consistent with adult substance use research, greater emphasis will be placed on ways to sustain gains over an extended posttreatment period and to re-intervene with more intensive care when needed. It is expected that this research will benefit from technological advances that are "adolescent-friendly" and make use of the Internet (e.g. programmed e-therapy; chat rooms for convenient impromptu or scheduled continuing care sessions), smart phones with global position technology (e.g. to warn of certain antecedent locations associated with use), and short message services (e.g. text messages to ask for monitoring information or provide support).

SEE ALSO

Evidence-Based Treatment, Motivational Enhancement Approaches, Screening and Interventions in Medical Settings Including Brief Feedback-focused Interventions, Cognitive Behavioral Therapies, Contingency Management, Community Reinforcement Approaches: CRA and CRAFT

List of Abbreviations

ACC assertive continuing care

A-CRA adolescent community reinforcement approach

AOD alcohol or other drug
CBT cognitive behavioral therapy
CM contingency management

CRA community reinforcement approach

ER emergency room

FBT Family Behavior Therapy FSN family support network

MET Motivational Enhancement Treatment

MI motivational interviewing
TIP Teen Intervention Program

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Gender-Specific Treatments for Substance Use Disorders

Christine Grella

University of California, Los Angeles, CA, USA

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INTRODUCTION

Since the 1970s, the field of substance abuse treatment has witnessed tremendous growth in the availability of substance abuse treatment services developed specifically for women. Traditionally, substance abuse treatment programs were designed for male clients who were predominantly referred into treatment through the criminal justice system. However, the proportion of women substance abusers in treatment has steadily increased in the past several decades. At present, women comprise approximately 30% of all admissions into substance abuse treatment, although these rates vary by type of treatment modality and setting. Concurrent with the increase in women

seeking or receiving treatment has been the development of treatment approaches, services, and programs designed specifically for women with substance use problems.

DEVELOPMENT OF "GENDER-SPECIFIC" TREATMENT FOR WOMEN

Prior to the 1970s, a generic treatment model was prevalent, in which there was little recognition of the specific treatment needs of women, as compared with those of men. Beginning in the 1970s, spurred by the women's movement's emphasis on the role of gender in social life and gender-based discrimination, there

was an increasing sensitivity to the issue of gender with regard to substance use and addiction. The focus at this time was primarily on gender differences in the initiation of substance use and progression to dependence, and in the physiological effects of alcohol and drug use; social stigma attached to alcohol and drug use among women, especially among mothers; and barriers encountered by women in seeking and receiving services.

This focus on gender differences logically led to the development of separate treatment programs for women in order to better address their treatment needs, particularly those related to pregnancy and parenting. Several national treatment demonstration projects focusing on substance abuse treatment for pregnant and parenting women were implemented in the 1980s, within the context of public concerns about cocaine/ crack use among pregnant women and mothers. These initiatives helped to foster the growth of women-specific treatment facilities and new treatment approaches. Subsequently, a body of research emerged that examined the characteristics of women who enter into substance abuse treatment; the organizational characteristics of treatment programs designed for women, or in which women are predominant; and the outcomes of women in gender-specific programs or of women who receive "specialized" treatment services within mixedgender programs.

A review of state guidelines regarding genderspecific treatment services for women has shown that there is substantial variability in treatment standards for women and pregnant women across the states. At present, over half of the states and the District of Columbia have some kind of standards for women and/or pregnant women beyond the block grant requirements. Variability exists in how these standards are implemented; these include the areas of licensing/ certification standards; administrative rules, regulations, and statues; contractual requirements; treatment guidelines; and funding applications. Moreover, there is a lack of uniformity in how the states define key constructs, including "gender-specific treatment," and in the level of specificity regarding expected treatment services for women.

PROFILE OF WOMEN WITH SUBSTANCE USE PROBLEMS

Women with substance use disorders typically have complex treatment/service needs given their multiple problems and the barriers they may face to obtaining needed services. Women often present to treatment with co-occurring substance abuse and mental health problems, limited employment skills and work history,

and prior interactions with the criminal justice system. Considerable research has shown that most women with substance abuse problems have been exposed to abuse, trauma, or violence as children and/or as adults. Most women substance abusers who enter into treatment are mothers and many have been separated from their children, either through informal arrangements with other family members or because their children have been put into foster care by the child welfare system.

In addition, many women substance abusers have physical health problems that stem from the consequences of their substance abuse and associated unhealthy and risky behaviors, including risks for HIV. These health problems are further compounded by their lack of access to or utilization of health care services, including preventative and reproductive health care services. Moreover, as compared with men with substance use problems, women tend to have more severe family and social problems; have higher rates of co-occurring mental disorders, particularly mood and anxiety disorders; and are less likely to have viable work skills or a history of paid employment.

Substance use among women may co-occur with other types of addictive behavior, such as shopping, Internet gaming, and gambling. Women with substance use problems may also have co-occurring eating disorders or engage in self-harming behaviors, as an outgrowth of anxiety and depression. Experience of intimate partner violence is pervasive among women substance users. Women with substance use problems may also perpetrate violence toward others, often within the context of abusive relationships in which alcohol and drug use are embedded within the relationship dynamics. Further, addiction may propel women into income-producing activities that distinguish them from women in the population at large, such as drug- or property-related criminal behavior and prostitution. Women substance users also face risks for HIV to a greater extent than men as a consequence of having drug-using partners who may have other sex partners; sharing injection equipment with sexual partners; and engaging in sex work for drugs or money.

It is important to note that women with substance use disorders are heterogeneous with regard to age (e.g. adolescents, young adult women, and older women), sexual orientation, race/ethnicity, ability, parenting status, location (e.g. rural versus urban), and socioeconomic status, and that these factors may influence clinical profile and treatment needs. Thus, the diversity among women with substance use problems needs to be addressed within the context of gender-specific treatment.

GENDER-SPECIFIC TREATMENT APPROACHES FOR WOMEN

Gender-specific substance abuse treatment services and programs for women generally focus on the psychosocial profile of substance-abusing women and their need for comprehensive services, particularly in regard to pregnancy and parenting, physical and mental health problems, employment and housing, and history of trauma and victimization. Some research suggests that women may be more responsive to treatment within women-only treatment facilities or groups because they feel less intimidated or concerned about being stigmatized in such settings, because of a desire to obtain services specific to their needs (e.g. for pregnancy or parenting), or because they seek shelter from intimate partner violence. Women may also feel safer and less vulnerable to harassment as well as better able to express their needs and feelings in gender-specific programs or groups. These emergent treatment approaches have been characterized as "gender-specific," "womanfocused," "gender-sensitive," or "gender-responsive."

Gender-specific treatment programs typically adopt treatment approaches or modalities that are modified from traditional treatment models. For example, many gender-specific treatment programs for women incorporate "empowerment" and supportive approaches to treatment, rather than traditional approaches that rely upon confrontational strategies to address "denial" among substance abusers. Empowerment approaches focus on identifying and building upon a woman's strengths, such as her nurturing and relational capacities, rather than focusing solely on her deficits. Such approaches are particularly important given the generally higher levels of psychological distress, trauma exposure, and co-occurring mood and anxiety disorders that characterize women who enter into substance abuse treatment and the need to enhance their sense of competency and self-efficacy.

Another factor that differentiates gender-specific treatment approaches is the greater emphasis on addressing relationship issues within treatment, including relationships with family members, spouses or partners, children, and others. Upon entry into treatment, women typically report more interpersonal problems and conflicts with others than do men. Women may be more willing to self-disclose interpersonal problems, but they may also place more primacy on their relationships with others within their identity and self-concept. However, women with substance use disorders may have more conflicted family relationships for a variety of reasons, including family members who are less tolerant of their alcohol or drug use, sexual partners who are not supportive of their efforts to stop their

alcohol or drug use, and problematic relationships with children stemming from the mother's substance use and lack of parenting skills.

CHARACTERISTICS OF GENDER-SPECIFIC TREATMENT SERVICES AND PROGRAMS

The proliferation of gender-specific programs in the past several decades has enabled the development of a rich body of research on the organizational characteristics of these treatment programs and the types of treatment services they provide. An early study conducted in the 1980s of 53 alcohol-treatment facilities in California showed that facilities in which there were higher proportions of women clients provided more services overall, and in particular more services for children, child care, and aftercare services. Subsequent studies have shown that treatment facilities that provide services to women only, or in which there is a higher concentration of women, typically provide a wider range of services designed to meet women's specific treatment needs.

Data collected from an annual national survey of treatment providers show that approximately 41% of all treatment programs (among those that accept women as clients) provide either a "special" treatment program or services specifically for women. Among these programs, 41% provide domestic violence services, 17% provide services for pregnant or postpartum women, 18% provide child care, and 9% provide residential beds for clients' children. Moreover, a greater proportion of programs that provide women-specific services, compared with those that do not, also provide other comprehensive services typically needed by women; these included housing assistance, employment counseling, and assistance with social services. Facilities providing a special program or service for women are more likely than other programs to be operated by private, nonprofit organizations and less likely to be operated by private, for-profit groups.

Surveys of treatment programs that receive a majority of their funding from private (i.e. nongovernmental) sources have shown similar findings regarding organizational characteristics as surveys of publicly funded providers. Private-sector programs with a "majority female caseload" are more likely than those in which women are a minority to provide child care, to have more family involvement in treatment, to provide treatment for psychiatric disorders, to employ counselors with master's level degrees, to receive more referrals from mental health sources and fewer workplace referrals, and to accept payment through public insurance. Another survey of outpatient substance abuse treatment

programs examined the organizational factors related to the provision of women's health services, such as gynecological exams, reproductive services, and prenatal services. Programs providing these services are more likely to receive funding earmarked for women's treatment, to be methadone providers, to have a greater proportion of staff who have been trained in women's treatment issues, and to be private not-for-profit units and public units, rather than for-profit.

National survey data have shown that the proportion of programs that provide services typically associated with women's treatment needs (i.e. child care, domestic violence counseling, family counseling, prenatal and postnatal care) gradually increased from mid-1980s, peaked in the mid- to late 1990s, and subsequently declined. The largest proportion of gender-specific facilities for women are among residential/therapeutic community (TC) programs (~20%); hence, women also constitute a greater proportion of clients treated within residential programs (~35%) compared with their representation in other modalities. Therefore, the vast majority of women receive treatment in mixed-gender outpatient programs, which has the lowest rates of providing women-specific services.

In addition, national survey data show that programs that provide "special services" for women (e.g. a women-specific program, group, or treatment track) are more likely to provide other services that address women's treatment needs (e.g. child care, transportation assistance, housing assistance, domestic violence counseling, employment counseling). Other studies have shown that gender-specific treatment programs for women provide a wider range of comprehensive services than mixed-gender programs, including prenatal, postpartum, and well-baby services; job training, life skills training, client advocacy, transportation, housing assistance; and peer support groups and aftercare. In addition, programs that are primarily publicly financed or not-for-profit are more likely to provide these services than those that are for-profit.

A recent panel study compared the provision of services relevant to women's treatment needs (e.g. prenatal care, child care, single-sex therapy, same-sex therapists, staff trained in women's treatment) in outpatient substance abuse treatment programs in 1995 and 2005. The study found that there were significant declines over this period in the provision of single-sex therapy and the percentage of staff trained to work with women in outpatient programs. Furthermore, private for-profit treatment units became more prevalent over the study period, and these programs are less likely than others to provide the range of services defined by women's treatment needs. There were also significant declines in the provision of same-gender group therapy in methadone programs from 1995 to 2000, as well as declines in

same-gender individual and group therapy in nonmethadone outpatient programs from 1995 to 2005. Taken together, these surveys indicate that the growth in gender-specific services for women has slowed within outpatient programs and that provision of these services may be influenced by the sources of financing for these programs.

Although women are a minority within the criminal justice system, in the past several decades there has been a more rapid increase in the incarceration rates of women for drug-related offenses, as compared with men. This difference primarily stems from women's greater involvement in drug- and property-related crime, as opposed to other types of criminal behavior, compared with men. Given the increased rates of incarceration of drug-using women, gender-specific treatment programs for women offenders have been developed in both correctional and community-based treatment settings. Substance-abusing women offenders have substantial needs related to mental and physical health problems, trauma history, HIV risks, parenting, employment, and economic self-sufficiency. In addition, women offenders face numerous stressors upon their reentry to the community, including their reexposure to social networks and relationships that may precipitate their relapse to substance use and criminal activity. Gender-specific treatment programs developed for women offenders place an emphasis on providing parenting skills training; assistance with family reunification, when appropriate, including with children who have been placed in the child welfare system; assistance with educational needs, literacy training, vocational skills, and employment; and supportive social networks to sustain recovery and avert recidivism.

Despite the greater availability of services that directly address women's treatment needs in womenonly programs, there remain gaps in the provision of needed services to women. As seen in one study of women who were referred into a gender-specific program for women by the child welfare system, fewer than half of the women who indicated they had specific treatment needs for child care, family counseling, job training, housing assistance, and benefits assistance actually received these services while in treatment. Thus, the provision of gender-specific services for women is neither universally available nor comprehensive throughout the broader treatment system.

OUTCOMES OF WOMEN TREATED IN GENDER-SPECIFIC PROGRAMS

Several early studies, predating the expansion of gender-specific programming for women, examined the outcomes of women who received treatment in women-only versus mixed-gender programs. An experimental study conducted in Sweden in the 1980s, conducted with women who were in the "early stages" of alcohol dependence, demonstrated reduced alcohol use and better social adjustment for women treated in women-only programs compared to those who were treated in mixed-gender programs. The authors surmised that women may be more likely to enter into women-only programs at an earlier stage of their addiction careers. In contrast, a nonexperimental study conducted in Australia in the 1990s, which enrolled women who had more severe alcohol and drug disorders, found no outcome differences in drug use, severity of depression, self-esteem, or social support network between women treated in women-only and those treated in mixed-gender programs. However, lesbian women, women with a history of childhood sexual assault, and women with dependent children were less likely to drop out of the women-only program.

In the ensuing years, based on data from the various treatment demonstration projects that enabled the expansion of services dedicated to women as well as from single-site clinical studies, a growing body of research has accumulated regarding the characteristics of women treated in gender-specific programs, and their posttreatment outcomes, as well as the outcomes of their children who also receive services. Several studies show that there are differences in the characteristics of women who receive treatment in gender-specific and mixedgender treatment programs. In an early study, women treated in women-only residential programs were more likely to have been sexually abused as children, to be lesbians, and to have dependent children, compared to women in mixed-gender residential programs. In another study, women who were treated in women-only residential programs had more severe problems and service needs at treatment entry (e.g. pregnant, homeless, longer duration of drug use, under legal supervision), but they were twice as likely to complete treatment as compared with women who were treated in mixed-gender treatment programs.

Several national and site-specific studies have shown that women who are treated in programs that provide gender-specific services are retained longer in treatment and have better outcomes, as compared to women treated in traditional mixed-gender programs that do not provide gender-specific treatment services. A national treatment outcome study found that pregnant and parenting women who were treated in residential programs in which there were higher proportions of other such women had longer stays in treatment and that longer stays, in turn, were positively associated with posttreatment abstinence. These programs also provided more comprehensive services, including those that addressed family, parenting, and mental health

needs. A nonexperimental study conducted in California compared women treated in women-only and mixed-gender programs, including both residential and outpatient programs. As found in other studies, women treated in women-only programs had greater problem severity in a number of domains including alcohol, drug, family, medical, and psychiatric. Moreover, they utilized more treatment services and had better drug and legal outcomes at follow-up as compared to women who were treated in mixed-gender programs.

In another study, providing women with transportation, outreach, and enhanced treatment services was associated with receipt of a greater number of services overall, which in turn was related to lower posttreatment drug use. Moreover, another study has shown that women who are treated in specialized long-term residential treatment programs for women are more likely than those treated in standard, mixed-gender programs to be referred to services (e.g. medical, dental, mental health, vocational) and to self-help groups at the time of discharge, and that they are more likely to participate in continuing care following their discharge. Further, this effect was enhanced among women who had completed the specialized residential treatment.

Taken together, this body of research has demonstrated that women have higher rates of treatment completion and better outcomes: (1) in residential treatment programs that have live-in accommodations for children; (2) in outpatient treatment that includes the provision of family therapy, individual counseling, and family services; and (3) when treatment includes comprehensive supportive services, such as case management, pregnancy-related services, parenting training/classes, child care, vocational training, and aftercare. In addition, women in substance abuse treatment who receive more health and social services report better outcomes and greater satisfaction with treatment, particularly when services are matched with their needs.

GENDER-SPECIFIC TREATMENT COMPONENTS ASSOCIATED WITH OUTCOMES

The proliferation of research on women-specific treatment has allowed for several reviews that examine the common elements associated with improved outcomes for women in substance abuse treatment. A meta-analysis of 34 treatment outcome studies showed that women who received substance abuse treatment in women-only programs, compared to those treated in mixed-gender programs, had better drug use outcomes following treatment. Similarly, women who were treated in women-only programs that had enhanced

programming (i.e. more intensive or specialized services), compared with those in standard womenonly programs, had better outcomes in several areas, including psychological well-being, attitudes and beliefs, and HIV risk reduction. Although overall effect sizes for these differences were modest, the largest effects were found in the area of psychiatric outcomes, with smaller effects for reductions in alcohol use, other drug use, and criminal activity.

Another systematic review of program factors related to successful treatment outcomes among women in 35 studies identified five factors: (1) single- versus mixedgender programs; (2) treatment intensity; (3) provision of child care; (4) case management; and (5) supportive staff and the provision of individual counseling. Similarly, a systematic review of 38 studies of substance abuse treatment for women, most of which were nonexperimental designs, identified six elements that are associated with better outcomes regarding treatment completion, length of stay, decreased use of substances, reduced mental health symptoms, improved birth outcomes, employment, self-reported health status, and HIV risk reduction. These elements are (1) child care, (2) prenatal care, (3) women-only program composition, (4) supplemental services and workshops that address women-focused topics, (5) mental health services, and (6) comprehensive programming.

An important consideration with regard to the adoption of gender-specific services is the generally higher cost of these services, due to the longer duration of treatment and inclusion of comprehensive services that increase costs, such as medical services, live-in capacity, and/or services for children, vocational services, mental health services, housing, and so forth. Yet, several studies have shown that despite the generally higher costs of gender-specific treatment for women, these costs are offset by the improved outcomes they yield. Costbenefit analyses have shown favorable results in residential versus outpatient treatment for women; in specialized versus standard residential programs for women; in substance abuse treatment that integrates "trauma-specific" services versus usual care; and in a multidisciplinary, comprehensive treatment program for pregnant women versus standard care.

METHODOLOGICAL ISSUES IN RESEARCH ON GENDER-SPECIFIC TREATMENT

Several methodological shortcomings to the extant body of research on women's treatment programs have been identified. These include (1) a limited range of treatment outcomes examined; (2) lack of experimental studies with randomized assignment to conditions; (3) lack of standardized measures; (4) inconsistent definitions for treatment factors and outcomes; (5) small sample sizes that lack statistical power, particularly for conducting subgroup comparisons; (6) lack of thorough program description that allows for replication of program models; (7) lack of thorough statistical analyses; (8) small effect sizes for observed outcomes; and (9) limited duration of follow-up periods. These limitations in methodological rigor, although not unique to this area of research, clearly qualify the conclusions that can be drawn from the extant literature on treatment outcomes for women who are treated in gender-specific programs or who receive specialized treatment services.

In addition to these methodological considerations, several exceptions to the findings regarding superior outcomes for women treated in gender-specific programs should be noted. An experimental study that randomly assigned participants to women-only versus mixed-gender day treatment programs found no beneficial effects of women-specific treatment. Moreover, other research has found no differences in the rates of retention and completion among either males or females who were treated in mixed-versus single-gender programs. However, research findings may be inconclusive because these studies failed to differentiate the client composition of the programs from the content of treatment/services that were provided. Thus, the construct of "gender-specific" treatment, and the "active ingredients" of treatment approaches designed for women, needs to be carefully defined and measured.

For example, traditional TC programs, even if gender-specific, may be clinically inappropriate if their emphasis on confrontation is not modified to accommodate the greater likelihood of trauma and abuse history among women, particularly among women in the criminal justice system where TC programs have been widely adopted. Further, it is assumed that the therapeutic dynamics within gender-specific programs for women differ from those in mixed-gender programs, yet many outcome studies examine only time in treatment or types of services provided, rather than the therapeutic aspects or key components of women-specific treatment that may be related to outcomes.

EVIDENCE-BASED TREATMENT APPROACHES FOR WOMEN WITH SUBSTANCE USE DISORDERS

Increasing emphasis has been placed on incorporating treatment approaches that have received empirical support from scientific research on treatment effectiveness and outcomes. Several treatment approaches have emerged as the primary evidence-based treatment practices within the field of addictions treatment. These include pharmacotherapy, relapse prevention/cognitive behavioral interventions, motivational interventions, contingency management, and trauma-specific interventions. These treatment approaches have either been modified or have the potential to be, in order to address the specific treatment needs of women. The evidence on effectiveness of these approaches for women, and their potential to address gender-specific treatment for women, is briefly described below.

Pharmacotherapy

Pharmacotherapy, mostly opiate-substitution therapies, has addressed the use of medications in the treatment of pregnant women, given considerations of prenatal exposure and birth outcomes, and the need to adjust dosing appropriately. Pharmacological treatment of opiate-dependent pregnant and postpartum women requires careful consideration of assessment and selection of appropriate maintenance medication; induction and stabilization; and medication management in relation to the various stages of pregnancy, delivery, postpartum, and aftercare. A large, multisite double-blind study recently showed that opiate-dependent pregnant women who receive buprenorphine have similar or improved outcomes (with regard to treatment adherence, birth outcomes, neonatal status) as pregnant women who receive methadone maintenance treatment. Apart from issues related to pregnancy, few clinically significant gender differences have been identified in the use of buprenorphine (a medication with both opioid agonist and antagonist properties) and methadone (an opioid agonist).

There is some evidence suggesting that, among patients with cocaine and alcohol dependence being treated with naltrexone (an opioid receptor antagonist), women have more side effects, less treatment adherence, more treatment attrition, and lower rates of abstinence in response to the same dose, as compared with men. Gender differences in pharmacokinetics (e.g. processes related to the absorption, distribution, metabolism, and elimination of a drug) may underlie differential responses to medications and their effectiveness in treating alcohol or drug dependence; however, research in this area is still limited.

Relapse Prevention

Relapse prevention approaches focus on teaching clients to recognize "cues" or "triggers" for substance use and to use cognitive behavioral strategies for coping with these triggers and avoiding relapse in those situations. Generally, gender differences have not been identified in response to relapse prevention interventions; however, there are differences in the factors and social contexts that are associated with relapse to substance use for men and women. For males, these include living alone, positive affect, and social pressures, whereas for females, relapse has been associated with not living with one's children, being depressed, having a stressful marriage, and being pressured to use by their sexual partners. Several factors that influence likelihood of relapse among women have been identified across studies: (1) low self-worth and its connection to intimate partner relationships with men; (2) interpersonal conflicts and/or negative emotional states; (3) less ability to sever relationships with one's drug-using network and to establish new relationships with nonusers; and (4) a lack of knowledge about alcohol and drug processes and relapse prevention coping skills.

Cognitive behavioral approaches can be tailored to help women identify the specific triggers and situations that may be likely to precipitate relapse, and to utilize effective coping strategies for dealing with those situations. In particular, given the higher rates of co-occurring mood and anxiety disorder among women, the role of psychiatric symptoms in precipitating relapse needs to be identified and appropriate mental health treatment provided. Current research in this area is focusing on identifying the key ingredients of cognitive behavioral approaches that are effective in reducing relapse for women. Thus, it is unclear whether the group dynamics in all-women groups that provide these interventions, or the gender-specific content provided within these groups, such as women's specific antecedents to substance abuse and cues and triggers to relapse, improve women's responses to cognitive behavioral interventions, or some combination of both process and content.

Motivational Interventions

Motivational interventions use therapeutic strategies to increase the individual's awareness of problems that stem from their substance use, to engage their commitment to behavior change, and to support ongoing efforts at behavior change that includes an understanding of relapse within the recovery process. Behavioral change is conceptualized as a dynamic process across stages, including precontemplation, contemplation, action, and maintenance. Brief motivational interventions may be delivered by counselors, nurses, or social workers in health care or social services settings, in conjunction with screening and referral to substance abuse treatment, or can be integrated within the therapeutic process of substance abuse treatment.

Few studies have actually examined gender differences in the effectiveness of motivational approaches, either in treatment engagement or outcomes. Motivational interventions can build upon the issues that are central to motivating women to address their substance abuse problems, particularly related to their identity, self-esteem, health, and relationships with children, other family members, and friends. Brief motivational intervention has been used to address alcohol and tobacco use among pregnant women in primary health care or prenatal care settings by providing information on the health effects of alcohol or tobacco use during pregnancy, with the aim of motivating women based on their desire to protect the health of their child.

Contingency Management

Contingency management approaches employ a schedule of rewards to strengthen the practice of desired behaviors (e.g. abstinence, prosocial activities). These rewards may be small gifts, cash, or vouchers, which can be accumulated based on the duration of abstinence attained, as well as reversed upon a relapse. Although few studies have identified gender differences in response to contingency management, some interventions have been developed specifically for women.

Most commonly, contingency management has been successfully used in smoking reduction programs for pregnant women who are receiving treatment for drug abuse and for pregnant women who are in treatment for alcohol or cocaine dependence. Contingency management for women can effectively utilize personal hygiene, household, or children's items as "prizes" for attaining or sustaining abstinence, based on urine test results. Contingency management interventions have also been combined with brief motivational interventions within the context of case management services for pregnant women.

Trauma-Specific Interventions

Several interventions have been developed to integrate treatment for the effects of trauma exposure, including co-occurring posttraumatic stress syndrome (PTSD), within the context of substance abuse treatment. Examples of these trauma-specific treatment approaches include *Seeking Safety*, which integrates cognitive behavioral strategies with group psychotherapy to address both PTSD and substance abuse disorders; *Beyond Trauma*, a curriculum that was developed specifically for women and employs "relational theory" to build upon the importance of relationships in women's emotional well-being; and the *Trauma Recovery and Empowerment Model*, which uses group therapy to

promote recovery skills and social functioning. Outcomes studies have shown promising outcomes for women who receive trauma-specific interventions, although mainly on reducing trauma-related symptoms, rather than in reducing alcohol and drug use.

CONCLUSIONS

There have been tremendous gains in recent years in our understanding of the influence of gender on the course of substance use disorders, the differential pathways into treatment, the clinical and service need profiles of women with substance use problems, and the factors related to treatment retention and outcomes in gender-specific programs. There is a rich body of research on the organizational characteristics of the programs in which women receive substance abuse treatment, the types of services that are provided in these programs, the changes in services provision over time, and the relationship of services received to treatment outcomes, including the cost effectiveness of gender-specific treatment for women.

emphasis on evidence-based treatment approaches within the field of addiction treatment provides further opportunities to tailor treatment protocols to increase their effectiveness with women, particubehavioral approaches that use cognitive behavioral therapies, motivational enhancement interventions, contingency management, and traumainformed interventions. At the same time, more developed conceptual models are needed that identify the mechanisms that underlie gender-specific treatment approaches and their effectiveness for women, as well as the comparative effectiveness of these approaches for different subgroups of women.

SEE ALSO

Evidence-Based Treatment, Motivational Enhancement Approaches, Cognitive Behavioral Therapies, Contingency Management, Behavioral Couples Therapy for Alcoholism, A Decade of Research on Recovery Management Checkups, PTSD and Substance Abuse Treatment

List of Abbreviations

PTSD posttraumatic stress syndrome TC therapeutic community

Glossary

Gender differences with regard to substance use, gender differences focus on how men and women differ in their background

FURTHER READING 185

- characteristics, initiation, and progression of substance use, family and social support, education and employment history, mental and physical health, parental status, service needs, patterns of treatment utilization, and treatment outcomes.
- Gender-responsive treatment according to Covington and Bloom (2006), gender-responsive treatment is "creating an environment through site selection, staff selection, program development, content, and material that reflects an understanding of the realities of women and girls and that addresses and responds to their strengths and challenges." Also referred to as "woman-focused" or "gender-sensitive" treatment.
- **Gender-specific treatment** refers to treatment programs or services that are specifically for women or men and are typically sex segregated, in contrast with "mixed-gender" programs or services.
- Program characteristics refers to the organizational features of treatment programs that may influence treatment processes and outcomes. These include program size; characteristics of staff, such as sociodemographics, education, training, and rate of turnover; revenue sources and program resources; stability of the program, such as its duration; types of services provided to individuals in treatment; linkages with other service providers; and overall program "culture" and "climate" that reflect the shared beliefs of staff about their mission and goals and attitudes toward treatment.
- **Trauma-informed services** according to Morrissey et al. (2005), trauma-informed services refer to the provision of a comprehensive array of services that include outreach, assessment, crisis intervention, trauma-specific counseling, ongoing treatment, parentskills training, resource coordination and advocacy, and peer-run services; trauma-specific service interventions; appropriately trained staff; integration of counseling and other services for treatment for mental health, substance abuse, and trauma-related problems; and inclusion of input from consumers.
- Treatment outcomes with regard to substance use, treatment outcomes refer to posttreatment relapse to substance use and may also broadly include mental and physical health status, employment, criminal activities and/or involvement in the criminal justice system, family and social functioning, and overall psychosocial functioning. Research has focused on gender differences in specific outcome domains and in the factors that are correlated with positive treatment outcomes.

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20

PTSD and Substance Abuse Treatment

Julian D. Ford

University of Connecticut Health Center, Farmington, CT, USA

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Individuals in treatment for alcohol and other substance use disorders (ASUD) often have faced adversity in their lives, including psychologically traumatic events. Community and clinical epidemiologic studies have found that individuals in treatment for alcohol and other ASUD, especially involving opiates, are likely to have experienced psychological trauma (e.g. 67–90% prevalence) and post-traumatic stress disorder (PTSD, i.e. 25–48% prevalence) at some time in their lives. These prevalence estimates for lifetime exposure to psychological trauma and PTSD are substantially higher than those from community epidemiological studies of adults and adolescents, which estimate 33–60% prevalence of exposure to psychological trauma and 4–7% lifetime prevalence of PTSD.

There also is substantial clinical evidence that PTSD and ASUD tend to exacerbate and sustain each other. Men and women with alcohol- or cocaine-related ASUD and PTSD were more likely than those without PTSD to report a craving for substances if reminded of past trauma or substance use. Women in ASUD treatment with comorbid PTSD-ASUD report more extensive trauma histories and severe PTSD symptoms (particularly avoidance, emotional numbing, and sleep difficulties) than women with PTSD only. Read and colleagues found that higher substance use levels or problems also are associated with more severe intrusive

and avoidance PTSD symptoms. Similarly, Seedat and colleagues found that higher substance use levels were associated with more severe dissociation symptoms. Conversely, Stewart and Conrod found that accident survivors or women who have been raped were more likely to have persistent PTSD if they had prior alcohol disorders than those with no alcohol disorder.

Given the frequent comorbidity of PTSD and psychological trauma history with ASUD, and the impairment resulting from this combination, clinical research and treatment development efforts have focused on three approaches to addressing PTSD in ASUD treatment services:

- 1. Determining whether, and how, psychological trauma history and PTSD can serve as prognostic factors in ASUD treatment.
- **2.** Developing and evaluating interventions that simultaneously treat PTSD and ASUD in an integrated concurrent or sequential intervention.
- **3.** Developing and evaluating screening for PTSD in ASUD treatment settings, in order to facilitate targeted delivery of integrated ASUD/PTSD treatment.

Research on the impact of psychological trauma and PTSD in ASUD treatment is nascent but could contribute to enhanced treatments for comorbid ASUD-PTSD. A

brief introduction to the definition and clinical features of psychological trauma and PTSD, and their relationship to ASUD, will be provided before reviewing relevant research in the three areas described above.

PSYCHOLOGICAL TRAUMA AND PTSD

Psychological trauma is defined in the American Psychiatric Association's *Diagnostic and Statistical Manual*, Fourth Edition Text Revision (DSM-IV-TR) as:

a traumatic event in which both of the following were present: (1) the person experienced, witnessed, or was confronted with an event or events that involved actual or threatened death or serious injury or a threat to the physical integrity of self or others (2) the person's response involved intense fear, helplessness, or horror.

Thus psychological trauma is a special case of the larger class of life stressors which is defined by objective threat of death (directly or as a witness) or of physical integrity (i.e. sexual assault or abuse) and intense subjective distress at the time of or shortly after the event(s).

PTSD is further defined in the *DSM-IV-TR* as present if, for more than 1 month, three types of symptoms occur and cause "clinically significant distress or impairment in social, occupational, or other important areas of functioning." The PTSD symptoms are as follows:

- Intrusive re-experiencing unwanted disturbing memories of traumatic event(s), including but not limited to flashbacks (experiencing the event as if it was occurring at the present moment) and psychologically or physically distressing reminders of past traumatic events, while awake or asleep (e.g. nightmares).
- Avoidance and emotional numbing efforts to avoid thoughts, feelings, discussion, people, places, or activities that are reminders of past traumatic events, amnesia for important portions of those events (which must be "psychogenic," that is, not due to physical injury or illness), generalized anhedonia, emotional numbing, detachment from relationships, and a sense that life will be cut short ("foreshortened future").
- Hyperarousal sleep difficulties, anger or irritability, problems concentrating, extreme watchfulness ("hypervigilance"), and an exaggerated startle response.

In order to qualify for a diagnosis of PTSD at least one intrusive re-experiencing symptom, three avoidance and emotional numbing symptoms, and two hyperarousal symptoms must occur.

In the proposed criteria for PTSD in the American Psychiatric Association's *DSM-5*, psychological trauma

has been re-defined as exposure to "death or threatened death, actual or threatened serious injury or actual or sexual violation," in one or more of the following ways:

- 1. Experiencing the event(s) him/herself.
- **2.** Witnessing, in person, the event(s) as they occurred to others.
- **3.** Learning that the event(s) occurred to a close relative or close friend; in such cases, the actual or threatened death must have been violent or accidental.
- 4. Experiencing repeated or extreme exposure to aversive details of the event(s) (e.g. first responders collecting body parts; police officers repeatedly exposed to details of child abuse); this does not apply to exposure through electronic media, television, movies, or pictures, unless this exposure is work-related.

Two key changes are proposed to the trauma criterion DSM-5. First, the requirement that the person experiences a subjective reaction of intense fear, helplessness, or horror at the time or soon after the traumatic event(s) has been removed. This may be relevant for individuals who have ASUD when exposed to psychological trauma or who develop ASUD thereafter, given evidence from a study by Ouimette and colleagues that comorbid ASUD/PTSD often involves heightened emotional numbing which may involve (or be exacerbated by) substance use as a self-medication tactic. Second, events are explicitly included that were not directly experienced or witnessed but that were learned about or seen in the aftermath and that involve family or close friends or gruesome death or bodily harm. The latter additions are particularly relevant in light of evidence of increased risk of ASUD (particularly problems involving alcohol use) among victims of political or domestic violence, and among first/emergency responders, military personnel, and others who routinely face extreme hazards or give aid to victims of psychological trauma.

Several revisions of the symptom criteria for PTSD proposed in the DSM-5 also may have a bearing on the ASUD-PTSD relationship and treatment for comorbid ASUD-PTSD. The symptoms of emotional numbing that formerly were grouped with avoidance symptoms have been expanded and separated out as a distinct feature labeled: "negative alterations in cognitions and mood that are associated with the traumatic event(s)." Specifically, symptoms have been added to describe post-traumatic alterations in beliefs ("persistent and exaggerated negative expectations about one's self, others, or the world" and "persistent distorted blame of self or others about causes or consequences of the traumatic event(s)") and emotions ("pervasive negative emotional state - for example, fear, horror, anger, guilt, or shame"). Exemplars of altered post-traumatic beliefs provided in the DSM-5 proposed revision are similar to cognitive distortions that have been found to occur commonly among individuals with ASUD (e.g. "I am bad," "No one can be trusted," "I've lost my soul forever," "my whole nervous system is permanently ruined," "the world is completely dangerous"). The inclusion of persistent negative emotions as PTSD symptom is relevant to ASUD treatment because pervasive negative mood has been found to be associated with alcohol craving, and difficulty with negative emotion regulation may share biological and behavioral substrates with addiction. Thus, the expanded cognitive and affective symptoms proposed for PTSD in the DSM-5 potentially offer additional addiction-related foci for addressing PTSD in ASUD treatment.

PSYCHOLOGICAL TRAUMA, PTSD, AND ASUD

Epidemiologic studies have shown that adults with ASUD (especially when those disorders involve opiates or cocaine) are at least 150% and as much as 10 times more likely to have PTSD than other adults, and adolescents with ASUD show a similar but somewhat lesser (i.e. 50–200%) increased risk of PTSD. PTSD is also associated with the risk of ASUD, particularly among adolescents for whom the risk of ASUD is as much as 14 times greater when PTSD occurs. Adults with PTSD have a 50–350% increased risk of ASUD.

PTSD and ASUD may co-occur for many reasons. The theoretical model with strongest empirical support is the "self-medication hypothesis," which suggests that ASUD represent an attempt to use substances to cope with PTSD symptoms. Both epidemiological and ASUD treatment studies provide additional support for the self-medication hypothesis, showing that PTSD more often pre-dates ASUD than vice versa, with only one exception in which 18-year olds were slightly more likely (54%) to report that alcohol dependence preceded PTSD than vice versa (46%). A prospective study of primarily white middle-class adults in a health maintenance organization (age 21-35 years) found that PTSD led to a fourfold increased risk of developing ASUD independent of the influence of prior conduct problems or depression, but ASUD did not increase the risk of either exposure to psychological trauma or PTSD. The strongest relationship between PTSD and ASUD was with abuse or dependence upon prescription drugs but not street drugs, consistent with the higher levels of use of prescription drugs versus street drugs by this particular subgroup of young adults. Similar findings of ASUD leading to an increased risk of PTSD (but not of trauma exposure per se) have been reported with alcohol and street drugs in studies of women, military veterans, and disaster victims. Thus, ASUD may

pre-date and lead to PTSD, but it is more likely that ASUD develop or are worsened as a result of attempts to cope with PTSD symptoms.

However, certain forms of illicit drug use may have a more complex relationship to PTSD symptoms than simply increasing their likelihood, prominence, or severity. Substances that are associated with increased arousal (e.g. cocaine, amphetamines) may be used to heighten PTSD hyperarousal and hypervigilance symptoms, or to counteract or compensate for post-traumatic dysphoria and emotional numbing. Consistent with this view, studies by Shiperd and colleagues and Waldrop and colleagues which found only partial support for the self-medication model reported no relationship between, respectively, "hard drug" use and PTSD, and greater use of cocaine at times of "pleasant interaction with others" by individuals with PTSD and ASUD.

PTSD also may play a role in the etiology of ASUD in adolescence. In the National Survey of Adolescents (NSA), Kilpatrick and colleagues found that PTSD increased the risk of ASUD and of associating with "deviant" peers (i.e. peers involved in delinquent activities, including substance abuse and conduct problems). Another study by Cornelius and colleagues assessed sons of men who had a lifetime history of substance abuse at several intervals from ages 12–14 to 25 years old, finding that PTSD was associated with both deviant peer associations and cannabis use disorders. Moreover, PTSD mediated the relationship between deviant peer associations cannabis use disorders. Further indirect support for this view comes from secondary analyses of NSA data by Ford and colleagues, which showed that youth who are exposed to multiple forms of traumatic stressors were particularly likely to develop both PTSD and ASUD, and to engage in delinquency and with deviant peers. Thus, among youth involved in delinquency or with deviant peers, PTSD may contribute to the development of ASUD.

Adults or adolescents who experienced extensive maltreatment or multiple forms of traumatic victimization are at risk not only for ASUD but also for severe problems with emotion dysregulation, dissociation, self-harm, impulse dyscontrol, and relational conflict and instability. Although not codified as a psychiatric diagnosis, this constellation of self-regulatory deficits has been described as a complex variant of PTSD. Complex PTSD symptoms may interfere with engagement, motivation, active participation, learning, and retention in ASUD treatment, and with the ability to inhibit substance cravings and impulsive substance-seeking, and to sustain substance-free relationships and relapse prevention behaviors. Therefore, it is important to examine the potential role of complex PTSD as a prognostic indicator in ASUD treatment.

PSYCHOLOGICAL TRAUMA HISTORY AND PTSD AS PROGNOSTIC FACTORS IN ASUD TREATMENT

PTSD has been found to negatively influence the course and outcome of ASUD treatment. Co-occurring PTSD and ASUD have been shown to be associated with poorer ASUD treatment recruitment and retention and outcomes. In a large multi-site study, Najavits and colleagues found that cocaine-dependent outpatients with comorbid PTSD improved less than ASUD-only participants on measures of alcohol use and psychosocial problems.

However, these findings of PTSD as a negative prognostic factor were not replicated in other studies. Pharmacotherapy, either associated depression symptoms with the selective serotonergic reuptake inhibitor antidepressant Sertraline or for alcohol craving with disulfiram and naltrexone, has been shown to be safe and effective with adults with comorbid PTSD and alcohol use disorders. Trafton and colleagues found that chartdiagnosed PTSD was not associated with differential opiate substitution treatment outcomes with military veterans. Similarly, Jaycox and colleagues found that PTSD was not related to poorer ASUD residential treatment retention by adolescents. However, teens in the latter study who had histories of psychological trauma were more likely to discontinue ASUD residential treatment than adolescents with no history of psychological trauma.

Although the evidence is sparse, PTSD (and psychological trauma history in adolescents) warrants careful attention clinically in ASUD treatment. Further evidence of the importance of addressing PTSD in ASUD treatment comes from a recent study by Norman and colleagues comparing cognitive-behavioral therapy for ASUD and depression with a 12-step Facilitation intervention. Participants with PTSD benefited equally to those without PTSD in terms of reduced severity of depressive symptoms and ability to achieve consistent abstinence from substances in treatment and for the first follow-up period. However, at a subsequent (18-month) follow-up assessment they reported a small proportion of days abstinent (i.e. 75% versus 91%).

A recent study by Cohen and Hien found that, although cognitive behavior therapy (CBT) for comorbid ASUD and PTSD had positive results for PTSD and substance use outcomes, there were no differences between persons receiving CBT and those who received no active treatment on outcomes consistent with the self-regulatory deficits in complex PTSD (e.g. depression, dissociation, social and sexual problems). Thus, complex PTSD symptoms may require treatment that specifically targets self-regulation skills, as discussed by Ford and

colleagues in their review of treatment models for complex PTSD.

Because complex PTSD symptoms may interfere with ASUD treatment, Ford and colleagues conducted secondary analyses of data from a multi-site study of the efficacy of contingency management (CM) in community-based clinics to examine both PTSD and complex PTSD symptom severity as prognostic indicators. Over and above the strong effect of CM intervention, the severity of complex PTSD symptoms - but not history of trauma exposure, PTSD symptom severity, or overall psychiatric symptom severity - predicted poorer outcomes in terms of retention in treatment and objectively verified continuous abstinence from cocaine and heroin use during treatment. Brief measures of PTSD and complex PTSD symptoms were used which did not permit inferences about either PTSD or complex PTSD as diagnostic syndromes, and a more definitive test of the study hypotheses would require the use of a structured interview (for PTSD or complex PTSD) or questionnaire (for PTSD) with continuous scores based upon the full set of PTSD and complex PTSD symptoms. Nevertheless complex PTSD symptoms emerged as an independent prognostic factor for cocaine- and heroinuse disorder treatment outcomes, but only in the CM condition. Complex PTSD symptoms also accounted for a relationship between having witnessed an assault and poorer treatment retention.

Although PTSD and complex PTSD symptoms were interrelated, only complex PTSD symptoms predicted immediate treatment outcome, consistent with Ford and Kidd's earlier findings with military veterans in treatment for chronic PTSD. Comorbid PTSD-ASUD often involves particularly severe PTSD symptoms, as does complex PTSD. Therefore, complex PTSD rather than PTSD per se may interfere with ASUD treatment if its symptoms are sufficiently severe to induce persistent self-medication. Another possibility is that complex PTSD's cognitive and emotional impairments might lead to poorer engagement in ASUD treatment. However, participants reporting more complex PTSD symptoms completed CM activities just as often as other participants, suggesting that complex PTSD does not reduce motivation or follow-through with ASUD treatment activities. Moreover, a high level of baseline PTSD symptoms was the strongest predictor of achieving abstinence at 9-month follow-up assessments, in contrast to prior studies' findings suggesting that PTSD symptoms are a negative prognostic indicator in ASUD treatment – but consistent with a recent study by Williams and colleagues with adolescents in ASUD treatment. The positive prognostic effect of PTSD held only for patients receiving CM, with 84% of PTSD participants achieving abstinence at 9-month follow-up compared to <67% by CM participants with no PTSD. Thus, CM may provide a welcome distraction from and adaptive focus for persons experiencing intrusive trauma memories or hyperarousal and hypervigilance, and an adaptive alternative focus for people experiencing these PTSD symptoms. CM also may serve as a source of predictability, controllability, and positive emotions in contrast to PTSD's negative cognitive biases and emotional distress and numbing. It is also possible that patients with severe PTSD symptoms received more services than those with less severe PTSD.

In light of the strong association between complex PTSD symptoms and a history of child abuse, the role of child abuse history as a prognostic factor in ASUD treatment warrants study. A study by Lester and colleagues with homeless cocaine-dependent adults who had extensive histories of childhood psychological trauma provided indirect support for this view, showing greater improvements in PTSD and related symptoms in CM treatments than in less-intensive treatment. CM could offer a sharp positive contrast to the confusion and coercion that characterizes child abuse, by providing concrete and relatively immediate positive reinforcement contingencies to establish a predictable and controllable opportunities to achieve tangible positive outcomes. Although child abuse is prevalent among homeless adults, the study by Lester and colleagues did not directly investigate the role of abuse history specifically as a predictor of treatment outcome.

Petry and colleagues conducted a more direct test of the prognostic role of child abuse in CM using data from three randomized trials of CM on in-treatment outcomes (retention, proportion of negative urine samples submitted, and longest duration of abstinence) and abstinence at a 9-month follow-up. Compared to patients without sexual abuse histories (N = 316), those with sexual abuse histories (N = 77) submitted a significantly higher proportion of negative urine samples in treatment. In CM, but not in standard care, patients with sexual abuse histories had significantly longer durations of abstinence during treatment than those without sexual abuse histories. Although sexual abuse history was not associated with abstinence 9 months after treatment, longest duration of abstinence intreatment was significantly associated with this longterm outcome. Results suggest that ASUD patients with childhood sexual abuse histories may accrue particular benefits during CM treatment which are associated with long-term abstinence.

Thus, psychological trauma history and PTSD may have quite different prognostic (and treatment planning) implications depending upon the type of psychological trauma, complexity of PTSD symptoms, and type of ASUD treatment. In order to capitalize selectively on these challenges and opportunities, several approaches to integrated PTSD/ASUD treatment have been

developed. A brief overview of models of integrated PTSD/ASUD treatment is provided in the next section.

INTEGRATED PTSD-ASUD TREATMENT INTERVENTIONS

ASUD clinicians and treatment programs do not consistently report evaluating PTSD nor offering PTSD treatment. Traditionally, individuals with ASUD have been recommended to seek PTSD treatment only after lengthy periods of substance use abstinence. Yet, even more than 10 years ago when the PTSD-ASUD link was just beginning to gain scientific and public attention, a study by Brown and colleagues reported that adults with co-occurring PTSD and ASUD preferred treatment for both PTSD and ASUD, and in an integrated manner rather than delaying PTSD treatment. Since then, several integrated PTSD-ASUD therapies have been developed and shown to have promising preliminary outcomes.

Three integrated treatment models combine CBT for PTSD with CBT for ASUD. Brady and colleagues developed a 16-session intervention combining a well validated behavior therapy for PTSD, prolonged exposure, with cognitive therapy, and pilot tested the model with cocaine-dependent adults with promising results for completers, but a high (60+%) drop out rate. A 12week partial hospital group CBT treatment for military veterans with comorbid PTSD/ASUD ("Transcend") was developed by Donovan and colleagues, using a modified version of prolonged exposure. In a pilot study, they reported clinically significant reductions in PTSD and alcohol and drug use that were maintained at 6- and 12-month follow-ups. Triffleman and colleagues developed Assisted Recovery Trauma and Substances (ARTS), a 40-session one-to-one therapy that sequentially provides 11 sessions of CBT for ASUD followed by 29 sessions of CBT for PTSD. When ARTS was compared to CBT only for ASUD, it was found to achieve similar reductions in PTSD symptoms and superior attendance and abstinence.

Three other integrated PTSD/ASUD interventions address complex PTSD symptoms as well as PTSD and ASUD. Seeking Safety, developed by Najavits, teaches more than 80 "safe coping skills" for PTSD and complex PTSD symptoms. Unlike CBT models that use prolonged exposure, Seeking Safety does not include detailed review of specific trauma memories. A series of field and clinical trial studies have been reported evaluating Seeking Safety groups with women in substance abuse treatment, incarcerated or homeless women, juvenile justice-involved girls, and male military veterans. Seeking Safety consistently was associated with reductions in PTSD symptoms, but less consistent reductions

in substance use problems or in complex PTSD symptoms, compared to ASUD standard care or relapse prevention interventions or general health education. Initial results from a recent study found no added benefit from Seeking Safety versus health education, but subsequent analyses by Hien and colleagues showed that Seeking Safety was associated with greater mean reductions in AIDS risk behaviors in the overall sample, and in substance use for participants with more severe initial substance use problems if they also experienced a reduction in PTSD symptom severity in the treatment.

Trauma Recovery and Empowerment Model (TREM) was developed by Harris and Fallot as an educational group intervention (like Seeking Safety) for women or men with co-occurring major mental illness, ASUD, and PTSD. TREM particularly focuses on addressing the cumulative effects of living with poverty and stigma following victimization trauma. Although prolonged exposure is not used in TREM, the group offers opportunities to disclose memories of psychological trauma in the form of telling one's life story. A recent multi-site study of multi-component treatment models for women with co-occurring psychiatric and addictive disorders and histories of exposure to violence by Morrissey and colleagues included Seeking Safety and TREM at several sites. Although neither model alone was found to be superior to a usual care condition, "small but statistically significant" benefits were found in PTSD and mental health symptom reduction when results were aggregated for both integrated PTSD/ASUD psychotherapy approaches across all sites and interventions. Thus, integrated ASUD/PTSD treatment was supported in general despite no clear evidence of superiority by either Seeking Safety or TREM.

Trauma Affect Regulation: Guide for Education and Therapy (TARGET) was developed by Ford and colleagues to be delivered as either a group or individual therapy, and has been evaluated in field and clinical trial studies with adults in outpatient ASUD treatment, low-income and incarcerated women, and adolescent boys and girls in or at risk for involvement in the juvenile justice system. TARGET teaches a selfregulation skill sequence designed to address complex PTSD and ASUD simultaneously by enhancing both cognitive information processing and emotion regulation and reducing impulsive or habitual substance use in response to craving or triggers. Like Seeking Safety and TREM, TARGET does not involve prolonged exposure but focuses on PTSD symptom control. Studies by Ford and colleagues and by Frisman and colleagues have reported reductions in PTSD and complex PTSD symptoms and post-traumatic cognitions that were greater in TARGET than in problem solving or supportive therapy or ASUD treatment as usual, with equivalent reductions in ASUD for both genders and all ethnocultural groups except for Black men. TARGET has also been found to be associated with reduced incidents of problem behavior and use of seclusion in juvenile detention centers.

SCREENING FOR PTSD IN ASUD TREATMENT

From a cognitive-behavioral standpoint, PTSD and ASUD result from dysfunctional (i.e. threat-based or addiction-based) beliefs, cognitive biases, and reactive behavior patterns that lead to an escalating sense of anxiety, anger, and helplessness. From a stress and coping perspective, PTSD and ASUD involve problematic coping with stressors that range in intensity from current reminders to traumatic events. The first step to ensure that these factors are addressed in ASUD treatment is to identify treatment recipients whose ASUD are impacted by PTSD or complex PTSD. Kimerling and colleagues found that a brief (<5 min) screening questionnaire had strong sensitivity and specificity for the identification of ASUD treatment recipients with undetected PTSD. In addition to providing information about clients' current functioning and treatment needs, initial PTSD screening provides an opportunity for psychoeducation that can enhance engagement in and motivation for ASUD treatment. For example, a screener could explain that unwanted trauma memories are actually signs of adaptive biological and psychological responses that are self-protective during traumatic events and problematic only when they persist and are unrecognized and unmanaged. In addition, persons with PTSD or complex PTSD may have difficulty gauging the severity of symptoms, potentially leading to under- or over-reporting. Education about PTSD in the screening process can facilitate more accurate identification and estimation of PTSD and complex PTSD symptoms.

A thorough review of traumatic stressors and PTSD or complex PTSD symptoms can be upsetting or demoralizing. Therefore, screening does not automatically involve obtaining a detailed trauma history or survey of PTSD symptoms. The validated brief screen does not specifically ask about any traumatic stressors and inquires only about the four types of PTSD symptoms (sub-dividing avoidance and emotional numbing into two separate items, consistent with research on the factor structure of PTSD) in general. Many PTSD-ASUD treatment recipients do not feel ready to disclose more than small amounts of information about traumatic experiences or PTSD symptoms until they have established a strong therapeutic alliance. In some cases, they may not be able to tolerate the intensity of their own reactions to disclosing the details of terrible personal FURTHER READING 193

memories. For others, this is merely a fairly rote recitation of a familiar list of problems that they believe will never change. Still others feel compelled to "tell all" either to justify their distress and their right to treatment, or because they do not know how to select manageable amounts of past memories and how to regulate the associated emotions. Screening therefore should not focus singularly on past traumatic events, but on how current stress reactions interfere with the current relationships and the attainment of life goals – and how treatment can help with this. Further research is needed to determine if additional or modified screening protocols or items are needed in order to identify ASUD clients with complex PTSD.

CONCLUSION

In light of the extensive and growing empirical database demonstrating a bidirectional relationship between ASUD and PTSD, and suggesting that not only PTSD but also complex PTSD symptoms may require systematic attention in ASUD treatment, integrated ASUD/PTSD represents a challenging but evidence-based paradigm shift. Fortunately, a psychometrically and clinically promising brief screening measure is available for substance abuse (or primary care) providers to use in identifying patients for whom traumatic stress symptoms are particularly relevant in planning and delivering ASUD treatment. Promising interventions for ASUD with childhood sexual abuse survivors and for integrated treatment of comorbid ASUD/PTSD offer the clinician researcher a growing variety of options. Further continued scientific and clinical studies nevertheless are needed in order to address unresolved questions related to the implementation of ASUD/PTSD treatment (e.g. timing, sequencing, and intensity of trauma-focused treatment) and how to ensure safety and enhance outcomes with cases complicated by complex PTSD impairment (e.g. self-harm, impulsivity, dissociation), continuing exposure to psychological trauma (e.g. ongoing domestic violence), continuing substance use to self-medicate PTSD symptoms.

SEE ALSO

Mindfulness

List of Abbreviations

ARTS Assisted Recovery Trauma and Substances ASUD alcohol and other substance use disorders CBT cognitive behavior therapy
CM contingency management

DSM-IV-TR Diagnostic and Statistical Manual, Fourth Edition Text

Revision

NSA National Survey of Adolescents PTSD post-traumatic stress disorder

TARGET Trauma Affect Regulation: Guide for Education and

Therapy

TREM Trauma Recovery and Empowerment Model

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www.istss.org – International Society for Traumatic Stress Studies. www.ncptsd.org – National Center for PTSD.

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Criminal Justice Interventions

Douglas B. Marlowe

University of Pennsylvania, Chadds Ford, PA, USA

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SUBSTANCE ABUSE AND CRIME

Substance abusers are disproportionately represented in the criminal justice system. More than 80% of offenders in the United States who were convicted of a drug- or alcohol-related offense, were intoxicated at the time of their offense, reported they committed the offense to support a drug habit, or have a significant history of substance abuse. Nearly one-half of prison and jail inmates meet diagnostic criteria for substance dependence or addiction. Conversely, approximately two-thirds of clients in residential substance abuse treatment and one-half of clients in outpatient substance abuse treatment are involved with the criminal justice system.

These figures are not merely attributable to individuals charged with drug offenses. In a national sample of United States booking facilities, positive drug tests were obtained from the majority of arrestees for most categories of crimes, including violent, theft, property, and drug crimes.

Substance abuse is associated with a two- to fourfold increase in the likelihood of continued criminal offending. Fortunately, providing substance abuse treatment can reduce recidivism rates by 6–36%; however, druginvolved offenders are notorious for failing to comply with conditions to attend substance abuse treatment. If they are not closely supervised and do not receive meaningful consequences for failing to comply with treatment-related conditions, approximately 25% of drug offenders referred to substance abuse treatment fail to enroll in treatment; and of those who do enroll in treatment, approximately one-half drop out before receiving a minimally sufficient dosage of 3 months of services.

A major goal, therefore, of effective correctional programming is to ensure that drug-involved offenders comply with their treatment and supervisory conditions. Despite traditional concerns that substance-abusing individuals cannot be coerced to get well, evidence suggests that individuals who enter substance abuse treatment under the threat of a legal sanction perform at least as well, and often appreciably better, than those entering treatment voluntarily.

A range of sentencing dispositions has been created to identify drug problems among offenders, refer them to treatment, and hold them accountable for showing up for the clinical interventions. The challenge is to select from among this array of options the most effective disposition for each offender that will optimize outcomes at the least cost to taxpayers and with the least threat to public safety.

SENTENCING OPTIONS

A continuum of sentencing options is available in virtually all US jurisdictions for intervening with druginvolved offenders. Programs at one end of this continuum emphasize public health or rehabilitation objectives using less restrictive means, whereas those at the other end emphasize public safety objectives applying restrictive conditions. Programs in the center strive to integrate elements of both public health and public safety approaches by combining criminal justice supervision with mandatory community-based treatment.

Pre-Plea Diversion

Offenders who have been charged with relatively minor crimes may have the opportunity to avoid a criminal record by remaining arrest-free for a specified period of time, satisfying minimal reporting obligations and completing applicable treatment requirements. Upon satisfaction of the conditions, the charges are dropped and the record may be expunged. Although the record may not be literally erased from criminal justice databases, record expungement ordinarily entitles the individual to respond truthfully on an employment application or similar document that the arrest or conviction did not occur.

Disposition Before Judgment

Most jurisdictions have statutory provisions offering certain drug offenders an opportunity for diversion "with teeth." This model may go by various names, but has been generically referred to as disposition before judgment or probation without verdict. The offender is required to plead guilty or no contest (nolo contendere) to the charge(s) and the plea is held in abeyance while the offender completes a term of probation with

conditions for treatment and supervision. Satisfaction of the conditions leads to the plea being retroactively vacated or withdrawn, and perhaps to the opportunity for record expungement. Because the offender has already pled guilty to the charge(s), failure to complete treatment can lead to immediate sentencing. This arrangement offers additional coercive leverage to keep offenders engaged in treatment and compliant with their supervisory conditions.

Drug Courts

Drug courts are special dockets or calendars within the criminal court system, in which a judge supervises the diversion program. Participants appear in court frequently for "status hearings" during which the judge reviews their progress in treatment and may apply gradually escalating punitive sanctions for infractions or rewards for achievements. Participants must also complete a mandatory regimen of drug abuse treatment and random weekly drug testing. Typically, defendants must plead guilty or stipulate to (acknowledge) the facts in the criminal complaint as a condition of participation in drug court. Pre-adjudication drug courts often include a diversion component similar to disposition before judgment, in which graduates can have the charge(s) dropped and the record expunged. Postadjudication drug courts enable graduates to avoid a sentence of incarceration, shorten the term of probation or consolidate multiple probation sentences.

Intermediate Punishment

Intermediate punishment refers to a category of community-based sentences that are imposed in lieu of incarceration. Examples include military-style boot camps, intensive supervised probation (ISP) programs, correctional halfway houses, day-reporting centers, home detention, and electronic monitoring. The aim of these programs is to safeguard public safety while at the same time reducing correctional costs and avoiding the debilitating effects of institutional incarceration.

Incarceration

Incarceration in county jail or state prison is authorized by statute or sentencing guidelines for many drug-related offenses, including possession, possession with the intent to distribute drugs, sales, and manufacturing. The recommended range for the term of incarceration is typically predicated on offense-based factors, including the amount and type of drug that was involved, the offender's prior offense history, and whether the crime involved distribution or manufacturing as opposed to simple possession. There

may also be opportunities for a "downward departure" or "upward departure" outside of the recommended range based upon specified mitigating factors, such as demonstrated efforts at rehabilitation, or aggravating factors, such as dealing drugs near a school zone.

EVIDENCE-BASED SENTENCING

Although a range of sentences is often available for many drug-involved offenders, sentencing practices have tended to over-rely on certain dispositions for a wide range of cases. For example, the US "War on Drugs" of the 1980s imposed mandatory minimum sentences and longer prison or jail terms for various types of drug crimes, including some drug-possession offenses. Although this strategy appears to have contributed to a plateau or reduction in then-rising crime and violence rates, it paid insufficient attention to countervailing considerations of cost and the psychosocial impact of incarceration on individuals, their families, and their communities. The result has been skyrocketing correctional budgets, population caps imposed on some state prisons by the federal courts in response to unconstitutional overcrowding, and devastation for over-burdened minority and lower income communities.

At the other end of the sentencing continuum, a voter initiative known as *Proposition 36* in California emphasized a one-size-fits-all approach intended to be diametrically opposed to the War on Drugs. Pursuant to this initiative, a large proportion of drugpossession offenders were diverted into treatment in lieu of incarceration, and the courts were effectively disabled from responding to noncompliance with appreciably more than an extension of probation and relatively toothless demands for more treatment. The results were predictably lackluster. Roughly onequarter of the offenders never arrived for a treatment session, 50% of those who did arrive for treatment dropped out in less than 3 months, and only onequarter completed treatment. Worse still, criminal recidivism rates actually increased.

Evidence-based sentencing is a relatively new concept that seeks to avoid this over-reliance on any one disposition for all or most drug-involved offenders. Emphasis is placed, instead, on selecting dispositions that can optimally balance the interests of public safety, cost, and psychosocial impact on offenders. The goal is to choose the disposition in each case that presents the least objectionable risk of recidivism and the greatest likelihood of improving the welfare of the offender, and can do so at the least cost to taxpayers.

RISK AND NEED ASSESSMENT

To be successful, evidence-based sentencing requires drug-involved offenders to be assessed along two dimensions that have been empirically proven to predict success in correctional rehabilitation: (1) prognostic risk and (2) criminogenic needs.

Prognostic Risk

Prognostic risk refers to characteristics of offenders that predict poorer outcomes in standard correctional rehabilitation programs. Among drug-involved offenders, the most reliable and robust prognostic risk factors include a younger age (especially younger than age 25), male gender, early onset of substance abuse or delinquency (especially by early adolescence), prior felony convictions, previously unsuccessful attempts at treatment or rehabilitation, a co-existing diagnosis of antisocial personality disorder (APD), and a preponderance of antisocial peers or associates. Typically, individuals with these high-risk factors must be closely supervised and held accountable for their actions in order to succeed in treatment and desist from substance abuse and crime.

Importantly, in this context, the term "risk" does not necessarily refer to a risk for violence or dangerousness, but rather to a risk of failing to respond to standard interventions, and thus for continuing to engage in the same level of drug abuse or crime as in the past. In other words, it refers to a relatively poorer prognosis for success in standard rehabilitation services. This is why it is most accurately referred to as prognostic risk.

This distinction is crucial because some criminal justice officials may screen high-risk offenders out of more intensive treatment programs because they perceive them as being a threat to others or less worthy of the services. On the contrary, research reveals that the higher the prognostic risk, the more intensive the services should be. Most risk-assessment tools which are administered in routine correctional practice were validated against the likelihood of offenders absconding on bond, violating the terms of their probation or being re-arrested; and not against the likelihood of committing a violent act. Such tools should be used to screen highrisk cases in to more intensive programs rather than screening them out of those programs. Although assessment tools do exist to measure risk of violence, they are most commonly used when treating habitual sex offenders or conducting forensic evaluations in serious felony cases.

Criminogenic Needs

Criminogenic needs refer to clinical disorders or functional impairments that, if ameliorated, significantly reduce the likelihood of continued engagement in crime. The most common criminogenic needs among offenders include substance dependence or addiction, major psychiatric disorders, and serious functional impairments, such as brain injury or a lack of basic employment or daily living skills. Failing to address these serious deficits or impairments leaves the individual vulnerable to repeated failures and continued involvement in antisocial activities. On the other hand, effectively addressing these deficiencies is associated with improved functioning and the avoidance of crime.

As will be discussed, formal substance abuse treatment is often required for addicted offenders to ameliorate cravings and withdrawal symptoms, teach concrete skills to resist drugs and alcohol, and provide effective coping strategies for dealing with daily stressors and challenges. In some cases, medication or residential services may also be required, at least during the early phases of treatment. Failing to provide an adequate dosage and level of treatment for these high-need individuals is associated with significantly poorer outcomes and higher recidivism rates.

However, an important, but often overlooked, fact is that more than half of drug-involved offenders are *not* clinically addicted to drugs or alcohol. Research indicates that at least 55% of drug-involved offenders are substance *abusers*. These individuals may repeatedly ingest drugs or alcohol under circumstances that are potentially dangerous to themselves and others, but their usage is largely under their voluntary control and they do not suffer from cravings to use the substance or withdrawal symptoms when they attempt to become abstinent.

Substance abusers are best suited to what is called secondary prevention – also referred to as early intervention according to American Society of Addiction Medicine criteria. Secondary prevention is indicated when clients are engaged in health-risk behaviors, but have not, as yet, developed a clinically significant disorder. Examples of secondary prevention services might include psycho-educational interventions, which teach participants about the dangers of drugs and alcohol; and activity-scheduling exercises, which re-orient participants' daily pursuits away from drug-related peers and events. These services would rarely be sufficient alone to intervene with offenders who are addicted to or dependent on drugs or alcohol.

The important point here is that formal substance abuse treatment services can be contraindicated for nonaddicted offenders. Placing nonaddicted, low-need offenders into intensive treatment programs has been associated with significantly poorer outcomes and higher recidivism rates. Perhaps spending time with addicted peers unduly normalizes the drug-using lifestyle, or perhaps treatment requirements may interfere

with their engagement in productive activities, such as work, school or parenting. Regardless of the rationale, it is clear that providing too much treatment is not only a potential waste of precious resources, it can lead to what are called *iatrogenic effects*, in which outcomes are made worse.

MATCHING DISPOSITIONS BY RISKS AND NEEDS

Research reveals that different sentencing dispositions produce better outcomes for different types of druginvolved offenders. For example, drug courts have been shown to produce the largest effects for offenders who are clinically addicted to drugs or alcohol and also have substantial prognostic risk factors for failure in less intensive programs. The average effect of drug court is estimated to be approximately twice the magnitude for high-risk offenders than for low-risk offenders. This translates into greater cost savings for taxpayers. Drug courts that serve high-risk offenders are estimated to return 50% greater cost benefits to their communities than those serving low-risk offenders. The intensive level of supervision provided by a judge, coupled with weekly drug testing, intensive treatment, and gradually increasing sanctions and incentives, appears to be well suited for this population.

On the other hand, the full menu of services provided in drug courts appears to be unnecessary, or perhaps counterproductive, for low-risk or low-need individuals. For example, several studies have shown that low-risk drug offenders performed at least as well, and sometimes better, when they were not required to appear frequently before a judge in court. The low-risk individuals fared well when they were supervised, instead, by clinical case managers who reported on their progress to the judge and requested court hearings only when needed to address poor compliance in treatment. Not only does this approach reduce the supervisory burden on the court, it also reduces the degree of contact between the high-risk and low-risk participants. Research reveals that mixing high-risk and low-risk participants together can lead to negative effects for the low-risk individuals because they may adopt antisocial attitudes or values. Keeping the populations separate helps to avoid this iatrogenic effect.

Recent studies have reported promising outcomes for what are referred to as *coerced abstinence* programs, such as Project H.O.P.E. (Hawaii Opportunity Probation with Enforcement). In these programs, offenders are closely monitored via weekly drug testing and probation appointments and they receive gradually escalating sanctions for infractions, typically involving brief periods of jail detention. Participants may be referred

to substance abuse treatment if they are not responding adequately to the sanctions regimen or if they request treatment; however, treatment is not ordinarily a core component of the intervention and is not provided to many participants. A substantial proportion of highrisk offenders who had previously been noncompliant on probation or pre-trial supervision were shown to significantly improve their performance after entering these programs.

Although research has not yet addressed this issue, it is reasonable to hypothesize that coerced abstinence programs such as H.O.P.E. may be well suited to highrisk, nonaddicted offenders; whereas programs such as drug courts, which place a central emphasis on substance abuse treatment, may be better suited to high-risk offenders who are also clinically addicted to drugs or alcohol. More research is needed to determine the optimal target population for coerced abstinence programs.

The matching effects that are beginning to emerge in the research literature have not gone unnoticed by the criminal justice system. Recent amendments sentencing statutes or guidelines in some states are authorizing or requiring judges to at least consider issues of effectiveness and cost-effectiveness when rendering sentencing decisions. In addition to (not instead of) considering other important value-laden issues, such as victims' sentiments, judges, defense counsel, and prosecutors are being encouraged to include information on effectiveness and cost-effectiveness in their calculus of decision-making when advocating for or rendering sentencing dispositions. In a small number of states, information about prognostic risk and criminogenic needs is explicitly referenced in sentencing guidelines or statutes as factors to be considered in sentencing.

These developments are new and considerably more effort will be required before evidence-based sentencing becomes a generally accepted practice in the criminal justice system. Nevertheless, the momentum is beginning to move in this direction. This momentum is influenced in no small part by the fact that the correctional system is overburdened with huge numbers of nonviolent drug-involved offenders, and state and federal budgets are buckling under the weight of enormous prison and jail expenditures; yet, crime and substance abuse rates have barely budged or are merely shifting in character. Evidence-based sentencing offers a possible roadmap to address these serious economic and social problems.

EVIDENCE-BASED TREATMENTS

A good deal of research has focused on identifying effective treatment and prevention services for druginvolved offenders. It is no secret that substance abuse treatment is sparsely available and of notoriously poor quality in the criminal justice system. In many jurisdictions, less than 10% of probationers and 20% of inmates with substance abuse problems have access to substance abuse treatment services on any given day. Where treatment is available, it is often not evidence-based, lacking in a coherent focus or structure, and delivered by inadequately trained staff. The services also tend to be indistinguishable from those that are provided to noncriminal-justice involved populations, and thus might not adequately address the unique needs and risk factors presented by offenders.

Counseling Interventions

The most commonly administered "treatment" in correctional programs is drug education groups, which have been shown to have minimal effects for offenders. Another common form of treatment is what is loosely defined as drug-focused group counseling, which often does not follow a standardized curriculum and thus is of unknown quality and content.

Evidence is clear that the most effective counseling interventions for offenders are highly structured and behavioral or cognitive-behavioral in orientation. Contingency management (CM) programs are one example of a behavioral intervention that has shown substantial promise for drug-abusing offenders. Participants are closely monitored for treatment compliance and substance use via frequent drug testing and careful attendance reporting, and they receive rewards of gradually escalating magnitude for attending sessions or providing drug-negative urine specimens. The rewards are often provided in the form of institutional privileges, reduced program requirements, gift certificates, or payment vouchers that can be exchanged for a limited menu of goods or services. Importantly, CM programs appear to be equally effective for high-risk, antisocial participants who would ordinarily have a poor prognosis for success in standard treatment conditions.

Cognitive-behavioral treatments (CBTs) focus on identifying and correcting clients' irrational or dysfunctional thought patterns. Substance abuse and antisocial behavior are often triggered or exacerbated by offenders' misinterpretations of and overreactions to common events. For example, an offender who has been passed up for a job promotion might overreact and conclude that his supervisor is vindictive or out to get him. Given this interpretation of events, it might seem justified to quit the job, use drugs or get into an altercation with the supervisor. This type of dysfunctional thought pattern is often pervasive and rigid among high-risk, antisocial offenders. Nonaddicted offenders may also benefit from CBT interventions that focus on general

errors in thinking, rather than on substance abuse specifically.

Research is convincing that CBT interventions can significantly reduce crime and substance abuse. Metaanalyses reveal an average reduction in crime of approximately 20-30% for the most commonly administered CBT programs, which include Moral Reconation Therapy, Reasoning and Rehabilitation (R & R), and Thinking for a Change. The effects are significantly larger when the programs target high-risk offenders who are most likely to manifest these irrational criminal-thinking patterns. Not surprisingly, the programs are also most effective when treatment providers are well trained on the curriculum, fidelity to the intervention is monitored through integrity checks to be sure it is administered correctly, and treatment providers have graduate-level mental health or substance abuse treatment backgrounds.

In addition, larger effects are reported when the curriculum includes components that focus on anger management and interpersonal problem-solving. Many high-risk offenders get into trouble with the law because they are not adept at finding nonconfrontational solutions to interpersonal conflicts, and they tend to lose their temper quickly before thinking logically and calmly about how to resolve problems. Focusing on these specific deficits is often a key to achieving long-term improvements in their functioning.

As mentioned previously, formal substance abuse treatment is often required for addicted offenders to ameliorate cravings and withdrawal symptoms, teach concrete skills to resist drugs and alcohol, and model effective coping strategies for dealing with daily stressors and challenges without resorting to substance use. Substance abuse treatments that have shown significant improvements for addicted offenders also tend to be highly structured, cognitive-behavioral in orientation, follow a manualized curriculum, are delivered by well-trained staff, and are continuously monitored for fidelity to the model.

One example of a well-studied curriculum is the MATRIX Model, developed by researchers at University of California at Los Angeles, which has shown significant positive effects for offenders addicted to stimulants such as cocaine and methamphetamine. The MATRIX Model includes components that help participants identify and avoid their triggers for substance use, engage in drug-incompatible activities that compete against substance use, and manage their experiences of cravings and negative affects. This intervention has demonstrated particularly beneficial outcomes when it was administered within the context of a drug court program, presumably because the influence of the court helped to retain the offenders in treatment and reinforced their adherence to the curriculum.

For juvenile and young adult offenders, the most effective treatments also tend to be family or systemsbased. This means that family members, teachers, and other community role models are included in the intervention and learn how to effectively supervise, interact with and intervene with the offender. For example, (MST), Multi-Systemic Therapy developed researchers at the Medical University of South Carolina, has demonstrated significant positive effects for drugabusing juvenile delinquents. Like the MATRIX Model, MST has produced particularly beneficial outcomes when it was delivered within the context of a juvenile drug court program.

Medically Assisted Treatment

Medically assisted treatment (M.A.T.) for addiction is unlikely to be available for most offenders. Less than 5% of offenders on probation or parole have access to effective pharmacological treatments for addiction, such as buprenorphine, methadone, or naltrexone. Only about 12% of state prison inmates and 40% of county jail inmates have access to M.A.T. The reason that a relatively greater percentage of jail inmates has access to M.A.T. is that many of them are being held pending trial or release on bond; therefore, they may be entitled to be continued on medication regimens they were previously receiving in the community. Once they have been convicted and sentenced, however, it is considerably less likely that offenders will be maintained on a pharmacological regimen for addiction while serving their sentence or when released on community correctional supervision.

This is highly unfortunate, because a number of wellcontrolled, experimental studies have demonstrated that the use of M.A.T. can significantly improve outcomes for addicted offenders. For example, methadone or buprenorphine maintenance initiated prior to and immediately after release from jail or prison has been shown to significantly increase the likelihood that opiate-addicted inmates would enter treatment in the community; reduced illicit opiate use; reduced rearrests, technical parole violations and re-incarceration rates; and reduced incidences of mortality and hepatitis C infections. Yet, despite these positive results, the use of these medications, which have "agonist" properties, remains rare. Agonist medications stimulate the central nervous system in much the same manner as illicit drugs. Because they have the potential to be addictive themselves, and can produce euphoria in nontolerant individuals, they tend to be fiercely resisted by criminal justice professionals, who may view their usage as like "substituting one drug for another."

Fortunately, positive outcomes have also been reported for "antagonist" medications, such as naltrexone, which are nonaddictive and nonintoxicating. Naltrexone blocks PRISONER REENTRY 201

the effects of illicit opiates and partially blocks the effects of alcohol, without producing psychoactive effects of its own. At least two experimental studies among opiate-addicted probationers and parolees have reported significant reductions in opiate use and re-arrest rates for offenders receiving naltrexone. The recent introduction of a "depot" form of naltrexone, which can be administered via monthly injections, offers the potential to ensure greater compliance among offenders with the medication regimen.

Despite strong resistance to M.A.T. among some elements of the criminal justice system, its use is clearly endorsed by leading scientific and practitioner organizations. For example, the National Institute on Drug Abuse, in a 2006 publication entitled *Principles of Drug Abuse Treatment for Criminal Justice Populations* [NIH Pub. No. 06-5316], concludes that "[m]edications are an important part of treatment for many drug-abusing offenders" (p. 5), including medications such as methadone and burpenorphine. An important task now is for the scientific community to impress upon criminal justice professionals and policymakers the importance of M.A.T., educate them about the facts concerning these proven treatments, and dispel any myths or misconceptions about their usage.

Correctional Therapeutic Communities

A series of studies of what are called correctional therapeutic community (TC) programs have also reported highly favorable results for drug-involved offenders. TCs are specialized residential programs that isolate participants from drugs, drug paraphernalia, and affiliations with drug-using associates. The peers in TCs utilize a "milieu" therapeutic approach in confronting maladaptive personality traits, discouraging and punishing inappropriate behaviors, rewarding positive behaviors, and providing mentorship and camaraderie. Interventions often include community meetings, process groups, and altruistic volunteer activities. In recent decades, TC programs have also substantially incorporated CBT principles and practices into their curricula.

Because inmates released from jail or prison are often disenfranchised from their families and communities, may not have access to sober living quarters, and may still be under the authority of the correctional system, TC residential programming is often particularly well suited to this group of offenders. However, correctional TC programs are also utilized as an alternative disposition to incarceration.

In the prison system, TC programs are commonly administered on segregated units. Prisoners with long sentences who have previously completed the programs may serve as senior mentors or peer supervisors on the unit; however, correctional staff always have ultimate authority to determine which inmates are eligible for the program and what consequences should be imposed for accomplishments or transgressions. Following their release from custody, parolees may be transferred to a TC program in a community halfway house or work-release center to complete the therapeutic regimen.

The timing of inmates' sentences is often a critical factor in determining whether they gain access to TC programs. Inmates must have sufficient time remaining on their sentences to complete the curriculum, but preference is also typically given to inmates who are eligible for release within the next year or two. Because TC slots may not become available at just the right time to thread this needle, many deserving and eligible inmates never gain access to TC programs.

PRISONER REENTRY

Addicted offenders are at heightened risk for relapse to substance abuse, criminal recidivism, and associated health consequences immediately following release from prison or jail. Nearly one-third of inmates resume substance abuse with 2 months of leaving prison and over 95% resume substance use within 3 years. Twothirds of released inmates are re-arrested for a new crime within 3 years of their release and roughly one half are re-incarcerated. Released inmates are also at significantly elevated risk for drug overdose and mortality or morbidity. One reason for this is that their physiological tolerance to drugs or alcohol may be greatly reduced after a period of enforced abstinence during custody. Therefore, they may be at risk after release for an accidental overdose if they return to their previous level of substance ingestion.

Unfortunately, reentry programs for drug-involved offenders have often been found to produce nonsignificant or even iatrogenic effects, in which crime rates and re-incarceration rates have actually increased. The reasons for this are varied, but at least three basic errors in program implementation have commonly been identified.

First, many reentry programs have administered unstructured and nonevidence-based treatment services which, as discussed earlier, tend not to produce positive gains. Second, many programs have failed to maintain a sufficient dosage of services after the offenders were released from custody. Not surprisingly, a rapid degradation in the quality and intensity of services after release is unlikely to maintain positive effects in community. Finally, many programs have tended to over-rely on revocations and re-incarceration for technical violations, rather than applying gradually escalating sanctions. Technical violations refer to

behaviors that are not, in and of themselves, illegal but violate the conditions of supervision. For example, alcohol consumption is legal for most adults but may violate the terms of an offender's parole. Re-incarcerating offenders for technical violations is apt to be very costly and is unlikely to produce longstanding gains once the offenders have completed the full term of their incarceration and are no longer under the authority of correctional officials.

For example, a program known as Project Greenlight in New York City shortened the R & R curriculum, discussed earlier, to about half its intended length and provided nonstandardized family and pre-vocational services. In addition, the offenders received little if any augmented services after release from custody. The result was significantly higher rates of re-arrests, technical violations, and re-incarceration as compared to matched comparison samples of parolees who did not participate in Project Greenlight.

Similarly, a national project known as the Serious and Violent Offender Reentry Initiative (SVORI) provided \$100 million in federal grants to local communities to enhance treatment services for parolees both pre- and post-release. The results revealed that male offenders did not receive appreciably more treatment services following their release than did matched comparison samples of parolees. Not surprisingly, they also had no better outcomes in terms of re-arrest and re-incarceration rates. Female offenders, on the other hand, did tend to receive more treatment services. Possibly as a result of this, they also had significantly lower re-arrest rates. Notably, however, despite being re-arrested for new crimes significantly less often, the female SVORI participants were re-incarcerated more often, suggesting their parole was more likely to be revoked for technical violations. As a result, SVORI was unlikely to be costbeneficial for the female offenders.

As discussed earlier, studies of correctional TC programs have reported more favorable outcomes for drug-involved inmates and parolees. Three-year longitudinal evaluations of correctional TC programs in several states, including New York, California, and Delaware, suggest that to be maximally effective, TC services should be provided along the full continuum of reentry, from in-prison treatment through treatment in a work-release or halfway facility to outpatient continuing care. Participants who completed the full continuum of TC programming exhibited substantial reductions of 30–50% points in substance use and crime. Because self-selection may have played a role in some of these findings, the magnitude of the effects might be expected to be somewhat lower in typical correctional practice. Many offenders choose to drop out of TC programs and may achieve relatively poorer outcomes as a result. Nevertheless, the findings are promising and emerge as an evidence-based practice against a disappointing backdrop of often poor outcomes for this hard-to-treat group of offenders.

More recently, reentry drug courts have emerged as a way of applying the power and authority of the court to keep parolees engaged in treatment and compliant with their supervisory conditions. There have only been a few studies of reentry court programs and the findings are somewhat mixed. A 3-year evaluation in Harlem, NY found that participants in a reentry court were convicted of new crimes significantly less often than matched comparison parolees; however, they were re-incarcerated for technical violations more often. This suggests that reentry courts may be susceptible to making the same mistakes of the past in over-relying on revocations for technical infractions. Faithful application of the drug court model would dictate administering gradually escalating sanctions for infractions, and reserving re-incarceration for repetitive or serious violations.

A more recent study of a Federal reentry court in Boston produced more consistently favorable outcomes. Participants in the C.A.R.E. (Court Assisted Recovery Effort) program satisfactorily completed their supervision requirements and were re-arrested significantly less often than matched comparison offenders on traditional supervised release. Because the C.A.R.E. participants both offended less often and completed the terms of their supervision more often, this suggests that the program did not over-rely on technical violations for infractions, which is more consistent with the drug court model.

In summary, research on effective reentry programming for drug-involved offenders is still very much in its infancy. Evidence has uncovered a number of common errors in practice that are associated with insignificant or poor outcomes, and is beginning to identify programs that appear capable of achieving positive results. Considerably more effort is required to confirm the positive effects of these newer programs and identify the specific interventions and procedures within the programs that may be responsible for improved outcomes.

RACIAL, ETHNIC, AND GENDER RESPONSIVENESS

Research reveals that racial and ethnic minority offenders are less likely than nonminorities to receive the appropriate dose and modality of treatment given their clinical needs. For example, minority offenders who are clinically assessed as requiring residential treatment are more likely to be mismatched to a lower level of outpatient treatment. Minority offenders are also

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more likely to receive an incarcerative sentence than a treatment-oriented community disposition for what would appear to be relatively comparable offenses. Not surprisingly, this often translates into poorer outcomes in correctional rehabilitation.

Racial and ethnic minority offenders are also more likely to present with other prognostic risk and criminogenic need factors that may complicate the management of their case when they do enter treatment-oriented diversion programs. For example, studies in drug courts have frequently reported that racial minority participants were less likely than Caucasians to be employed, had significantly lower incomes and were more likely to be addicted to crack cocaine. This, in turn, predicted poorer outcomes in the programs. In other words, racial identity per se did not appear to be responsible for poorer treatment outcomes; rather, other factors that were correlated with race, such as socioeconomic status, appear to have been responsible.

These findings place an onus on the criminal justice and substance abuse treatment systems to do a considerably better job of identifying prognostic risk factors and criminogenic needs among minority offenders, and matching them to appropriate sentencing dispositions and therapeutic regimens. Putting aside the obvious ethical and moral implications of providing disparate treatments for minorities, the criminal justice system is required by the constitutional principles of due process and equal protection to treat all citizens fairly and equivalently. It is therefore legally necessary to develop and evaluate programs that can produce equivalent outcomes for racial and ethnic minority offenders.

At a minimum, researchers should determine whether existing treatment curricula elicit equivalent effects for racial and ethnic minority participants. For example, MST for youthful offenders and the MATRIX Model for adult offenders, discussed previously, appear to produce comparable effects across various racial and ethnic sub-groups. In addition, it is important to develop culturally sensitive and proficient programs that are specifically tailored to the needs of minority participants. Unfortunately, research is still in its relative infancy in terms of proving which culturally tailored programs produce superior outcomes for minorities in controlled studies. Considerably more work is required to develop and evaluate such programs in a rigorous and defensible manner.

Gender issues are also critically important for the treatment of offenders. Research indicates that holding separate treatment groups for male and female offenders tends to produce better outcomes, especially for the women. There are many possible reasons for this. Women and men may have different dynamics or histories related to their addiction, which may make it difficult for them to address their problems in mixed

groups. For example, men are more likely to be introduced to drugs by peers, whereas women are more likely to be introduced to drugs by intimate partners. As a result, men and women might need to employ different strategies for avoiding relapse situations.

In addition, many women in addiction treatment and correctional settings have been the victims of physical abuse, sexual abuse, or domestic violence. Discussing such matters in the presence of male peers may be embarrassing or may make them feel unsafe. Similarly, many males may not want to discuss comparable experiences of victimization in front of women for fear of appearing weak.

Another concern related to mixed-gender treatment is the phenomenon of the "rehab romance." As clients struggle through their early recovery, they may misinterpret intense emotional reactions or attachments that are often triggered in treatment groups for a romantic interest or compatibility. In reality, rehab romances frequently do not work out, often resulting in relapse for one or both parties. Lastly, some drug-involved offenders may be "relationship predators" and treatment groups may offer them an opportunity to seek out emotionally vulnerable or unstable individuals. It is incumbent upon treatment providers, therefore, to take decisive measures to ensure male and female offenders do not spend unsupervised time with each other outside of the treatment program.

CONCLUSION

The substance abuse treatment and criminal justice systems deal with many of the same individuals. Involvement with either system increases the odds many fold of involvement with the other system as well. Unfortunately, for decades neither system adequately recognized the implications of this "comorbidity" or adapted their procedures to accommodate the needs of the large population of drug-involved offenders. Sentencing and correctional supervision practices often failed to address the criminogenic needs of these individuals, and treatment practices often failed to address their prognostic risk factors and the very real threat they may present to community well-being and public safety.

This is beginning to change. Judges, prosecutors, and defense lawyers are becoming better educated on the principles of evidence-based sentencing, which can lead to more effective, safe, and cost-effective dispositions. Treatment providers, on the other hand, are learning to apply structured, evidence-based treatments that are more suitably tailored to the criminal-thinking patterns and other risk factors presented by offenders, which are apt to complicate the clinical picture. The

result has been promising research findings that are beginning to identify the basic principles for effective treatment and supervision of drug-involved offenders. More research is needed to continue this line of work and contribute to better practices and policies that will advance the interests of public health and public safety.

SEE ALSO

Cognitive Behavioral Therapies, Contingency Management, Driving While Impaired (Treatments), Ethical Issues in the Treatment of Drug Dependence, Dissemination of Evidence-Based Treatment into Practice, Drug Decriminalization and Legalization

List of Abbreviations

APD antisocial personality disorder
C.A.R.E. Court Assisted Recovery Effort
CBT cognitive-behavioral treatment
CM contingency management

H.O.P.E. Hawaii Opportunity Probation with Enforcement

ISP intensive supervised probation or parole

M.A.T. medically assisted treatment
 MST Multi-Systemic Therapy
 NIH National Institutes of Health
 R & R reasoning and rehabilitation

SVORI Serious and Violent Offender Reentry Initiative

TC therapeutic community

Glossary

Antisocial personality disorder (APD) a psychiatric diagnosis characterized by an adolescent onset and continuous manifestation of criminal or delinquent misconduct, a failure to fulfill basic responsibilities, and a lack of remorse for the misconduct. Individuals with APD typically have a poor prognosis in standard treatment or rehabilitation programs, but respond appreciably better to programs that are highly structured and behavioral or cognitive-behavioral in orientation.

Coerced abstinence programs programs that closely monitor offenders' behaviors, including drug use and treatment attendance, and apply gradually escalating punitive sanctions for infractions, often including brief periods of jail detention.

Correctional halfway house a transitional facility run by the corrections department that houses inmates in community-based living quarters.

Correctional therapeutic community (TC) a residential treatment program that applies milieu principles, community peer interactions, and other therapy techniques to alter the behavior of drugabusing criminal offenders. TC programs may be located within separate units of prisons or jails, and in community work-release centers or halfway houses.

Correctional work-release program a residential program run by the corrections department that houses inmates in community-based quarters. Inmates typically attend work, school, or treatment in the community during the day and return to the residence in the evenings.

Criminal thinking irrational or maladaptive attitudes or perceptions on the part of some offenders that cause or exacerbate criminal activity.

Criminogenic needs clinical disorders or functional impairments that, if ameliorated, significantly reduce the likelihood of continued engagement in crime. Common examples include substance dependence or addiction, major psychiatric disorders and serious functional impairments, such as brain injury or a lack of basic employment or daily living skills.

Day-reporting centers community programs typically run by the probation, parole, or corrections department, to which offenders are required to report and spend several hours per day on the premises.

Disposition before judgment also known as probation without verdict, an opportunity for diversion after entering a guilty plea or acknowledging factual guilt. Satisfaction of enumerated treatment or supervision conditions leads to the plea being retroactively vacated or withdrawn, and perhaps to the opportunity for record expungement.

Downward departure a decision by a criminal court to impose a shorter or less severe sentence than is indicated by the sentencing statute or guidelines. The sentencing judge must typically base the decision to grant a downward departure on specific mitigating factors, such as demonstrated efforts at rehabilitation or a genuine expression of remorse.

Drug court a special docket or calendar within the traditional criminal court system, in which a judge supervises a diversion program. Participants appear in court frequently for status hearings, during which the judge reviews their progress in treatment and may apply gradually escalating punitive sanctions for infractions or rewards for achievements. Participants must also complete a mandatory regimen of drug abuse treatment and random weekly drug testing.

Drug-involved offender an individual who has been charged with or convicted of a drug offense, was intoxicated at the time of a criminal offense, committed an offense to support a drug habit, or has a documented history of drug abuse.

Drug offender an individual who has been charged with or convicted of drug possession, possession with the intent to distribute drugs, drug dealing, drug manufacturing, or another offense categorized as involving illicit drugs.

Evidence-based sentencing the explicit consideration of effectiveness and cost-effectiveness in rendering criminal sentencing decisions.

Expungement see record expungement.

Halfway house see correctional halfway house.

High-need offender an offender manifesting a clinical disorder or functional impairment that typically requires remediation to ensure future desistence from crime.

High-risk offender an offender with characteristics that tend to predict poorer outcomes in standard rehabilitation or treatment programs. High-risk offenders typically require enhanced supervision and accountability to perform well in treatment.

Iatrogenic effects unintended or unpredicted negative or worse outcomes produced by an intervention.

Intermediate punishment also referred to as intermediate sanctions, a category of criminal sentences imposed in lieu of jail or prison. Examples include military-style boot camps, intensive supervised probation (ISP) programs, correctional halfway houses, day-reporting centers, home detention, and electronic monitoring.

Jail a county or local correctional institution that houses offenders being detained prior to trial or release on bond, or convicted of crimes typically carrying sentences of less than 1 year.

Low-need offender an offender who does not manifest a clinical disorder or functional impairment requiring remediation to ensure future desistence from crime.

Low-risk offender an offender who does not exhibit characteristics that would predict poor outcomes in standard rehabilitation, and

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- thus who has a good prognosis. These individuals generally do not require intensive supervision and may respond negatively to being treated alongside more serious offenders.
- **Parole** early release from incarceration prior to serving the maximum allowable prison or jail sentence. Parolees are supervised by special officers who enforce the conditions of early release.
- **Pre-trial supervision** supervision by special officers of individuals who have been charged with, but not convicted of, a crime. The court may impose requirements of pre-trial supervision, such as drug testing or treatment, as a condition of being released on bond prior to trial.
- **Post-adjudication drug court** a drug court program in which a final conviction is entered and participants complete the drug court in lieu of a longer or more severe sentence.
- **Pre-adjudication drug court** a drug court program in which successful graduates have their guilty plea withdrawn or vacated and may have the opportunity for record expungement.
- **Pre-plea diversion** a program that permits an individual charged with a relatively minor criminal offense to avoid prosecution by satisfying certain supervision and treatment conditions.
- **Prison** a state correctional institution that houses offenders convicted of crimes typically carrying sentences of longer than 1 year.
- **Prisoner reentry** the process of returning and reintegrating inmates into their communities after release from jail or prison.
- **Probation** a sentence to community supervision instead of incarceration. Probationers are supervised by special officers who enforce conditions set by the sentencing court.
- Probation without verdict see disposition before judgment.
- Prognostic risk characteristics of offenders that predict relatively poorer outcomes in standard correctional rehabilitation programs. Individuals with prognostic risk factors typically require more intensive monitoring and accountability to perform well in treatment or supervision.
- Proposition 36 a voter initiative in California that requires courts to sentence nonviolent drug-possession offenders who do not have a history of another exclusionary offense to probation with treatment conditions. Successful graduates have the plea vacated. Participants are generally entitled to three opportunities for diversion before incarceration may be imposed.
- **Recidivism** any return to criminal activity after the index arrest episode, typically measured by re-arrests or re-convictions for new crimes.
- Record expungement a process for removing an arrest or conviction from an individual's criminal record in response to meeting certain requirements, such as completing a treatment or diversion program. Although the record may not be literally erased from criminal justice databases, expungement ordinarily entitles the individual to respond truthfully on an employment application or similar document that the arrest or conviction did not occur.
- Reentry see prisoner reentry.
- **Reentry court** a program that applies court supervision to the management of parolees or other inmates conditionally released from prison or jail. Not all participants in a reentry court may have drug-related problems.
- Reentry drug court a program that applies the court-supervised drug court model to the management of drug-involved inmates released on parole or other conditional release from prison or jail.
- **Revocation** the removal of an offender from probation or parole for violating the conditions of supervision. Offenders are often, but not always, returned to custody upon a revocation.
- **Technical violation** a behavior, such as alcohol consumption, that is not illegal for most adult citizens, but may violate the conditions of probation, parole, or pre-trial supervision.
- **Therapeutic community (TC)** see correctional therapeutic community (TC).

Upward departure a decision by a criminal court to impose a longer or more serious sentence than is indicated by the sentencing statute or guidelines. The sentencing judge must base the decision to impose an upward departure on specific aggravating factors, such as dealing drugs near a school zone.

War on drugs refers to an Executive Order issued by Former President Ronald Reagan. Federal and state laws enacted pursuant to this Executive Order increased prison penalties and established mandatory minimum sentences for various drug offenses, including some drug-possession offenses.

Work-release program see correctional work-release program.

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Relevant Websites

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- http://www.ojp.usdoj.gov/BJA Bureau of Justice Assistance.
- http://www.courtinnovation.org Center for Court Innovation.
- http://www.AllRise.org National Association of Drug Court Professionals.
- http://www.ncsc.org National Center for State Courts.
- http://www.ncjfcj.org National Council of Juvenile and Family Court Judges.
- http://www.nicic.gov National Institute of Corrections.
- http://www.tasc.org National Treatment Accountability for Safer Communities.
- http://www.pewcenteronthestates.org Pew Center on the States.
- http://www.ibr.tcu.edu Texas Christian University Institute of Behavioral Research.

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Driving While Impaired (Treatments)

Thomas G. Brown, Junaid Bhatti, Ivana Di Leo Research Centre of the Douglas Mental Health University Institute, Verdun, QC, Canada

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INTRODUCTION

Road traffic crashes (RTC) lead to approximately 1.3 million deaths and 20–50 million injuries worldwide annually. Human factors (e.g. speeding and other unsafe driving maneuvers, driving while impaired with alcohol or drugs, driver error, distraction, fatigue, neglect of seat belt use) play a contributing role in up to 95% of RTC. This chapter focuses on current efforts to reduce this significant burden on global health with respect to one particularly lethal contributor to RTC, driving while impaired with alcohol and/or drugs (DWI).

DWI is implicated in from 20 to 40% of all RTC. Among the many psychoactive substances that can

impair safe driving ability, alcohol is the one most often detected in DWI-related traffic events. Compared to $0.0\,\mathrm{g}$ alcohol/dl blood concentration (i.e. $\mathrm{BAC}=0.0\%$), RTC risk is 4–10 times higher at BAC between $0.05\,\mathrm{and}$ 0.07%. Accordingly, the criminal statutory limits for DWI and the administrative thresholds that trigger more severe relicensing sanctions are most frequently set at BAC of 0.05–0.08% and 0.02–0.05%, respectively.

The diversity of licit and illicit drugs with varying degrees of potency, purity, and performance- impairing properties, in addition to their potential synergistic effects when combined with alcohol and/or other substances, makes defining impairment and hence

detection and prosecution of drug-impaired drivers an ongoing challenge. As a result, many jurisdictions have adopted per se laws whereby detection of any illicit drugs in the organism when driving is grounds for a conviction. In addition, courts increasingly recognize a detection of drug-impaired driving executed by Drug Recognition Experts using a highly structured roadside behavioral assessment. These and other measures for dealing with DWI with drugs are receiving growing attention from road traffic administrators and researchers.

DWI is a tenacious problem. Large-scale international efforts to curtail DWI, after realizing significant progress over the past few decades, have stalled since the 1990s, with some jurisdictions more recently showing a slight uptick. Unfortunately, a first conviction for DWI fails to deter many drivers from continuing to commit DWI. Approximately 20% of female and 38% of male DWI first-time offenders are reconvicted within 5 years of their conviction. The transition from first time to repeat offender status (i.e. recidivism) is accompanied by heightened risk, as recidivists contribute disproportionately to traffic-related morbidity compared to other driver groups. Overall, stabilization in the epidemiology of DWI and the risks associated with recidivism make effective prevention and intervention efforts vital to reduce the health burden of DWI.

WHO ARE DWI DRIVERS?

At its core, DWI involves an individual engaging in an episode of excessive alcohol or drug use, the availability of a vehicle, and his/her propensity to drive it. At the same time, the DWI population is a heterogeneous one with a broad continuum of risk, ranging from drivers who may accidently, rarely, or sporadically drive impaired to a "hardcore" group who frequently drive impaired despite social and legal deterrents. The characteristics possessed by DWI drivers are also markedly heterogeneous.

The sentinel feature of impaired driving is substance misuse. The rate of abuse and dependence among DWI offenders is significantly higher than in the general population. Resolution of substance abuse and dependence will likely reduce DWI risk in many drivers. At the same time, contrary to popular perception, alcohol and drug problems do not explain all DWI risk in the general driving population. The majority of DWI drivers do not possess a substance use disorder diagnosis, but rather sporadically engage in heavy drinking and/or substance use. Consistent with the alcohol preventive paradox, it is the low risk and sporadic heavy drinkers and approximately 20% of the population who consume an average of ≥1 ounce of

alcohol per day who are responsible for most DWI-related consequences.

Along with substance misuse, several other characteristics have been consistently correlated to DWI offender status. These include male sex, single marital status, hostility, sensation seeking, psychopathic deviance, poor psychosocial and socioeconomic functioning, legal problems, disrespect for legal authorities and sanctions, family history of alcoholism, and engagement in other risky driving behaviors. In addition to the above, other factors correlated to recidivism status are younger age, early onset of alcohol problems, and high BAC at the time of arrest. At the same time, knowledge of these correlates is inadequate for both disentangling the heterogeneity in the DWI population and accurately discriminating between non-offenders, offenders, and recidivists. Consequently, there is no one feature (e.g. alcohol dependence) that satisfactorily explains all DWI phenomena.

Finally, many individuals in the DWI driver population possess attitudes that challenge efforts to change DWI behavior. These include the tendency to minimize personal concern for their DWI risk by believing that bad outcomes are unlikely and happen to other drivers, by overestimating their control over DWI risks (e.g. intoxication), and by considering that their driving skill are superior compared to other drivers. As counterproductive as these attitudes may be for motivation to change DWI behavior, they are reinforced to some degree by reality: negative consequences associated with DWI (e.g. crashes and arrests) are unlikely events.

The next section briefly highlights a number of methodological challenges that vex both our understanding of DWI and our ability to mount evidence-informed approaches to DWI reduction.

METHODOLOGICAL ISSUES IN EVALUATING DWI INTERVENTION PROGRAMS

A number of methodological and conceptual issues hamper the ability to evaluate DWI program effectiveness. One methodological concern involves sampling. Many intervention evaluation studies recruit samples from among convicted DWI offenders attending remedial programs as part of their sentence or to reacquire their license. Though convenient, this strategy is vulnerable to bias from local, legal, and geographic dispositions regarding DWI and self-selection into study participation. It also fails to sample from two important subgroups who together account for the majority of drivers in the DWI population: namely, those who drive impaired but are not caught and convicted, and those

who, following a conviction, fail to participate in remedial programs. This may positively bias the results by including individuals sufficiently motivated and resourced to participate in such programs (their costs are usually borne by the driver) and who self-select into research studies. In addition, most interventions are embedded within a system of DWI countermeasures. Potential synergistic effects, negative and posicontributed by systemic tive, factors implementation integrity) and other parallel intervention initiatives complicate the appraisal of the unique benefits of a specific program component.

The most obvious outcome of DWI intervention is a reduction in DWI-related crashes and morbidity. Unfortunately, the dependent variables frequently used to gauge program impact, either through study design or availability of data, are indirect and vary across studies. Change in the frequency of documented DWI-related crashes and fatalities, arrests or convictions, self-reported DWI events, and indices of alcohol and drug misuse are common dependent variables for program evaluation. Although documented DWIrelated crashes (e.g. postmortem blood assays) are objective measures, they may be susceptible to factors unrelated to prevention program impact, such as reporting fidelity, and seasonal driving patterns and regional fluctuations (e.g. in gas prices) that can reduce driving exposure. As measures of individual intervention outcome, self-reported measures of substance use and DWI behavior are convenient measures yet susceptible to distortion, especially when collected in the oftenadversarial environment of DWI assessment and enforcement. Alternatively, biological markers of alcohol dependence (e.g. gamma-glutamyl transferase, carbohydrate-deficient transferrin) are objective alternatives to self-reported substance use. Nevertheless, the level of chronic alcohol misuse the most reliably detect does not appear to be characteristic of the majority of DWI drivers. Moreover, the causal contribution of alcohol use in DWI is likely mediated by multiple additional factors in most offenders. The use of objective biomarkers of acute drug use in DWI is an emerging technology. In addition, linking their detection to DWI is a major administrative and scientific challenge as traces of many substances are detectable in the organism for days and weeks after last use. Finally, individual socioeconomic and environmental factors not directly related to DWI risk can influence the probability of being either arrested by police or successfully prosecuted, including gender, vehicle type, access to competent legal representation, prevailing per se BAC thresholds, traffic density, rural versus urban settings, availability of public transportation, and enforcement vigor.

Given these issues, triangulation using multiple outcome indices is optimal. At the same time, different

indices provide unique information that can at times lead to conflicting inferences about program effectiveness. Changes in DWI-related crash rates are not synonymous with changes in the rate of rearrest or in the severity of alcohol misuse. In sum, in the absence of a "gold standard" for gauging outcome, conclusions about a DWI intervention's effectiveness need to take into account the specific objectives of the program and the indices used to measure their attainment.

CONCEPTUAL FRAMEWORK FOR UNDERSTANDING DWI INTERVENTION EFFECTIVENESS

There is a consensus that the effectiveness of individual intervention components is increased when provided as part of a well-integrated broad-based system. A "system" refers to which strategies and countermeasures are implemented and how they are delivered, as well as the structures and agencies charged with their delivery to a targeted group. In DWI, a system typically involves multiple component programs (e.g. legislation, policy, enforcement, remedial intervention) deployed at multiple levels and by multiple agencies. Given the manifold ways in which traffic safety promotion generally, and DWI prevention specifically, are executed, adoption of a conceptual framework can help to organize the various DWI strategies currently in place and contextualize their appraisal. Several schemas are appropriate for the analysis of DWI. From a public health perspective, DWI can be viewed as the interplay of factors contained in the epidemiological triangle: agent (psychoactive substances and vehicles), environment (e.g. existing laws and enforcement), and host (i.e. the driver and passenger).

Another tripartite model that has been adopted by the US National Institute of Drug Abuse and the European Monitoring Centre for Drug and Drug Addiction is broadly equivalent to the above schema, but is more specific to substance misuse problems. In the DWI context, it involves the following dimensions: (1) universal prevention which targets the general population prior to the occurrence of a DWI event; (2) selective prevention which targets drivers with above average risk for DWI offending relative to the overall population (e.g. first-time offenders); and (3) indicated prevention which targets DWI offenders with more established signs of recidivism risk (e.g. previous DWI convictions, diagnosis of substance dependence, high arrest BAC). Environmental prevention is another element typically considered though it is formally outside this model. In DWI, this could involve micro-level strategies such as installation of an Interlock device that prevents ignition of an vehicle by a driver whose BAC is above 0.02%, or macro-level community and regulatory level strategies such as roadside sobriety checks and legislation that sets fines and punishments. As such, some environmental prevention initiatives for DWI may be subsumed within one or more of the other prevention levels.

In sections that follow, DWI intervention approaches are summarized and considered broadly in light of the drivers they target (i.e. universal, selective and indicated, environmental prevention) and secondarily the putative contributory factors (i.e. agent, host, environment) they seek to act on. The scope of measures currently deployed to combat DWI is vast. Only some of the better-documented and/or more pervasive approaches in the developed world are surveyed here, with special emphasis given to selective and indicated prevention efforts.

UNIVERSAL PREVENTION APPROACHES FOR DWI

Public Information and Education

One of the most fundamental universal prevention approaches to promote traffic safety is the provision of public information and education. Public information programs involve mass media campaigns whereby information is disseminated using modalities such as television, radio, Internet, and print. Education attempts to provide more information about a problem and may use mass media modalities as well as person-to-person contact. These programs aim to provide information about a health-related issue and encourage healthy individual behavior. Evaluations of public information campaigns with deterrence themes (e.g. awareness of enforcement activities and legal consequences) and social and health consequences themes (e.g. modeled positive behavior alternatives to DWI; fear appeals using graphic depictions of emotional and physical consequences of DWI crashes) have been carried out. While they fail to provide unequivocal evidence for their effectiveness in reducing DWI or alcohol-related crashes, they have been associated with modest but significant reductions (≈13%) in alcohol-related RTCs lasting more than 3 years. Importantly, economic analyses suggest that overall, societal benefits from these programs outweigh their costs.

It is noteworthy however that one social theme, the fear appeal, is controversial. Its intuitive appeal contributes to its pervasiveness. Nevertheless, critics have argued that when fear appeals are of insufficient intensity and fail to present positive alternatives, they produce poor outcomes, quickly induce "fear appeal fatigue" and increase maladaptive defensiveness and reactance that could even contribute to increased DWI,

especially in young drivers drawn to risk taking. Finally, their benefit was greatest when they were (1) carefully planned; (2) well executed; (3) attained adequate audience exposure; and (4) embedded as a facet of a comprehensive countermeasure strategy including such measures as visible and rigorous law enforcement.

Host Factors: Young Drivers

Reduction in BAC levels in young drivers is particularly desirable given: (1) their higher crash risk compared to adults; (2) their greater susceptibility to alcohol's impairing effects on performance; (3) their inexperience in both driving and substance use; and (4) they possess other individual risk factors such as greater sensation seeking, more limited planning capacities, and greater impulsivity that contribute to risk taking. Adolescents are also readily accessible in school settings for participation in educational interventions prior to or at an early stage in their driving careers. Investigation of the effectiveness of school-based instructional programs, peer organizations, and social norming campaigns for reducing DWI-related RTC, deaths and injuries has yielded evidence for their effectiveness in reducing self-reported driving with a drinking driver but more equivocal evidence for effectiveness in reducing drinking and driving. The best results were obtained from programs possessing an interactional component.

Agent Factors: Alcohol Availability

Server intervention training programs provide education and training to the employees of venues where alcohol is served to prevent client intoxication and DWI. Practices acquired in training include providing food with drinks, slowing service to rapid drinkers, refusing to serve intoxicated clients, and discouraging them from driving. There is evidence for the effectiveness of such programs especially when training was of high quality, provided using face-to-face interactions, was accompanied by active support from venue management, targeted cessation of client drinking or a client moving to a safe drinking environment, and was combined with community mobilization and rigorous enforcement of venue rules and licensing laws. Hence, while this approach can be effective when applied under "ideal" conditions, in practice achieving and sustaining the required high level of implementation integrity are major challenges.

Environmental Factors: Alternate Transportation and Designated Driver Programs

A common target for community-based mass media campaigns is to encourage the use of alternative transportation (e.g. public transportation, regular or subsidized low-cost commercial taxi services, or volunteer shuttle services) or designated driver (e.g. informal arrangements made between friends) strategies when planning or after drinking occasions. While these programs are regularly implemented in some jurisdictions, especially during holiday periods, there is a lack of research in their effectiveness. The available evidence is equivocal concerning their impact. Worryingly, many such programs resulted in flawed application of the approach by many drivers or their companions that could potentially provide a false sense of security, such as no insistence on total abstinence for the designated driver, or failure to designate a driver prior to drinking.

Laws and Policy

Agent Factors: Alcohol Consumption Policy

One public health policy approach to DWI has been to focus on reduction of overall alcohol consumption in the general population. In many jurisdictions, laws specifically target young drivers and their access to alcohol. These include setting a legal drinking age (e.g. 18 years in Canada, 21 years in the United States), zero tolerance for alcohol use during probationary licensing, and administrative license revocation following underage drinking violations. These measures have been found to be associated with reductions in the involvement of underage drivers in fatal crashes and in their BAC levels.

Environmental Factors: BAC Level Specified in Per Se Laws

Consistent evidence indicates that decreases in legal BAC laws from 0.10% to 0.08% have diminished alcohol-related crash fatalities in the United States and Canada. Lowering per se legal BAC levels from 0.08% to 0.05% in European and Australian jurisdictions, and from BAC 0.05% to 0.02% in some jurisdictions such as Sweden, have also been associated with important reductions in DWI-related traffic crashes and fatalities. At the same time, disentangling the impact of adjustments in BAC laws from other initiatives that typically accompany their implementation, such as publicity and enforcement among others, is problematic. Overall, BAC 0.05% seems to represent the level at which most drivers' driving performance deteriorates to a degree where their crash risk increases significantly. Moreover, it is also the level where convergence occurs between public perceptions related to "enough to drink" and acceptance of legal BAC, and police discretion and willingness to enforce DWI laws.

Environment Factors: Enforcement and Sanction Strength

The perceived and actual probability of DWI arrest are pervasively argued to be critical ingredients in the deterrence value of DWI enforcement measures, more so than increasing the severity of penalties following a conviction alone. Selective or random breath testing carried out in sobriety checkpoints and increased police patrols can increase both the perception and actual risk of arrest. As such enforcement efforts are directed at the general driver population, they are referred to as general deterrence. Evaluations of the impact of sobriety checkpoint programs have produced strong evidence for the effectiveness of both selective and random breath testing checkpoints in reducing alcohol-related crashes, fatalities, and injuries. Exactly how these programs work is uncertain, however, as straightforward relationships between the crash reductions and amount and the type of enforcement activities have not been detected. More importantly, widespread deployment has been mitigated in many jurisdictions by legal obstacles (e.g. probable cause requirements for an arrest), cost, lack of police resources and funding, poor support from community groups, and negative perceptions concerning overall effectiveness and efficiency.

An almost reflexive social and political strategy to deter DWI is to impose increasingly heftier fines and the threat of prison terms for first-time DWI offending. Despite possessing intuitive appeal and relative simplicity of deployment, mandatory fines and jail penalties do not demonstrate either general deterrent effects or effectiveness in deterring re-offending among first-time DWI offenders. This lack of evidence is magnified by the high social cost and inherent risks (e.g. violence, contact with a harder core criminal element, inability to support families) of incarceration.

Similarly, many licensing administrations modulate sanctions following a DWI conviction as a function of a driver's arrest BAC. The premise of this approach is that a high BAC (e.g. 15% in many jurisdictions) reflects a higher risk for RTC, recidivism, and more severe alcohol problems. Hence, individuals seeking to be relicensed following a high BAC arrest face heftier fines, longer license suspensions, mandatory installation of an Interlock device, and participation in more intensive remedial programs. While high BAC is consistently related to RTC risk, its relationship to either DWI recidivism risk or the severity of alcohol problems in firsttime offenders is less clear. Thus, though modulating sanction severity to arrest BAC is a popular approach, there is need for systematic evaluation of its implementation and impact to support its effectiveness.

SELECTIVE PREVENTION APPROACHES FOR DWI

Given the rarity of a DWI arrest, many high-risk drivers drive undetected until after dozens or even hundreds of DWI occasions. Identification and intervention with DWI drivers as early as possible, especially before a catastrophic DWI event has occurred, are clearly advantageous objectives. Two propitious targets for selective prevention initiatives then are injured DWI drivers identified in emergency rooms and trauma centers, and drivers arrested for a first DWI offense.

Host Factors: Alcohol Detection and Brief Intervention Programs

An opportunistic psychosocial intervention approach to DWI reduction in higher-risk individuals, prior to even a first arrest and conviction for a DWI offense, involves screening and brief intervention in emergency rooms and trauma settings. The premise of this approach is that these situations offer a singular opportunity to both detect injured individuals with an elevated risk for alcohol-related injury and provide a brief intervention (i.e. one session lasting several minutes) at a "teachable moment" that potentiates its impact. The format of these programs varies widely, but the more consistent elements include systematic screening using standardized instruments, such as the Alcohol Use Disorders Identification Test, objective feedback about an individual's substance misuse as a way to rapidly increase problem recognition, clear advice to change, motivational techniques, and provision of information of available resources that can facilitate change in problem behavior.

Screening and brief intervention in emergency rooms and trauma centers have shown consistent benefits in significantly reducing high-risk drinking and readmissions in nondependent drinkers and in individuals admitted for alcohol-related injuries over variable periods of time. Most available studies to date have not focussed specifically on drinking drivers or alcohol-related traffic crashes or fatalities. Nevertheless, the evaluation of emergency room programs for injured and high-risk drivers, offered either alone or in combination with other therapeutic elements, has provided evidence for their effectiveness in reducing DWI arrests, drink-driving incidents, and self-reported problem drinking patterns.

Pragmatic challenges face the deployment of such programs. Trauma centers and emergency rooms are busy and chaotic environments. Moreover, patients in these settings may not be well disposed to answering questions about their substance use or having a discussion with a stranger not directly involved in the treatment of their injuries. In addition, the adoption of systematic screening for substance misuse and brief intervention in front line medical environments, despite being considered a best practice, has been uneven. Reasons for this include lack of time, cost, inadequate training, stigma, and confidentiality concerns. At

the same time, these obstacles are gradually being overcome

Host Factors: Administrative Relicensing Interventions

In many jurisdictions, a first-time DWI conviction leads to mandated assessment for sanctioning and the setting of relicensing requirements. These assessments often use information from administrative databases on driver socio-demographics, driving history, BAC at time of arrest, and alcohol biomarkers, as well as from self-reported psychometric assessments of alcohol misuse and other DWI-related variables. When judged "high risk," the offender is mandated to more intensive assessment, monitoring, and preventative intervention, all at his/her expense – which may be in the hundreds or thousands of dollars. Beyond assessment, offenders considered to possess significant substance abuse problems may be prescribed formal rehabilitation, self-help group attendance, and active follow-up and/or monitoring. Offenders deemed low risk are obliged to participate in less intensive remedial procedures. For some of these individuals, merely engaging in assessment and receiving feedback about their results may have a therapeutic value. Participation in such remedial programs is generally considered beneficial in reducing DWI risk, indicated by a modest yet significant 7-9% reduction in DWI recidivism with participation compared to no participation.

There are major shortcomings in the pragmatic operation of these programs. One is that many DWI offenders delay their engagement in remedial relicensing programs beyond the time they are eligible to do so, and sometimes indefinitely. Investigation into this hard-to-reach population reveals that they appear to be a more deviant group who frequently continue to drive unlicensed and are at greater risk for DWI when they do. They also possess severer and more persistent alcohol problems, show lower psychosocial and cognitive functioning, and are reluctant to pay the costs associated with participation in relicensing programs. As relicensing programs involve education, assessment, and substance abuse counseling, robust participation is a requisite for detection of high-risk offenders and provision of the remedial help they require. As with license suspension programs, this has led to calls for adaptations to encourage better and timelier participation, such as lowering the cost of participation.

Another problem stems from the field's current inability to accurately discriminate between low- and high-risk offenders. Risk assessment procedures rely heavily on self-report instruments that can be falsified by individuals who are motivated to present themselves in an overly positive light. Available objective measures, such as elevated arrest BAC or alcohol biomarkers,

though impervious to falsification, are not always obtainable and have been inconsistent in predicting DWI recidivism risk. Moreover, there is a strong emphasis on detection of severe alcohol and drug use disorders that many risky offenders do not possess, especially young drivers who, though statistically a high-risk subgroup, do not often suffer from severe substance abuse. Perhaps as a result, contemporary assessment protocols have been found to possess no better than 70% sensitivity and 50% specificity, performance that is clinically problematic. This level of uncertainty is troubling because it reduces the effectiveness of a major underpinning of many relicensing programs, namely a graded approach to risk reduction.

There are also other potential consequences of the inability to discriminate between offenders. A high level of false negatives results in failure to identify at highrisk individuals and potentially incapacitate them from the road and/or provide them the remediation (e.g. Interlock devices) they require. False positives can lead to frequent overuse of interventions with offenders who do not require them. This is not only inefficient but can also contribute to the desensitization of offenders to interventions they may require in future. It may also disadvantage undeserving drivers by, for example, prolonging licensing periods or increasing the requirements for relicensing that can result in social and economic hardships. More research and development into valid methods of DWI risk assessment are urgently needed.

Agent Factors: Administrative License Revocation or Suspension

Many jurisdictions have provisions to allow for administrative measures such as car seizure, temporary suspension, or revocation of driver's licenses immediately following a DWI arrest. These provisions serve several functions, including: (1) general deterrence by representing a foreseeable penalty for DWI; (2) specific deterrence by the incapacitation of a DWI driver who may be at risk for further DWI; and (3) celerity by optimizing the deterrence impact of DWI laws through linking immediate consequences to problem behavior. As in the evaluation of any particular component of an overall DWI countermeasure strategy, the impact of this specific tactic is difficult to disentangle from the other countermeasures that inevitably accompany it. Nevertheless, institution of such provisions has been associated with small but significant (i.e. 5%) reductions in fatal crash involvement, irrespective of whether driver BAC was low (i.e. 0.01–0.07%) or higher. Moreover, in line with the celerity principle, license suspensions handed down some time after convictions were less effective as a deterrent of further DWI compared to more immediate suspensions. One factor that diminishes the impact of administrative license revocation (ALR) and suspension (ALS) programs is that a majority of drivers drive without a license during or after their suspension period. Though these unlicensed drivers tend to drive less, their risk of RTC is elevated when they do.

INDICATED PREVENTION APPROACHES FOR DWI

Indicated prevention approaches aim at reducing DWI in drivers with established risk. The most unequivocal indicator of increased risk is previous DWI arrests and/or convictions. At the same time, the concept of the "hard-core," high-risk, intervention refractory offender subsumes not only recidivists, but also drivers who regularly drive impaired but have not been previously arrested. Features characterizing these hard-core drivers include a high BAC on arrest, a substance use disorder, and history of engaging in multiple high-risk driving behaviors, including previous DWI. The measures that are ordinarily directed at these drivers involve deterrence, removal of the vehicle or the driver from the road, and remediation efforts to decrease substance misuse and dependence. Several of the administrative measures described above for deployment in selective prevention are used in indicated prevention initiatives as well. In high-risk DWI offenders, however, they are more strictly applied through increased sanction and sentence severity, longer duration license suspension and vehicle impoundment, and more intensive remedial program participation as requisites for relicensing. Below, the measures that are commonly applied to recidivists are summarized.

Host Factors: Court-Based DWI Programs

A DWI court is a specific court system that targets the alcohol and drug abuse in DWI recidivists. In most jurisdictions, however, the general court system also plays a key role in the graded legal response for preventing DWI recidivism following a driving-related criminal code violation. Among the DWI court's main objectives are identification of offenders with elevated DWI recidivism risk, referral of high-risk offenders to mandated substance abuse treatment and/or other interventions (e.g. victim impact panels, self-help groups, education sessions, frequent alcohol and drug testing, intensive community monitoring and supervision), and creation of a non-adversarial court environment. Courts can take other legal actions including suspension of licenses, seizure of vehicles, and imposition of mandatory sentences.

The advantage of the court setting is that this is where the majority of DWI offenders can be reached. This is significant, as many DWI drivers do not seek relicensing, which can trigger a risk evaluation and remediation if appropriate. Moreover, judges are increasingly cognizant of the opportunity their court-rooms provide for not only protecting the public, but also changing problem behaviors associated with DWI. At the same time, DWI courts face significant pragmatic hurdles. Assessment of DWI risk in the court context, like in relicensing settings, is problematic. This short-coming could challenge a court's ability to modulate mandated intervention content and intensity based on valid risk assessment. Finally, there is little evidence of the effectiveness of mandated treatment in lowering DWI risk or RTC.

Given the multiplicity of ways in which courts may intervene in DWI, both generalization of data on outcomes from one program to another and identification of effective individual program components are difficult. Nevertheless, some information is available. Several pilot projects of DWI courts have found that compliance by offenders was good, and that participation was associated with lower rearrest rates compared to nonparticipants or comparison groups. Court programs with intensive monitoring and supervision have also been associated with reduction of recidivism for up to 5 years post conviction. More rigorous evaluation of different court-based approaches to DWI is clearly needed.

Host Factors: Individual Treatments for DWI

There are few therapeutic approaches designed specifically to address DWI. Most DWI treatments overlap in content and methods with substance abuse treatment and focus on reduction of substance misuse. Referral to specialized substance abuse treatment, follow-up, and monitoring by counselors involved in ALS programs, and possibly installation of an Interlock device for a period of time, are typical elements in the intervention plan for high-risk offenders. Substance abuse treatment may involve a combination of different psychosocial therapeutic components, including multimodal treatment, cognitive-behavioral treatment, relapse prevention, 12-step approaches, behavioral couples therapy, contingency management, among other evidence-informed practices. Overall, participation in these programs is likely to reduce the risks of DWI attributable to more severe substance abuse problems.

Many offenders exhibit poor problem recognition of their substance misuse and DWI behavior. This leads to many offenders being unwilling to fully engage in remedial programs or even consider the need for behavioral change. Engaging these offenders in a rehabilitative process represents an important therapeutic challenge. Interest is growing in motivational interventions in DWI settings as a means toward

enhancing problem recognition, commitment to behavioral change, and adherence to the remedial process. These interventions are being deployed in the court and in the hospital settings discussed above, and as stand-alone interventions.

One sophisticated motivational approach, Motivational Interviewing (MI), is a brief intervention lasting from one to four sessions that has been applied to the treatment of various tenacious problem behaviors, including substance use disorders, pathological gambling, and high-risk sexual practices. It incorporates a precise empathic communication style and an assortment of therapeutic tactics to (1) increase intrapersonal dissonance between clients' deeply held values and current problem behaviors, (2) resolve deep seated ambivalence about change, (3) enhance willingness and autonomy to take action, and (4) reinforce self-efficacy. The MI research consistently indicates its ability to efficiently produce outcomes comparable to other longer-duration psychotherapeutics, and to increase engagement and adherence to treatment. Hence, it seems well suited to the challenge of intervening with recalcitrant, treatment-shy DWI offenders.

Studies evaluating MI specifically with criminal offender groups, including DWI, are relatively rare and mostly preliminary in both their objectives and design. Nevertheless, the available evidence indicates that MI provided to DWI offenders resulted in greater adherence to remedial programs, better outcomes when combined with existing DWI interventions such as Interlock and incarceration, and a significant reduction in high-risk drinking days over a 1-year period when offered as a stand-alone intervention to recidivists with alcohol abuse problems. More research to establish its independent impact on DWI and RTC is needed. At the same time, like in most psychotherapeutic methods, effectiveness is contingent on the clinician attaining an adequate degree of mastery. With its nondidactic approach, specific communication style and a complex bouquet of tactics, MI requires highly motivated staff to learn it, and prolonged supervision to elevate and sustain its practice integrity. These conditions may hamper across-the-board implementation of MI in a DWI service context.

A promising specialized approach to DWI recidivism is the Preventing Alcohol-Related Convictions program (PARC). This program differentiates itself from most existing ones by focusing on the driving side of the DWI equation as opposed to the drinking side. Thus, intervention targets the decision-making process involved in controlling vehicle usage before drinking (i.e. when the offender is not intoxicated). This is in contrast to attempting to control drinking and/or driving after drinking has occurred, when rational

decision-making capacities and the ability to resist social and environmental triggers are impaired. A large-scale trial indicated that this approach was superior to usual care in first-time offenders. This result is intriguing by suggesting that the PARC program strikes at the core of why some DWI offenders persist in drinking-driving even in the face of increasingly severe consequences. Recent studies into the neuroscience of problem behaviors such as alcohol abuse, gambling, and risky sexual practices reveal that individuals who persistently engage in these self-destructive behaviors are prone to dysregulation of the paralimbic system involved in decision making. This may lead to a style of decision making that favors greater short-term gains (e.g. the convenience of driving to a drinking venue) even when accompanied by greater potential losses (e.g. an accident or a DWI arrest) versus smaller gains (e.g. a safe ride home) but smaller potential losses (e.g. no DWI risk). DWI recidivists are more likely to be impulsive, and there is emerging evidence that they have executive control and decision-making difficulties similar to the above risk groups when sober as well. More research is needed to evaluate whether the PARC approach works equally well with recidivists, especially those who may suffer from persistent decision-making impairments.

Agent Factors: Vehicle Impoundment

Vehicle impoundment programs seek to incapacitate the DWI offender's vehicle and remove the high-risk offender from the road, and secondarily to act as a deterrent. Duration of impoundment is variable, from days to months depending on the number of previous DWI convictions and possibly other extenuating circumstances. Costs for towing, storing, and ultimately reacquiring the vehicle are borne by the offender. The evidence suggests that impoundment reduces DWI rearrest and crashes in the year following impoundment. To be effective, impoundment must be executed immediately following an arrest to avoid the driver from selling or otherwise disposing of the vehicle. The deterrent impact is weaker on post-impoundment recidivism and not significant for DWI deterrence in the general driver population.

Administration of impoundment programs is complicated in many instances. For example, about half of drivers, usually owners of lower value vehicles, abandon their vehicles rather than pay storage costs and other fines to retrieve their vehicles. The community is left to absorb these costs. There are reports of multiple offenders intentionally driving valueless vehicles for this reason. DWI offenders and offenders who drive with suspended licenses are frequently apprehended in vehicles registered to others, complicating the impoundment and seizure process. This can also result

in adversity for innocent owners of vehicles who depend on them for vocational and transportation purposes. Other concerns relate to the potential for job loss for the offender. Little systematic investigation of these issues has been undertaken.

Agent Factors: Interlock

Interlock devices are usually offered on a voluntary basis to offenders in order to shorten their license suspension period. They are typically offered to firsttime offenders as a way to expedite relicensure, but can become mandatory for life for drivers who want to reacquire their licenses after multiple convictions. Once installed in the offender's vehicle, the driver must blow into the device to start and continue operating their vehicle. Readings over 0.02% result in ignition being cut. There is consistent evidence that Interlock devices installed in the vehicles of DWI offenders and recidivists as part of a relicensing program significantly reduce DWI rates in the order of 40–90% during the time of installation. The device's usefulness as a behavioral change strategy for preventing recidivism is weak, however, with recidivism rates returning to preinstallation levels once it is

Despite the proven capability of Interlock program participation to curtail DWI, uptake by offenders has been incremental. The expense of installation and servicing of the device, which can run up to several thousand dollars depending on the duration of installation, is borne by the offender. This cost, coupled with the low socioeconomic status and willingness to drive unlicensed observed in many offenders, may be preventing greater Interlock program participation. Future investigation into Interlock uptake could appraise the impact of reducing program cost and/or providing other positive incentives for voluntary participation. At the same time, such strategies for increasing participation in Interlock programs, or any other effective DWI remedial programs for that matter, are controversial because they may be perceived as rewarding offenders for their delinquent behavior.

Ongoing research is investigating the predictive and adaptive utility of Interlock data. Strands of evidence suggest that individuals who continue to blow positive after a learning period are more likely to recidivate once the device is removed. This finding, if sufficiently validated, could help administrators adjust the length of time the device must remain installed in the vehicle to ensure maximum public safety. In some jurisdictions, indications of continued positive blows are grounds for expulsion from the Interlock program. The resulting prolongation of the license suspension period is used as punishment to encourage an alteration of drinking behavior. More study of the

comparative impact of these different modalities of Interlock use is needed. Finally, there have been attempts to couple installation of Interlock with other therapeutic elements that target more enduring behavioral change beyond removal of the device. The available evidence suggests that adding a brief, therapeutic motivational component to the Interlock approach can help to maintain gains reliably observed while the device is installed. Further research is needed to understand how to extend the benefits of Interlock device installation in preventing DWI by also achieving more persistent behavioral change.

CONCLUSION

DWI is a major preventable public health concern. Significant strides have been made in the last decades in reducing RTCs related to DWI. More recently, these declines have stalled in much of the developed world. Moreover, rates of DWI-related RTCs are climbing in developing countries as individual access to private transportation grows. Ongoing efforts are needed to develop theory and evidence-based approaches to DWI risk assessment protocols and prevention approaches, and to rigorously evaluate their practical effectiveness in the field. In some instances, better reconciliation and integration of apparently conflicting responses to DWI, namely punishment, deterrence and intervention, are also deserving of continued attention.

SEE ALSO

Motivational Enhancement Approaches, Screening and Interventions in Medical Settings Including Brief Feedback-focused Interventions, Criminal Justice Interventions, Behavioral Couples Therapy for Alcoholism, Treatment-as-Usual for Substance Abuse in Community Settings

List of Abbreviations

ALR administrative license revocation ALS administrative license suspension

DWI driving while impaired by alcohol and/or drugs

MI motivational interviewing

PARC Preventing Alcohol-Related Convictions program

RTC road traffic crashes

Glossary

BAC blood alcohol concentration measured in g alcohol/dl blood and expressed in % (i.e. BAC of $0.05 \, \mathrm{g}$ alcohol per dl blood = 0.05%).

Brief intervention brief intervention is typically one or more sessions of intervention that lasts 5–60 min. Common elements include the detection of substance use problems using standardized screening instruments, and interventions that involve the provision of feedback concerning the extent of an individual's use relative to his/her normative group and its risks, provokes increased problem recognition and cognitive reappraisal concerning substance misuse, and delivers clear advice to change.

Designated driver a driver who has been appointed to remain sober and be the driver after a drinking event. These are typically informal arrangements made between friends and colleagues.

Interlock device a device that is installed in a vehicle that prevents ignition of an vehicle by a driver whose BAC is typically above 0.02%.

Motivational interviewing a brief intervention lasting from one to four sessions. It incorporates a precise empathic communication style and an assortment of therapeutic tactics to: (1) increase intrapersonal dissonance between clients' values and current problem behaviors, (2) resolve ambivalence, (3) enhance willingness and autonomy to take action, and (4) their self-efficacy to do so.

Per se drunk driving law a law that states that someone is guilty of driving under the influence if their blood alcohol content is at or above a certain level (e.g. BAC \geq 0.08%).

Preventing Alcohol-Related Convictions program (PARC) this approach focuses on the driving side of the DWI equation as opposed to the drinking side. This intervention targets the decision-making process involved for controlling vehicle usage before driving to a drinking venue (when the offender is sober), in contrast to attempting to control their drinking and/or driving after arrival when the driver is more vulnerable to the effect of alcohol on rational decision-making and the social and environmental triggers for drinking.

Recidivists repeated DWI offenders.

Sobriety checkpoints a roadblock conducted by law enforcement officials who stop vehicles in order to establish whether the driver might be legally impaired to drive.

Victim impact panels under court order, DWI offenders must witness the impact of drunk driving on the lives of its victims through panel presentations from a victim of DWI, a rescue professional and/or from another DWI offender.

Zero tolerance law a law that makes it illegal for individuals to be driving with a BAC greater than 0.00%.

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23

Mindfulness

Tony Toneatto

University of Toronto, Toronto, ON, Canada

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INTRODUCTION

Among Buddhist teachings on classical mindfulness that are recognized by all Buddhist traditions, two major types of meditative practice have been described in considerable detail: concentration meditation and insight meditation. While different Buddhist traditions may emphasize either insight or concentration practices, mindfulness meditation typically combines both. The mindfulness (sati in Pali, smrti in Sanskrit) is commonly translated as the recollection or recall of the present moment. As a means of recall, remembrance, or recollection (of the present moment), it is a valuable technique or strategy for combating the tendency toward ruminative distraction during meditative practice. This meaning of mindfulness emphasizes the recollection of the present moment by shifting attention away from mental objects other than the one that is the meditative focus (e.g. breath, sound, image) in the present moment.

Traditionally, concentration practices sustain bare attention on the breath as the primary meditation object

while remaining simultaneously aware of the body and mind. Such bare attention permits the awareness of subjective experience but devoid of the projections and associations with which we automatically perceive such experience. Effort is made to maintain attention on the meditative object without distraction. When any cognitive event distracts attention away from the breath, introspective awareness is applied to label the distraction and the act of mindfulness serves to return the attention once again to the breath. Through such repeated labeling, the arising of subjectivity is separated from the specific content of that subjectivity. Only when the mind can hold an object stably for a sustained period can the contents of mind be fully and vividly experienced. Understood in this way, the concentrative aspect of mindfulness meditation is stressed and can be described as focused (on a meditative object), microscopic (free of distraction), and narrow in its scope (less aware of other mental activities).

However, mindfulness is also described as a form of attention and introspective awareness directed toward 220 23. MINDFULNESS

subjective experience itself in order to discern its intrinsic or "authentic" nature. Rather than viewed as a distraction or obstacle to the tranquility associated with concentration meditation, mental content is directly observed in insight meditation. Through the moment-to-moment experience of subjective events within the context of the mental stability and tranquility induced by concentration practices, the transitory of all subjective experience, their ephemeral and constructed nature, is directly observed or cognized. As a result, mindfulness helps to increase the awareness of the habitual patterns of preoccupation with maladaptive mental content. Understood this way, the *insight* aspect of mindfulness is stressed. Mindfulness (insight) meditation, in contrast to concentration meditation, is less focused, macroscopic, and broad.

Thus, the assumptions underlying insight meditation locate emotional and behavioral distress in dysfunctional attitudes about cognition, rather than in the content of dysfunctional cognitions, per se. According to Buddhist psychology, the type of insight that sustained bare attention facilitates differs from the insights that are derived from content-focused therapeutic interventions such as psychotherapy cognitive-behavior therapy. For this reason, mindfulness approaches are often considered to be metacognitive in nature, emphasizing that the beliefs that are held about cognition itself can be the source of significant emotional distress. Through repeated labeling of mental process rather than actively engaging with mental content, habitual, reflexive reaction patterns diminish and attenuate, and skillful responses are more likely to occur.

When the cultivation of sustained and increasingly extended periods of attention on an object through concentration practices (bare attention) train is integrated with introspective insight awareness, a deeper understanding of the moment-to-moment arising of subjectivity is achieved. This understanding facilitates a novel, deconstructed experience of self and the phenomenal world.

Sustained mindfulness practice also facilitates perceptual and cognitive regulation, the repeated switching between attention to, and introspective awareness of, subjective experience. Such cognitive and perceptual fluidity helps increase mental flexibility through an attitude of nonidentification with cognitive experience. Such mental suppleness or flexibility is often considered a feature of optimal mental health. Unlike cognitive-behavioral therapy, which deliberately requires the active exposure to undesirable mental events and targeted efforts to restructure or otherwise modify subjectivity, mindfulness is a natural process of experiencing subjective events without interruption, rejection, judgment, or manipulation

regardless of content. Mindfulness encourages an attitude of tolerance or acceptance (but not indulgence) of subjective experience and facilitates adaptive, flexible, nonautomatic response to such experiences through the cultivation of moment-to-moment awareness and observation of mental events as they naturalistically arise, briefly abide, and subside.

Buddhist-based meditation described above and secular mindfulness meditation that is of great scientific interest currently differ in several important ways. In traditional Buddhist meditation, the goal of mindfulness practice is to realize specific insights (or wisdom) into the nature of consciousness culminating in the experience of enlightenment or nirvana. Such insights are considered radically transformative of the personality, influencing the experience of oneself, others, and one's own internal and external environment. Secular mindfulness, in contrast, stresses the impermanence of thoughts and emotions related to self and the dis-identification with the habitual, reflexive qualities of maladaptive mental patterns with the goal of increasing mental and behavioral flexibility and thereby reducing psychological distress.

The core skill defining secular mindfulness has been described as the capacity to respond to cognitive events (which can include thoughts, beliefs, images, feelings, perceptions, sensations, memories) with an attitude of acceptance, nonjudgment, and present-focused awareness. This capacity is thought to assist the individual to decenter from negative mental states.

MINDFULNESS-BASED INTERVENTIONS

The most popular secular mindfulness program, Mindfulness-Based Stress Reduction (MBSR), has been shown to reduce psychological morbidity associated with chronic illness, emotional dysfunction, and behavioral disorders in several extensive reviews of this literature. In addition to the formal sitting meditation that is at the center of the 8-week MBSR program, there are several additional practices that complete the program (i.e. eating exercise, body scan, yoga, walking, meditation) and a day-long retreat between weeks 6 and 7.

Although the popularity of MBSR has grown in the absence of rigorous empirical evaluation, recent controlled trials have shown impressive reductions in psychological symptomatology associated with medical illness (e.g. chronic pain, cancer, anxiety disorders, rheumatoid arthritis, eating disorders, and fibromyalgia) and enhanced emotional well-being in nonclinical samples. Adaptations of MBSR for preventing depressive relapse (Mindfulness-Based Cognitive Therapy (MBCT)) and addiction relapse (Mindfulness-Based

Relapse Prevention (MBRP)) have also been developed. Moreover, mindfulness-related interventions have been integrated into a number of empirically supported psychotherapies, including Dialectical Behavior Therapy and Acceptance and Commitment Therapy.

MINDFULNESS MEDITATION AND ADDICTION RECOVERY

Although there is no definitive or specific Buddhist psychology of addiction and recovery, the core teachings of this tradition from which mindfulness-based practices originate hold that emotional suffering and distress is caused (or more accurately, conditioned) by "craving." Craving, distinguished from mere desire, refers to an attributional or projective process in which the object of the craving (for example, a psychoactive substance or associated subjective experiences) is perceived as wholly positive, desirable, or needed (without taking into consideration its negative aspects or consequences). As a result, the object of the craving is obsessively sought after. Or, in contrast, the object of the craving is perceived as wholly negative, undesirable, or unwanted (without taking into consideration its positive aspects or consequences). As a result, the object of the craving is obsessively avoided. Thus, the addict perseverates, repeating actions (i.e. consume a drug) that have produced the desired outcome (i.e. euphoria) or to avoid or escape an unpleasant emotional state based on prior experiences with the psychoactive substance.

Whether it is seeking pleasure or avoiding an uncomfortable situation through, for example, food, entertainment, sex, exercise, or psychoactive substances, craving is a relatively common experience. Addiction to psychoactive substances, according to Buddhist psychology, is thus not fundamentally different from other "cravings" and represents a "false refuge" since the craving for drug-induced experiences ultimately produce the consequences that the individual wishes to avoid and do not actually realize for the individual what they are seeking (e.g. happiness, coping, and health).

Given the highly cognitive nature of the addictive process, there are many reasons why mindfulness meditation can be considered a potentially important component of addiction treatment. Firstly, mindfulness meditation facilitates a detached awareness of subjective experiences (e.g. thoughts, feelings, sensations), an especially useful set of skills for those in early addiction recovery for whom subjective awareness can be unpleasant, overwhelming, and distressful. The natural impulse for addicted individuals is to overidentify with subjective experience and hence seek methods to rapidly

modify (i.e. avoid unpleasant or intensify pleasant) subjective experience using a psychoactive drug. Mindfulness meditation, instead, encourages a radically different approach to subjective experience, especially undesirable ones, focused on observation, description, awareness, and nonjudgment of such experience. Such practice facilitates the addicted individual's ability to hold or contain the affects they would otherwise wish to regulate through substance use. Through such practice, insight into the impermanent, temporary, and transitory nature of cravings and other addiction-related cognitions is facilitated. The fruit of such practice is an awareness-based response in the presence of substance use triggers rather than one that is impulsive, habitual, or automatic.

Secondly, mindfulness meditation improves coping with cravings, an inevitable and serious threat to recovery. The craving response creates a complex cognitive system consisting of environmental cues, rigid cognitive responding, positive outcome expectancies for the effects of the substance, and motivation to engage in substance consumption to reduce negative effect. Mindfulness may serve to disrupt this system through heightened awareness and acceptance of the craving response within an attitude that defines the essence of mindfulness: nonjudging, analyzing, or reacting. By repeatedly interrupting this system, mindfulness can be construed as a form of counterconditioning in which metacognitive awareness replaces the positive and negative reinforcement associated with consumption of the addictive substance. As a metacognitive skill, mindfulness may enhance the ability of the individual to cope effectively with urges and cravings by modifying how the individual perceives addiction-related beliefs. Thus, mindfulness meditation can weaken the conditioned association between a craving and substance use.

Thirdly, mindfulness meditation can, through concentration on the breath as an anchor for awareness, enhance the ability to concentrate and focus the mind and reduce the tendency toward distraction that can characterize the early phases of recovery. Relying on the meditative object, such as the breath, can help ground one's awareness in the here-and-now and attenuate ruminative tendencies.

Fourthly, mindfulness interventions are particularly appropriate for addictive disorders given the central role of cognitive distortions, overidealization of sensory experiences, and fear of aversive emotions that have been shown to mediate addictive behavior and relapse. Mindfulness-based interventions have increasingly been shown to be effective in reducing the intensity of variables that are implicated in addiction relapse (e.g. negative affective states, such as depression and anxiety). For example, MBCT, an

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intervention that is specifically designed to reduce the rates of depressive relapse following treatment has been shown to assist individuals in decentering from depressogenic cognitive and affective states. Since addiction relapse is also highly associated with cognitive and affective states, training in mindfulness may be effective in reducing addiction relapse as well.

MECHANISMS OF THE CLINICAL EFFECTS OF MINDFULNESS-BASED INTERVENTIONS

The precise mechanisms of action that underlie the action of mindfulness meditation await definitive elucidation. Mindfulness has been described as a metacognitive state of detached awareness of one's thoughts or a form of emotion-focused coping that modifies the response to stress or change rather than reflexively reacting to it. By bringing awareness to a stressful situation rather than automatically or impulsively reacting, the number of choices available to the individual to influence the next moment is increased. Mindfulness meditation may assist the individual to reduce the tendency to respond to negative mental and physical states with a cascade of negative discursive thought (leading to rumination) or maladaptive behaviors phobic behavior, avoidance, impulsivity, substance use). Through regular and consistent practice, the mindfulness practitioner may learn to discriminate between the constant stream of cognition that characterizes normal waking consciousness and the "observer" or "cognizer" of such cognition and to lessen the tendency to identify with the content of cognitive processes. This discriminative skill allows the individual to disrupt automatic, conditioned, or impulsive response to such cognitions. Decentering from dysfunctional thinking (i.e. process focus) is a defining feature of mindfulness in contrast to efforts to alter specific beliefs (i.e. content focus) commonly within psychotherapeutic approaches psychopathology.

To the degree that one is able to observe one's subjectivity, one is no longer embedded or fused with its content. The result is a profound shift in one's relationships to thoughts and emotions with concomitant clarity, perspective, objectivity, and equanimity. Mindfulness meditation is also believed to reduce cognitive reactivity, the degree to which a mild dysphoric state reactivates negative thinking patterns. While developed within the context of depression relapse, cognitive reactivity has applications to understanding addiction relapse. Previous substance use may condition a link between specific thinking and emotional patterns and

substance use. Even mild reactivation of these mental events may trigger a cycle of ruminative and cognitive activity that exacerbates negative affect trigger urges and cravings for substance and increases the likelihood of ingesting the psychoactive substances.

Drawing on information-processing theory, a model of addiction in which mindfulness plays a central role posits that mindfulness promotes attention to cognitive, sensory, and affective responses. This attention (1) sensitizes the addicted individual to linkages between emotional distress and drug use that they may have not been aware of and (2) reduces the individual's avoidance of negative affect and cognition, thereby desensitizing the individual to the aversive aspects of these cognitive states and reducing the need to escape using psychoactive substances.

Alternative conceptualizations of mindfulness suggest that mindfulness meditation may exert its beneficial effects by producing a fundamental shift in perspective, reperceiving. Reperceiving has been empirically shown to comprised three components: intention, attention, and attitude. Through the simultaneous cultivation of these three components, a shift in perspective occurs (i.e. "reperceiving") in which the meditator learns to dis-identify from the contents of awareness and perceive moment-by-moment experience with greater clarity and objectivity. Reperceiving modifies the relationship between the individual and their own subjectivity and resembles other constructs such as decentering, de-automatization, and cognitive defusion.

Conditioning and learning processes such as habituation and desensitization have also been suggested as mechanisms of mindfulness. For example, the process of desensitization as a result of prolonged exposure may lead to symptom relief in patients with chronic pain and anxiety as the individual becomes more adept at tolerating, holding, or containing negative affect.

Meditation has often been confused with relaxation. While relaxation is often a welcome outcome of sustained concentration meditation, this is not the intent of such practices. Concentrative meditative practices are intended to create the ideal internal environment to allow the accurate discernment into the nature of subjectivity (i.e. insight). In addition, neurophysiological research suggests that mindfulness meditation is a unique form of consciousness and not reducible to mere relaxation. A randomized trial comparing mindfulness meditation to relaxation found that both interventions produced lower overall psychological distress compared to the control group, but only the mindfulness group also reduced rumination and distraction, an outcome consistent with the goals of mindfulness meditation, but not necessarily associated with relaxation practice.

REVIEW OF THE MINDFULNESS MEDITATION AND ADDICTION TREATMENT LITERATURE

The efficacy of meditative practices as an intervention in both substance abuse treatment and mental health treatment has supportive evidence dating several decades. Early research showed positive results for the effects of Transcendental Meditation (TM), a Hindubased spiritual practice, as a substance abuse intervention. However, this research will not be reviewed here since the key TM technique is the repetition of a unique mantra syllable believed to be endowed with spiritual and magical potency rather than the development of mindfulness, insight, or meditative skills, per se.

To date, relatively few studies have investigated the efficacy of mindfulness-based interventions for the treatment of addictive behavior. In a recent review of mindfulness meditation for psychoactive substance abuse, 17 studies were identified that integrated mindfulness-related approaches into addiction treatment:

Classical Vipassana Meditation (VM; 1 study): this meditative practice adheres most closely to classical Buddhist teachings and typically consists of 10 consecutive days of 10–11 h of intensive daily meditative practice, conducted in silence.

MBSR (8 studies): tested the efficacy of MBSR or some variant of MBSR that modified some of its core techniques. For example, the duration of the interventions ranged from five, 90-min sessions over 7 weeks with less than 50% of the session content devoted to mindfulness meditation in some studies to eight, 2–2.5-h sessions over 8 weeks, with the majority of each session devoted to mindfulness meditation. Only two studies included the full-day retreat that is recommended as part of the traditional MBSR program and which serves to strengthen the mindfulness skills through intensive practice.

Spiritual Self-Schema therapy (3-S therapy; 3 studies): spiritual self-schema therapy has been developed for the treatment of addiction and HIV-risk behavior and consists of an 8- or 12-week-long course synthesizing a lifestyle-based psychotherapy based on the Eight-Fold Path, a central component of Buddhist psychology, with cognitive self-schema theory. All three studies used manualized 3-S therapy delivered in an individual and/or group format, during 1- to 2-h-long sessions per week.

Acceptance and Commitment Therapy (ACT, 3 studies): with its roots in behaviorism and behavioral analysis, integrates mindfulness among a number of other cognitive-behavioral interventions including exercises to reduce cognitive fusion, undermine experiential avoidance, clarify life values, development of a transcendental self, and several other explicitly psychotherapeutic interventions.

Dialectical behavior therapy (DBT, 2 studies): initially developed for the treatment of chronically suicidal clients with borderline personality disorder has been adapted for addictive disorders. DBT consists of strategies from cognitive and behavioral therapies (with a problem-solving focus) and acceptance strategies (i.e. mindfulness) adapted from Zen theory. DBT also includes techniques specifically formulated to assist individuals with severe self-regulatory deficits such as training in dialectic thinking, treatment strategies that balance change versus acceptance, interpersonal effectiveness, and emotion-regulation skills.

This chapter will explicitly exclude the DBT and ACT studies since both are comprehensive and multimodal treatments that integrate mindfulness in nontraditional formats (e.g. eschewing sitting meditation), but are not primarily mindfulness-based treatments. In addition, the understanding of mindfulness differs somewhat in both ACT and DBT from the description provided in the introduction. These treatments are also explicitly psychotherapeutic in nature with the goal of directly modifying cognitive and behavioral psychopathology. As a result, it is impossible to infer from the results of these interventions the unique impact of mindfulness meditation and are thus not of direct relevance for understanding mindfulness-based interventions for addiction. These treatments are better considered cognitive-behavioral treatments in which mindfulness plays a significant but subsidiary role. In addition, Self-Schema Therapy will not be reviewed, as this treatment is a lifestyle-focused, comprehensive, spiritual psychotherapy that is closely tied to Buddhist concepts. As with DBT and ACT, mindfulness is included as one of eight specific interventions based on the Buddhist eightfold path but cannot be described as mindfulnessbased. Thus, only the nine studies that specifically evaluated mindfulness-based interventions will be briefly reviewed.

Residential Populations

Four studies, none of which employed randomization, focused specifically on residentially treated substance abusers in which mindfulness meditation formed a component of a multimodal treatment program for addiction. In a nonrandomized study of residents of an addiction recovery house, study participants self-selected into the mindfulness group and received 2-h mindfulness sessions once weekly for 8 weeks in addition to their standard treatment program. On days in between mindfulness sessions subjects listened to an audio-guided mindfulness instructions. Assessments of the effect of the mindfulness intervention were conducted at 8 weeks (post-intervention) and at a 5-month follow-up. No differences

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were found between the groups (those who chose the mindfulness treatment versus those who did not) on measures of substance use, interpersonal problems, and measures of psychological health (e.g. spirituality, optimism). Several methodological concerns (e.g. small sample size, self-selection, no control for the mindfulness intervention) tempered any conclusion about the efficacy of mindfulness for addiction. However, the authors suggested that the benefits of mindfulness practice may not have been readily detectable by the assessment measures adopted in their study. Objective measures of mindfulness were not included.

A quasi-experimental evaluation of the MBSR as an adjunctive treatment of substance abuse in a therapeutic community compared to treatment as usual (TAU) found no significant group differences on any measure (e.g. anger control, self-control, social support seeking, hostility). The effect of mindfulness on substance use patterns specifically was not reported nor was mindfulness objectively assessed.

In an uncontrolled study of residents of a therapeutic community, the MBSR decreased salivary cortisol levels indicating reduced stress but found no change on a psychometric measure of perceived stress. Changes in substance use behavior were not assessed. The absence of a control group precludes any inference about the mechanism producing the changes in cortisol levels. Mindfulness was not objectively assessed.

More recently, a mindfulness-based therapeutic community (MBTC) intervention was compared to TAU (historical control) in a therapeutic community of DSM-IV diagnosed substance dependence. Both the MBTC and control groups showed a decrease on a psychometric measure of stress over time with significant reduction by the MBTC group in muscle tension and emotional irritability. However, these benefits did not extend beyond 3 months with both groups showing similar results. Again, the uncontrolled nature of this research precludes any firm conclusions. Mindfulness was not objectively assessed.

Incarcerated Populations

The benefit of the VM in a medium-security incarcerated population was evaluated in a nonrandomized study. Those uninterested in participating in the VM course were assigned to a case-matched "treatment as usual" group who were allowed to attend other rehabilitation courses of their choice (e.g. Alcoholics Anonymous, social skills training). The VM course consisted of several hours of daily meditation, held in silence, except for oral instructions that emphasized acceptance, nonjudgment, and nonreaction to thoughts and feelings. Teachings on basic Buddhist principles, including the Four Noble Truths and meditation, were provided.

Compared to the control group, the VM participants reported significant reductions in substance use (alcohol, marijuana, crack cocaine), fewer alcohol-related negative consequences, lower levels of psychiatric symptoms, higher levels of optimism, and higher levels of internal alcohol-related locus of control. At 3 months after release from prison, those who had participated in the VM group had significant decreases in thought avoidance, which was shown to partially mediate the reduction in alcohol use post release and suggesting that thought acceptance could be a possible mechanism of therapeutic action. Adherence to mindfulness practice was not assessed during or following the mindfulness course, so it is not possible to assess whether participants understood and correctly practiced mindfulness meditation, and therefore it is not clear whether the effects of course participation were due to mindfulness training or other confounding course characteristics. In addition, no objective measures of mindfulness were administered.

Outpatient Populations

Several either uncontrolled or nonrandomized studies on outpatient populations have been conducted. A randomized, controlled trial compared an 8-week outpatient MBRP program to TAU in individuals with substance use disorders who had first completed intensive inpatient or outpatient treatment. While the relation between depressive symptoms and substance use was significantly mediated by craving in the TAU, it was not found to be significant in the MBRP group supporting the hypothesis that mindfulness meditation attenuated the association between negative affect and self-regulation through substance use. However, no group differences in several aspects of mindfulness (observing, describing, nonjudgment of inner experience, and nonreactivity to inner experience) or substance-related problems were found. The intervention (MBRP or TAU) did not predict days of alcohol or drug used 4 months post-intervention.

Individuals with alcohol and/or cocaine use disorders randomly assigned to a mindfulness training or cognitive-behavioral treatment found no group differences in drug use, which was assessed weekly. Response to a personalized, imaginably administered, stress provocation test was assessed posttreatment. The provocation test showed a reduced response on psychological and physiological indices of stress in the mindfulness training group compared to cognitive-behavioral therapy. An objective measure of mindfulness, the Five Facet Mindfulness Questionnaire, did not show a significant change as a result of the mindfulness intervention. Attrition of over 50% reduced the generality of these findings.

An uncontrolled pilot study of MBSR on smoking cessation required subjects to quit smoking during

week 7 of the 8-week MBSR program. Six weeks later, about half of the sample was confirmed as abstinent from smoking for the prior week. Smoking abstinence was correlated with meditation compliance. Mindfulness was neither formally assessed at baseline nor at the end of treatment. Lack of a control group precludes a definitive interpretation of these results.

The MBRP, in an uncontrolled study of 15 alcoholdependent, outpatient-treated subjects, showed no significant change in alcohol consumption (% days abstinent, heavy drinking days, total number of drinks), craving, liver enzymes, serum interleukin, or salivary cortisol 2 months following the meditation intervention. However, reduction on measures of psychometric measures of depression, anxiety, and stress were found post-meditation. This study was one of the few to actually measure levels of mindfulness prior to and post-intervention using the Mindfulness Attention and Awareness Scale, which showed significant but modest increases in mindful awareness.

SUMMARY OF MINDFULNESS-BASED INTERVENTIONS

Mindfulness-based interventions cannot at the present time be described as demonstrating empirical effectiveness. The outcomes that were reported are generally quite disappointing with the mindfulness intervention not bestowing any decided benefit in modifying substance use in the short-term or the long-term. Surprisingly, the specific impact of mindfulness mediation on patterns of substance use behavior was infrequently assessed or reported, ostensibly the most important variable in evaluating the efficacy of mindfulness-based interventions. Studies that showed mindfulness to have some benefit are difficult to interpret since the studies were not properly controlled, and the outcomes could be explained by a host of confounding variables.

Mindfulness meditation research has been criticized for their lack of scientific rigor. A major criticism concerns the lack of high-quality, randomized control studies (e.g. active or plausible controls where the key element of mindfulness-based approaches, sitting meditation and related practices, is excluded). No study combined both randomization and a credible control group. Indeed, uncontrolled or case series were the most common research design. In addition, small sample sizes, high rates of attrition, infrequent follow-up, absence of psychometric measures of mindfulness meditation also characterized this body of research.

Particularly noteworthy was the general neglect of objective measures of mindfulness such as the Mindful Attention and Awareness Scale or the Five Facet Mindfulness Scale, which were administered in only a very small number of the studies reviewed. This is an especially glaring weakness of the mindfulness literature since it is simply assumed that those who receive this intervention will practice it properly (e.g. skill in perceiving subjective experience as impermanent, de-identifying with cognition, allowing mental events to arise and subside within a context of nonjudgment, accepting, tolerance). Yet, not one of the research studies reviewed measured any of these key constructs. Thus, outcome measures did not permit assessment of variables that could be specifically related to mindfulness meditation, but instead tended to focus on variables that reflected the outcome of mindfulness (e.g. hostility, depression, and social support). Instruction in mindfulness meditation does not ensure that mindfulness skills have been acquired or even practiced. Only through formal or objective assessment using psychometrically validated instruments of which there are several available can the impact of meditative practice be empirically demonstrated. Thus, it is not possible at this time to evaluate whether the mindfulness intervention even had an impact on mindfulness skills in most of the studies reviewed.

Measures of the process of mindfulness meditation were entirely lacking. Very little is known about what the participants in the reviewed studies are actually doing when they are practicing mindfulness. No study assessed what subjects actually did while they practiced mindfulness meditation. Not one study was able to verify that the participants were even practicing mindfulness meditation rather than engaged in some other activity such as fantasizing, sleeping, reverie, daydreaming, etc. While some studies did inquire as to whether the participants practiced mindfulness or the basic frequency of practice such assessments are far from an adequate evaluation of this core construct. As with all mindfulness meditation studies, it is not possible to determine whether subjects actually meditated at all and what they were actually doing while they meditated.

Furthermore, there appears to be an absence of consensus about an operational definition of "mindfulness," reflecting the ongoing debate about such practices in the general meditation literature. Mindfulness meditation interventions fail to distinguish between attention and awareness as two distinct components of meditation, raising doubts about what exactly practitioners are doing when they are practicing modern mindfulness-based interventions and what instructors are teaching. This distinction often escapes the attention of the mindfulness-researchers themselves.

Thus, the absence of methodologically rigorous research precludes a definitive statement about the future potential of mindfulness meditation for the treatment of addiction. The current evidence is not supportive of this approach at the present time.

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FUTURE DIRECTIONS FOR RESEARCH

The most important objective for future research on mindfulness meditation is to clearly define mindfulness practice and to develop psychometrically robust measures of actual meditative practice (rather than outcomes of practice such as a decrease in dysphoric affect or increase in coping skills). Of course, the methodological quality of the research requires the adoption of study designs that can lead to valid inferences and attend to threats to internal validity. Several other reviews have spoken to this issue, and their conclusions will not be repeated here in detail other than to emphasize that sample size, follow-up, attrition etc., must all be seriously attended to if this modality is to receive a fair evaluation of its efficacy. While randomized control trials are the most common approach to achieve this, other methodologies should be explored such as applied behavioral analysis or intensive case studies in which the assessment of what subjects are actually doing when their practice can be assessed and monitored. One might raise the question of whether randomized controlled trial (RCT) methodology is most appropriate for evaluating mindfulness given the requirement of a positive attitude toward this modality in order to practice it properly and to realize its benefits.

The following recommendations that would improve the quality of mindfulness meditation research and the treatment of addiction can be suggested: (1) continuing to manualize mindfulness meditation therapies especially when they have been modified in individual studies to facilitate study replication and pooling of data; (2) assessment of subjects' mindfulness meditation practice intensity and changes in the degree of mindfulness; (3) mechanism of mindfulness meditation should be a component of the clinical assessment; (4) "dismantling" studies to determine necessary and sufficient elements of mindfulness meditation will assist in developing effective interventions; (5) inclusion of credible control therapies in order to conclusively establish treatment efficacy; (6) inclusion of objective measures of mindfulness where possible (e.g. biomarkers, imaging studies) to elucidate a mechanism of action.

In conclusion, existing data do not permit any particular type of mindfulness meditation to be recommended for any substance use–related condition at the present time. While many of the studies showed some positive effects of mindfulness meditation interventions compared to baseline, these effects were not always found, often short-term, and tended to apply to nonsubstance-related variables. While the promise of mindfulness meditation as an efficacious treatment

for psychoactive substance use disorders remains unfulfilled at the present time, there is sufficient evidence to recommend continued investigation of this modality.

SEE ALSO

Therapeutic Communities, Cognitive Behavioral Therapies

List of Abbreviations

ACT Acceptance and Commitment Therapy

DBT dialectical behavior therapy

MBCT Mindfulness-Based Cognitive Therapy

MBRP Mindfulness-Based Relapse Prevention

MBSR Mindfulness-Based Stress Reduction

MBTC mindfulness-based therapeutic community

TAU treatment as usual

TM Transcendental Meditation

VM Vipassana Meditation

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http://www.mbct.com/ – Mindfulness-Based Cognitive Therapy. http://www.mindfulrp.com/default.html – Mindfulness-Based Relapse Prevention.

http://www.umassmed.edu/cfm/stress/index.aspx – Mindfulness-Based Stress Reduction.

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Psychological Treatments for Pathological Gambling

Benjamin J. Morasco*, \$\square\$

*Mental Health and Clinical Neurosciences Division, Portland VA Medical Center, OR, USA

\$Department of Psychiatry, Oregon Health & Science University, OR, USA

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PATHOLOGICAL GAMBLING NOSOLOGY, PREVALENCE, AND DEMOGRAPHIC CORRELATES

The Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM-IV) defines pathological gambling (PG) as an impulse-control disorder that involves persistent and recurrent gambling that is disruptive to one's personal, familial, or vocational life. To meet criteria for a diagnosis of PG, 5 out of 10 diagnostic criteria must be endorsed. These symptoms include preoccupation with gambling; tolerance; repeated unsuccessful efforts to stop or control gambling; withdrawal symptoms (restlessness, irritability) when attempting to reduce or stop gambling; gambling as a method of escaping from problems or relieving dysphoric mood; chasing losses; lying to others about the extent of gambling; committing illegal acts to finance gambling; impaired relationship, career, or education due to gambling; and relying on others for money to relieve a desperate financial situation caused by gambling.

Much of the diagnostic criteria for PG are based on the substance use disorder (SUD) literature, as five of the above symptoms are adapted from criteria for substance dependence. There is a debate in the empirical literature regarding the classification for PG. Future versions of the DSM are considering the inclusion of PG within a class of addictive behaviors, which would include traditional SUDs.

PG has also been called compulsive gambling and a gambling addiction. Although not a formal diagnosis, problem gambling is a term commonly used for individuals who meet some of the diagnostic criteria for PG, but who do not meet full criteria for a diagnosis. Disordered gambling is a commonly used term to summarize PG and problem gambling.

The overall prevalence of PG has been studied in several epidemiological investigations. Results appear somewhat dependent upon the methodology used to assess PG. Recent large-scale epidemiological surveys in the United States suggest that the rate of PG ranges from 0.4 to 2.0% of the general population. Rates of problem gambling are higher, and may comprise as much as an additional 4% of the population.

Higher rates of PG have been detected in certain populations. Individuals with psychiatric disorders and SUDs are significantly more likely to meet criteria for PG than those without. Higher rates of PG have also been associated with certain demographic characteristics, including adolescents and young adults, individuals of non-white ethnicity, lower socio-economic status, people who are divorced or separated, and males. Recent data also indicate that rates of problem and PG are disproportionately higher among patients being seen for treatment in primary care medical settings, individuals with chronic illnesses, and among people who are medically disabled.

DIAGNOSTIC ISSUES AND ASSESSMENT OF GAMBLING SEVERITY

The most commonly administered measure for assessing gambling severity is the South Oaks Gambling Screen (SOGS). The SOGS is a 20-item self-report questionnaire with scores ranging from 0 to 20. Scores of 3–4 indicate problem gambling, although some studies have used lower cut-off scores. Scores of 5 or higher indicate probable PG.

The SOGS has good reliability and validity in clinical samples and has been translated into more than 20 languages. Advantages of the SOGS include its extensive use in research studies, which provides large empirical databases to compare results. The SOGS is easy to administer and score, and the questions have high face validity. Disadvantages of the SOGS include the following: it has not been updated for DSM-IV criteria, it was not developed as a diagnostic measure, it places an over-emphasis on financial problems, and it has a high false-positive rate. Within clinical settings, the SOGS may best be used as a screening method to detect problem gambling. When the screen is positive, measures with better sensitivity and specificity may be used for diagnostic purposes.

The National Opinion Research Center DSM Screen for Gambling Problems (NODS) is a 17-item interviewer-administered questionnaire. The NODS assesses past-year and lifetime gambling problems. Questions are consistent with DSM-IV criteria for PG. Scores of 5 or higher on the NODS suggests PG, with scores of 3 or 4 indicating problem gambling. Initial psychometric studies evaluating the utility of the NODS indicate that it has good reliability and validity.

The Structured Clinical Interview for DSM-IV (SCID) was developed specifically to assess for psychological disorders. Although the SCID as a whole has demonstrated utility in clinical and research settings, the psychometric properties of the gambling subscale have not been rigorously evaluated. One structured interview that may aid in assessing PG is the Gambling Behavior Interview (GBI). The GBI includes items that measure the 10 diagnostic criteria for PG as well as other questions of gambling severity.

In research settings, where a goal may be to obtain data on the frequency and severity of gambling and gambling-related problems, other measures may be used to supplement traditional diagnostic tools. The Timeline Followback (TLFB) is a commonly used assessment method that uses calendar prompts to elicit frequency and intensity of specific behaviors. The TLFB is frequently used in studies examining SUDs and has been adapted for use with PG. For gambling assessment, the TLFB provides a validated measure of the frequency and financial costs of gambling. The Addiction Severity Index (ASI) is the most widely used measure for evaluating the severity of substance use problems. Given the high comorbidity between PG and other SUDs, a gambling scale for the ASI was developed (ASI-G). The ASI-G has demonstrated adequate internal consistency and convergent validity with other measures of gambling severity, including a collateral informant and clinician-rated scales. Although the ASI-G may not be used to diagnose PG, the measure provides a score of gambling severity and impairment due to gambling.

In summary, there have been a variety of self-report and clinician-administered measures that have been developed for diagnostic issues and problem severity. Within clinical settings, there may be several screening questions that could be used to quickly evaluate whether more intense assessment is indicated. One question may relate to frequency, such as "Have you ever placed five or more bets in a year?" The most commonly endorsed DSM-IV symptoms by pathological gamblers include preoccupation with gambling, chasing losses, and lying to others about the frequency or severity of gambling. If any of these symptoms are endorsed, it may warrant more intensive follow-up assessment. Validated psychological measures are available to provide measures of severity and clinical diagnoses.

PSYCHOLOGICAL TREATMENT OPTIONS FOR PG

Psychosocial treatment options remain in a relatively early stage, but have been evolving over time. Early investigations were conducted with traditional behavioral therapy methods, but studies were limited in terms of research methodology and statistical power. Studies have emerged in recent years that are driven by psychological theory and include sophisticated research designs and adequate sample sizes. Results from these studies are promising and suggest that there are effective ways to treat PG. Psychological interventions for PG have primarily been based on treatment approaches for traditional SUDs, and adapted for use in this unique population.

Natural Recovery

There are compelling data to suggest that a significant proportion of problem and pathological gamblers recover without treatment. A summary of epidemiological studies found that approximately one-third to one-half of pathological gamblers are in recovery. A recent analysis by Slutske that examined data from two very large US epidemiological surveys, which were stratified to resemble the US population, found that over one-third of individuals with lifetime PG did not experience any problems with gambling in the past year. This occurred despite only a small proportion of individuals having ever sought formal treatment for gambling.

Gamblers Anonymous (GA)

Among pathological gamblers who seek treatment, GA is the most commonly utilized approach. GA is modeled after the 12-step approach of Alcoholics Anonymous and is available throughout the United States. Despite its comparatively wide-spread use, few empirical studies have evaluated the effectiveness of this approach. Studies that have evaluated enrollment in GA yield mixed results. In an early report of 232 individuals who attended at least one GA meeting, Stewart & Brown found that only 8% of participants maintained gambling abstinence for 1 year. Approximately 20% of participants did not return to GA after their first meeting and 70% of participants stopped attending meetings prior to their 10th meeting.

More positive outcomes for GA have been detected when this modality was used in conjunction with professional gambling treatment. In a study by Petry of 342 pathological gamblers enrolled in professional treatment, 48% of patients who also attended GA meetings maintained abstinence from gambling 2 months into treatment. This rate was significantly higher than the patients who did not attend GA, 36% of whom reported abstinence in the same time period. The findings suggest that participation in GA in conjunction with professional gambling treatment may help to promote and maintain

abstinence from gambling. However, the findings should not be considered causal, as external factors such as treatment motivation may have led patients to also participate in GA. Patients who are more motivated for change may work harder in treatment and may be more likely to have successful outcomes.

Brief Advice

In a recent study by Petry and colleagues that included 180 disordered gamblers, researchers demonstrated efficacy for brief advice in helping individuals who were not specifically seeking gambling treatment to help reduce the frequency and severity of their gambling behavior. Participants were randomly assigned to a no treatment control condition, 10 min of brief advice about gambling that included personal feedback and concrete suggestions for reducing gambling, one 50-min motivational enhancement therapy (MET) session, or one session of MET plus three additional sessions of cognitive-behavioral therapy (CBT). In the post-treatment assessment session, those in the brief advice condition had significantly decreased their gambling relative to the no treatment control condition. Treatment gains remained at the 9-month follow-up evaluation. Individuals randomly assigned to brief advice evidenced greater reductions in the frequency and severity of gambling relative to those assigned to the control condition.

Given the brevity with which it occurred, this brief advice approach may be well-suited for individuals with less severe forms of gambling problems, such as problem gamblers, in primary care settings where providers must quickly evaluate and treat a range of concerns, as well as in traditional mental health settings. The advice offered in this intervention included the following recommendations: (1) gamble to have fun, not to make money; (2) only gamble what you can afford to lose (pay monthly bills first); (3) set a dollar limit for each gambling session and stick to the limit; (4) set a time limit for each gambling session; (5) leave checks, credit cards, and ATM cards at home; (6) take your winnings home; and (7) casinos/video lottery machines/state run lotteries set the odds and they are not in the business to lose money. These recommendations are consistent with a harm reduction approach to gambling problems and may be particularly palatable for patients who do not wish to entirely abstain from gambling.

MET

MET was originally developed to treat alcohol and SUDs, and has been adapted to treat PG with some

success. In the first comprehensive evaluation of the utility to treat gambling problems with MET, Hodgins and colleagues randomly assigned 102 disordered gamblers to one of three conditions: a wait-list control, a workbook containing cognitive-behavioral exercises, or a MET session with the self-help workbook. The self-help workbook alone did not lead to greater reductions in gambling compared with the wait-list group. However, the self-help workbook combined with the MET session resulted in the greatest reductions in PG symptoms. Follow-up assessments of patients in the active conditions found that MET was associated with greater reductions in gambling days, money lost, and gambling severity scores, and that some benefits of the MET were apparent 24 months after the intervention. Follow-up studies by this research team and others have yielded similar results, that brief MET sessions alone or in combination with self-help materials are effective in reducing the frequency and severity of problem and PG.

A recent study by Petry and colleagues randomized 117 disordered gambling college students to one of four conditions: an assessment-only control, 10 minutes of brief advice, one session of MET, or one session of MET plus three sessions of CBT (the study design is similar to that reported above, in the Brief Advice section). Gambling was assessed at baseline, week 6, and month 9 using validated outcome measures. Compared to the control condition, those individuals who received any of the active interventions displayed significant decreases in gambling frequency. The MET condition significantly increased the odds of a clinically significant reduction in gambling at the 9-month followup, relative to the control condition. Participants assigned to other conditions had benefits on some, but not all measures of gambling. The results indicate that brief interventions, and MET in particular, are efficacious in reducing gambling problems among college students.

In the above study by Petry and colleagues, participants randomized to MET received a 50-min individual therapy session, which took place immediately after the baseline assessment. Participants received personalized feedback about their gambling, which placed the severity of their behavior in comparison with national data. With the therapist, participants explored positive and negative consequences of gambling and discussed how gambling fit with their life goals and personal values. Participants also completed a change plan worksheet, which involved discussing the changes that could be made, reasons to make the change, steps to be taken in making the change, a review of support persons available to assist, and problem-solving obstacles that could interfere with the change plan.

CBT

Cognitive and CBT approaches have been the most widely studied treatment for PG. Initial behavioral therapy studies were met with mixed results. Early studies included aversive therapy, systematic desensitization, and imaginal desensitization. These included case reports, descriptive studies, and several randomized trials, though these were largely underpowered. More recently, a greater emphasis has been placed on cognitive processes that impact gambling (e.g. automatic thoughts, cognitive distortions). Most CBTs now include a focus on building skills toward relapse prevention, problem solving, and development of alternative behaviors.

In the largest randomized trial evaluating the efficacy of psychological interventions to treat PG conducted to date, Petry and colleagues randomized 231 pathological gamblers to one of three treatment conditions: referral to GA, GA referral plus a CBT-based self-help manual, or GA referral plus individual CBT. The CBT self-help manual and individual sessions both consisted of eight chapters or sessions, which covered identification of triggers, functional analysis of triggers and consequences of gambling, engaging in alternative activities, self-management of triggers, coping with urges to gamble, gambling-refusal skills, cognitive distortions related to gambling, and relapse prevention. Gambling was assessed at baseline, 1 month, 2 months, 6 months, and 12 months after the baseline assessment. Collateral informants also provided independent assessments of participants' gambling. Outcomes included reductions in gambling disorder symptoms, number of days of gambling, and amount of money gambled. Using an intent-to-treat analysis, participants assigned to the individual CBT plus GA referral group had significantly greater improvements than participants assigned to GA referral only on all outcome measures. Individual CBT participants also had longer-term benefits of therapy that did not occur in the other two conditions. A secondary analysis of the outcome data found that short-term treatment benefits were mediated by the development of new coping skills.

A recent randomized trial by Carlbring & Smit examined the efficacy of receiving CBT-based materials, designed to reduce the frequency, and severity of gambling, via the Internet. Participants were randomized to a self-guided CBT or to a wait-list control group. The treatment was guided, as participants had exposure to a professional therapist, which included e-mail and weekly telephone calls. A total of 66 participants with PG, and without severe symptoms of depression, were assigned to one of the two conditions. The Internet-based self-guided CBT intervention resulted in significant improvements in PG, anxiety, depression, and

scores on quality of life. Results were significant at the end of treatment and maintained at the 36-month follow-up session. The results from this study suggest that professionally developed CBT materials, delivered in conjunction with minimal therapist contact, may be effective in helping patients reduce their gambling. This finding is particularly important given that only about 10% of pathological gamblers ever seek formal professional treatment.

Other studies have found support for CBT-based treatments to address PG. There are mixed data regarding the best modality of treatment, as recent studies suggest that participants assigned to group therapy may not improve to the same degree as individuals assigned to individual therapy.

Summary

Although CBT and brief interventions have support for treating PG, work remains in optimizing treatment outcomes. Two recent studies have been conducted that modify traditional interventions in hopes of improving upon treatment outcomes. Grant and colleagues adapted Petry's traditional CBT treatment model to include imaginal desensitization and MET techniques in 68 pathological gamblers. They found that the combined intervention was superior to referral to GA, and that participants who failed to respond to GA had significant improvement following later treatment with the new intervention. A study conducted by Korman and colleagues evaluated an integrated 14-week CBT treatment for problem gambling and anger management in 42 problem gamblers with anger problems. Participants randomly assigned to the integrated CBT and anger management treatment demonstrated significant improvements in gambling behavior, as well as decreased anger and substance abuse.

These studies are just two examples of some of the different ways researchers are beginning to modify existing treatments in order to improve participant outcomes. Given the high rates of psychological comorbidity with PG, future investigations may also integrate treatments for PG with empirically supported interventions for mood, anxiety, and SUDs.

IDENTIFYING THE MOST IMPORTANT FACTORS TO ADDRESS IN CBT FOR PG

In a recent report, Morasco and colleagues reviewed the individual CBT sessions among pathological gamblers enrolled in a randomized clinical trial. The goal was to describe the content of participants' responses to individual CBT exercises. All participants (n = 84) met criteria for PG and received an 8-session manualized CBT delivered in individual therapy. The following is a summary of the 8-session CBT model, which includes participants responses to each session.

Session 1 focuses on developing a better understanding of the context in which the participant gambles. This focuses on identifying triggers to gambling, and includes certain events, days and times, people, and emotions that have been associated with gambling. Using a structured hand-out, the therapist reviews triggers for gambling with each client. The most commonly reported triggers to gamble among this sample of treatment-seeking pathological gamblers were lack of structured time (reported by 51% of the entire sample), negative emotional state (45% of the sample), encountering reminders of gambling such as an advertisement for a casino or watching sports on TV (37%), and having readily available access to money (33%).

In Session 2, participants are introduced to the concept of a functional analysis. This consists of reviewing the precipitants, behaviors, and consequences (both positive and negative) of gambling. In therapy sessions after conducting several functional analyses, the cyclical nature of gambling is highlighted, as the negative effects of gambling lead directly to the triggers for gambling, which often results in additional gambling episodes. The most commonly reported positive consequences of gambling, which are highlighted as being relatively short-term and transitory, include enhancement of a positive emotional state (endorsed by 80% of participants), having an escape (53%), the opportunity to win money (26%), and companionship (26%). The most commonly reported negative consequences of gambling, which are highlighted as being more long-term and enduring, were inducement or exacerbation of a negative emotional state (reported by 62% of participants) and losing money (47%), or more generalized financial problems (42%).

The focus of Session 3 is on increasing positive events. For many pathological gamblers, gambling has become the recreational activity of choice, to the detriment of other social and leisurely activities. After having a detailed discussion of recreational activities that could be incorporated into daily life, the therapist focuses on high-risk times for gambling. These high-risk times may be similar to the triggers that were reported in Session 1 (e.g. home alone and bored with nothing to do, when feeling depressed or angry). In the subsequent week, clients are encouraged to proactively participate in a new activity during high-risk times. The most common high-risk times reported by treatment-seeking pathological gamblers included specific days of the week (such as payday or weekends; reported by 33% of participants), when having a significant negative fluctuation in mood (reported by 30% of participants), and a lack of structured time (22%).

Session 4 is explicitly focused on the development of new coping methods for managing gambling urges or cravings. In session, participants were primarily taught a variety of short-term coping methods, while higher-level cognitive coping strategies were introduced in later sessions. The most common coping strategies that were reported by participants were distraction (45% of participants endorsed this) and avoidance (40%). Seeking support from professionals or friends was rarely endorsed (4% of participants).

Methods for handling cravings and urges to gamble were introduced in Session 5. Participants were encouraged to focus on the ways in which they experience cravings. They were taught to urge surf as a method for observing how they focus on gambling urges and the therapist highlighted the ways in which physical sensations and thoughts become paired with gambling urges. In session, participants summarized the most common ways in which they experienced cravings. The most frequently endorsed categories for the way in which gambling cravings are experienced were a specific body or physical reaction (e.g. heart pounding, tightness in stomach; reported by 36% of participants), nonspecific physical sensation (e.g. feeling antsy or flushed; 30%), or having specific thoughts (e.g. dreams of winning big; 25%) or emotions (such as being stressed out; 25%).

Assertiveness training is introduced in Session 6. The initial focus of the session is on gambling-refusal skills, but treatment also includes general assertiveness training. Three interpersonal styles are described (passive, aggressive, assertive), participants are coached on alternative methods for dealing with others, and roleplay is utilized to cement new skills. When participants were asked the most common situation in which assertiveness skills were needed, the most common response was not applicable (48%), as respondents indicated that they primarily gamble alone. Other participants indicated that social pressure (39%) and environmental cues (20%) are situations in which gambling-related assertiveness skills would be useful. For those individuals who indicated that they did not feel pressure to gamble from others, the focus of the session was on general assertiveness training, as passive or aggressive responding often has unanticipated effects, including increased gambling in many instances.

In Session 7, participants were introduced to cognitive distortions and the way these are associated with the maintenance or exacerbation of gambling. Several gambling-specific cognitive distortions were described, including the tendency to over-estimate the odds of winning, the gambler's fallacy, availability heuristic, and illusory correlation. The most common self-deceptions endorsed by participants included specific betting strategies (reported by 48% of participants) and

luck-based approaches (38%). Participants were taught cognitive restructuring methods, ways to develop alternative thoughts, and encouraged to accurately evaluate the effectiveness of their betting strategies.

In Session 8, the final treatment session, the therapist and participant review the coping methods that have been most helpful for the client thus far. They also identify alternative coping methods that may be useful in the future. Relapse prevention strategies are emphasized and participants are encouraged to problem-solve methods for dealing with high-risk situations in the future. In this final session, participants were asked to identify the most common coping strategies they currently utilize when confronted with a gambling urge or trigger. These are potentially the same coping methods that were queried in Session 4. In contrast to Session 4, when participants reported primarily relying on avoidance and distraction, these same participants now reported utilizing more sophisticated and enduring coping methods, such as seeking social support (endorsed by 67% of participants), seeking professional or para-professional support (43%), and implementing cognitive coping skills (31%).

These data highlight specific cognitive and behavioral strategies that may be useful in the treatment of PG. Data suggest that the coping strategies utilized by patients change over time, focusing less on short-term avoidance and distraction, and more on proactive methods for dealing with the trigger. Empirical data indicate that developing and practicing new coping skills are associated with improvement in symptoms of PG.

SUMMARY

Problem and PG impact a significant proportion of the population and are associated with decreased health and quality of life. Disordered gambling occurs at higher rates among certain subgroups in the community, such as individuals with SUDs, psychiatric disorders, among medical populations, and adolescents. Initial treatments for PG have been developed and tested. Studies suggest brief MET and CBT approaches are efficacious in reducing the frequency and severity of gambling. Additional research is needed to evaluate whether these approaches are appropriate for the majority of potential clients, or if specific interventions need to be developed for certain high-risk or difficult to treat groups.

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represent the official views of the National Institutes of Health, National Institute on Drug Abuse, or the Department of Veterans Affairs.

List of Abbreviations

ASI Addiction Severity Index
CBT cognitive-behavioral therapy
GA Gamblers Anonymous
GBI Gambling Behavior Interview
MET motivational enhancement therapy

NODS National Opinion Research Center DSM Screen

for Gambling Problems **PG** pathological gambling

SCID Structured Clinical Interview for DSM-IV

SOGS South Oaks Gambling ScreenSUDs substance use disordersTLFB Timeline Followback

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HIV/AIDS and Substance Abuse

Wayne E.K. Lehman, Michele Gould, Patrick M. Flynn Institute of Behavioral Research, Texas Christian University, Fort Worth, TX, USA

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INTRODUCTION

The spread of the human immunodeficiency virus (HIV) is as much a psychological and sociological phenomenon as it is a biological one. Although biology details how the virus is transmitted from specific body fluids of a host to the bloodstream of recipient, human behavior and social cultures and mores influence the ways in which the virus spreads from one person to another and within and across different subpopulations of people. The two most common mechanisms for transmission are sexual behaviors and injection drug use. Substance use of course plays a central role in the spread of HIV through injection drug use. Substance use also plays a major role in the spread of HIV through sexual behaviors for several important reasons. First, injection drug users (IDUs) can transmit HIV to their noninjecting sexual partners. Second, some forms of drug use are associated with increased sexual appetite which can lead to an increase in sex risk behaviors, and third,

substance use can lead to poor decision making and result in engaging in risky sexual behaviors while under the influence of drugs that the person may not have engaged in when not using drugs.

This chapter will describe some of the important elements of the HIV/AIDS substance use relationships. We will start with a brief history of the Acquired Immune Deficiency Syndrome (AIDS) epidemic and current trends in infection rates, then discuss transmission of HIV, injection and sex risk behaviors that can lead to transmission, the role of substance use in HIV risk, HIV in criminal justice settings, and multifaceted approaches for HIV prevention.

HISTORY OF AIDS EPIDEMIC

HIV is believed to have entered the United States as early as the 1970s; however, its impact was not fully realized until the 1980s. In 1981, two infectious diseases

began emerging among male homosexuals in the San Francisco and New York metropolitan areas: Kaposi's sarcoma (KS) and *Pneumocystis carinii* pneumonia (PCP). Treatment in non-immunosuppressed people usually was positive and nonlife threatening, however, the opposite proved true in this population. In June 1981, five cases of PCP were formally reported by the Centers for Disease Control (CDC). Two of the five people identified in this group had died from PCP. Shortly after the announcement from CDC, it was clear that there was a significant public health threat. By the end of 1981, there were over 700 confirmed cases of AIDS in the United States.

Until the end of November 1981, the CDC, scientific and medical communities believed that the syndrome was being transmitted through males having sex with males (MSM), though it could not definitively prove this was the mode of transmission. In December 1981, cases of AIDS among IDUs, both male and female, were being reported. Two months later, in January 1982, the disease began showing up in hemophiliacs and Haitians. AIDS was not limited to North America. By the end of 1982, there were reports of AIDS in South America, Europe, Africa, and Australia. In 1983, the disease was being reported in children and non-IDU women, suggesting mother-to-infant and heterosexual transmission. Every region in the world had been affected by 1985, when China identified its first cases of AIDS.

Scientists, clinicians, and public health professionals scrambled to understand how to prevent the spread of this new deadly disease whose etiology was yet to be determined. There was no known treatment and no known test for the virus for several years. Prevention efforts were complicated further as it was believed that there was a significant latency between the times of viral exposure until clinical symptoms began appearing in individuals. It was clear that the disease targeted the immune system making individuals susceptible to various opportunistic infections and these infections were resistant to standard therapy. It was likely transmitted through either sexual contact, sharing of needles between IDUs, and tainted blood products. The prognosis of AIDS was dismal, as more than 1/3 of all cases died from the disease.

Then in 1984, huge advances were made in the discovery of the virus suspected of causing AIDS. Researchers identified lymphodenopathy-associated virus (LAV) and human T-lymphotropic virus type III (HTLV III). It eventually was established that the two viruses were very similar, and the scientific community agreed on the name HIV and accepted that it was the virus that caused AIDS. Less than 2 years later, in early 1985, the Federal Drug Administration (FDA) approved the first enzyme linked immunosorbant assay (ELISA)

test kit to screen for antibodies to HIV. The first FDA approved medication, Azidothymidine (AZT), was introduced for treatment of HIV in 1987. Vaccines and other drugs were subsequently invented for the prevention of PCP, treatment for KS, and cytomegalovirus (CMV).

By 1996, there were 11 Antiretroviral Treatments available, and the age of highly active antiretroviral therapy (HAART) emerged. HAART is a combination of three or more antiretroviral drugs in combination and has led to significant decreases in morbidity and mortality. AIDS death rates declined by 89% from 1990 to 2003. AIDS was changed from a near universal fatal disease to a generally manageable, chronic illness as long as HAART therapy is continued. HAART has the ability to reduce viral loads in infected patients to undetectable levels in the blood, which also has important implications for reducing transmission to non-infected partners.

TRENDS IN THE HIV/AIDS EPIDEMIC

At the peak of the HIV/AIDS epidemic in 1985, there were over 130,000 cases of HIV/AIDS reported in the United States. Whites accounted for the largest proportion of cases of HIV/AIDS, representing more than 60% of cases reported. This trend has shifted dramatically over the years, and beginning in 1992, African Americans accounted for more than 50% of newly diagnosed HIV infections. This reflects a highly disproportionate distribution of the disease among African Americans because they comprise only 13% of the overall US population. The Hispanic population also has a disproportionate number of HIV infections, representing 20% of newly diagnosed HIV cases and 16% of the US population. Estimates have shown between 2006 and 2009, approximately 40,000 new HIV infections are diagnosed in the United States each year.

AIDS diagnoses peaked between 1991 and 1993 with 80,000 new cases reported each year. There was a dramatic decline in the number of AIDS cases between 1994 and 1999 when it dropped to 40,000 cases per year, and has remained steady at this rate through 2009. Deaths from AIDS peaked at the end of 1995, with 50,000 deaths, and have stabilized at approximately 18,000 deaths per year in the United States. Between 1985 and 2008, the trend for AIDS diagnoses follows that of HIV diagnoses. In 1985, whites represented 60% of AIDS cases, and steadily declined to 38% in 1995, and currently are at around 28% of cases. African Americans showed a steady increase in AIDS diagnoses, going from approximately 25% of cases in 1985 and now represent over 50% of newly diagnosed AIDS cases. Hispanics have also steadily increased in AIDS diagnoses, increasing from 15% in 1985 to over 20% of cases in 2008.

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Recent global estimates show that 2.6 million new HIV cases were diagnosed and there were approximately 1.8 million deaths from AIDS. Sub-Saharan Africa has the highest rate of new HIV infections with 1.8 million new cases per year. The mode of transmission is different from other countries where the highest incidence is in MSM. In Sub-Saharan Africa, over 80% of cases are transmitted through heterosexual contact. There are over 22 million people living with HIV in that region, and approximately 1.3 million deaths per year. South and South-East Asia have the second highest rate and account for 4.1 million people living with HIV. North America has 1.5 million cases, Central and South America and Eastern Europe and Central Asia each account for 1.4 million people infected with HIV.

Global estimates have shown that between 1998 and 2003, 13.2 million people worldwide were IDUs. HIV prevalence among IDUs of over 20% was reported in centralized pockets in over 25 countries. The 25 countries include USA, Canada, Ukraine, Russia, Netherlands, Argentina, Brazil, Uruguay, Puerto Rico, India, Malaysia, Myanmar, Nepal, Thailand, Serbia, China, Viet Nam, Nepal, Portugal, Italy, and Montenegro. IDUs posed a significant threat to the epidemic since the 1980s in the United States. The risks associated with IDUs include sharing needles and also other injection paraphernalia, including cotton swabs, rinse water, and cookers. In addition, using drugs impairs judgment and can lead to risky sexual behavior. Between 1984 and 1985, there were over 30,000 new cases of HIV among IDUs. It remained steady in this group until 1990, when it dropped to around 10,000 new cases per year and has stabilized at this rate through 2009. This represents around 12.5% of HIV cases in the United States.

This group is a major carrier of the infection into the general population, as estimates show that heterosexual transmission by IDUs is as high as 70% of new infections in this population. The heterosexual transmission of HIV has shown an upward trend and is the second largest growing group of HIV infections in the United States. In 1985, heterosexual transmission represented less than 10% of new HIV infections. It steadily increased between 1992 and 2000, when it exceeded the number of new cases due to IDUs. Heterosexual transmission currently accounts for more than 30% of new HIV infections in the United States. The transmission rate among IDUs has shown a downward trend since 1981. The estimated transmission rate among IDUs has decreased dramatically over the years from 92 transmissions per 100 cases in 1981 to 5 transmissions per 100 cases in 2006.

There are differences between ethnic groups and gender in the incidence of HIV in IDUs as reported in 2009. More specifically, 50.4% of all cases of HIV

associated with IDU occurred among African American males and 54.4% among African American IDU females, compared to 17.4 and 25.5% in their white counterparts, respectively. Heterosexual transmission in African Americans was much higher than whites, with males accounting for 66.7% and females at 66.5% of new infections, compared to 11.1% in white males and 15% in white females.

Significant preventive efforts have been targeted at the IDU population by the CDC, National Institutes of Drug Abuse, World Health Organization, United Nations, State and County Health Departments, Department of Corrections, Syringe Exchange Programs, and Substance Abuse Programs. Success in the efforts of each of these programs is evidenced by the dramatic decrease in the incidence of HIV and AIDS cases among IDUs. They decreased from 30% of all HIV/AIDS cases in the early 1980s, down to 12% of all HIV cases by 2009. African American IDUs account for a disproportionate amount of cases of HIV and AIDS and efforts should continue to be targeted to this population. The other group that deserves continued preventive efforts is heterosexual cases of HIV associated with IDU since this group has shown a steady increase in HIV cases since the epidemic began in the early 1980s.

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HIV can reside in several different body fluids, and can be transmitted when there is an exchange of fluids from an infected person to an uninfected person. Body fluids that can carry HIV include blood, semen (including pre-seminal fluid or pre-cum), vaginal fluid, and breast milk. Although HIV is rarely detected in the saliva of HIV+ people and in the rare cases it has been detected, it is at much lower levels than in other more suitable body fluids. However, blood mixed in the saliva from sores or cuts in the mouth can carry the virus.

HIV can be transmitted any time the virus has a chance for entering the bloodstream of a noninfected person. Skin that does not have cuts, abrasions, or sores provides a very reliable barrier against HIV, which cannot enter the bloodstream through unbroken skin. HIV can enter the bloodstream through a number of different venues, however. These include the lining of the anus or rectum, the lining of the vagina or cervix, the opening of the penis, the mouth if there are sores, cuts, or bleeding gums, other cuts or sores on the skin, and through contaminated needles or syringes.

Sexual Transmission of HIV

AIDS.gov, an official US Department of Health and Human Services website, lists different sex behaviors in

order of level of risk for transmission. Sexual behaviors, in order of risk, go from anal sex to vaginal sex to oral sex.

The riskiest form of unprotected sex is receptive anal sex. HIV is present in male sperm and seminal fluid and during anal sex this gets deposited in the rectum. The lining of the rectum is thinner and less pliable than the lining of the vagina and thus is more prone to damage during sex such as tears, cuts, or abrasions. Damage to the rectal lining may be present even when there is no visible bleeding. Insertive anal sex is also considered very risky because the partner may have sores in the rectum that are not visible and small, even unnoticeable tears or cuts on the penis can allow easy entry of the virus. In addition, fluids containing HIV can enter the urethra of the penis allowing infection.

Vaginal sex is also considered a high-risk activity, although it is considered much more risky for the woman than for the man. During unprotected vaginal sex, semen is deposited in the vagina which can enter the vaginal walls through the lining or through tiny cuts or abrasions. Risk is increased if the woman has a sexually transmitted disease or other vaginal infection. Although risks for men during vaginal sex is less than for women, as HIV in infected vaginal fluid or blood can enter the penis through the urethra or small tears or cuts.

Oral sex carries risk of transmission that is somewhat lower than for anal and vaginal sex. Saliva is not a suitable medium for HIV and HIV is rarely detectable in saliva of infected persons. However, performing oral sex on an infected man who ejaculates into the mouth carries risk of infection because the semen carries HIV and it can enter the bloodstream of the recipient through bleeding gums or sores or tears in the lining of the mouth. An uninfected man who is receiving oral sex from an infected person is at much lower risk of infection but there is some risk of virus transmission if blood from sores or cuts is present in the mouth of the person performing oral sex. Because the HIV virus can be present in vaginal secretions of an infected woman, performing oral sex on a woman can result in infection if the virus has a pathway to the bloodstream of the person performing the oral sex through cuts or sores in the mouth. But because the virus is generally not present in the saliva, a woman receiving oral sex from an infected person is at relatively low risk of infection unless the partner has cuts or sores in the mouth or lips.

Sexually Transmitted Diseases and HIV

The presence of a sexually transmitted disease (STD) increases the probability of HIV transmission. According to CDC estimates, people who have an STD are 2–5 times as likely as uninfected persons to acquire HIV if they are exposed to the virus through sexual contact. HIV+ persons who also have an STD are more

likely than HIV+ persons who do not have an STD to transmit the virus to uninfected persons.

Persons who do not have HIV but have an STD appear to be more susceptible to HIV infection due to genital ulcers that provide an easier pathway for HIV to enter the bloodstream, and inflammation from genital ulcers or from non-ulcerative STDs (e.g. chlamydia, gonorrhea, and trichomoniasis) can increase the concentration of cells in genital secretions, such as CD4+ cells, that provide hosts for HIV. STDs also increase the infectiousness of HIV+ persons by increasing shedding of HIV in genital secretions. Men who have HIV and gonorrhea are more likely than those who are infected only with HIV to have HIV in genital secretions and can have much higher concentrations of HIV in their semen, which increases infectiousness.

Condom Use and Sexual Transmission

There are two primary methods of preventing sexual transmission of HIV. The first is to not engage in risky sexual activities. These risky activities include having sex with multiple partners, having sex while under the influence of drugs or alcohol, having sex with strangers, and having sex with HIV+ partners or with partners where HIV status is unknown. Of course, the only true risky sexual activity for contracting HIV is having sex with an HIV+ partner. However, the other activities such as multiple partners, having sex under the influence, having sex with strangers, trading sex for drugs or money, increases the likelihood of having sex with an HIV+ partner.

Throughout human history, limiting sexual activity between humans has been fraught with failure. The CDC reports that latex condoms, when used consistently and correctly, are highly effective at preventing transmission of HIV. Large numbers of both laboratory and epidemiological studies have shown conclusively that consistent use of latex condoms provides a high degree of protection from infection. However, latex condoms do not provide 100% protection as there may still be some exposure to blood or other fluids containing HIV through cuts or sores in areas not protected by the condom, or condoms may fail or come off during sex. Polyurethane condoms are available from several manufacturers as an alternative to people who are allergic to latex. Advantages of polyurethane is that it conducts heat better and is thinner than most latex condoms and has very little odor. However, the material does not stretch as well as latex and, thus slippage and breakage is more common. The effectiveness of polyurethane condoms in preventing STDs is still being studied. Another non-latex alternative is a condom made of polyisoprene. It is considered as strong and safe as latex, is thicker than latex but it stretches well and has lower TRANSMISSION OF HIV 239

slippage and breakage rates than latex. Polyisoprene condoms are FDA approved and considered an effective barrier to HIV and STD pathogens. A third alternative are condoms made of natural animal membranes, such as lambskin. These condoms are not considered to provide any protection against HIV or other STDs.

The CDC recommends that the only 100% effective method is to avoid having sex with HIV+ partners or be in a long-term monogamous relationship with a partner who has been tested and is known to be uninfected.

Transmission Among IDUs

Injection drug use often takes place in social settings where users gather to inject their drugs. These social settings, often called "shooting galleries," provide social support, a relatively safe place to inject drugs that have been recently purchased, and often, a source of injecting equipment if the users do not have their own. The shooting galleries are often located near the place where the user can purchase drugs so the drugs can be consumed almost immediately after purchase.

A common activity in shooting galleries is the sharing of equipment. This sharing serves several purposes. First, users do not have to obtain their own equipment and carry it with them increasing risk of arrest. Sharing of equipment also serves a social purpose in which the user shares the act of injecting in a supportive environment in which they are not considered outcasts. For new IDUs, the shooting gallery helps the naive user learn the injection process.

The injection process often involves multiple steps. First, the powdered drug is mixed with water to dissolve it. This often takes place in a "cooker", which can be a metal spoon or bottle cap. The solution is heated in the cooker to dissolve the drug. This solution is then drawn into a syringe, often through a wad of cotton which is used to strain the solution. The combination of cooker, cotton, and needle/syringe are often referred to as "works."

When this process occurs in a social setting using shared works, there are a variety of points in the process that can contribute to transmission of HIV. First, when an HIV+ user injects drugs into a vein, small traces of blood remain on the needle. After inserting the needle into a vein, the user will first draw blood into the syringe to insure that they have properly hit the vein. After injecting the drug, they will sometimes draw blood into the syringe multiple times in a process called "booting" to make sure that all traces of the drug are used. If the user is HIV+, the needle and syringe contain contaminated blood that can then be passed to the next and subsequent users who inject with that syringe.

Virus transmission can occur, however, even if the user does not share needles or syringes. Sometimes,

when a drug solution is cooked, several users will draw the drug into their syringes from the same solution. If an earlier user uses a needle that has traces of contaminated blood on it, this blood can be transmitted to the drug solution and passed on to other users who draw from that solution. Other times, the solution might be all drawn into one syringe and then injected into the barrels of syringes for other users, in a process referred to as "backloading." This process allows addicts to share the drug supply equally. A process called "frontloading" is when the drug solution is drawn with the needle from the back of another syringe. So even though needles and syringes are not being shared in this process, blood traces containing HIV can still be transmitted from one user to another.

HIV can also be transmitted when multiple users share the same cooker, the cotton used to strain the solution, or the water used to rinse syringes. Users will sometimes "beat" the cotton by shooting a small amount of water from the syringe into the cotton in an attempt to wash out as much of the drug as possible. If the syringe is contaminated with HIV, the cotton and cooker can then become contaminated. Rinse water is used to rinse syringes between users, not in an attempt to sterilize them as much as to keep them from clotting. In many places where IDUs gather to inject drugs, clean rinse water is not available and is reused and shared. When any of these steps of the process are shared by multiple users, one of which is HIV+, the virus can be transmitted to others even when needles or syringes are not shared.

Disinfecting Syringes with Bleach

Several steps can be taken to reduce risks of HIV transmission in social settings where drugs and equipment are shared. Users who carry their own equipment and works and who do not share it with others can virtually eliminate their risks for HIV infection. However, in many locales, possession of injection equipment is illegal and puts the user at risk for arrest. Even users who provide their own equipment may find themselves in occasional situations where they need to borrow syringes and share works to inject. When needles or syringes are shared between users, the CDC recommends disinfecting the syringe with full-strength household bleach, using a three-step flush, disinfect, rinse process. In the first step, clean water is drawn into the syringe in order to flush out blood, drugs, and other matter from the syringe. The syringe is tapped or shaken to dislodge particles and then the water squirted out and discarded. This step is repeated until no more blood can be seen. Water alone does not disinfect the syringe and does not kill virus particles that might remain in the syringe even after flushing. Filling the syringe with full-strength household bleach (5.25% sodium hypochlorite) and leaving the bleach in the syringe for at least 30 s will kill virus particles remaining in the syringe. This bleach is then squirted out and discarded and finally the syringe is rinsed by filling with water again to rinse out the bleach. The rinse water is then discarded.

Although laboratory studies have shown undiluted household bleach to be effective at killing the HIV virus, actual practice by IDUs may not be as effective for several reasons. First, users may not follow all of the necessary steps or follow procedures correctly. Fresh, clean water may not be available. Users often do not want to carry bleach because it can identify them as drug users. Bleach is weakened when exposed to warm temperatures, sunlight or air so bleach actually used to clean syringes in practice may not be as strong as fresh bleach. In addition, although disinfecting syringes with bleach can help prevent HIV transmission, it does not sterilize the needle and thus users can get other infections from sharing needles.

Drug Use and HIV Risk

Non-injection drug use of course does not involve the sharing of needles, syringes or works that can lead to transmission of HIV between users. However, there are still important relationships between non-injection drug use and risk for HIV infection. Sexual transmission of HIV is by far the most common means of infection, and as the CDC has pointed out, two primary means of avoiding infection through sex is (1) to avoid having sex with HIV+ partners by abstinence or a long-term monogamous relationship with a person who has been tested and known to be HIV negative, or (2) using a condom correctly and consistently (100% of time when having sex). However, sexuality is a central part of personal identity and sex is a very powerful drive in humans. Even when people have the knowledge they need to identify and avoid risky situations, they often continue to make poor decisions and engage in risky behaviors.

Drug use affects judgment and lowers inhibitions. According to the National Institute on Drug Abuse (NIDA), drug and alcohol intoxication increases brain dopamine in limbic regions of the brain and lowers the threshold for reward stimulation and also lowers sensitivity to stimuli that predict delayed negative outcomes. People with substance use disorders often value immediate, smaller rewards more than delayed but often larger rewards and are often insensitive to the negative consequences of HIV-risk behaviors. People under the influence of drugs will often take more risks than when sober and engage in riskier sexual activities. This can include having multiple partners, having sex with partners who are considered higher risk (e.g. sex with

strangers, sex with partners who also have multiple partners, sex with IDUs), and having unprotected sex.

CRIMINAL JUSTICE SETTINGS

HIV infection is particularly prevalent in criminal justice populations, due in part to the large number of drug-involved offenders in jails and prisons. The Bureau of Justice Statistics reported that in 2008, a total of 21,987 state or federal inmates, or 1.5% of the total prisoners, were HIV+ or had confirmed AIDS. This prevalence rate is more than three times the rate of HIV cases in the US population reported by the CDC in 2006 (0.45%). HIV+ cases were more prevalent among state inmates (1.6%) than among federal inmates (0.8%). Female inmates were more likely to be HIV+ (1.9%) than were male inmates (1.5%). The three largest states in terms of number of HIV+ inmates were Florida, New York, and Texas, which combined accounted for 46% of all state inmates who were HIV+ or had confirmed AIDS, even though the three states account for only 24% of all state inmates. New York reported that more than 5% of male and more than 10% of female inmates were either HIV+ or had confirmed AIDS. There were also significant regional differences in HIV prevalence, with 3.2% of inmates in the Northeast, 1.9% of inmates in the South, 0.8% in the Midwest, and 0.7% in the West. The Bureau of Justice Statistics also reported that 24 states tested all of their inmates either at admission or some time during custody. All states and the federal system tested inmates if they had clinical indications of HIV or if the inmate requested a test, 42 states and the federal system tested after incidents where an inmate might have been exposed, and 18 states and the federal system tested inmates in specific high-risk groups.

Data have shown that HIV-infected inmates have high testing and treatment rates in prison. The prison setting offers opportunities for systematic testing of a high-risk population, as well as the provision of effective HIV care. However, continuation of care upon release back to the community is often poor as a result of inconsistent linkage to care and disruption of ART – with consequent loss of viral suppression and increased risk of HIV transmission. Many inmates released from prison perceive their infection as a secondary priority to other needs, such as housing, family reconciliation and avoidance of substance abuse relapse, and thus a large proportion of released individuals fail to maintain viral suppression. In addition, many released inmates return to high-risk behaviors after release, and coupled with loss of viral suppression, create a significant public health concern. A 4-year study of HIV+ inmates released from Texas state prisons found that only 5% of released inmates filled a prescription for HAART within 10 days, only 18% did so within 30 days of release, and 30% did so within 60 days. However, inmates who received formal assistance in completing application forms to obtain medications post-release had higher rates of filling prescriptions than those who did not receive assistance.

PREVENTION AND INTERVENTION PROGRAMS

The CDC recommends a comprehensive approach to preventing blood-borne infection among IDUs, HIV as well as Hepatitis B and C and others. These include substance abuse treatment, community outreach, increasing access to sterile syringes, interventions in the criminal justice system, strategies to prevent sexual transmission, HIV counseling and testing and partner counseling and referral services, services for IDUs living with HIV/AIDS, and primarily drug prevention.

Substance Abuse Treatment

NIDA reports that drug abuse treatment has been an effective HIV prevention method. Effective treatment helps users stop or reduce their drug use which leads to reductions in risk behaviors, including reducing or stopping frequency of injecting drugs, reducing risky injection practices, and reducing participation in risky sex. In addition to the direct effects of reductions of drug use on these behaviors, drug treatment services also play important roles in providing current education about HIV/AIDS, counseling and testing services, referrals for medical services, education, and training on less risky injection practices and sex behaviors.

Injection Risk Prevention

Although substance abuse treatment is an effective method for reducing injection and sex risk behaviors, many IDUs are not in treatment for various reasons, including waiting lists for treatment slots, lack of accessible treatment services, or users not being ready for or wanting to receive treatment. These groups of out-of-treatment users, however, maintain risky practices that increase their own risk of contracting and/or spreading HIV and of acting as conduits of HIV spread to nondrug using populations. Harm reduction programs have been developed to reduce risks in these populations. Two important approaches have included needle exchange programs and community outreach.

Syringe Exchange Programs

Another method used to reduce the spread of HIV among IDUs is through syringe exchange programs (SEPs, sometimes referred to as needle exchange programs). In these programs, users can either exchange their used syringes for an equal number of new, sterile syringes, or receive new syringes without the requirement of an exchange. SEPs have been used in a large number of countries, most prominently in Western Europe and in Australia.

The first SEPs in the United States were established in Tacoma, Washington; Portland, Oregon; San Francisco; and New York City in the late 1980s. Programs operated in a variety of settings including storefronts, vans, sidewalk tables, health clinics, and other places convenient to IDUs. Some programs also offered a variety of other services in addition to syringe exchange, including HIV/AIDS education and counseling, condom distribution, substance abuse, medical treatment referrals, or other social service referrals, distribution of alcohol swabs, on-site HIV testing and counseling, screening for other infections, and some primary medical services.

Needle exchange programs have long been controversial in the United States. Critics argue that such programs do not reduce the spread of HIV among drug users, that providing needles to drug addicts encourages, or at minimum, condones illegal drug use, can lead to increases in needle use, and send the wrong message about the dangers of drug use. Use of federal funds for SEPs was banned in 1988 and the ban was renewed annually by Congress. However, the ban was lifted in December 2009, as part of an appropriations bill for labor, health, and education. Although the bill did not provide any new federal monies for SEPs, it allowed programs to use federal funds to provide clean needles.

The CDC reports that there is a large amount of literature showing that SEPs have had significant positive effects on preventing adverse health consequences of injection drug use and that they were not associated with increases in drug use or promoting initiation of injection use. SEPs have also been shown to increase use of substance abuse treatment and other services that can reduce HIV infection. A recent report of several major reviews published in the online version of the journal Addiction in 2010 concluded that there was tentative evidence to support the effectiveness of SEPs in preventing HIV transmission. There is sufficient evidence to support the effectiveness of SEPs in reducing selfreported injection risk behaviors, but insufficient evidence to support the impact of SEPs on preventing Hepatitis C transmission. The conclusions argued that the evidence for effectiveness was weaker than given credit in the extant literature but that the lack of evidence was primarily a function of limitations of the studies and

research methods and the tentative evidence should not be interpreted to mean evidence for ineffectiveness.

Community Outreach

Another component of the comprehensive approach advocated by the CDC is community outreach. Many drug users are not involved in substance abuse treatment or do not access other traditional venues providing prevention, medical, mental health, or social services. Community outreach programs are often designed to go to the drug users in the community and reach them where they congregate. Outreach is typically conducted face-to-face by outreach workers who are often former users themselves. Outreach workers attempt to develop trust with drug users in their environment and typically work from a harm-reduction model, working to get them to change their high-risk injection and/or sex behaviors. Services offered involve distributing substance abuse and HIV literature, training on safer injection and sex practices, distribution of condoms and bleach kits, and information about available services (e.g. substance abuse treatment, medical and mental health services, housing, and others). Outreach can be extended by working with social and drug-using networks of IDUs. For example, network leaders are recruited and trained on risk-reduction and prevention techniques and using social learning methods. They are also trained to be mentors, to model safer techniques to others and to motivate their network members to reduce risk behaviors.

The CDC reports that studies of outreach programs have regularly reported reductions in stopping drug injection or reducing frequency of injection, reducing sharing of syringes and works, and reducing crack use. Follow-up outcomes of community outreach programs have also shown increases in needle disinfection, condom use, and entry into substance abuse treatment. Studies have also shown that peer-driven interventions conducted by trained out-of-treatment drug users can extend the reach of harm-reduction programs to social and drug-using networks and can be effective at getting network members to reduce risky practices although they have not been as effective at getting network members to change sexual practices.

Highly Active Antiretroviral Therapy

HAART is a customized combination of several different medications that control viral load, helps to delay the onset of AIDS symptoms in HIV+ persons and helps delay progression of AIDS. HAART, when used as directed, can reduce viral loads to undetectable plasma levels. This does not mean that the virus is eliminated from the body, but that it is reduced to levels that

cannot be detected by available tests. However, less is known about viral loads in other fluids such as seminal or vaginal fluid, as these are typically not measured. Although antiretrovirals (ARVs) are associated with lowered viral loads in seminal and vaginal fluids, the virus has been shown to persist in cells in seminal fluid and breakthrough shedding of the virus in vaginal fluid has been observed during HAART therapy. In addition, some studies have observed that some people on HAART who have demonstrated undetectable viral loads have temporary small increases of viral load. Thus, undetectable plasma viral loads do not necessarily indicate that transmission of the virus cannot occur.

Use of HAART can be problematic for some drug users as the medications in HAART can interact with medications often used to treat drug addicts, which can have the effect of decreasing the effectiveness of both treatments. Some of the medications used in HAART can reduce methadone levels in the blood, making the treatment less effective. Substance use can also interfere with adherence to HAART because of conflicting needs and unstable lifestyles that can make it difficult to maintain a consistent treatment regimen. Noncompliance with the HAART regimen can result in increased viral loads and increased infectiousness.

A study reported in 2011 followed 1,763 heterosexual, serodiscordant couples (i.e. one member of a couple was HIV+ and the other member was not) from cities in nine different countries. Couples were randomly assigned to immediately begin antiretroviral treatment therapy or to wait until their immune system was compromised to a specified level or they experienced an AIDS-related symptom. From 2005 until 2011, when results were reported, 28 cases of seroconversion were reported in which the infected partner was the source of the infection. Of these, 27 were in the group that deferred ARV therapy, and only 1 was in the group that began ARV treatment immediately. These results indicate that early ARV therapy can act as a significant preventive effort for sexual transmission of HIV.

SUMMARY

The face of HIV and AIDS has changed dramatically since the early days of the epidemic in 1981. The development of HAART has changed the disease from an almost certain death sentence to a manageable, chronic condition and is proving to be an essential part of a comprehensive prevention protocol. In spite of advancements made in treatment and prevention, HIV and AIDS still infect large numbers of people and more progress needs to be made. Increases in HIV infections among African Americans are troubling, as are increases in heterosexual transmission, and the high

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prevalence in criminal justice populations. The role of substance abuse in HIV infection through injection drug use, sexual partners of IDUs, and the role of alcohol and other drugs in poor decision making and participation in high-risk sexual behaviors should also continue to be a focus in any comprehensive HIV program.

SEE ALSO

Harm Reduction Approaches, Policies and Interventions to Reduce HIV Risk

List of Abbreviations

ARVs antiretrovirals

CDC Centers for Disease ControlFDA Federal Drug Administration

IDUs injection drug usersKS Kaposi's sarcoma

MSM males having sex with males
NIDA National Institute on Drug Abuse
PCP Pneumocystis carinii pneumonia
STD sexually transmitted disease

Glossary

Acquired Immunodeficiency Syndrome (AIDS) AIDS is the actual disease that is caused by HIV and is defined as having a CD4 cell count of below 200 or experiencing at least one AIDS-defining complication.

Highly active antiretroviral therapy (HAART) a medication used to treat HIV and AIDS that consists of three or more antiretroviral drugs customized for each individual patient. The advent of HAART has led to a very substantial decrease in HIV-associated morbidity and mortality.

Human immunodeficiency virus (HIV) a retrovirus that infects humans and interferes with the immune system by destroying CD4 cells, a type of white blood cell that plays a significant role in fighting disease. It can reside in blood, seminal fluid, vaginal fluid, and breast milk.

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Treatment-as-Usual for Substance Abuse in Community Settings

Elizabeth J. Santa Ana*, **, Bianca Jardin^{\$,} **

*Charleston VA Medical Center, Charleston, SC, USA \$Hollings Cancer Center, Charleston, SC, USA **Medical University of South Carolina, Charleston, SC, USA

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WHAT IS COMMUNITY-BASED TREATMENT?

According to the US Institute of Medicine's Committee on Community-Based Drug Treatment report, community-based agencies are the "backbone" of the US treatment system. Their history can be traced back to the 1970s and 1980s, around the time when a host of community-based programs for alcohol and drug dependence emerged. The nature and structure of these community programs varied widely, as they were designed to meet the specific treatment needs of individuals within their respective communities, giving rise to a unique or alternative system of addiction treatment at the public, private, and individual levels. For example, public facilities providing housing and food services for the needy began creating addiction treatment programs, as well as private not-for-profit community mental health centers. Similarly, churches implemented their own drug addiction treatment services. Individuals in recovery elected to start community treatment programs, such as Alcoholics Anonymous and other 12-step programs. While these facilities varied in their specific ideology regarding the nature and treatment of addiction, they shared a mutual goal of providing alcohol and drug treatment to individuals residing in their local communities.

At that time, community-based treatment was segregated from mainstream medical and mental health services, and treatment practices were based on the "folk wisdom" of individuals in recovery. Educational lectures or films, confrontational interventions, mandated Alcoholics Anonymous, and milieu therapies were among the most commonly used interventions. Treatment practices consisted of a miscellany of techniques, many of which were adopted from the disease model of alcoholism, Alcoholics Anonymous, or other 12-step related programs.

Today the US substance abuse treatment system remains primarily community-based and many clinicians continue to practice strategies with which they are familiar as well as comfortable. However, the standard of care has been evolving in parallel with state and third-party reimbursement mandating that community treatment programs deliver evidence-based treatments (i.e. treatments that possess scientific evidence

for their efficacy). Similarly, there is an increased demand from the public sector and from the courts for substance abuse treatment specialists to provide scientifically valid interventions to their clients. Moreover, greater integration of substance abuse treatment with mainstream health care requires that evidence-based treatment become the standard of treatment in the field.

Given this change in the health care system, the Institute of Medicine (IOM) issued a landmark report in 1998 promulgating their recommendations for bridging the gap with the goal of forging partnerships and fostering communication between researchers, treatment professionals, policymakers, and the public sector. The recommendations made by the IOM committee were directed toward increasing research activities between investigators working in university settings and health care providers working in community treatment programs. A major development in response to this report was the establishment of the National Institute on Drug Abuse (NIDA) Clinical Trials Network (CTN; http:// drugabuse.gov/CTN/) in 1999. The primary goal of the NIDA-CTN was to initiate a research infrastructure between the research community and community treatment programs for evaluating behavioral, pharmacological, and integrated treatment interventions in rigorous, multisite clinical trials. These trials involve "real world" therapists working with a diverse patient population across a broad range of community treatment settings. Similarly, the Substance Abuse and Mental Health Services Administration (SAMHSA) "Blending Initiative" was implemented in 2001 in order to promote the adoption and implementation of research findings from the NIDA–CTN trials into community-based practice. This initiative is a wide ranging network of partnerships between addiction researchers, community treatment program providers, policymakers, and technology dissemination agencies.

The success of this and similar initiatives, however, is largely contingent upon first acquiring an accurate understanding of what essentially constitutes treatment-as-usual (TAU) within community settings primarily because without this information it is difficult to determine the elements of empirically supported treatments (ESTs) that may already be in broad clinical use and the extent to which clinicians are already delivering efficacious interventions. Unfortunately, identifying the standard practices that occur in community treatment programs has proven to be difficult due largely to very limited information. Moreover, the information that does exist is derived primarily from self-report surveys completed by program directors and agency clinicians working within these settings; therefore, reliance on subjective methods of data collection introduces experimental problems (e.g. demand characteristics) that raise concerns about the accuracy of survey responses.

This chapter will explore the information that is currently available regarding current treatment practices and services delivered in community-based substance abuse treatment programs providing primarily psychosocial interventions and not clinics that provide exclusively methadone treatment services. We discuss the degree to which community treatment agencies are using practices that are "empirically supported" or "evidence-based."

TAU BASED ON NATIONAL SURVEY DATA

The SAMHSA publishes an annual survey, referred to as the National Survey of Substance Abuse Treatment Services (N-SSATS), which is the most comprehensive survey examining the nature of TAU provided in substance abuse treatment facilities in the United States. The most recently published data (2009) from this survey demonstrated that 13 513 substance abuse treatment facilities actively served over 1.18 million clients seeking treatment throughout the United States. Of these treatment facilities, 58% were operated by community-based private nonprofit agencies, 29% were owned by private for profit agencies, and 13% were publicly operated by federal, state, or local government. The majority (81%) of all treatment agencies provided outpatient treatment (i.e. intensive, day treatment/partial hospitalization, and/or less frequent aftercare services), while 26% offered residential treatment either in addition to outpatient care or alone. Only 12% of outpatient treatment facilities offered methodone or buprenorphine treatment services. With regard to the substance abuse problem treated, approximately 92% of treatment facilities reported treating clients with both alcohol and drug dependence, 81% reported treating clients with drug abuse only, and 79% reported treating clients with alcohol abuse only (Note: facilities may be included in more than one category such that figures exceed 100%).

With regard to the types of services provided, the majority of treatment facilities (98%) provided assessment and pretreatment services, including screening for substance abuse and mental health disorders, community outreach, and interim services for clients in need of services when immediate admission was not available. Almost all of the treatment agencies (99%) provided ancillary services, with substance abuse education (95%), case management (77%), social skills development (68%), and mental health services (56%) being the most common types of ancillary services offered. Pharmacotherapies were administered in 47% of treatment agencies. The nicotine replacement therapy was provided by 19%, acamprosate by 17%, buprenorphine by 17%, naltrexone by 16%, disulfiram by 16%, and

methadone by 11% of treatment agencies (Note: Facilities providing medication for substance dependence tended to provide more than one type of medication so that figures exceed 47%). Nearly all the treatment agencies (99%) provid individual or group substance abuse counseling.

In terms of the types of clinical or therapeutic approaches provided among agencies, substance abuse counseling (96%) and relapse prevention (87%) were identified as approaches that were used "always" by nearly all facilities. Cognitive-behavioral therapy (91%), motivational interviewing (85%), anger management (83%), brief intervention (80%), and 12-step facilitation (79%) were reportedly used "often" or "sometimes" by more than half of treatment agencies. Trauma-related counseling (65%) and contingency management (60%) were identified as used "at least sometimes (e.g. always, often, or sometimes)." The least often utilized approaches (i.e. those approaches used "rarely" or "never") for more than half of all agencies, including those agencies unfamiliar with the approach, were rational-emotive therapy (51%), the matrix model (63%), and community reinforcement-plus-vouchers (86%).

TREATMENT PRACTICES OF COMMUNITY PROVIDERS BASED ON INDEPENDENT EVALUATION

Although the latter information provides insight into the types of counseling services offered at communitybased clinics, these data do not speak to the integrity to which these approaches are utilized. To date, only a few systematic and independent evaluations (e.g. assessment of audio, digital, or video recordings) of the types of techniques used by clinicians working in community-based treatment programs have been conducted. In one study, Santa Ana and colleagues provided a description of the "usual care" therapeutic strategies delivered by clinicians to their clients in the early phase of treatment within nine community treatment programs. These clinicians were participating in two National Institute on Drug Abuse Clinical Trial Network effectiveness protocols headed by Carroll and colleagues at the Yale University School of Medicine. The first protocol involved the delivery of a usual care "onesession" standard intake assessment in sites that offered a single-assessment appointment to their patients followed by assignment to group counseling; the second protocol provided TAU across three counseling sessions delivered during the first 4 weeks of treatment, referred to as the "three-session" protocol. Counseling time in the one-session protocol was approximately 2 h in duration, whereas counseling time in the three-session protocol was approximately 45-55 min. The investigators were

primarily interested in describing the primary counseling strategies that characterized TAU in the one- and three-session protocols, and whether interventions from these sessions were associated with ESTs. To verify the latter both the one- and three-session protocols were compared to a one-session motivational interviewing assessment and a three-session adaptation of motivational enhancement therapy.

The patients in these protocols (one-session protocol, n=423; three-session protocol, n=461) were primarily in their early to mid-1930s seeking outpatient treatment for mixed primary substance abuse problems (e.g. alcohol, cocaine, marijuana, opiates, methamphetamines, benzodiazepines), with the majority of patients in both protocols diagnosed as alcohol dependent. The clinicians, consisting of addiction counselors, social workers, psychologists, and marriage and family therapists, had approximately 6 years of substance abuse counseling experience and were predominantly Caucasian women in their late 1930s. Approximately 40% of these therapists endorsed a history of a previous substance abuse problem.

Prior to the start of the NIDA-CTN trials, the investigators surveyed the clinicians, senior clinicians, and site directors from the participating community treatment programs about their use of various treatment strategies. A wide range of practice orientations were endorsed. Most indicated that they were using an eclectic approach, but that they were primarily adhering to the 12-step disease model (e.g. emphasizing total abstinence, discussing concepts such as spirituality, powerlessness, and loss of control), relapse prevention/ cognitive-behavioral therapy (e.g. skills training, cognitive restructuring, focus on cognitions), motivational interviewing or motivational enhancement therapy, and providing some counseling regarding HIV risk behavior reduction. Based on these reports, the investigators anticipated that TAU would be characterized by interventions derived from these types of treatment practices. The investigators also hypothesized that counselors would use a broader range of EST-based interventions (e.g. relapse prevention/cognitive behavioral or "skills training" strategies) in the three-session protocol compared to the one-session protocol due to the more extended length of counseling time that the threesession protocol afforded.

To test these hypotheses, the investigators conducted blind independent ratings of 379 randomly selected audio tapes (n = 160 tapes in the one-session protocol; n = 219 tapes in the three-session protocol) derived from 25 clinicians who implemented TAU. Using a reliable and valid rating system for evaluating therapist adherence (i.e. the extent to which a range of counseling interventions were delivered) across several types of ESTs and commonly used interventions in addiction

treatment, clinicians were rated on their adherence to 31 types of counseling strategies. Ten of these counseling strategies were consistent with motivational interviewing, five of which included basic motivational interviewing skills (e.g. open-ended questions, reflective statements, fostering a collaborative atmosphere), while the remaining five items included advanced motivational interviewing skills, such as heightening discrepancies and change planning. The other 21 counseling strategies assessed two categories of drug counseling interventions. The first category included items "antithetical" to motivational interviewing, referred to as "motivational interviewing (MI) inconsistent" strategies, such as confrontation of denial, unsolicited advice, and emphasis on abstinence. The second category included items representing approaches "other than" motivational interviewing (i.e. "general drug counseling strategies"), such as skills training, disease model, and psychodynamic interventions. Table 26.1 presents the means and standard deviations for the independent adherence ratings and item frequencies in the one- and three-session protocol TAU sessions.

In the one-session protocol, the clinician interventions that dominated TAU were assessing and monitoring substance use and social functioning (e.g. work, family, partner, social network), followed by asking open-ended questions, discussing the client's medical problems including use of medications for substance use or psychiatric problems, reviewing symptoms related to psychopathology, discussing the problems for which the client entered treatment, reflective listening, and orienting the client to the program. The next most common counseling strategies were therapist disclosures unrelated to the problems of the client (e.g. informal discussions such as personal information, current events, shopping), giving unsolicited advice, asserting therapeutic authority, behaviors associated with an MI style such as rolling with resistance and empathic listening, case management, and psychoeducation.

In the three-session protocol, TAU consisted of high levels of assessment of social functioning, use of openended questions and reflections, inquiries about problems for which the client entered treatment, and giving unsolicited advice. The next most common interventions were assessing and monitoring substance use, asserting therapeutic authority, self-help group involvement, and therapist disclosures unrelated to the problems of the client. The only skills that were consistently present and associated with a specific ESTs were motivational interviewing skills, although these were generally limited to the use of basic MI skills (e.g. open-ended questions, reflections) as opposed to advanced MI skills such as heightening discrepancies and change planning.

Most notable, however, were either very low levels or the absence of the types of interventions that the clinicians indicated they used frequently prior to the initiation of the protocol, such as cognitive-behavioral therapy (skills training, cognitive restructuring, focus on cognitions), HIV risk behavior reduction, and skills associated with the 12-step/disease model, such as emphasizing abstinence, spirituality, powerlessness, and loss of control. As mentioned previously, the authors of this study anticipated that there would be more opportunities in the three-session protocol for clinicians to use an increased variety of interventions associated with ESTs, but the frequency and range of types of specific counseling strategies did not increase across the three sessions. These data were largely inconsistent with the descriptions provided by site directors who reported using "moderate to high" levels of ESTs in their standard practice as well as with the therapeutic strategies clinicians stated they were delivering. Overall, independent ratings of audio-taped sessions from the one- and three-session protocols indicated that TAU was characterized primarily by assessment of substance use and social functioning as well as a variety of other nonspecific counseling skills (e.g. problem discussion, assessing medical issues and medications, informal discussions, basic MI skills), but that ESTs on the whole were rarely implemented in the early phase of individual substance abuse treatment in community treatment programs.

Of interest was the finding that "therapist disclosures unrelated to the problems of the client" (i.e. therapist informal discussions and topics irrelevant to the client's treatment needs) occurred more often than specific drug counseling strategies (e.g. relapse prevention skill building). This was a surprising finding that occurred in 60% of sessions in the one-session protocol and 48% of sessions in the three-session protocol. Referred to as "chat," these particular discussions may be potentially disruptive to treatment, as they involve therapist personal disclosures that are unrelated to the clients' treatment, which may, in turn, detract from the client's presenting problem.

These data were further examined by Martino and colleagues to explore which types of informal discussions were used by clinicians in community treatment programs as they were delivering TAU and to investigate whether such discussions enhanced or hindered the treatment process. These investigators examined the relationship between therapist informal discussions and client motivation, treatment outcome, and therapeutic alliance. Independent raters coded audio recorded sessions of 60 counselors totaling 736 counseling sessions. Results from the independent ratings indicated that a large proportion (88%) of counselors engaged in informal discussions and that these discussions occurred in 42% of sessions. Informal discussions primarily consisted of personal information

TABLE 26.1 Mean Adherence Ratings and Item Frequencies in Treatment-as-Usual (TAU) in the One-Session (n = 160) and Three-Session Protocols (n = 219)

	One-session protoc	ol*		Three-session protocol**		
	Adherence***			Adherence		
Item rated	% of sessions	M	SD	% of sessions	M	SD
Addiction Counseling Intervention	ons					
1. Assessing/monitoring substance use	0.98	5.8	1.3	0.67	2.8	1.7
2. Social functioning and factors	0.98	5.5	1.4	0.95	4.7	1.8
3. Medical/Medication	0.93	3.8	1.6	0.28	1.5	1.1
4. Psychopathology	0.92	3.7	1.4	0.24	1.5	1.0
5. Program orientation	0.78	3.5	2.0	0.31	1.6	1.2
6. General discussion and self-disclosure	0.60	2.8	2.0	0.48	2.3	1.8
7. Give unsolicited advice and direction	0.58	2.6	1.9	0.64	3.1	2.0
8. Assert therapeutic authority	0.54	2.5	1.9	0.53	2.5	1.8
9. Self-help group involvement	0.76	2.4	1.1	0.55	2.4	1.7
10. Psychoeducation about substances	0.47	2.2	1.7	0.25	1.6	1.2
11. Case management	0.50	2.2	1.6	0.23	1.4	0.9
12. Formal treatment planning	0.38	2.0	1.5	0.14	1.4	1.0
13. Spirituality/Higher power	0.47	1.7	0.9	0.17	1.4	1.0
14. Emphasis on abstinence	0.25	1.4	.08	0.12	1.2	0.6
15. Risk behavior reduction	0.19	1.3	0.9	0.03	1.1	0.4
16. Confront denial or defensiveness	0.13	1.2	0.8	0.18	1.4	1.1
17. Psychodynamic interventions	0.06	1.1	0.8	0.10	1.2	0.7
18. Powerlessness and loss of control	0.04	1.1	0.5	0.11	1.2	0.6
19. Reality therapy principles	0.06	1.1	0.4	0.14	1.3	0.8
20. Cognitions	0.03	1.0	0.2	0.11	1.2	0.8
21. Skills training	0.02	1.0	.01	0.04	1.1	0.3
Basic MI Skills						
22. Open-ended questions	0.88	4.2	1.8	0.91	4.4	1.8
23. Reflective statements	0.79	3.5	1.9	0.81	3.7	1.9
24. Motivational interviewing style	0.53	2.5	1.7	0.57	2.6	1.7

(Continued)

TABLE 26.1 Mean Adherence Ratings and Item Frequencies in Treatment-as-Usual (TAU) in the One-Session (n = 160) and Three-Session Protocols (n = 219)—cont'd

	One-session protoc	ol*		Three-session protocol**			
	Adherence***			Adherence			
Item rated	% of sessions	M	SD	% of sessions	M	SD	
25. Fostering collaborative atmosphere	0.46	2.0	1.3	0.42	1.9	1.3	
26. Affirm strength and self-efficacy	0.43	1.8	1.3	0.51	2.0	1.3	
Advanced MI Skills							
27. Problem discussion and feedback	0.89	3.7	1.6	0.77	3.1	1.7	
28. Motivation to change	0.45	1.8	1.1	0.28	1.5	0.9	
29. Change planning discussion	0.28	1.5	1.	0.19	1.4	1.1	
30. Pros, cons, and, ambivalence	0.19	1.4	1.0	0.08	1.2	0.6	
31. Heightening discrepancies	0.03	1.0	0.3	0.12	1.2	0.6	

^{*} Treatment-as-usual delivered within a single intake assessment session.

Mean adherence ratings are based on the following sample sizes within each protocol for each condition: One-session protocol (n = 160); Three-session protocol (n = 219). Santa Ana, E.J., Martino, S., Ball, S., Nich, C., Frankforter, T., Carroll, K.M., 2008. What is usual about treatment-as-usual: Independent audiotape ratings drawn from two multisite effectiveness trials. *Journal of Substance Abuse Treatment* 35, 369–379.

(e.g. pets, vacation preferences), addiction problems of the therapists' significant others, the therapist's health problems, the therapist's personal opinions, current events (e.g. the news), and the therapist's personal feelings about the client. On average, therapists were found to engage in such informal discussions once or twice per session. While a higher frequency of informal discussion was not related to client treatment retention or substance use outcome, it was associated with a stronger therapeutic alliance, particularly in the three-session protocol.

The authors speculated that "a little informal discussion" may have enhanced the client's perception of the therapist as "warm and genuine." Therapists who give information about themselves, particularly when they share with their clients that they have experienced similar problems, may be viewed by their clients as authentic. Other therapist statements, such as expressing positive opinions toward the patient, may result in enhancing the therapeutic bond. Indeed, this notion of sharing personal information with the client has been described in previous literature as potentially beneficial toward the therapeutic relationship between the therapist and patient. However, the findings reveal that there is a fine line, as the authors also found that a high frequency of informal discussion was negatively associated with client motivation; the more a therapist engaged in "chat," the greater likelihood the client was less motivated to change his or her substance use. Overall, these data suggest that too much therapist informal discussion can impede the therapeutic process and may result in thwarting client motivation. Thus, it appears that the type of therapist informal statements may have an impact on the therapeutic relationship. For example, unhelpful therapist comments, such as talking about current events at length or disclosing work-related problems, appear to be distracting to the therapeutic relationship.

THERAPEUTIC ALLIANCE AND CLIENT OUTCOME

A growing body of literature has demonstrated that therapeutic alliance and interpersonal skills, including therapist factors such as warmth, genuineness, empathy, affirmation, and support, are associated with improved client retention and outcome. In contrast, evidence suggests that negative therapist behaviors, such as depression, hostility, controlling, and blaming produce the opposite effect (i.e. negative client outcome). Therapist effects may also explain why some standard (i.e. non-empirically supported) substance abuse counseling approaches are as effective as evidence-based approaches.

^{**} Treatment-as-usual delivered across three sessions within a 28-day period.

^{***} Adherence ratings are on a 7-point Likert scale: 1 = not at all, 2 = a little (once), 3 = infrequently (twice), 4 = somewhat (3-4 times), 5 = quite a bit (5-6 times), 6 = considerably (>6 times/more depth in interventions), 7 = extensively (high-frequency/characterizes entire session).

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In a study that highlights this finding, Morgenstern and colleagues examined the effectiveness of cognitivebehavioral treatment (CBT) compared to TAU for 252 clients seeking treatment for a substance abuse problem in a community treatment program located in the US North East. CBT was provided in two levels: a high-standardization CBT condition that relied on a therapist manual including review of session tapes and supervisory feedback; and a low-standardization CBT condition without adherence constraints where therapists were encouraged to use their own clinical judgment and could integrate 12-step interventions as they deemed appropriate. Both CBT conditions were compared to TAU, which consisted of the delivery of substance abuse counseling that was typical of what counselors normally provided, including reliance on self-help supports. Contrary to the investigator's expectation that the two CBT conditions would improve intermediate (3-month) and posttreatment (9-month) substance abuse outcomes compared to the TAU condition, no significant differences between any of the three treatment conditions were found with regard to the percent of days of which alcohol and drugs were consumed. Therapeutic alliance, a factor common across treatment conditions, explained a significant proportion of the variance, suggesting that standard substance abuse counseling that includes the therapeutic alliance factor may be more effective than previously thought.

These results are consistent with evidence showing that nonspecific factors (e.g. feeling understood, being respected, having someone be interested) are not exclusive to any one approach and can have a significant impact on client outcome. The authors of this study speculated that the relatively good outcomes in their TAU condition raise further questions regarding the "necessary and sufficient" components of effective substance abuse treatment, although their findings may be associated with overlapping patient treatment goals. It may be that few differences in outcome between treatment conditions were associated with clients who were committed to behavior change or to a shared abstinence goal. More studies are needed that elucidate the impact of ESTs relative to standard substance abuse counseling on nonoverlapping differences in patient and agency factors, such as variations in desire for abstinence, failure to achieve abstinence by the end of standard treatment, and reliance on group versus individual therapy as well as other differences in settings and clients.

While treatment alliance and other nonspecific factors (being accepted, being encouraged to face difficulties) appear to account for a significant amount of variance in treatment outcome, these factors do not account for all of the variance. Indeed, there is substantial evidence in the field showing that specific treatments are consistently more effective relative to others in the

treatment of drug and alcohol dependence. Likewise, clinicians vary widely in their effectiveness in working with clients and in their delivery of specific treatments. Given these differences in outcomes based on the type of treatment provided, and the individual therapist who delivers the intervention, optimal outcomes should be realized when treatments with the greatest potential for making the most beneficial impact are provided by therapists who are able to foster strong therapeutic alliances.

In a NIDA-CTN multisite randomized clinical trial conducted by Ball and colleagues who evaluated the effectiveness of motivational enhancement therapy (MET) consisting of MI strategies compared to care-asusual among 461 participants seeking treatment for substance use problems, participants assigned to both conditions exhibited reductions in substance use through the 1-month treatment phase. However, participants in MET were more likely to maintain their reduced level of substance use over the 3-month follow-up period, whereas participants in the standard care condition increased their level of substance use. Martino and colleagues, examining data derived from this study, found that counselors trained in motivational interviewing were less likely to engage in therapist informal discussions (i.e. "chat") than counselors without such training and that, in turn, the therapists who tended to engage in informal discussions were less likely to provide basic and advanced motivational interviewing skills. Rather, they were more likely to rely on strategies inconsistent with MI or they delivered MI will less proficiency. This finding indicates that therapists trained in an evidence-based intervention such as motivational interviewing may be more likely to deliver the intervention with greater skill and may be less likely to engage in distracting or unhelpful informal discussions that may serve to reduce client motivation.

LIMITATIONS

The data presented in this chapter provide some important insights into the nature of substance abuse treatment in community-based treatment settings. Nevertheless, there are several limitations with which to be mindful. To date, very few studies have attempted to independently evaluate the nature and process of TAU in community treatment programs. These studies have focused exclusively on the early sessions in treatment, and as such, data based on these studies may not be representative of the types of counseling skills that occurred in the later stages of treatment, particularly where clinicians may have been given the opportunity to shift their focus toward providing more direct substance abuse interventions involving ESTs. For

example, the types of interventions that occur in the early sessions of treatment may be associated with customary agency practices emphasizing extensive patient evaluation, assessment, and completion of agency paperwork that serves to limit opportunities for engaging in other interventions. Thus, we have only a limited glimpse of what actually occurs during the course of TAU in community treatment programs. Nevertheless, as discussed previously, data from the three-session protocol indicated that when clinicians were afforded more time and opportunity to shift focus, they did not increase their level of general counseling or interventions associated ESTs across sessions when opportunities for doing so became available.

Another limitation is that clinician behaviors may differ when sessions are audio recorded relative to when they are not, and hence different use of treatment strategies may occur in the natural setting. Finally, the data that describe TAU taken from existing surveys and independent ratings were derived from collaborations between community treatment organizations and major medical school research centers and, as such, these clinical treatment programs may not be representative of all community treatment programs that do not partner with universities.

CONCLUSION AND FUTURE DIRECTIONS

The dissemination and implementation of ESTs in community settings have many far-reaching implications, most notably the potential to enhance the overall quality of substance abuse treatment and improve the nation's public health. In recognition of this important undertaking, the goal of the Institute of Medicine's (1998) landmark report is for community treatment programs to adopt evidence-based treatment practices. For that goal to be realized, researchers must deliver their findings into the hands of clinicians and other treatment professionals. Maintaining accurate identification of the standard treatment practices that occur in community treatment programs will allow investigators to determine the degree to which dissemination efforts are effective over time. The objective data reported in this chapter provide a picture of standard treatment practices in the early phase of treatment and its objective assessment represents an initial step that must continue to evolve in community-based programs, particularly for evaluating the usual care practices in later stages of treatment. If ESTs are indeed making headway in community treatment programs, investigators should observe greater integration of ESTs in therapy sessions based on objective ratings compared to the current status of the data.

Efforts to identify standard practice, in turn, may assist in identifying current barriers for the adoption of ESTs in community treatment programs as investigators seek ways to improve these. Researchers will also be in a better position to elucidate the impact of scientifically based treatments as well as measure their incremental benefit relative to nonspecific factors so that these areas may be combined for enhanced treatment outcome. With that regard, the discrepancy between self-reported standard treatment practices to that of objective data is problematic, and future studies should seek to investigate methods for narrowing this discrepancy. Several innovative strategies discussed in the dissemination literature for bridging the gap between standard practices in community settings and evidence-based treatments include dissemination of manual-guided therapies, providing workshops and providing ongoing supervision for delivering ESTs, and providing clinician incentives for the delivery of ESTs (e.g. leave time for training with pay, bonuses, promotions, and pay raises). Further research is needed to determine whether these strategies could be effective at enhancing the rate at which ESTs are delivered.

SEE ALSO

Health Care Reforms and Treatment for Substance Use Disorders, Improving the Quality of Addiction Treatment, Evidence-Based Treatment, Screening and Interventions in Medical Settings Including Brief Feedback-focused Interventions, Dissemination of Evidence-Based Treatment into Practice, Motivational Enhancement Approaches

List of Abbreviations

CBT cognitive-behavioral treatment
CTN Clinical Trials Network
ESTs complete the supported treatment

ESTs empirically supported treatments

IOM Institute of MedicineMI motivational interviewingNIDA National Institute on Drug Abuse

SAMHSA Substance Abuse and Mental Health Services

Administration treatment-as-usual

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TAU

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Disparities in Health Services for the Treatment of Substance Use Disorders

Paul M. Roman

Owens Institute for Behavioral Research, University of Georgia, Athens, GA, USA

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INTRODUCTION

Differences in the incidence and prevalence of substance use disorders (SUDs) in various segments of the population are the basis for considering *health disparities*. Health disparities (which can be viewed as objective facts or subjective perceptions) are defined here as cross-group variations in relevant biological traits or in exposures to agents in the environment that lead to differential rates of disease among segments of the population. Similarly, a 2000 definition promulgated by the National Institutes of Health (NIH) states: "A population is a health disparity population if there is a significant disparity in the overall rate of disease incidence, prevalence, morbidity, mortality, or survival rates in the population as compared to the health status of the general population." In other words, "health

disparities" refer to persistent differences between groups in one or more measurable dimensions of health status. A subjective element is commonly assumed, namely that these differences represent social injustice and are "wrong," avoidable and correctable, and/or that resources can/should be brought to bear to alleviate these impacts.

A closely intertwined issue is the subject of this chapter *health care disparities* within the delivery of treatment services for SUDs. A widely used summary definition supported by NIH includes health care disparities related to race, ethnicity, socioeconomic status (SES), and markers of social disadvantage result from a complex confluence of patient, clinician, and system levels factors. From this definition, the variables involved make for what is definitely a complex topic.

This chapter is limited in its focus to the United States, although many of the principles enunciated here have universal application. Cross-national discussions of health care disparities are beyond the present scope since each involves consideration of the values of a given culture and the health care system provided to address SUDs in that setting. While international organizations such as the United Nations has promulgated definitions of adequate health care that attempt to transcend a variety of forms of age, gender and ethnic discrimination at the national level, these "ideals" are neither consensual nor accurate in reflecting the range of values that guide decisions about resource allocation around the world. Thus, sweeping international generalizations rarely go beyond catalogs of one or another's perception of unmet needs.

The design and organization of health care systems essentially define health care disparities. The source of payment for health care is fundamental in structuring these disparities. Where a high level of access to health care is seen as a right of citizenship in a nation, health is usually sponsored by the state and paid for directly or indirectly by taxation. While all nations have some form of publicly provided health care, the scope of its availability and the "depth" of access are highly variable. Thus, in the United States, publicly funded health care is theoretically available to all who are defined as in poverty, health care for the remainder of the population has been, largely by default, the combined responsibility of employers and employees since the post–World War II period. This has left gaps in coverage for those not fully employed and those not in poverty, such as the elderly, whose needs have been largely addressed by Federal health programs, and the "working poor," who are presently the target for enhanced coverage under Federal legislation presently under court challenge. Nations throughout the world vary in the mixtures of employer involvement and publicly provided health care, with no two nations being exactly the same. Thus, health care disparities abound throughout the world but their scope and depth is a combined function of national values that define such disparities (or not) and which provide health care through structures driven by highly variable economic streams.

Considering disparities of care in relation to SUDs adds further complications in attempting an internationally focused discussion. Nations vary in the extent to which SUDs are viewed as a medical problem in contrast to an issue that is the primary responsibility of the criminal justice system. The manner in which the medical/criminal justice responsibilities are divided varies across nations. In nations such as the United States, a much higher proportion of services for the treatment of SUDs is provided under government auspices that is true for many other disorders but at the same

time, there is a public controversy about the extent to which such care actually should be regarded as health care. In other nations, the treatment of SUDs is fully integrated into the medical care system while in some settings, there is substantially more investment in care than in the United States, but the treatment system remains largely segregated. Thus to maintain some control over the subject matter, this discussion is largely limited to the United States.

OVERALL LOW UTILIZATION OF TREATMENT FOR SUDs

Differences in the nature, availability, and utilization of treatment for SUDs are the basis for research and policy interest in health care disparities. For those with SUDs and those organizations providing treatment for SUDs, this is not a trivial or minor issue. At present, a single fact dominates any consideration of the utilization of treatment services for SUDs in the United States. This is the gross underutilization of this care by those who are defined to need it, coupled with a common pattern of treatment entry following many years of individuals' evident symptomatology. From this latter point, it can be concluded that in general, patients arrive for treatment much sicker than they might need to be, making greater demands on the providers of care. Typical estimates indicate that the average entering patient has suffered from a SUD from 8 to 10 years.

Common estimates based on nationally representative surveys suggest that as few as 15% of those who need treatment (as defined primarily by their patterns of use of one or more psychoactive substances without in-depth information on social functioning) at a given point of time are actually utilizing treatment for their SUDs. This, however, is both a flexible and controversial definition, regarded by many as an exaggeration to increase attention and resource allocation for SUDs. The "on-the-ground" reality which drives actual diagnoses of SUDs guided by the American Psychiatric Association's Diagnostic and Statistical Manual is highly dependent on social reactions and definitions held by "significant others." The formal diagnoses center on impairment in the target individuals' ability to perform expected social roles, and the extent of perceived danger that the individual presents to herself or himself and others.

Observers easily overlook the extent to which social interaction and social role performance are the pivot for SUD diagnoses, recognizing of course that such behavior which is primarily "alcoholic" must be accompanied by excessive use of alcohol but diagnosis of "drug dependence" may only require what some regard as modest or "normal" use of other psychoactive drugs.

This suggests that many persons dependent on drugs and/or alcohol may be socially integrated on the point that their role performances or relation with others is not significantly impacted. It is clearly the case that such integration may be a function of different levels of material, social, and cultural capital that are distributed unevenly across the social structure, correlated in complicated ways with health care disparities.

The assumption that some people with SUDs simply "fit in" to their role expectations does not explain the very low utilization of SUD treatment. Other factors such as the availability of treatment, routes to treatment, perceptions of treatment, and the manner in which treatment is provided are part of this explanation as well. But the pattern of nonuse of apparently needed SUD treatment in the United States is dramatic. Across the range of medical disorders, it is indeed one of the largest, most notable, and least understood of all health care disparities.

THE HISTORICAL AND CONTEMPORARY POLICY CONTEXT

Explanation of the discrepancy lies in the fact that SUD treatment is a relative newcomer to the world of medical care, and it is neither completely welcome nor integrated as of yet. The integration of SUD treatment into the broader medical care system is a major concern of this decade and is being addressed by increasing the involvement of primary care medicine on several fronts, such as screening all patients for evidence of SUDs and direct delivery of medically assisted drug treatment.

While implementation of these steps, to say nothing of a broader implementation plan for complete integration, is a distinct challenge, the change that has occurred over the last 90 years is remarkable. Alcohol distribution and consumption was officially, from 1920 to 1933, a moral issue commanding massive societal attention through National Prohibition. Patterns of apparent alcohol dependence are now in many ways couched in medical definitions and concepts. Likewise, the nonmedical use of many psychoactive substances was fully criminalized from the 1920s until the 1960s when change began to occur. Extensive societal investment in massive international machinery to support "drug prohibition" remains very active today. But in the midst of many anomalies, the medicalization of both alcohol and drug problems continues. Social, political, and organizational forces at present and into the immediate future bode for increased integration of SUDs treatment into the broader realm of medical care, with this specialty interest definitely to be reshaped in yetunknown ways by these new interactions.

Another contextual fact that accounts for disparities in the delivery of SUD treatment is the overall nature of delivery of health care in the United States from both public and private providers. Disparities of all sorts and varieties constitute the engine that is driving health care reform in the United States. The overall "system" within which SUD treatment delivery is now partially embedded involves an inchoate complex of responsibilities for financing treatment that includes individuals, the federal government, all state governments, independent private for-profit insurers, not-for-profit systems of insurance, and employers, who pay (with a high level of discretion in coverage) a massive proportion of both direct health care costs and insurance premiums. These sources lead to wildly complex differences, contingencies, and exigencies when comparisons are made across a random group of patients being treated for the same SUD but "covered" by different sources paying for some portion of their treatment.

All of the different sources of financing listed above are involved in determining reimbursement for different types of SUD treatment. In addition, and in contrast to nearly all other medical care, SUD treatment financing is heavily influenced by state- and territorial-level "authorities" which make policy decisions about the use of public reimbursement funds, treatment quality standards, and licensing requirements for personnel working in the treatment of SUDs in a given state. These officials are frequently political appointees. Whether politically appointed or not, the national profile of these authorities is that credentials vary widely and their tenure is very unstable, as is their organizational location in state government and consequent reporting relationships. It should be obvious that this unique ingredient of the SUD policy structure adds complexity and confusion to an already muddled reimbursement apparatus. This inadvertent design for reimbursement (and thus access to treatment) is indeed "a perfect storm" for assuring widespread disparities in health care delivery for patients with SUDs.

NEW POLICY INITIATIVES AFFECTING DISPARITIES IN THE DELIVERY OF SUD TREATMENT

Federal legislation has addressed the treatment of SUDs as a national health care disparity by proscribing wholesale discrimination by health insurers and providers of health in sharply limiting the needed treatments for SUDs (and psychiatric disorders). The mechanism is the Wellstone–Domenici Act of 2009, providing for *parity* of SUDs and psychiatric disorders with other medical disorders in third-party reimbursement for treatment. The results of this legislation are not yet

visible in large-scale increases in either the numbers of new patients entering treatment for SUDs or in an increase in the average "dosages" of treatment received by SUDs patients. Some cynics argue that without rigorous enforcement, insurers will find legal loopholes to effectively evade the parity provisions of this Act. Such a conclusion is premature what is known from research about the time required for diffusion and implementation of policy innovations.

This Act may be seen as significantly bolstered by a second and later mechanism, the Federal Affordable Care Act of 2010 (ACA), or health care reform. In this legislation, the ACA has throughout provisions for a strong orientation toward reducing health care disparities. There is another mechanism beyond parity that will potentially lead to a direct increase in patient utilization of SUD treatment, the expansion of Medicaid eligibility and coverage to many in the "working class" who have been particularly shortchanged in health insurance coverage for SUD treatment that may have been provided by their employers. Perhaps of greater significance, the ACA specifically aims at a greater integration of SUD treatment into primary and general medical care through the establishment of "medical homes."

This will potentially reduce disparities in SUD treatment "across the board" from a demographic perspective by earlier identification of SUD problems before these behaviors impact social, psychological, and organic functioning. This will be accomplished not only by reducing the segregation of SUD care in a specialty network "outside" the medical mainstream, but by educating and motivating all medical care professionals to become involved in SUD treatment as a vital and legitimate component of overall medical care.

There is a massive literature documenting differences across different demographic groups in the rates of SUDs, the rates of different SUDs, and the rates of utilization of treatment for SUDs. Differences in access to high-quality services have also been documented for mental and behavioral health conditions. Focusing more specifically on the content of treatment, recent research has revealed significant racial and ethnic differences in the likelihood that patients receive psychotropic medications. Research on disparities related to physical and mental health has generally focused on the experiences of individual patients, with ample evidence that these disparities persist even after controlling for factors such as income and health insurance. The relationship between physicians and patients has also been studied as a mechanism for producing disparities.

The contention of "disparity" can be made with a wide variety of criteria. The intent here is not to review the statistical findings of studies such as those cited (that document SUD treatment disparities in great abundance) but focus instead upon the conceptual, methodological, and policy issues that make this both a matter of importance and a conundrum.

SOCIOCULTURAL VECTORS AFFECTING DISPARITIES IN SUD TREATMENT

The topics of health disparities and treatment disparities have been explored from different perspectives for many decades, and have foundations in social epidemiology and health services research. Concerns about these differences in the context of social justice and social policy are, however, of more recent origin. As the sociologist Robin Williams described in his classic text, American Society, there are deeply ingrained value orientations in the United States emphasizing racism and racial superiority. Enslavement of American Indians and Africans marked American history from its beginnings up until the Emancipation Proclamation, and many features of segregation and prejudice persist through the present day. Repeated waves of immigration follow the course of American history, each accompanied by prejudice and discriminatory action toward newcomers, including often-exaggerated claims that different immigrant groups are responsible for introducing routine alcohol consumption in the nineteenth century that fostered the growth of the urban saloon, and more recently, that newcomers brought new and dangerous psychoactive drugs into American culture. Likewise, within the culture of inequality, women were subordinated within the US constitution and gender equality is still incomplete despite substantial legislation and cultural change.

Thus, the statistical confirmation indicating that the US patients would be treated differently on the basis of their demographic characteristics is no surprise. Blatant denial of health care on the basis of race was once the norm. In the realm of treatment for SUDs, rare documentation of the denial of alcoholism treatment ("because they did not need it") in 1967 to African Americans in North Carolina has recently been provided by the British psychiatrist, Griffith Edwards. More recently, there is strong evidence of young African American adult males' drug-linked criminal activity leading to exceptionally high rates of imprisonment.

Health care disparities may directly reflect health disparities other than the actual availability and delivery of treatment for SUDs, for example a demographic group that is more heavily exposed to the availability of illegal drugs may receive a lower quality of health care for SUDs. A different example is partly independent of disease prevalence, namely where the planning of health service availability fails to provide equal geographic coverage for different populations to access

services relative to actual need, or fails to take into account the link between treatment availability and access to transportation in sparsely populated rural areas. An even different perspective is reflected where services are apparently of reasonable quality and of adequate accessibility, but utilization varies inexplicably across different population subgroups. These utilization differences can often be broken down further into differences in treatment entry, treatment engagement, treatment completion, and participation in long-term follow-up.

Health disparities within SUD treatment that contains a number of ironies easily become conundrums. The fact that certain subgroups apparently are resistant to use services made conveniently available to them in apparently attractive venues is among these ironies but another is that in terms of service development and availability, "more is not necessarily better." This may be demonstrated by the possibility that the provision of either more specialized health care or less of this health care to distinctive social and demographic groups may be viewed both positively and negatively. More care for SUDs may be viewed as deliberately stigmatizing and disabling certain subgroups or creating indirect forms of social control directed toward a particular group.

Thus, increased SUD care of a particular type may be perceived by some portions of a socially marginalized group as undesirable control while others representing the interests of this same group see a relative deficit of particular health care as social neglect. An example is found in apparent higher rates of attention-deficit disorder among African American youth as compared to other ethnic groups but a lower rate of pharmacological treatment of African Americans as compared to other ethnic groups. Others view pharmacological treatment of youth in any form as subtle social control without informed consent, particularly when consenting parents are convinced that their child has a disease or disorder that must be treated. Depending on the perspective of the observer, opposing views of the appropriateness or the intention of the same observed pattern of treatment could coexist.

Epidemiological data can be the source of these dilemmas. One of the goals of epidemiology is to identify correlates of factors that cause disease. When these factors are linked to social and demographic characteristics, the next step is to design interventions that effectively alter or neutralize the etiological vectors. This often results in one or more specific demographic groups being targeted for the intervention because epidemiological studies have revealed that they are both afflicted by the disease and exposed to the particular etiological vector, leading to the further assumption that their vulnerability to the vector leads to the disease,

and that reducing or eliminating their exposure to it will eliminate the disease.

It is very common to assume that the demographic characteristics of the patients who are treated for a given disease potentially represent factors that may play a role in the etiology of the disease. Such an assumption could be true if all of the afflicted patients are in the treated population, and that any deficiencies in data collection are spread randomly across this "totally treated" population. This problem may come to be reflected in a very recent application of epidemiological methods to treatment utilization where patterns of high use are identified as "hot spots" within which delivery systems may be redesigned.

In summary, health care disparities exist, to a degree, in the eye of the beholder. There are indeed linkages between any form of medical treatment and social control. Diagnosis and treatment (in that order) label individuals and may alter their eligibility to participate in certain roles, such as marriage or employment. This is particularly problematic with treatments for SUDs that have low "success rates" where the patient may be doubly labeled as having the disease and having failed at completing or responding appropriately to the treatment regimen. To the extent that such experiences are linked with marginalized social statuses, a tripled labeling process occurs that can lead to further marginalization, loss of social capital, and social exclusion.

At the same time, treatment of SUDs are usually intended to be liberating, to increase opportunities for social integration and participation, and to enhance the patient's social capital. The manner in which the perceived outcomes of treatment lead in these negative or positive directions is likely a strong determinant of subcultural norms on the utilization of treatment for SUDs.

DEFINITIONAL CONTEXTS FOR HEALTH CARE DISPARITIES IN TREATMENT DELIVERY FOR SUDs

The patterns of delivery of services for SUDs result in multiple definitions that can be used to define the existence of disparities in the delivery of health care. Paramount among these is the rigid definitions of long-term unbroken patterns of abstinence from drug and alcohol use that are used to define treatment success. Specifically, the use of this outcome criterion may generate artificial estimates of health care disparities in the delivery of SUD treatment services. These behaviors occur in the uncontrolled environments outside treatment, and typically without significant ongoing contact with treatment. Thus, whatever vectors may have differentially affecting the drinking and drug use behavior of

demographic groups prior to treatment will do so following treatment, when these measures are taken.

Such definitions are a direct heritage from the 12-step programs that were the foundation for much SUD treatment in the United States, and these definitions are not shared by treatment systems in many other nations. Within Alcoholics Anonymous (AA) and Narcotics Anonymous (NA), the goal of affiliation is long-term "sobriety" (a pattern of positive and constructive living characterized by participation in normative social roles of family, work, and community), central to which is abstinence from drugs and alcohol. A form of "keeping score" within these groups is counting the number of days, weeks, months, or years from the last use of drugs, which is the basis for recognition and support from fellow members, but not necessarily the reward of status or prestige. 12-step group members may count their last drink or "use" day as a "birthday," and "chips" which mark distance from these anniversaries are commonly handed out. Perhaps surprisingly, a "slip" or relapse back to drinking or drugging by a member is not viewed with disdain, degradation, or even disappointment in that such events are regarded as a natural part of the recovery process within the programs. Indeed, such events, very often leading to loss of control, serve to be key reinforcements and confirmations of the assertions that one cannot "use" drugs or alcohol in a manner similar to "normal" individuals.

Such an oddly flexible norm does not translate very effectively into the bureaucratic organization of treatment. Instead, in-treatment or posttreatment outcome has typically been defined in terms of "time from last drug/drug use." Standards vary, but many SUD treatment programs regard a 1-year period of abstinence as a sound measure of a successful treatment outcome, with 6 months seen as significant progress.

Using these criteria results in notably poor records of treatment success, with an outcome of 25% reporting 12-month abstinence being "very good." It should be noted that most of the data for posttreatment outcome are based on self-report, which may lead to overestimates of success. Many programs use urine testing to measure drug use during treatment, and while it is often used during posttreatment, particularly in criminal justice-linked treatment, it is expensive. Treatment programs and researchers have struggled with "the criterion problem" for decades, but programs' deviation toward reporting "softer" standards of "improvement" are acceptable only if they are accompanied by the "hard" data on abstinence.

While the potentially self-defeating nature of these abstinence-based outcome criteria are recognized by most working in SUD treatment, the measures are very attractive to government officials representing structures of rules in that they are countable, unambiguous, and

certainly easy to understand in contrast to alternative measures involving mystifying terminology and clinical "mumbo-jumbo" describing improvement of the patient following treatment. Complicating the issue further is the apparent widespread public acceptance of this criterion, coupled with very positive public attitudes toward the principles of 12-step programs and ironic agreement with one of AA's own informal acronyms, KISS (Keep It Simple, Stupid). The long-term abstinence criterion for treatment success is, without doubt, simple. The final irony is that while 12-step programs acknowledge respect but do not award significant status and prestige to their members on the basis of the length of their abstinence, broader American society has come to do so.

Perhaps the rigid use of these rigid criteria will fade with integration of SUD treatment into the broader health care system. As such integration moves forward, perhaps there will be greater recognition that this broader system has no parallel to the outcome criteria used in SUD treatment. The practice of medicine is based upon a harm reduction model, administering interventions with a goal of improving patient functioning, not moving patient functioning to some absolute standard. Treatment success in medical care is not marked by the total disappearance of symptoms, although in diseases such as cancer this may be desired. More to the point is the extent to which criteria reflect on the quality of the service itself. Within broader medical care, conformity to recommended posttreatment regimens are patients' responsibilities, not those of the professionals who delivered the interventions. Thus, a diabetic or cardiac patient who deviates from dietary proscriptions and relapses as a consequence is not viewed as a failure of medical care but as a failure of personal self-control. By contrast, the SUD patient who resumes using drugs or alcohol is seen as behaving in a manner reflecting ineffective treatment. And in some circumstances, the treatment provider's responsibility for this aspect of patient behavior is inferred to persist for years!

The "criterion problem" definitely contributes to confusing, erroneous, and misleading information about health care disparities in SUD treatment because so many persons are "lost" in the treatment process. Creating new measures of improvement during and following treatment, followed by the universal adoption of such standards, would greatly improve the quality of this information, and would also provide data of much greater utility to comprehensive delivery systems such as the "medical home" that is envisioned as the centerpiece of future American health care.

Beyond the outcome criterion issue and the way it may blur data on health disparities in the delivery of SUD treatment, other dimensions of the process of treatment delivery for SUDs may distort information on differential use of treatment. First is the matter of identification of SUDs and the manner in which social visibility may play a role. Specifically, many SUDs are identified indirectly through the criminal justice system in that persons charged with criminal offenses are found to have SUD disorders. Given the known pattern of higher visibility to police and other agents of social control in urban areas, among minority groups, among youth, among males, among African Americans and Hispanics, in urban neighborhoods with high levels but varying combinations of these demographic characteristics, it is clear that to the extent that SUDs are identified through mechanisms of formal social control, apparent differences in rates of SUDs may become evident and added to other "counts" that suggest health disparities.

One specific mechanism that plays an increasingly important role at the intersection between the criminal justice system and the SUD treatment system is the drug court. Drug courts process a selected (but nonrandom) subgroup of persons who come to be identified with SUDs through criminal justice system identification processes. These persons are, in various contexts, given choices about entry into treatment versus entry into incarceration, with these choices introducing another nonrandom selection. To an extent, members of the next level of subgroup perceive themselves as "coerced" into SUD treatment through this mechanism, leading to different treatment outcomes. With the exception of psychiatric treatment, no other component of the health care system has coerced patients. It is evident that all of these selection and sub-selection events add demographic information to repositories ultimately used to calculate health disparities, creating uncontrollable biases in the data.

Beyond identification and the largely unknown processes leading to the decision to enter SUD treatment (other than criminal justice identification) is the problem of treatment entry and engagement, which again has some sharp differences from other components of the health care system, and generates data that can be used misleadingly to calculate health care disparities. When data have been collected on the topic, substantial portion of persons who contact a SUD treatment center for an appointment never show up. Often, this is linked to overcrowded schedules and delay in appointments, both of which are well known throughout the US medical care system, but are more pronounced, overall, in SUD treatment. During the next two steps, actual induction into the treatment system and engagement in care, there is a very high degree of loss among SUD patients. Investigations have yielded multiple explanations, including simple confusion by patients about what they are expected to do next, rudeness and alienation of patients, unusual long waits, and inaccurate information. Some patients leave treatment by being

"put off" by the overall environment and other patients, becoming unwilling to give up their substance use, and seeing the expectations of treatment as overwhelming. Others attend one or two sessions of treatment and believe that they know the expectations and do not need to attend further sessions, and/or that they have learned what is necessary to achieve abstinence/sobriety and may proceed to do so.

In any event, virtually all research on SUD treatment finds the flow of patients to follow the pattern of a funnel, with loss of significant numbers of patients at each phase of the treatment process, including from session to session, and clearly into the posttreatment phase where patients are commonly contacted for follow-up support and to collect posttreatment information. This attrition clearly has substantial effects on the generation of data about health care disparities, but few studies have systematically reconstructed the "demographics of loss" such that we know little about the selectivity of subgroup membership in these processes.

PROBLEMATIC SUBGROUPS WITH DISPARITIES IN THE TREATMENT OF SUDs

There is a very extensive literature describing a multitude of health care disparities linked to either SUD treatment generally, to specific components of treatment that appear differentially employed with different demographic groups, and variations in access to what is defined in several different ways as "quality" treatment. This may refer to the degree of utilization of "evidencebased practices," the variation in the treatment regimens that are accessible in a particular program, or the presence of "treatment tracks" designed for specific demographic categories such as the elderly, women, specific ethnic minorities, or those with varying sexual orientations. The following overview is not exhaustive in any respect, but provides a flavor for the types of issues that arise in considering health care disparities in SUD treatment.

Ethnic minorities are prominent in these studies, illustrating several issues. Entry into treatment is governed by a wide range of different cultural and subcultural traditions and norms, representing in some instances careful concern about the human body while in others describing weakness and an inability to meet expected demands. Treatment entry and engagement needs to be appropriately designed to address these considerations.

The elderly, a very rapidly growing subgroup in American society, have been recently discovered to sharply underutilize SUD treatment that is apparently needed. Among the issues here are accessibility to SUD treatment through transportation and physical accessibility issues for entry and movement around a facility, the multiple disabilities and medications used by the elderly that may be affected by SUD treatment regimens, and the lack of role expectations which make the definition of a "problem" difficult for people who may have little or nothing to do. Again, it is clear that effective treatment needs to be specifically adjusted to accommodate this group.

As with the elderly, special issues arise in providing SUD treatment to youth. By definition, the SUD experience of youth is relatively brief and occurs before engrained role relationships of work, family, and friendship have developed, and thus should offer greater opportunity for minimizing long-term effects. Youth often enter treatment under what would be labeled coercion except that by definition they have few rights, and treatment entry is rarely seen as their decision right. This may, however, create basic reluctances and resistances, reflecting their fluid life stage characterized by developmental challenges in the physical, psychological, and social realms. This clearly suggests the need for expertise in developmental psychology in the counseling process, with an ability to teach out the abnormal consequences of SUDs and the normal patterns of developmental conflict and rebellion before diagnosing serious co-occurring disorders. Youth are subject to exploitation in programs with adults, and thus must be segregated to some degree, yet the pressures of peer influence can generate further problems associated with segregation.

Persons dwelling in sparsely populated rural areas may simply have no access to SUD treatment. Facilities are always designed on the basis of expected utilization, regardless of public or private support, and the presence of comprehensive facilities in remote areas simply cannot be justified. When treatment appears to be reasonably accessible, transportation is nearly always a problem outside urban areas and is not the type of concern that accompanies expertise in counseling and treatment delivery. The accessibility issue is exacerbated when considering the needs for a continuum of care that includes long-term follow-up. One of the exciting uses of current technology is the increased employment of the computer and the Internet for access to counseling in rural areas.

Gender is a major concern in considering health disparities in SUD delivery. From the earliest days of treatment delivery, it has been designed as if SUDs exclusively afflicted males. At one point there were doubts that 12-step programs, which began as exclusively male, could effectively accommodate women, but this issue seems to have diminished somewhat with greater similarity in the social role structures of men and women. There are at least two care-related issues affecting women almost exclusively. These are

the common problems of victimization through male violence, which can be at least a threefold issue in treatment: protection against further violence, treatment of the physical consequences of violence, and treatment of the psychological consequences. Further, many women with SUDs are responsible for dependent children, and accommodation of children during SUD treatment can be a massive challenge, particularly when the children also need treatment attention and/or sustained schooling activity.

DILEMMAS IN CONSIDERING DISPARITIES IN TREATMENT FOR SUDs

Research that systematically considers the life-careers of persons with SUDs is at its early stages, but nearly all such studies seem to offer surprises. A common finding is that a large proportion of patients go "in and out" of recovery at different points in their life cycles. On the one hand, this observation seems to affirm the stigmatizing "chronic relapsing brain disease" model of addiction, yet the evidence also demonstrates remarkable patterns of "comebacks" rather than typical downward spirals to early death that would be implied by the chronic disease model. This type of life-career investigation is not typical of other medical research where treatment episodes rather than personal trajectories are the more common model for long-term studies.

In contrast to other disorders, an unknown and essentially unmeasurable amount of treatment occurs in 12step programs and other social support structures where records are not kept and data are not entered into systems of evaluation. AA is ironically the cornerstone of treatment for alcohol use disorders in the United States, yet its organizational and programmatic nature precludes its participation in community of care delivery. This is perhaps even more problematic in the case of NA where the target behavior is much less prevalent and the policy needs for accurate counting of treatment episodes are more acute. Hence, health care disparities in SUD treatment evident from treatment censuses may have a different profile if participation in the anonymous 12-step and social support programs could be counted.

Another contrast to the treatment of other disorders in the medical care system is the occurrence of recovery without formal intervention. While there are occasional records of miraculous cures and other recoveries from disease or disorder in general medical care, "spontaneous remission" from a SUD is not newsworthy; estimates indicate that as many as one-third of persons who develop SUDs recover "on their own" without any treatment intervention or involvement in a 12-step or social support program. The few studies that have

examined this phenomenon have found that personal religious experiences rank as the most common denominator of experience across such groups, but it is clearly difficult to generate good representative sampling to conduct such research, as well as to construct useful retrospective measures of who among the spontaneously remitted "really" had a SUD.

The existence of this phenomenon is a conundrum for the entire network of professionals and organizations involved in SUD treatment, since it seems to imply that some kind of effective "folk" activity creates outcomes similar to those generated by relatively expensive treatment, that the estimates of treatment needs are actually largely overestimated because evidence of spontaneous remission indicates that a large proportion of the untreated population with SUDs will recover without treatment, and it may suggest that some proportion of patients undergo expensive treatment unnecessarily since they would have recovered on their own. These intriguing questions, which are completely outside the paradigms of most medical care, rarely are addressed and are in fact excluded from most summary discussions about SUD treatment needs or policy considerations. The unknown demographics and understudied experiences of spontaneous remitters are problematic for the study of health care disparities in the need for and utilization of SUD treatment.

SPECIFIC POLICIES THAT HAVE ADDRESSED DISPARITIES IN TREATMENT FOR SUDs

A rich area for considering the anomalies and contradictions in the definition of health disparities is the development of social policy. Several brief examples illustrate these issues. A first example shows policy change reflecting demographic change. Reaching back into the nineteenth century, David Courtwright has alluded to how in 1880, middle class women using both medications and over-the-counter remedies that contained opiates and cocaine were the typical addicts in the United States, and there was little concern should their addictions be maintained on morphine by their family physicians. When the profile of the opiate addict slowly morphed into that of the working and lower class (often foreign-born) men by 1920, maintenance with opiates became outlawed.

More than 50 years later, leadership of the new National Institute on Alcohol Abuse and Alcoholism (NIAAA) in 1971 sought to differentiate its identity from that of its predecessor organizations by focusing on a "new" socioeconomic category of alcohol-dependent people, the majority of adult Americans who are employed. In so doing, a multifaceted campaign made

exaggerated assertions that prior intervention efforts had focused almost exclusively on Skid Row public inebriates. The new NIAAA focus was to be on the "95%" of the alcohol-dependent population that was respectable, employed but whose alcohol-related behaviors were "hidden" through a complex system of naivete, denial, and cover-up that marked both employment settings and middle class culture. Through deploying consultants to every state, "Project 95" endeavored to create workplace-based identification and referral programs for these "hidden" patients, an effort that eventuated in the rapid growth of employee assistance programs and semi-privatized treatment centers to serve the resulting referrals. The ultimate goal, achievement which remains relatively undocumented, was to reduce the health disparity in alcohol-related treatment for the working, middle, and upper social classes.

In the mid-1970s, a relatively small set of scientific findings, the conclusions of which remain controversial, formed the core of a movement that led to a policy change that had health disparity implications. This was the rediscovery that heavy drinking by mothers (coupled with poor pre-natal care) created the risk for fetal alcohol syndrome among offspring, marked by permanent forms of retardation and physical malformations. The idea of the linkage between maternal behavior and this presumably preventable outcome soon was translated into the broader concern with fetal alcohol effects, and the asserted need for all pregnant women to avoid all alcohol during pregnancy. The spin-off effects of this campaign were to create a health disparity in alleging previously undetected problems in children, and by identifying an equivocal etiological vector, namely drinking in any amount by pregnant women. The most visible resulting actions were eventual inclusion of this concern on warning labels included on all packaged alcoholic beverages (but not on alcohol decanted into other containers in commercial settings) to alert pregnant women, as well as prominent signs in many drinking venues which served as further possible education for pregnant women as well as stigmatizing devices should pregnant women choose to drink in those settings.

A very different type of disparity was highlighted by the Federal Drug Addiction Treatment Amendment (DATA) of 2000 that restricted the administration of buprenorphine for the treatment of opiate addiction to specially certified primary care physicians. These physicians were in turn limited to no more than 30 opiate-dependent patients at one time, a limit later raised to 100 such patients.

The disparities being addressed by this policy were threefold. The essential context is that the only maintenance that had been available to opiate addicts since the 1960s was methadone, distributed primarily through

highly regulated clinics that had over time become stigmatized, provided services in a demeaning context, and operated in what are often perceived as dangerous neighborhoods. Methadone is also available in some comprehensive SUD treatment centers, but this source accounts for only a small amount of use, and requires passage through a different set of perceived "social barriers" for many prospective patients.

The first goal of the DATA policy was to address a neglected group of potential patients, namely to provide treatment access to working and middle class people who were opiate dependent and who were perceived as unlikely to utilize methadone clinics but who regularly sought the services of a family doctor or primary care physician.

Second, the disparity of the existing service was directly addressed. Some policy advocates wanted to revamp the methadone system generally, and offer all addicted patients seeking opiate maintenance to be able to obtain it in a medicalized, clean, safe setting where they were treated with the respect that is supposed to be part of the culture of medical care. Presumably, they would not be bound to utilize only expensive buprenorphine since DATA allowed for certified physicians to also distribute methadone if they chose and adopted proper procedures.

The third target was to mainstream SUD treatment into general medical care via the utilization of the primary care setting. This would presumably have multiple impacts in reducing health care disparities through a degree of destigmatization of SUD treatment, through greater participation of the primary care physician in the identification and treatment of other SUDs within the broader practice setting. This integration could also serve to meet other medical care needs of SUD patients in a "one-stop" fashion, and likely have a dampening effect on longer health care cost utilization.

This ambitious innovation has met with limited success. A substantial proportion of the physicians who have been certified to provide treatment for these SUDs have not begun to do so, and this reluctance has not been systematically investigated. A perceived shortfall of this treatment regimen, again not well documented by research, is that counseling and psychosocial therapy that is supposed to accompany the medication delivery is not adequately provided in these settings, or are adequate linkages developed for coordinating its provision in another setting. A positive and partially unexpected outcome of providing this service delivery platform is its apparent utilization by those affected in the apparently rising epidemic of prescription opiate dependence, many of whom are from middle class settings.

A final example has already been described, namely the outcome of the very popular social policies implemented through drug courts. Through their higher surveillance in neighborhoods with high crime rates, police identify through arrest-accused perpetrators who have SUDs, generating higher SUD prevalence rates. Selecting from this population for participation in drug court, the process offers a somewhat "loaded" choice between prison and treatment, with those accepting the latter contributing to what might be regarded as artificially inflated data about SUD treatment use by lower SES young African American males.

RESEARCH ARTIFACTS AFFECTING THE MEASUREMENT OF HEALTH DISPARITIES

In creating assumptions about health disparities in SUD treatment, several issues in research design come to the fore as potentially problematic. First is a version of what is called the "ecological fallacy" in several different types of social science research.

The problem develops in this manner. Survey or epidemiological research may find a higher-than-normative prevalence of a certain attribute or experience among a racial, ethnic, gender, or age group. Examples might be a high rate of employment problems or a high rate of reported childhood abuse in the home committed by various family members. These findings are seen as "keys" to increasing treatment impact within a particular demographic group, and addressing these issues becomes part of a specialized treatment track designed for patients who are members of this group.

It is, however, extremely unlikely that all patients sharing a certain demographic category also share the subject attribute or experience. Indeed, it may be found in a majority of members of a given group, but sometimes the reported difference is only a statistically significant difference, which may be minimal, highlighting the importance of distinguishing between substantive and statistically significant differences. In any event, the particular version of the "ecological fallacy" occurs when it is assumed that because a person is a member of this demographic category, they have the subject attribute when in fact it is only the case that they have a higher likelihood of possessing the attribute or having the experience. A further assumption here is that patients are randomly selected into SUD treatment from a given demographic group, that is that they enter treatment with representation of the etiological traits or experiences at identical rates that they appear in the entire population of the demographic group.

When this reasoning is used to construct a treatment track or particular regimen for a demographic group, it is likely that particular interventions may be assumed to be relevant or important for people who in actuality CONCLUSION 265

have not had the subject experience or possess the subject attribute, despite their membership in the higher prevalence group. This leads to either useless administrations of the particular intervention, or possibly to damaging or insulting interventions where the patients have no connection with the problem that is being addressed.

This version of the ecological fallacy may be an argument against treatment tracks intended to address disparities. If assignment to the track is made with awareness that the design of its components may be differentially relevant to each patient and that treatment should take these differences into consideration, it may be argued that the utility of the track fades into a more effective and medically sound approach of a carefully designed individual treatment plan for each patient, regardless of their demographic memberships.

Closely related and part of this research problem is the issue of adequate sampling that is used in research. At present, there are several well-designed US national samples that include good representation of the general population but relatively few studies that provide good representation of persons in treatment for SUDs. None of these national samples is, however, adequately comprehensive to include good subsamples of all of the demographic subgroups that are believed to have inadequate access to the SUD treatment that they need. Further, the time and contact limits of data collection from individuals within large national samples prevent opportunities to conduct in-depth data collection necessary for clinical use. Thus studies with top quality clinical data often preclude adequate sampling to make generalizations that are scientifically defensible. The dilemma of in-depth data versus sound sampling is a classic double bind.

Two other problems worthy of mention are relevant to generating quality data related to health disparities are difficult for researchers to avoid. First, in the conduct of clinical trials, it is necessary to generate the "cleanest" possible data without compromising scientific quality. While it is assumed that top quality data are always generated by a randomized clinical trial (RCT) where all the scientific rules are followed, nearly all clinical trials exclude patients whose characteristics are difficult to randomize and whose presence may add hopeless contamination to the analysis of the effects of the intervention. Such characteristics often include very young or very old age, presence of psychosis, co-occurring physical illnesses, or (on occasion) having exhibited the target SUD for a very long time. As critics have pointed out, the research designs that succeed in removing these potential contaminants also succeed in removing characteristics of the real world. The end result is placing unknown limitations on the clinical utility of data since SUD treatment organizations cannot refuse to treat the patients who present themselves with the contaminants that were removed from the RCT.

Second is the manner in which culture and demographic characteristics affect the data collection processes themselves, which in the case of research on SUDs almost always involve some aspect of self-report or use of various types of agency records. Self-reports are social behaviors that have been studied extensively. Ideally, these reports are coupled with physiological measures that independently verify substance use behaviors, but this is obviously expansive, evasive, and rarely accomplished with large, representative samples. Cultural norms guide individual decisions about reporting deviant use of legal substances or uses of illegal substances. Such admissions may be seen as humiliating and shameful. Otherwise, subpopulations likely to be characterized by disparity in utilization of SUD treatment may view surveys as efforts at identification, despite repeated assurances of confidentiality. Despite explanations, respondents may not understand the purpose of surveys as anything other than surveillance. Thus, coupled with disparities in exposure to causal factors and use of treatment, the factor of disparities in reporting evidence of SUDs needs to be considered in making generalizations.

CONCLUSION

Health care disparities in the delivery of treatment for SUDs embed many complex issues that relate to overall social policy about responsibility for SUDs. While there is frustration in many quarters about the evident disparities in care for SUDs, the era in which these issues have been addressed with rationality and with an aim toward maximizing the use of scientific knowledge is actually very brief. Perhaps the starkest contrasts are found in National Prohibition about 90 years ago, and the unquestioned imprisonment of drug addicts under Federal auspices as recently as 60 years ago. Treatment for SUDs is novel to much of the public, encouraging suspicion, confusion, and doubt. Thus, while some groups urge for greater access to treatment for SUDs, others see it as unwelcome social control. It is a particularly challenging arena for research, for these health disparities are a "braid" of social facts, social values, and social policies.

SEE ALSO

Gender-Specific Treatments for Substance Use Disorders, Criminal Justice Interventions, Health Care Reforms and Treatment for Substance Use Disorders,

Ethical Issues in the Treatment of Drug Dependence, Improving Medication Use in Addictions Treatment

List of Abbreviations

AA Alcoholics AnonymousACA Affordable Care Act of 2010

DATA Drug Addiction Treatment Amendment

KISS Keep It Simple, Stupid NA Narcotics Anonymous

NIAAA National Institute on Alcohol Abuse and Alcoholism

NIH National Institutes of Health RCT randomized clinical trial SES socioeconomic status SUD substance use disorder

Glossary

- **Epidemiology** the science concerned with the study of the factors determining and influencing the frequency and distribution of disease, injury, and other health-related events and their causes in a defined human population.
- **Health care disparities** persistent differences between groups in one or more measurable dimensions of accessing, receiving, or utilization of a certain type of health care service.
- **Health disparities** persistent differences between groups in one or more measurable dimensions of health status.
- **Medication-assisted treatment** addiction treatment involving a combination of medications designed to curb target substance use coupled with ongoing counseling focused on psychosocial adjustment.
- Randomized clinical trial a clinical study where volunteer participants with comparable characteristics are randomly assigned to different test groups to compare the efficacy of therapies.

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A Decade of Research on Recovery Management Checkups

Christy K. Scott, Michael L. Dennis, Belinda Willis, Lisa Nicholson Chestnut Health Systems, Chicago, IL, USA

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MANAGING ADDICTION AS A CHRONIC CONDITION

There is now consensus among substance abuse treatment researchers that addiction to alcohol and drugs constitute a chronic condition. Moreover, there is increasing agreement that if substance abuse treatment is to be practical and effective, health care policymakers and professionals must manage addiction with a clear understanding of its chronicity. Numerous retrospective and prospective treatment studies make a strong case for a shift in perspective and protocols. For example, Dennis, Scott, and colleagues recently found that the median time from first use to a year of abstinence was 27 years, and the median time from first treatment to a year of abstinence was 9 years with 3–4 treatment episodes.

To enhance understanding on the issues facing the treatment community as well as the concerns of the larger community of health care policymakers, Scott and colleagues looked at the frequency and direction of transitions between points in the relapse, treatment

reentry, and the recovery cycle over 2 years. They found that approximately 33% of individuals moved from one point in the cycle to another during each quarter; 82% transitioned at least once and 62% transitioned multiple times. In addition, it was clear that prolonged, complex service histories were especially prevalent when addiction was accompanied by one or more psychiatric or social pathologies. The remaining key question then is: what new and innovative treatment protocols are needed to manage drug and alcohol addiction, a clearly chronic condition?

Addiction is protracted like other chronic conditions such as mental illness, hypertension, diabetes, and congestive heart failure. And like these conditions, addiction can also be arrested, but, when relapse occurs, it is frequently severe despite acute episodes of stabilization. How can a health care system intelligently accommodate these often dramatic ebbs and flow cycles of addiction? Or perhaps more to the point, have those responsible for national health care policy faced the realities of addiction as a chronic condition? Have they

accepted the fact that the majority of persons leaving treatment will resume alcohol and drug use in the first year following treatment, most within the first 30–90 days? Have they admitted that a single episode of treatment will not likely result in immediate and long lasting positive outcomes? And have they acknowledged that by all practical measures, the widely used acute care model of treatment for individuals suffering from chronic substance use is inadequate?

Not only is acceptance of the chronicity of addiction vital for substance abuse treatment to evolve effectively, the institutionalization of new protocols is logical and necessary. Managing chronic conditions as such has reduced their severity and progression. In a recent review of 22 continuing care studies (conducted in Hong Kong, Sweden, Taiwan, and the United States), only 38% of these studies lasting for 3 months or less produced positive findings. In contrast, 100% of the studies lasting for more than 12 months produced positive results. Effective interventions were also characterized as being more "assertive" with regard to (1) contacting patients, (2) flexible scheduling/placement to accommodate patient choice, and (3) including recovery support services (including self-help). Kristenson and colleagues experimented with the use of quarterly checkups for up to 4 years as part of physician visits in Sweden. Participants who received such checkups reported fewer days of being sick and fewer hospital days in the first 6 years and had lower mortality rates over the 10–16 years.

EVOLUTION OF THE RECOVERY MANAGEMENT CHECKUP MODEL

Building on both general chronic care models and addiction specific studies, Scott and Dennis developed a recovery management checkup model (RMC) to effectively support the management of addiction as a chronic condition marked by cycles of recovery, relapse, and repeated treatments. The core assumption underlying this work is that long-term monitoring through regular checkups and early re-intervention will facilitate early detection of relapse, reduce the time to treatment reentry, and consequently improve long-term participant outcomes. The original objectives of the RMC manual-guided protocol were to (1) provide ongoing monitoring, (2) identify individuals who had relapsed or were at risk of relapsing, (3) link them to treatment, and, consequently, (4) reduce substance use and substance-related problems.

Over the past decade this model has been modified and tested in three clinical trials involving 1355 men and women. In all three trials, participants were randomly assigned to either a control group (assessment only) or the RMC condition. In the first two trials, men and women were recruited at the largest substance abuse treatment provider in Illinois, and in the third trial, women offenders were recruited at the largest single site country jail in the United States. The evolution over the past decade of each of the major components of the RMC model and related outcomes is discussed in the upcoming sections.

Monitoring

When considering ways to implement monitoring and early re-intervention as a mechanism for managing addiction, characteristics of the condition posed significant and unique challenges. For example, the transient, chaotic, and clandestine lifestyle that accompanies addiction often results in physical and social mobility, which often leads to residential instability and, thus, makes it difficult to provide ongoing monitoring. Furthermore, the nature of substance-abusing lifestyles contributes not only to unstable living arrangements, but also often to alienation from friends and family members. A common feature of programs designed to help manage other chronic medical conditions is to garner the support of friends and family to help manage the patient's condition; however, the social isolation that often accompanies years of substance use may prohibit this approach. The high rates of multimorbidity such as homelessness, acute psychiatric illness, and criminal justice involvement concomitant with substance abuse also presented significant barriers to successful monitoring of the condition over time. Through the mid-1990s, studies in the addiction field suffered from such high attrition rates that the feasibility of providing ongoing monitoring with this population was questionable.

In the mid-1990s, as part of two earlier studies, Scott developed and demonstrated a proactive method to address the challenges of monitoring individuals with substance use disorders; indeed, this work ushered in the feasibility of a new approach that would reliably achieve 90%, or higher, follow-up, regardless of client characteristics and level of care. This standardized proactive set of procedures was used to (1) maintain contact with participants regardless of high rates of mobility, (2) quickly detect when locating information was no longer accurate, and (3) provide adequate time to relocate participants prior to the interview date. At the same time these procedures relied on the most efficient and cost-effective strategies.

Participants were interviewed quarterly for 2 years in the first study and quarterly for 4 years in the second study. In the third study, women offenders were interviewed upon admission and release from jail, 30, 60, and 90 days post release and quarterly thereafter for 3 years. As shown in Table 28.1, quarterly follow-up rates

TABLE 28.1 Comparison of RMC Condition by Study

	Early re-intervention experiment 1 (ERI-1)	Early re-intervention experiment 2 (ERI-2)	Recovery management checkups for women offenders (RMCWO)
Total sample size (RMC only)	N = 448 (RMC n = 224)	$N = 446 \text{ (RMC } n = 223)^*$	$N = 480 \text{ (RMC } n = 238)^{**}$
Dates	2/2000-3/2002	2/2004-5/2009	8/2008-3/2013
Design	Random assignment to RMC versus control	Random assignment to RMC versus control	Random assignment to RMC versus control
Interview assessment waves	Treatment intake and quarterly for 2 years (91–96% per wave)	Treatment intake and quarterly for 4 years + 5 year follow-up (93–97% per wave)	Jail entry, release month for 90 days post release and then quarterly for 3 years post release (90–95% per wave)**
Biological testing	On-site saliva and offsite urine*** at 12 and 24 months post intake interviews	On-site urine*** with proactive probing quarterly post intake interviews; HIV testing at intake and 5 years later	On-site urine*** with proactive probing at monthly and quarterly post intake interviews; HIV testing at release and 3 years post release
Linkage meeting using motivational interviewing, scheduling, and case management	Yes	Yes	Yes
Transportation and staying through intake	Starting after 9 months as needed	As needed from beginning	As needed from beginning
Treatment engagement specialist	No	Yes	Yes
HIV intervention	No	No	Monthly interventions for 90 days and boosters quarterly as needed for 3 years
Crime reduction intervention	No	No	At the time of the monthly and quarterly post intake interviews
Further reading	Dennis et al. 2003; Scott et al. 2005, 2009, 2010	Scott and Dennis 2009, 2010; Dennis and Scott, in press	Scott and Dennis, under review

^{*} Data only used through year 2 to facilitate comparisons.

for all waves across all three studies exceeded 90%, clearly demonstrating the feasibility of providing quarterly monitoring with individuals who have chronic substance use disorders.

Assessment and Linkage to Substance Abuse Treatment

A modified version of the GAIN was administered quarterly to identify individuals who had relapsed or felt they needed treatment. For those individuals who were also assigned to the RMC condition, a linkage manager used motivational interviewing (MI) techniques to provide personalized feedback to participants on the status of their condition and related problems, help participants resolve their ambivalence about their dependence and move toward a commitment to change

by accessing additional care, address existing barriers to treatment, and schedule an assessment and facilitate reentry (reminder calls, transportation). MI is an effective evidence-based method for resolving the ambivalence that prevents many individuals from making desired changes in their lives. For individuals who refused treatment, an "alternative plan" was developed that included various activities that the individuals agreed to engage in to reduce or stop substance use. Some of the activities included in the "alternative plans" are attending 12-step meetings, going to church, and reconnecting with former friends and family in recovery.

Results from the first clinical trial indicated that RMC participants were significantly more likely than those in the control condition to return to treatment, to return to treatment sooner, and to spend more subsequent days in treatment. RMC participants also experienced

^{**} Follow-up still in progress at the time of this chapter; follow-up rates here and results in the next table are based on the 262 interviewed at 24 months by July 12, 2011 (129 assigned to RMCWO).

^{***} Saliva and/or urine only attempted for interviews done in research offices; they were completed on over 90% of those (which is over 80% of all interviews).

significantly fewer total quarters in need of substance abuse treatment and were less likely to still be in need of treatment 2 years after intake.

While the intervention was successful in the first clinical trial, it required quarterly checkups over 12 months to significantly improve treatment participation and quarterly checkups over 24 months to improve subsequent participant outcomes. In an effort to reduce this timeline and expedite the impact of the intervention for participants, implementation data from the first clinical trial were used to identify modifications to the original RMC protocol. Data indicated that providing transportation to clients for their treatment intake appointment increased show rates. Therefore, offering transportation was incorporated as a required component for the second and third studies. Treatment intake completion rates increased to 42% in the second clinical trial. In the third clinical trial, which is only at the midpoint of data collection, the rate averaged 28% over 24 months, but varied from 54% at the time of release to 37% at 3 months post release to 21% at 24 months.

Another challenge identified in the first study was the low treatment retention rate; in the first trial, only 39% of the people who accessed treatment stayed 14 days or more, and participants who stayed 14 days or more demonstrated better outcomes. To address this low rate, a highly specified treatment engagement and

retention protocol was implemented in studies 2 and 3. The protocol included a specific telephone and face-to-face contact schedule, and an agreement between treatment and research staff that the linkage manager would have the opportunity to intervene with participants who wanted to leave treatment or that staff wanted to ask to leave treatment prematurely. Treatment retention rates increased in the next two trials.

Average Effect on Treatment Utilization and Substance Use

Table 28.2 shows the average effect of RMC compared to the control group in the first two clinical trials after 24 months. RMC participants were significantly more likely than those in the control group to return to treatment sooner and there were increases in the percentage of individuals who ever reentered treatment and the number of days of treatment they received over 2 years. Results are similar in the third clinical trial at 24 months, but data collection is less than half completed at this writing and, therefore, results are considered preliminary.

Table 28.2 also summarizes the impact of RMC on substance use. In the first two studies, RMC was associated with more days of abstinence than the control over 24 months and at the 24-month observation, though it

TABLE 28.2 Outcomes by Experiment

		ERI-1 (months 4-24)			ER	ERI-2 (months 4-24)		
Outcome variable	Good is	Control	RMC	d	Control	RMC	d	
N per condition		224	221		216	218		
Between months 4 and 24 (630	days)							
Months to reenter treatment**	Up	21	13	0.22*	21	10	0.43*	
Reentered treatment by month 24	Up	51%	60%	0.21*	37%	55%	0.40*	
Total days of treatment	Up	40	63	0.27*	36	53	0.23*	
Total days of abstinence	Up	490	497	0.04	430	480	0.29*	
No. of Successive quarters of Unmet need for treatment	Down	2.31	1.86	(0.19)*	3.41	2.59	(0.32)*	
At 24-month interview								
Days of abstinence (out of 90)	Up	72	71	(0.05)	61	68	0.23*	
In need of treatment at last wave	Down	44%	34%	(0.21)*	57%	46%	(0.24)*	

^{*} Based on those completed through December 7, 2011.

Bold = $d \ge 2$, *P < 0.05.

^{**} Control based on maximum months over follow-up time at 24-month observation (between 3 and 24 months for ERI 1 and 2); RMC based on how long it took the experimental group to get to the same place.

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only reached significance in the second clinical trial. As noted above, the theory behind RMC is that proactive monitoring and early re-intervention will reduce the time someone stays in the community in need of treatment. As shown in Table 28.2, RMC was associated with significantly reducing the successive number of quarters used in the community in the first clinical trial (2.31-1.86=0.44 quarters) and in the second clinical trial (3.41-2.59=0.82 quarters) RMC participants were also significantly less likely to be in need of treatment at 24 months. Once again, preliminary data from the third trial demonstrate a similar trend for each of these measures.

HIV and Crime Assessment and Intervention

As discussed earlier, the core assumption underlying the model tested in these studies is that long-term monitoring through regular checkups and early re-intervention will facilitate early detection of relapse to substance use, reduce the time to substance abuse treatment reentry, and consequently reduce long-term substance use. These were primary outcomes for studies 1, 2, and 3. However, the third clinical trial involved women offenders with not only substance use disorders but also high rates of HIV risk behavior and high risk for recidivism to the criminal justice system. In order to address these challenges, the RMC model was accordingly expanded to include an intervention designed to reduce HIV risk behavior and criminal justice involvement. To that end, as part of the monthly (30, 60, and 90 days post release) linkage meetings, linkage managers provided a modified women-focused HIV risk reduction intervention, which comprised (1) assessment and feedback on HIV behavior, HIV knowledge, and condom self-efficacy, (2) assistance in understanding related health conditions, (3) health promotion skills (assertiveness and communications, self-empowerment, avoiding violence), and (4) HIV risk reduction materials (HIV treatment referrals, male and female condoms). Thereafter, a booster session was provided quarterly on an "as needed" basis. The booster session provided the same information as the monthly sessions and was conducted when any unprotected sex, multiple sex partners, sex trading, or needle use was reported.

In order to reduce recidivism to the criminal justice system, RMC linkage managers discussed any illegal activity reported in the previous 30 days. Furthermore, a risk reduction plan was developed that outlined several techniques to avoid future illegal activity (i.e. avoiding certain neighborhoods, avoiding persons committing crimes, and thinking through the consequences).

After the first 90 days post release meeting, preliminary data indicate that the RMC condition was

associated with significantly more accurate answers on a test of HIV knowledge. At 24 months women in the RMC condition were significantly more likely to use condoms and demonstrated a trend toward fewer sexual partners. At 24 months women in the RMC condition also reported significantly lower scores on the GAIN's illegal activity scale, which is a measure based on the days of illegal activity, illegal activity for money, and illegal activity to secure alcohol or other drugs. It also measures whether or not these activities took place under the influence of alcohol or other drugs. These preliminary results show that RMC may be effective in addressing not only substance use disorders in women offenders but may also be helpful in reducing rates of HIV risk behavior and illegal activity.

DISCUSSION

Over the past decade, the RMC model has been modified and tested in three clinical trials. Components of the RMC model were designed to address the duration and cyclical nature of dependence via quarterly monitoring and linkage to treatment. These regular checkups provided a proactive approach to help participants learn to identify symptoms and resolve their ambivalence about their substance use, to offer the opportunity for multiple episodes of care in the context of chronic care management, and to include an engagement and retention component to retain participants in treatment. Results from each of these three clinical trials demonstrate the feasibility of using ongoing monitoring and early intervention as a mechanism for addressing the cyclical nature of addiction.

These studies demonstrated the feasibility of implementing quarterly monitoring and recovery management checkups as well as determining the impact on participant outcomes 2 years after the initial treatment episode. However, while the intervention was successful, it required 24 months to impact participant outcomes, and only 39% of those who accessed treatment stayed for 14 days or more. The second clinical trial improved upon the first by adding two important modifications to the original design: transportation to treatment assessments was incorporated as a required component and an engagement and retention protocol was implemented. Data from second clinical trial provided evidence regarding the feasibility of replicating the RMC model and improving its implementation. Data from the third clinical trial, while preliminary provides evidence regarding the feasibility of replicating the RMC model in a very different population and context, as well as expanding its focus to include the consideration of HIV risk behaviors and criminal activity. In all three clinical trials, high follow-up rates and high participant agreement to return to treatment were achieved.

Relative to the first clinical trial, participants in the second clinical trial were more likely to attend the linkage meetings, complete the assessment, access treatment, and remain in treatment for at least 14 days. In the third clinical trial, the preliminary findings are promising and also show an increase in condom use and a decrease in the reported number of sexual partners, as well as less involvement in illegal activity.

Results also indicate that the modifications to the RMC model likely contributed to more participants returning to treatment sooner and staying in treatment longer, thus improving participant outcomes. It is also consistent with continuing care research that longer term and more assertive monitoring can improve outcomes. Thus, the clinically significant reduction in the successive quarters of unmet need for treatment shown in these clinical trials demonstrates the effectiveness of RMC for managing dependence over time. Preliminary finding also suggest that RMC can be effective at addressing other areas such as HIV risk behaviors and involvement in criminal activity.

STRENGTHS AND LIMITATIONS

These three studies have numerous strengths: random assignment, sample sizes, repeated observations, high follow-up rates, detailed measurement, randomization, and replication across three cohorts. However, it is also important to note the limitations. First, comparisons between studies are based on cohorts that differ in setting (treatment versus jail) and years of recruitment (recruited in 2000–2004 versus 2008–2010) and are hence quasi-experimental at their best in nature. Second, for logistical reasons, recruitment for each study was limited to a single site, with predominately African American inner city participants who had high rates of co-occurring mental disorders, homelessness, and criminal justice system involvement. In the future, it would be useful to replicate this work with a more representative sample of the US public treatment and/or justice system, in other countries and/or less severe clinical samples.

IMPLICATIONS

Addiction like other chronic conditions is often marked by cycles of relapse, multiple treatment episodes, and intermittent periods of abstinence over many years before reaching sustained recovery. Results from the three RMC clinical trials provide evidence that ongoing monitoring, feedback, and early re-

intervention can be effective methods of managing recovery over time. Ideally, such services would be paid for and become a requirement for treatment program licensure, accreditation, and funding. Those requirements would be best linked to a larger strategy of reorienting addiction treatment from a predominantly acute care model of intervention to a service model that provides services ranging from a brief intervention to long-term recovery management. However, the implications of shifting to a chronic care model are significant. That shift will require a radical redefinition of the continuum of care, new service philosophies, new service delivery technologies, and a fundamental rethinking of systems of reimbursement for addiction treatment and recovery support services.

The shift will also require various stakeholders to address a number of critical issues. The first relates to the manner in which posttreatment monitoring, support, and early re-intervention services can be integrated into the current continuum of care. A second issue is how to make these services accessible to all participants who enter treatment with high problem severity, complexity, and chronicity.

Another critical issue is where (organizationally speaking) and by whom these posttreatment recovery support services will be best delivered. The data supporting RMC have been generated by services provided by clinical and nonclinical staff employed within a research organization. Additional research is needed to determine if the effectiveness of such services differs across types of organizations, or differs based on whether they are delivered by clinical or nonclinical staff. Regardless of who ultimately delivers posttreatment recovery support services, considerable thought will need to be given to the recruitment, orientation, training, and supervision of individuals performing these functions. Experience to date also suggests the need for a substantial investment in articulating the ethics and etiquette of conducting RMC across diverse clinical populations and cultural contexts.

An important step in moving forward will be to estimate the costs associated with ongoing monitoring and early re-intervention. It may be that RMC will cost more than standard care (significantly more days of treatment by the RMC participants translates into higher costs for this group, at least for treatment provision in the short term). Though the results demonstrate the efficacy of RMC, cost offset (not just cost) data is also important as it is much more likely that a program would choose to adopt RMC if it not only led to better outcomes, but also could be shown to reduce subsequent costs. Other steps might include (1) testing the model with different populations such as pregnant and postpartum women, male and female offenders leaving jail or prison, or adolescents, (2) determining when a participant can be

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transitioned from quarterly to biannual checkups based on need, (3) determining whether more frequent or even continuous monitoring would improve outcomes; and (4) testing the impact of linkages to less formalized types of care such as recovery coaches or faith-based interventions.

Whatever direction the treatment system decides to move in implementing posttreatment care, it is clear that RMC, by providing ongoing monitoring, feedback, and early intervention, is an effective way of managing chronic addiction and recovery over time. The second trial improved over the first by adding transportation to treatment and a more proactive approach to maintaining participants in treatment resulting in better outcomes. So far, the third trial has demonstrated the feasibility of providing RMC to a different population (incarcerated women) and also demonstrated that RMC could effectively address other areas of concern such as HIV risk behaviors and criminal activity. The results of these three clinical trials indicate that the RMC model contributes to participants returning to treatment sooner and staying in treatment longer, thus having better outcomes.

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List of Abbreviations

GAIN Global Appraisal of Individual Needs

MI motivational interviewing RMC recovery management checkup

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Technology-Delivered Treatments for Substance Use Disorders: Current Status and Future Directions

Warren K. Bickel*, Lisa A. Marsch^{\$}, Alan J. Budney[#]

*Addiction Recovery Research Center, Virginia Tech Carilion Research Institute, Roanoke, VA, USA *Center for Technology and Behavioral Health, Dartmouth Psychiatric Research Center, Department of Psychiatry, Geisel School of Medicine at Dartmouth, Lebanon, NH, USA *Geisel School of Medicine at Dartmouth, Lebanon, NH, USA

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INTRODUCTION

A technology-delivered treatment is any intervention based on or assisted by a technological "media that enables users to access information and services of interest, control how the information is presented, and respond to information and messages in the mediated environment (e.g. answer questions, send a message, take an action in a game, receive feedback, or make a response to previous actions)" (Street and Rimal, 1997, p. 2). In this chapter, we review the current status and postulate future directions of technology-delivered treatments for substance use disorders. In our view, at least three contextual factors enhance the opportunity, importance, and timeliness of the use of such interventions for substance use disorders.

First, the revolution underway in information technology (e.g. computer and telecommunications technology) is expanding in scope and reach. Wireless technologies including smartphones, tablet computers, and wireless local areas networks are making computer and Internet use much more accessible and affordable. Increasingly, information technology is weaving its way into the daily lives of many and influencing everything from commerce to international policy. Information technology is also bringing about great changes in the health care system through the use of distance medicine approaches. Indeed, telemedicine renders distance an irrelevant feature of the health care experience by permitting the utilization of medical expertise at a central site to address a variety of health care challenges at remote locations. These advances are highly welcome, given that difficulty in accessing state of the art or specialty care can result in failure to obtain effective treatment for disease processes while they are still tractable. In the field of addiction, however, opportunities for optimally utilizing technology have only begun to be explored and are a long way from being fully realized.

Second, an important ongoing context for the field of addiction treatment is the current worldwide recession. Indeed, at the time of the writing of this chapter, the world is reeling from the worst recession since the Great Depression. As a consequence of the economic downturn, various communities throughout the United States are making decisions to limit or decrease various services, taking actions ranging from closing schools to not illuminating streetlights. At the same time, the demand for drug abuse treatment remains high and may be increasing, partly as a result of the recession, while only a fraction of those with substance use disorders are able to access treatment. Thus, if we wish to have a large impact on access to treatment, we will have to reconsider our current treatment models and explore innovative approaches to increase treatment access in a cost-effective manner.

Third, the health of the drug abuse treatment system is less than optimal and faces many challenges. These challenges, in addition to insufficient services to meet demand, include difficulty in recruiting and retaining providers of service, limited treatment financing, and a slow adoption of research-based innovations. And even with optimal interventions, treatment response remains limited, with many clinical studies resulting in only a small percentage of patients showing consistent improvements. Moreover, treatment staff turnover may result from a variety of conditions that produce 'burnout,' including the limited therapeutic outcome among their patients and the repetitive nature of much of the therapy offered in such settings. Lastly, the therapies provided by counselors and therapists often are not evidence-based, and when evidenced-based treatment is provided, more recent scientific advances are not readily integrated into those treatments.

The nexus of these contextual factors, and their associated opportunities and challenges, provides a novel space for reframing and reconsidering how substance abuse treatment is delivered. In that space, we can consider innovative means to deliver treatment in ways that take advantage of the advances in information technology, while recognizing the limitations of resources for, and the challenges associated with, current substance abuse treatment. Exploring that emerging opportunity is fundamentally what this chapter is about. In that exploration, we address five topic areas: (1) the logic of technology-delivered treatment, (2) early efforts to apply information technology

in the field of addiction as well as other fields, (3) the current status of technology-delivered treatment, (4) novel content for technology-delivered treatment, and (5) an extrapolation of the future of new technological developments and the opportunities they afford for treatment delivery.

THE LOGIC AND POTENTIAL BENEFITS OF TECHNOLOGY-DELIVERED TREATMENT (TDT)

The assumptions undergirding the use of technologydelivered treatment (TDT) derive from and are supported by efforts in the substance abuse treatment field to develop instruction manuals for ('manualize') specific evidence-based treatment approaches. These manuals codify the specific content and sequence of content necessary for achieving therapeutic outcomes. The original goal of these manuals was to permit systematic replication of new therapies and facilitate treatment adoption. The specificity of these manuals provides the opportunity to reconsider the means of delivery of these treatments. If they can be manualized, then in principle, they can be computerized and delivered via the Internet or other information technology. Additionally, the use of information technology allows for the incorporation of important methods that can be employed to demonstrate, illustrate, and support the acquisition of therapeutically important skills and knowledge (e.g. fluency training, scenario planning, video clips to model specific behavior).

The benefits of TDT are severalfold. Some of these benefits are of greatest importance to the providers or payers of care, some are most applicable for patients, while still others are relevant for both groups.

Starting with the providers and/or payers of treatment, technology-delivered treatment provide several substantial benefits. First, the most expensive components of delivering substance abuse treatment result from the cost associated with the personnel who deliver the treatment. Delivery of treatment via informational technologies has the potential to dramatically lower costs even in hybrid models where therapists also participate and monitor the use of technology-based treatment.

Second, another concern for the payer of treatment is the extent to which evidence-based treatments are being conducted and delivered with fidelity. Treatments provided without being faithful to intended procedures render the treatment as not evidence-based and likely less efficacious. The use of these technologies to deliver treatment ensures that treatment delivery is consistent and conducted with fidelity.

Third, in our current system, retooling treatment delivery to incorporate recent advances in the science of treatment can be a long and expensive task, requiring treatment programs to adopt new practices and providers to obtain suitable training and practice. On the other hand, when information technology is used to provide treatment, new information can be incorporated easily and exported quickly. This is particularly true when technology-delivered interventions are webbased, such that updates in program content can be incorporated centrally and made readily and concurrently available to all end users. Thus, technology-based delivery has the potential to rapidly and continuously innovate contemporary treatment models with the latest scientific advances and in essence would permit continual improvement of the treatment system. Indeed, this delivery mechanism may provide a means to provider adoption of science-based enhance interventions.

Fourth, exporting treatments to new, sometimes remote areas remains another challenge for the substance abuse treatment community. Treatment delivered via information technology can be exported easily to the places where it is needed, especially in light of rapidly expanding communication infrastructures.

Next, let us consider the benefits for patients receiving care delivered via information technology. First, one challenge in delivering treatment in any setting is that of ensuring access. Delays to treatment entry can result from either waiting lists or challenges of getting transportation to the treatment facilities. In principle, treatments delivered via a mobile device or a computer can be immediately available and accessible without effortful or long commutes.

Second, discussing sensitive issues of addiction and other topics such as HIV status may render the process of therapy very challenging if not highly threatening to some patients. Several studies have demonstrated that the use of information technology as the means of treatment delivery results in more accurate reporting of sensitive information from the patient and may be perceived as less threatening. In one study regarding HIV education, a significantly greater percent of opioid-dependent patients were interested in receiving additional HIV services after receiving a computer-based HIV education intervention compared to patients enrolled in a therapist-delivered HIV education intervention (Marsch and Bickel, 2004).

Third, the typical provision of treatment is restricted by the counselor's schedule (during fixed office hours, typically on week days) and therefore may not correspond with the availability of potential patients, who may be engaged in other activities such as employment. The use of information technology to deliver treatments provides the opportunity for patients to receive therapy at times that are convenient for them regardless of the time of day. In principle, treatment via the Internet could be available on a 24-hour/7 days per week basis.

Several benefits of TDT are relevant to all groups: providers/payers of treatment and patients. For example, computerized therapy, when properly delivered, requires active responding by the patient to demonstrate that they are acquiring relevant information. No doubt effective counselors/therapists require patient participation, but technology-based programs will do so consistently, regardless of external demands, and minor or major challenges in life. Therefore, technology-based programs benefit the patient by building their skills and knowledge base and providers as well as payers of treatment who are assured that clinically important information/skills are acquired.

Another joint benefit of TDT is that they can be constructed so as to tailor or customize the treatment (see Current Status section below). Therapy provided via information technology often can be customized based on the current circumstances of the patient. Again, highly skilled therapists can and do customize treatment. However, computerized therapy can serve to provide evidence-based approaches tailored to the individualized needs of patients. In addition, use of computer-generated speech technology can accommodate illiterate patients in a fashion similar to therapists. Finally, computer-based interventions may allow patients to engage in therapeutic activities for a greater period of time than would be possible with a therapist alone, review repetitive but necessary skills training, and complete therapeutic tasks that the therapist may find uninteresting or repetitive.

Early Efforts to Use TDT for Addiction and Other Disorders

The opportunities associated with the use of information technology for behavior change were recognized early on by several innovators. These researchers used information technology across several different platforms or technological devices, including desktop computers, email, hand-held devices, telephone-accessed computer systems, video-disk training, and virtual reality (VR) systems. The disorders for which computers have been employed to provide treatment or promote health behaviors include Alzheimer's, arthritis, asthma, anxiety, depression, diabetes, heart disease, HIV, and hypertension.

We begin here with a brief example of this early work from the anxiety and depression literature that was in large part this start of the TDT approach reviewed here. Early implementation of information technology to target these disorders may have resulted from the early adoption and use of treatment manuals for these disorders. As noted earlier, manuals that specify the use of certain sequences of procedures are potentially easily adapted via information technology approaches for delivery to the patient. For example, computer programs have successfully implemented certain behavioral therapy techniques consisting of very specific components such as cognitive restructuring, relaxation training, systematic desensitization, and self-exposure treatment.

In these early applications of computerized behavioral treatments, comparable results were generally observed between the computer-delivered and therapist-delivered treatments. For example, in a 1990 study by Selmi et al., depressed patients were randomly assigned to receive either computer-delivered, cognitive behavioral therapy (CBT), therapist-delivered CBT, or were placed on a waiting-list (control). Both active treatments significantly reduced depression relative to the control group at the end of treatment and at a 2-month follow-up. The two treated groups did not differ from each other. Additionally, 50% of the computer group and 42% of the therapist group were improved at the end of treatment, while only 17% of the controls showed improvement. Thus, both active treatments demonstrated efficacy in this study, but the computer- and therapistdelivered treatments were almost equally efficacious.

Although in these early applications computer- and therapist-delivered treatments appear to not differ dramatically in their efficacy, they did differ in terms of the cost of treatment. That is, a computer-based treatment can be used numerous times with most of its expense associated with the one-time purchase of hardware and software, while the cost of the therapist-delivered treatment is a fixed cost per use (i.e. therapist salary). In a 1997 study by Newman et al. examining this issue, the cost of a computer-based treatment for panic disorder was estimated to have saved \$540 per patient or 32% relative to a therapist-delivered treatment for panic disorder.

In summary, the early use of information technology to deliver treatment in anxiety and depressive disorders (the first researched area of computer-delivered therapy) suggests that such technological approaches to therapy are generally as effective as counselor-based treatment while being less costly.

Treatment of Substance Use Disorders

Information technology was used to assess and treat substance abuse disorders in several early efforts. A considerable focus of this research was on the computerized assessment of substance use and the computerization of interviews and questionnaires. Comparisons of these computerized assessments with more traditional methods have found them to be acceptable to patients.

For example, Skinner and Allen (1983) asked substance abusing patients to rate computer-based, face-to-face, and self-report assessments. Patients rated the computer-based assessments more favorably than face-to-face interviews or self-report on several dimensions (i.e. the computer assessment was rated as more relaxing, more interesting, faster, and shorter). No differences in rates of substance abuse were reported across the three methods. Other studies have found increased reporting of sensitive thoughts, symptoms, or behaviors via the use of computer-based assessments. Validation studies conducted with other populations confirm that computer assessment is reliable, valid, and equivalent to clinician-administered scales.

A few trials have been conducted to examine the use of computer-delivered therapy for substance abuse. Studies related to smoking treatment have successfully used computer-generated personalized messages and feedback to promote smoking cessation, encourage movement of smokers along the stages of change, or promote nicotine fading procedures; however, these studies were either not controlled trials or patients in these trials generally did not interact with information technology on a regular basis to receive some aspect of therapy (e.g. patients generally received a computer-generated, personalized letter or report based on their self-reported smoking status).

During this early period of application of information technology, to our knowledge only three controlled clinical trials examined the efficacy of interactive computerdelivered therapy for substance abuse. The first study, by Schneider et al. (1990), used the CompuServe computer network to provide an interactive behavioral smoking cessation program. There were four treatment groups: (1) full computer-based smoking cessation program with a stop-smoking online forum, (2) the full program without the online forum, (3) a sham program with the online forum, and (4) a sham program without the online forum. The 1158 participants were randomly dispersed between treatment groups. The individuals receiving the full program achieved significantly better abstinence rates at 1- and 3-month followups relative to those receiving the control treatment, irrespective of the online forum. However, overall utilization of these resources was poor, and there was no difference between the groups at the 6-month follow-up.

The second controlled study of interactive therapy, referred to as the Drinkers Check-up, was from a line of research conducted by Hester and colleagues. In the first experiment (1997) in the series, 40 heavy drinkers were randomly assigned to receive a computerized version of a behavioral self-control training program either immediately after pretreatment assessment or after a 10-week waiting period. Compared to the

pretreatment drinking levels of both the experimental treatment group (35.2 drinks) and the delayed treatment group (34.3 drinks), patients in the experimental group who received the computer-based intervention reduced their drinking significantly to between 13.8 and 14.5 drinks per week. Importantly, once the delayed treatment group received treatment, they also significantly reduced their drinking from 34 drinks during baseline to 20.8 standard drinks. These effects were long-lasting, with treatment gains maintained over a 12-month follow-up period. These investigators replicated these results using a motivational treatment approach.

In a third controlled study of TDT in the substance abuse population, conducted by Marsch and Bickel (2004), computer-delivered HIV/AIDS education was compared to therapist-delivered HIV/AIDS education among opioid-dependent, injection drug users (IDUs) receiving buprenorphine treatment. Thirty participants were randomly assigned to one of the two conditions (15 per condition). In the computer-based training, IDUs received computer-based HIV/AIDS education using a computer-assisted instruction (CAI) that incorporates a fluency-building engine. Fluency-building technology requires the user to develop a predetermined level of accuracy and speed in responding during an active learning process. As a result, the interactive program can be adjusted based on a given user's level of responding. Indeed, fluency-based programs have been demonstrated to promote mastery of a specific content area and improve both short- and long-term retention of the material. Additionally, the computerized fluency-building program provided performance feedback and remediation for errors. IDUs in the counselor-based training condition received HIV/AIDS education in the context of one or more counseling sessions with a trained, masters-level substance abuse therapist and viewed a videotape on drugs and AIDS. Patients who received computer-based instruction learned significantly more information and retained significantly more of that information at a 3-month follow-up, a finding attributed to the fluency-building component of the computer intervention. Participants in the computer-based training condition liked the teaching medium significantly more than those in the therapist-delivered program. Also, at the end of treatment, patients were asked if they would like to receive more information about AIDS, including HIV/AIDS pamphlets and information on being tested for HIV. Significantly more (approximately 80%) patients receiving the computer-based training requested such information while considerably fewer (approximately 20%) of those receiving the therapist-based training requested that information. Both groups of patients exhibited significant reductions in HIV-risk behavior, with no differences between groups observed on this outcome measure. This study demonstrated that computer-based HIV/AIDS education may constitute an effective, systematic intervention that is attractive to IDUs and cost-effective.

CURRENT STATUS OF TDT FOR SUBSTANCE ABUSE

The use of technology for treating substance use disorders is increasingly being recognized in the research community and among funders of research as offering great potential, and the number of research projects in this area has been rising in recent years.

Evidence-Based Behavioral Therapies for Treating Substance Use Disorders

At least four evidence-based behavioral therapies for individuals with substance use disorders have recently been computerized and demonstrated to be efficacious.

First, there is the Therapeutic Education System (TES), an interactive, self-directed, web-based version of the evidence-based psychosocial intervention rooted in the community reinforcement approach (CRA). TES includes over 65 interactive, multimedia modules, including some focused on basic cognitive behavioral relapse prevention skills (e.g. drug refusal skills, managing thoughts about drug use, conducting functional analyses, and self-management planning); some related to the prevention of HIV, hepatitis, and sexually transmitted infections; and others that teach skills that may help improve psychosocial functioning (e.g. employment status, family/social relations, financial management, communication skills, decision-making skills, management of negative moods, time management, and recreational activities). The evidence-based content in TES is provided using informational technology. Specifically, TES uses fluency-based CAI, grounded in the fluency teaching approach to continually assess (via interactive quizzes) a patient's grasp of the material and adjust the pace and level of repetition of material in order to promote mastery of the skills and information being taught. TES also creates an experiential learning environment via the use of interactive videos of actors modeling various behaviors in order for the program user to better learn the modeled behavior (e.g. progressive muscle relaxation, drug refusal skills). It employs a variety of interactive exercises to enhance learning (e.g. graphics and animation) and personalize content for participants (e.g. personalized functional analysis). Further, TES can optionally include a flexible system for tracking and reinforcing target behaviors (e.g. abstinence) and monitoring earnings via evidence-based contingency management procedures. An electronic reporting system within the TES program allows therapists to view summaries of their patients' activity and progress, recommend modules to be covered, and integrate patients' use of TES into their counseling sessions.

In 2008, Bickel et al. initially evaluated TES in a randomized, controlled trial assessing its efficacy with opioid- or cocaine-dependent patients receiving outpatient treatment with buprenorphine (n = 135). Participants were randomly assigned to one of three study conditions for 23 weeks: (1) 30 min TES thrice weekly with biweekly counselor contact and incentives for opioid- and cocaine-negative urine samples, (2) 30 min therapist-delivered CRA with incentives for opioid- and cocaine-negative urine samples, or (3) standard counseling. Outcomes as measured by continuous weeks of cocaine and opioid abstinence for the computer-delivered, therapist-delivered, and standard treatments were 7.78 (standard error of the mean (SEM) = 1.17), 7.98 (SEM = 1.09), and 4.69 (SEM = 0.88)mean weeks of abstinence, respectively. The therapistdelivered and computer-assisted therapy did not produce significantly different outcomes on this measure, but both produced significantly better abstinence compared to standard treatment. Participants in the therapist-delivered and computer-assisted interventions achieved comparable results on measures of treatment retention, Addiction Severity Index scores, and therapeutic alliance with their counselor. Importantly, computer-assisted treatment reduced interaction with counselors by 80% and is estimated to have reduced the cost of effective treatment by over 70%. Overall, results from this efficacy research are highly promising and clearly support the efficacy of the computerized package of CRA plus incentives. Due to its strong efficacy data and its considerable potential to promote the widespread dissemination of evidence-based psychosocial treatment for individuals with substance use disorders, TES has been included in a number of other large-scale evaluation projects funded by the National Institute on Drug Abuse (NIDA), including a multi-site study conducted in 10 substance abuse treatment settings on NIDA's Clinical Trials Network platform as well as a multi-site study in 10 criminal justice settings across the United States.

The second technology-based behavioral therapy, which delivers a computerized version of CBT, was developed by Carroll and colleagues (2008). This program, called Computer-based Training in Cognitive Behavioral Therapy or CBT4CBT, is composed of six sessions focussing on (1) understanding and changing patterns of substance use, (2) coping with craving, (3) refusing offers of drugs and alcohol, (4) problem solving skills, (5) identifying and changing thoughts about

drugs and alcohol, and (6) improving decision-making skills. Module content is presented using video-taped vignettes illustrating the various skills taught within the program. In a randomized, controlled trial, 77 individuals entering treatment for substance dependence were randomly assigned to either standard treatment or standard treatment plus access to CBT4CBT for an 8-week intervention period. Participants in the group that received CBT4CBT as an adjunct to standard treatment submitted a lower percent of drug-positive urine samples (34% positive) relative to those in the standard of care condition (53% positive). Treatment involvement and the completion of homework (in between sessions) were strongly related to outcomes from the CBT4CBT intervention.

third technology-based behavioral therapy, a computerized version of motivational enhancement therapy (MET), was developed by Ondersma et al. (2005). This brief MET-based intervention, called the Motivational Enhancement System, was primarily designed for postpartum women who reported drug use before pregnancy. The intervention has three sections based on principles of motivational interviewing (MI) and brief intervention including: (1) feedback to the user about the negative consequences of drug use, her readiness to change, and her drug use as compared to that of all adult women (based on her responses to questions posed by the program); (2) pros and cons of drug use and related change; and (3) review of the participant's interest in change with the opportunity to set goals regarding drug use. In an initial evaluation of this program, 30 women were randomly assigned to the brief computerized intervention or to a control group. Participants in the intervention group reported that the intervention was highly acceptable and that it significantly increased their motivation to reduce drug use at post-intervention and 1-month follow-up (d = 0.49). The promise of this brief intervention was further underscored in a 2007 evaluation with 107 postpartum women randomly assigned to the brief intervention or a control condition. Illicit drug use declined among individuals in the intervention group and slightly increased in the control group.

In the fourth study utilizing a technology-based behavioral therapy program, Kay-Lambkin et al. (2009) evaluated a computer-based intervention for individuals with comorbid depression and alcohol/cannabis problems. This program, which teaches skills found in CBT, while using an MI therapeutic style, includes content underscoring the relationship between substance misuse and depressive symptoms. In a randomized controlled trial, 97 individuals from the target population received a brief intervention for depressive symptoms and substance misuse followed by one of three conditions: (1) no further treatment,

(2) nine sessions of MI and CBT delivered by a psychologist, or (3) nine sessions of MI and CBT delivered by a computer. Results indicated that two MI/CBT groups produced better outcomes than a brief intervention alone on measures of cannabis and other substance use, with the group receiving the computerized intervention showing the largest effects. Additionally, MI/CBT produced better outcomes than the brief intervention on measures of depression, with the in-person treatment producing better short-term outcomes but the computerized intervention producing comparable outcomes at a 12-month follow-up.

Additional Novel TDT for Substance Use Disorders

In addition to technology-based, psychosocial treatment interventions for substance use disorders (as reviewed above), several additional empirically supported technology-delivered interventions have been developed for individuals with substance use disorders.

For example, novel research led by Jesse Dallery (2005, 2007) has focused on promoting smoking cessation using an entirely automated, Internet-based contin-(abstinence management reinforcement) intervention, called Motiv8, to obtain video-based evidence of smoking behavior and reinforce evidence of behavior change (e.g. smoking reduction or abstinence). Mōtiv8 is a web-based platform that delivers reinforcement in the form of electronic vouchers (statements of earnings) based on evidence of meeting targeted behavior change goals. A critical feature of Mōtiv8 is its ability to remotely observe, via a web camera, objective evidence of the presence or absence of behavior (e.g. participants providing carbon monoxide (CO) breath samples—a reliable and valid measure of smoking status—via an at-home monitor with each at-home reading recorded by web camera, and then receiving reinforcers for meeting targeted CO levels). Several studies have shown that the Motiv8 intervention reliably promotes smoking abstinence in heavy smokers, rural smokers, and adolescent smokers. These results demonstrate the powerful early onset of efficacy of the CO intervention and the feasibility of delivering reinforcement for smoking abstinence over the Internet.

Additionally, innovative work led by Kenneth Silverman has focused on the development and evaluation of a novel, web-delivered, employment-based intervention for chronic drug users called the Therapeutic Workplace. The Therapeutic Workplace is designed to address the interrelated problems of poverty and drug addiction. In this model, participants are eligible for employment in a work setting contingent upon the provision of drug-free urine samples, and are then taught skills via

the web-based system that are later applied to various work tasks (via the web-based Therapeutic Workplace system). Incentives (payment for work) are delivered contingent upon the quality of work performance. The Therapeutic Workplace model has reliably produced marked reductions in drug use and has underscored the potential utility of workplaces (that use long-term contingency management interventions) as long-term therapeutic agents in the treatment of substance dependence.

FUTURE DIRECTIONS OF TDT: CONTENT DEVELOPMENT

MET

As previously described, early efforts by Hester and colleagues in 2005 with a computerized tool for assessing alcohol use called the Drinker's Check-up began integrating content derived from the principles and procedures of MI. However, with the exception of a few studies such as those cited above with pregnant or postpartum women, little research on computerized MET procedures has appeared in the past decade. To more authentically replicate MET, some interactive programs have incorporated (putatively) important MET components of amplified reflection, summary statements, ambivalence development exercises, expression of empathy, individualized goal setting, and rolling with resistance. A few reports of such programs have appeared and more are likely on the horizon. However, there are limitations to programming that attempts to mimic personal interactions that involve the more sophisticated MET components such as expression of empathy or focused reflections. The strength of computer applications in this arena might stem from the fidelity and consistency of the delivery of other key components; moreover, the inherent impersonal nature of the computer may facilitate more open self-thought and dialogue by removing the interpersonal anxieties that sometimes block contemplation of sensitive topics.

CBT

As reviewed above, most computerized programs for individuals with substance use disorders to date have focused on delivery of CBT skills (e.g. TES programming). Recent research on video modeling of coping skill responses will likely encourage continued development of more comprehensive and sophisticated software programs utilizing this modality. Carroll's recently developed video-based CBT modeling program described above was shown to enhance coping skills used in the real world, which in turn predicted better

substance use treatment outcomes. This mediational finding has rarely been observed with therapist-delivered CBT research. One can envision future adaptations of the content and medium that involve direct practice of coping skills via immersion in VR programming or video gaming participation (see next section), which may further enhance patient learning and utilization. The content of such programming could be related to that currently used in role plays performed during therapy sessions and practice assignments completed outside of therapy sessions.

Web-Based Social Support

The importance of social support to successful recovery from substance use problems is well established. Over the past few years, self-help groups like AA and SMART Recovery have taken advantage of the Internet by establishing live web-based text and voice chat meetings that can be accessed at any time of day as well as forums and postings of educational materials and meeting information. Treatment researchers are likely to explore alternatives for using digital communication to provide therapeutic social support. Highly popular online social networks, such as Facebook or MySpace, could host groups from specific or nonspecific treatment programs. Such sites might serve as a source for active or emotional coping support; offer advice or encouragement in addressing urges to use or following a relapse; provide a place for group practice of therapeutic skills; or be a source for information about employment, school, recreation, or social activities. Social networking sites might also provide parents or spouses of substance abusers with social support and coping skill advice or training for dealing effectively with their family member. Use of digital technology can make access to support virtually immediate, a clear advantage over traditional group therapy or self-help meeting modalities. This form of remote social contact may also increase the probability that socially anxious persons will access social support when needed.

FUTURE DIRECTIONS OF TDT: TECHNOLOGICAL DEVELOPMENT

Existing technological platforms and devices such as short message service or texting (SMS), hand-held computer devices or personal digital assistants (PDAs), cell phones/smartphones, global positioning systems (GPS), VR, and video gaming offer a plethora of alternatives for innovative delivery of therapeutic interventions for substance abuse/use problems. Utilizing these mechanisms to address various health or human performance issues is already becoming a reality, as evidenced

by the coining of the terms for these emerging technologies, for example, ubiquitous computing (ubicomp) and ambient intelligence systems, which function as pervasive and intelligent service systems surrounding individuals by anticipating, adapting to, and meeting users' needs; eHealth (the use of electronic communication devices to provide health services and information); and mHealth (the mobile subset of eHealth). Moreover, the use of video games to promote health behaviors and the use of VR programs to assist with the treatment of some mental health disorders are currently being applied and studied. Below we offer a few illustrations of innovations that might be employed to intervene in substance use disorders in the near future. Many of these ideas and examples reflect applications either being contemplated for development and testing or are research projects currently underway.

Programmed SMS (texting) could prompt or remind individuals to use particular relapse prevention coping skills, provide regular educational messages to enhance learning of skills, or simply provide motivational or encouraging messages that might help maintain positive, recovery thoughts and behaviors. Such messages could be programmed by a clinical provider to occur on specific dates, times, and frequencies. The ubiquitous presence of cell phones in today's society would suggest that such use of SMS could be readily integrated into most patients' care.

Smartphones (i.e. mobile phones with computing ability and Internet connectivity) offer a myriad of intervention possibilities in addition to use of SMS. For brevity, we will discuss smartphone capabilities as encompassing that of a combination of a cell phone, a PDA, and a GPS. An important feature of smartphones is that they allow users to download and run complete software applications (apps) that provide opportunities for development and use of unlimited types of programs. Hence, smartphones could be used to deliver the therapeutic software applications including video modeling discussed earlier in the chapter, with the addition of being able to access such programs from anywhere at any time. Detailed active coping plans and strategies could be made readily available for real time use when needed via these devices. Patients could also gain mobile access to social support systems as discussed in the previous section.

A number of current research projects are exploring combined use of GPS and PDA capabilities to develop "warning" systems that would alert the patients when they enter environments that present high risk for drug use and potentially prompt them to engage in specific coping behaviors. GPS technology also would allow increased monitoring by those concerned with the whereabouts of the patient (e.g. concerned parents), which could be integrated into a comprehensive

therapeutic program. Others are seeking to integrate wireless devices that measure behavioral and physiological responses with smartphones to allow therapeutic interventions to automatically be delivered when physiological changes signal risk (e.g. of stress or craving).

Another promising development targeting primarily teens and young adults is the video game platform to promote learning experiences relevant to effective recovery from substance abuse. Games for this platform could provide a medium that includes modeling of coping skills via culturally and gender relevant characters and environments, and reinforcement of mastery and effective use of coping skills. The participant would be challenged with making key decisions and choices followed by realistic consequences (e.g. to win the game you need to achieve sobriety), which requires effective decision making and use of specific skills. The overall goal of these games would be to create an engaging, interactive experience that facilitates learning, plus encourages and motivates behavior change. Games directed at prevention of substance use and other health behaviors have already appeared in the literature.

A final example of nascent use of technology for substance abuse treatment is the employment of VR, i.e. computer-simulated experiences that utilize visual, auditory, tactile, or olfactory sensory features to facilitate active participation in simulated environments. VR has been used to enhance exposure therapies for specific phobias and for post-traumatic stress disorder. Potential applications for substance abuse interventions would include simulating real-life drinking or drug use environments that provide opportunities to practice skills consistent with successfully negotiating the scenes without lapsing to use. Again, culturally relevant environments and situations could be developed that would enhance participation and learning of effective behaviors. Currently, a number of research projects are using VR to facilitate cue exposure-type interventions designed to reduce or extinguish craving linked to environmental cues that might trigger relapse.

In summary, the near future offers a wealth of exciting possibilities for creative use of advanced technologies to better intervene in substance use disorders. The primary focus of these advances are likely to be (1) delivering active treatment components when and where they are needed in real time, perhaps to specific substance-using populations and (2) using digital simulations to create more realistic environments that may enhance participation in therapeutic activities, motivation to change, and learning of coping skills. Other inventive applications will inevitably emerge. For example, we are aware of several new research projects investigating the development and evaluation of webbased interventions for specific sub-populations of substance-using individuals including web-based

MET/CBT for individuals with marijuana use disorders, web-based behavioral therapy for adolescents with substance use disorders, web-based HIV prevention intervention for adolescents in substance abuse treatment, and online programming for opioid-maintained chronic pain patients with aberrant opioid-taking behavior. Additionally, several early stage projects are examining the use of online social networks as well as mobile phones and other mobile devices in the assessment and treatment of substance use disorders.

Barriers to the Adoption of TDT

As reviewed above, technology-based therapeutic tools hold great promise for increasing the likelihood of adoption of science-based behavioral interventions targeting individuals with substance use disorders (among other populations). Despite the wealth of research supporting a number of behavior change interventions targeting substance use disorders and related issues, substance abuse treatment programs have been particularly slow to adopt evidence-based practices. The realities of community-based treatment systems (especially marked limitations in resources) present numerous barriers to effectively transfer evidence-based programs into treatment practice. However, if adopted, technology-delivered behavioral interventions inherently contain many features that may facilitate the likelihood of adoption of innovations. They may function as 'clinician-extenders' that enable rapid and widespread diffusion of evidence-based psychosocial interventions to individuals with substance use disorders in treatment programs in a manner that ensures fidelity of intervention delivery and is cost-effective.

Despite the potential utility of technology-delivered interventions in substance abuse treatment programs, it is important to recognize that the majority (90%) of individuals with substance use disorders are not in substance abuse treatment. Thus, nearly 21 million Americans annually remain untreated for a substance use disorder, suggesting that the current treatment system is either inaccessible or unacceptable to most substance-abusing individuals (SAMHSA, 2009). Thus, in addition to their use in substance abuse treatment settings, evidence-based, technology-delivered interventions targeting substance use disorders could be offered within other systems of care, including an array of medical settings (e.g. emergency rooms, primary care settings, health clinics) and/or criminal justice settings (e.g. probation/parole settings, jails, prisons). However, challenges to delivering technology-based intervention in these nontraditional settings are similar to known challenges in delivering evidence-based care using more traditional approaches in substance abuse treatment settings, and include limited training, time, and (sometimes) interest among providers to deliver such interventions. Thus, technology-based therapeutic tools may meet a significant but currently unmet need in such nontraditional settings. Technology-delivered approaches may become increasingly important and clinically useful in light of the recently announced 2010 National Drug Control Strategy from the U.S. Office of National Drug Control Policy (ONDCP), which places a strong emphasis on integrating treatment for substance use disorders into other areas of health care (mental health clinics, infectious disease management programs, primary care clinics) where providers may have limited expertise in treating individuals with substance use disorders.

It is important to acknowledge that while technologybased interventions appear to be optimal for adoption in a wide range of service settings as well as direct to users in nonclinical settings, a number of factors will impact actual adoption. In order to effectively translate the science of technology-based interventions for individuals with a substance use disorder to practice, dissemination efforts must reach diverse stakeholders, with meaningful information and support material to optimize the potential of these interventions to have a substantive public health impact. Further research is needed on how to best reach various service system audiences to promote routine use of technology-based interventions in community-based systems of care. Additionally, further study is needed to better understand local, state, and federal policies, as well as reimbursement structures for payment of services within public and private sectors that may impact adoption of technology-delivered interventions in various systems of care. Current considerations regarding payment structures for technology-delivered services within the public health care system may lead to reimbursement structures that further promote the widespread deployment of technology-based therapeutic tools.

CONCLUSION

In the past two decades, the use of information technology to deliver treatments for substance use disorders has transitioned from a potential opportunity to a reality. Research clearly shows that technology-based treatments can be efficacious and are acceptable to patients. This next decade will likely involve a proliferation of innovative applications that promise to increase both access to and effectiveness of substance abuse treatment interventions. An important additional step is to empirically examine how this approach to treatment can be used to expand, extend, and reorganize our approach to the provision of treatment. For example, there may be reason to integrate these approaches into some

hybrid modality with other telemedicine approaches (e.g. holding meetings with counselors via videoconferencing). Another potential opportunity is the use of these lower-cost information technologies to deliver treatment to be used productively for continuity of care following an acute treatment episode. Additionally, the use of smartphones remains an important potential tool to exploit for this type of application.

This next decade may move the study of technology-delivered treatments of substance use disorders from the study of the efficacy of various treatment approaches to an examination of how to deliver them so that they have the broadest reach and greatest opportunity to positively affect the plethora of substance use disorders. The use of interactive information technologies is an important step that may have transformative impact on existing approaches to treatment and permit expansion of treatment, increasing its relevance to patients with the potential to deliver evidence-based treatments in a cost-effective manner.

SEE ALSO

Cognitive Behavioral Therapies, Contingency Management, Community Reinforcement Approaches: CRA and CRAFT, HIV/AIDS and Substance Abuse, Buprenorphine for Opioid Dependence, Evidence-Based Treatment

List of Abbreviations

CAI

CBT cognitive behavioral therapy CO carbon monoxide community reinforcement approach **CRA** global positioning systems **GPS** HIV human immunodeficiency virus **IDU** injection drug users MET motivational enhancement therapy MI motivational interviewing **NIDA** National Institute on Drug Abuse **PDA** personal digital assistant standard error of the mean SEM **SMS** short message service TDT technology-delivered treatment TES Therapeutic Education System ubicomp ubiquitous computing virtual reality

computer-assisted instruction

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Relevant websites

- http://www.ndri.org/ctrs/cth.html National Development and Research Institutes, Inc.
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Screening and Interventions in Medical Settings Including Brief Feedback-Focused Interventions

Catherine A. Haighton, Dorothy Newbury-Birch, Eileen F.S. Kaner Institute of Health and Society, Newcastle University, Newcastle upon Tyne, UK

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INTRODUCTION

A number of clinical methods have been developed to detect substance abuse. These include blood tests, urine toxicology screens, self-report measures, structured interviews, and educated guessing based on clinical experience. Blood tests (such as liver function tests) may detect organ damage or malfunction, but only identify those patients with long-term use in whom secondary symptoms have occurred. Early stage substance abuse is rarely identified by this means. In spite of the popularity of urine toxicology (in response to illicit drug use), these screens are able to identify only fairly recent use of a substance and provide no information about frequency or length of use. Urine, blood, and breath tests are all relatively unreliable indicators of alcohol use, as alcohol is metabolized quickly and is unlikely to be detected in body fluids. Educated guessing based on clinical experience may identify some users, but is heavily dependent on the practitioner's attitudes and experiences. Structured interviewing is time intensive and requires careful training and monitoring that is impractical in most medical settings. Therefore, the most effective method for detecting substance abuse is often via a validated questionnaire-based screening tool. Such screening tools are generally designed to be administered face-to-face, patient to provider. They are not designed to diagnose a substance abuse problem, but are intended to determine if a patient may be at risk or experiencing early stage harm from alcohol or drug use. This earlier detection of problems is generally a precursor to preventive interventions, which aim to avoid the development of serious problems or ameliorate early stage harm (secondary prevention). Thus, this chapter will focus on follow-up, after screening, in the form of brief, preventive interventions rather than treatment per se. However, if screening identifies severe substance use problems it can act as a precursor to assessment and thence specialist treatment.

SCREENING

A current debate concerns the relative merits of two different approaches to screening – universal screening, aimed at all patients attending a medical facility, and targeted screening, aimed at predefined groups of patients such as those attending new patient registrations in general practice, special types of clinic or ward where substance abusers are more likely to be found, and emergency department services where patients present with specific indications for substance abuse. Some research has shown that targeted screening is preferred by both practitioners and patients, but universal screening, if practicable, has the obvious advantage that substance abusers are less likely to be missed. The relative effectiveness, cost-effectiveness, and acceptability universal versus targeted screening in routine practice are the focus of ongoing research.

Screening for Alcohol

Clinicians are often familiar with laboratory indicators of excessive alcohol consumption, such as mean corpuscular volume, gamma-glutamyl transferase (GGT), and carbohydrate deficient transferrin. However, in medical practice, standardized questionnaires have been found to have a greater sensitivity and specificity than laboratory indicators; they are also far less intrusive and more acceptable to patients. In addition, questionnaire-based screening is less costly than laboratory analysis.

The CAGE questionnaire, named after its four questions, is one such example that may be used to screen patients quickly in a clinical encounter. CAGE is an easy to use, international screening test for identifying patients who are experiencing drinking and potential alcohol problems. The name CAGE is an acronym formed by taking the first letter of key words (cut down, annoyed, guilty, eye opener) from each of the four screening questions:

- 1. Have you ever felt you should cut down on your drinking?
- **2.** Have people annoyed you by criticizing your drinking?
- 3. Have you ever felt bad or guilty about your drinking?
- 4. Have you ever had a drink first thing in the morning to steady your nerves or to get rid of a hangover (eye opener)?

The CAGE questionnaire is best used in a clinical setting as part of a general clinical history taking and should not be preceded by any questions about alcohol intake because its sensitivity is dramatically enhanced by an open-ended introduction. Two Yes responses are considered clinically significant (sensitivity of 93% and

a specificity of 76% for the identification of problem drinking), compared with GGT liver function test that detects only a third of patients having more than 16 standard drinks per day. While the CAGE questionnaire has demonstrated a high effectiveness in detecting alcohol-related problems, it has limitations in people with less severe alcohol-related problems, white women, and college students.

The alcohol use disorders identification test (AUDIT) was the first screening tool designed specifically to detect hazardous and harmful drinking in both primary and secondary health care settings and across a range of different countries and drinking cultures. AUDIT is a 10-item questionnaire that includes items on drinking frequency and intensity (binge drinking), together with experience of alcohol-related problems and dependence (see Fig. 30.1). At a score of 8 or more out of a possible 40, the ability of AUDIT to detect genuine excessive drinkers (sensitivity) and to exclude false cases (specificity) is 92 and 94%, respectively. Thus, AUDIT is a highly accurate tool, which has been validated in a large number of countries with consistently strong psychometric performance. It is now regarded as the "gold standard" screening tool to detect hazardous and harmful drinking in primary care patients. When AUDIT has been applied in routine primary care, approximately one in five patients screen positive for hazardous or harmful alcohol consumption.

Nevertheless, even with just 10 items, the full AUDIT has been considered too lengthy for use in routine practice due to the limited amount of time available to clinicians. Moreover, since four out of every five patients tend to screen negative for hazardous and harmful drinking, clinicians need an efficient detection method of identifying relevant patients needing alcohol intervention. For this reason, several shorter versions of the AUDIT have been developed including the following:

- AUDIT-C the first three (consumption) items of the full AUDIT. A score of 5+ indicates hazardous or harmful drinking.
- AUDIT-PC the first two (consumption) questions of the full AUDIT plus items 4, 5, and 10, which focus on alcohol-related problems and possible dependence. A score of 5+ indicates hazardous or harmful drinking.
- Fast alcohol screening test a two-stage screening procedure based on four of the original AUDIT items. Item 3 is asked first and classifies over half of respondents as either nonhazardous or hazardous drinkers. Only those not classified at the first stage go on to the second stage, which consists of AUDIT items 5, 8, and 10. A response other than "never" to any of these three items classifies the respondent as a hazardous drinker.

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Question		Scoring System					
	0	1	2	3	4		
How often do you have a drink that contains alcohol?	Never	Monthly or less	2–4 times a month	2–3 times a week	4+ times a week		
How many standard alcoholic drinks do you have on a typical day when you are drinking?	1–2	3–4	5–6	7–9	10+		
How often do you have 6 or more standard drinks on one occasion?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily		
How often in the last year have you found that you were not able to stop drinking once you had started?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily		
How often in the last year have you failed to do what was expected of you because of drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily		
How often in the last year have you needed an alcoholic drink in the morning to get you going?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily		
How often in the last year have you had a feeling of guilt or regret after drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily		
How often in the last year have you not been able to remember what happened when drinking the night?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily		
Have you or someone else been injured as a result of your drinking?	No		Yes, but not in the last year		Yes, during the last year		
Has a relative/friend/doctor/health worker been concerned about your drinking or suggested you cut down?	No		Yes, but not in the last year		Yes, during the last year		

Scoring: 0–7 = sensible drinking; 8–15 = hazardous drinking; 16–19 = harmful drinking; 20+ = possible dependence.

FIGURE 30.1 Alcohol use disorders identification test (AUDIT).

• Single alcohol screening questionnaire – "When was the last time you had more than "x" drinks in one day?" (where x = 5 for men and 4 for women (US values) and 8 for men and 6 for women (UK values)) – Possible responses are never, over 12 months, 3–12 months, and within 3 months. The last response suggests hazardous or harmful drinking.

These short instruments take less time to administer than the full AUDIT but they are generally less accurate than the longer tool. In addition, they do not clearly differentiate between hazardous, harmful, and dependent drinking. Nevertheless, a recent review of AUDIT and its shorter variants reported that the shorter tools have relatively good psychometric properties and that AUDIT-C in particular was nearly as accurate as the full AUDIT. Thus, a pragmatic approach for primary care clinicians may be to use AUDIT-C as a prescreening tool to quickly filter out negative cases, and then administer the remaining seven AUDIT questions to the smaller pool of positive cases to provide an accurate and differential assessment of alcohol-related risk or harm.

Screening for Tobacco

There are a number of questionnaires that have been designed specifically to measure tobacco dependence. The most commonly used tobacco dependence measures are the Fagerström tolerance questionnaire (FTQ) and the Fagerström test for nicotine dependence (FTND). The scales' brevity and relations with relapse make them valuable clinical tools. The FTND (see Fig. 30.2) is preferred over the FTQ because of its enhanced reliability and equal or better predictive validity.

A 10-item self-report questionnaire, the tobacco dependence screener, has also been developed for screening for tobacco/nicotine dependence. However, tobacco/nicotine dependence is defined as a cluster of cognitive, behavioral, and physiological symptoms for which the individual attributes use of tobacco despite significant tobacco-related problems. Earlier detection of problems is necessary for preventive interventions,

which aim to avoid the development of serious problems or ameliorate early stage harm. Some screening tools are available that include questions about tobacco such as the World Health Organization Alcohol, Smoking and Substance Involvement Screening Test and because *any* current tobacco use places a patient at risk these screening tools only need to include a single question about tobacco use.

Screening for Other Drugs

Because drugs eventually show up in body fluids and hair, in one form or the other, clinicians can detect drug abuse by chemical analysis of a given specimen. The most common forms of analysis are of the hair, blood, saliva, sweat, and urine. As urine analysis is less invasive than blood analysis, it is typically the least expensive and can detect infrequent or recent single use and is the most commonly used drug test. However, these

1.	How soon after you wake up do you smoke your first cigarette?	
	Within 5 minutes	(3 points)
	5 to 30 minutes	(2 points)
	31 to 60 minutes	(1 point)
	After 60 minutes	(0 points)
2.	Do you find it difficult not to smoke in places where you shouldn't, such	as in
	church or school, in a movie, at the library, on a bus, in court or in a ho	spital?
	Yes	(1 point)
	No	(0 points)
3.	Which cigarette would you most hate to give up; which cigarette do you	u treasure
	the most?	
	The first one in the morning	(1 point)
	Any other one	(0 points)
4.	4. How many cigarettes do you smoke each day?	
	10 or fewer	(0 points)
	11 to 20	(1 point)
	21 to 30	(2 points)
	31 or more	(3 points)
5.	5. Do you smoke more during the first few hours after waking up than o	during the
	rest of the day?	
	Yes	(1 point)
	No	(0 points)
6.	6. Do you still smoke if you are so sick that you are in bed most of the	day or if
	you have a cold or the flu and have trouble breathing?	
	Yes	(1 point)
	No	(0 points)

Scoring: 7–10 points = highly dependent; 4–6 points = moderately dependent; less than 4 points = minimally dependent.

FIGURE 30.2 Modified Fagerström test for nicotine dependence. Adapted from Heatherton TF, Kozlowski LT, Frecker RC, Fagerström KO. The Fagerström test for nicotine dependence: a revision of the Fagerström Tolerance Questionnaire. Br J Addict 1991;86:1119–27

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tests provide no information about frequency or length of use and a distinction must be made between testing for drug use (such as random drug testing in the workplace) and screening in order to determine if a patient may be at risk or experiencing early stage harm from drug use and therefore benefit from preventive interventions. Screening tools are available for drug use or abuse.

The drug abuse screening test (DAST) was developed in 1982 and is still an excellent screening tool. It is a 28-item self-report scale that consists of items that parallel those of the Michigan alcoholism screening test (MAST). The DAST includes both the use of prescribed or "over the counter" drugs in excess of the directions and any nonmedical use of drugs. The various classes of drugs may include and are not limited

to cannabis (e.g. marijuana, hash), solvents (e.g. gas, paints etc.), tranquilizers (e.g. Valium), barbiturates, cocaine, and stimulants (e.g. speed), hallucinogens (e.g. LSD) or narcotics (e.g. Heroin). It does not refer to alcohol or tobacco. The DAST is one of the most widely used screening tests for drug abuse and addiction (see Fig. 30.3).

The DAST has exhibited valid psychometric properties and has been found to be a sensitive screening instrument for the abuse of drugs other than alcohol. A score of "1" is given for each Yes response, except for items 4, 5, and 7, for which a No response is given a score of "1." Based on data from a heterogeneous psychiatric patient population, cutoff scores of 6 through 11 are considered to be optimal for screening for

The following questions concern information about your involvement with drugs. Drug abuse refers to (1) the use of prescribed or "over-the-counter" drugs in excess of the directions, and (2) any non-medical use of drugs. Consider the past year (12 months) and carefully read each statement. Then decide whether your answer is YES or NO and check the appropriate space. Please be sure to answer every question.

	YES / NO	0
1. Have you used drugs other than those required for medical reasons?		*
2. Have you abused prescription drugs?		
3. Do you abuse more than one drug at a time?		*
4. Can you get through the week without using drugs (other than those required f reasons)?	or medica	al
5. Are you always able to stop using drugs when you want to?		*
6. Do you abuse drugs on a continuous basis?		
7. Do you try to limit your drug use to certain situations?		
8. Have you had "blackouts" or "flashbacks" as a result of drug use?		*
9. Do you ever feel bad about your drug abuse?		*
10. Does your spouse (or parents) ever complain about your involvement with dru	ugs?	*
11. Do your friends or relatives know or suspect you abuse drugs?		
12. Has drug abuse ever created problems between you and your spouse?		
13. Has any family member ever sought help for problems related to your drug us	se ?	
14. Have you ever lost friends because of your use of drugs?		
15. Have you ever neglected your family or missed work because of your use of	drugs?	
13. Have you ever neglected your family or missed work because or your use or t	arugo:	*
16. Have you ever been in trouble at work because of drug abuse?		
17. Have you ever lost a job because of drug abuse?		
18. Have you gotten into fights when under the influence of drugs?		
19. Have you ever been arrested because of unusual behavior while under the in	fluence o	f
drugs?		
20. Have you ever been arrested for driving while under the influence of drugs?		
21. Have you engaged in illegal activities in order to obtain drug?		*
22. Have you ever been arrested for possession of illegal drugs?		
23. Have you ever experienced withdrawal symptoms as a result of heavy drug in	ntake?	
= 0. That's you are compensation minutes and office and a recent of mounty and give		*
24. Have you had medical problems as a result of your drug use (e.g., memory lo	ss, hepat	titis,
convulsions, bleeding, etc.)?	′ '	*
25. Have you ever gone to anyone for help for a drug problem?		
26. Have you ever been in a hospital for medical problems related to your drug us	se?	
,		
27. Have you ever been involved in a treatment program specifically related to dr	ug use?	
OO Harranes have to do a second of set for machines with the control of		
28. Have you been treated as an outpatient for problems related to drug abuse?		
* Denotes questions used for DAST-10		

FIGURE 30.3 The drug abuse screening test (DAST). Adapted from Skinner, H.A. The drug abuse screening test. Addict Behav 1982; 7(4):363–71.

substance use disorders. Using a cutoff score of 6 has been found to provide excellent sensitivity for identifying patients with substance use disorders as well as satisfactory specificity (i.e. identification of patients who do not have substance use disorders). Using a cutoff score of <11 somewhat reduces the sensitivity for identifying patients with substance use disorders, but more accurately identifies the patients who do not have a substance use disorder. Over 12 is definitely a substance abuse problem. In a heterogeneous psychiatric patient population, most items have been shown to correlate at least moderately well with the total scale scores.

The DAST-10 is a 10-item, Yes/No, self-report instrument that has been shortened from the 28-item DAST taking less than 8 min to complete. The DAST-10 was designed to provide a brief instrument for clinical screening and treatment evaluation and can be used with adults and older youths. It is strongly recommended that the short MAST be used along with the DAST-10 unless there is a clear indication that the patient uses no alcohol at all. For the DAST-10, 0 indicates no problems reported, 1–2 low-level problem, 3–5 moderate problem, 6–8 substantial problem, and 9–10 severe problem (see Fig. 30. 3).

A single screening question "How many times in the past year have you used an illegal drug or used a prescription medication for nonmedical reasons?" has recently been shown to be successful at identifying drug use in primary care. The single screening question was 100% sensitive for identifying a drug use disorder and 74% specific. The single question screen accurately identified a broad spectrum of drug use in a sample of primary care patients. The use of a brief screen is often desirable in identification of drug use in primary care settings, which should in turn facilitate the implementation of brief intervention programs in this setting.

BRIEF INTERVENTIONS

Two basic forms of brief intervention have been identified, simple brief intervention (structured feedback and advice) and extended brief intervention (brief behavioral counseling).

Definition of Simple Brief Interventions

Brief interventions refer to a range of clinical activities focused on the use of a talk-based therapeutic approach aimed at changing certain health-limiting behaviors (usually smoking, heavy drinking, or other drug use) and their associated problems. Brief interventions have been applied opportunistically to nontreatment-seeking populations, with the core aim of secondary prevention, as well as to those undergoing treatment (sometimes referred to as brief treatments). Key components of brief interventions include simple structured advice, written information, behavior change counseling (BCC), and motivational interviewing and each of these elements can either occur alone or in combination with each other.

Brief interventions have also been delivered either in a single appointment or a series of related sessions. Sessions can last between 5 and 60 min, and while brief interventions for nontreatment-seeking populations do not tend to exceed five sessions in total, those in treatment can have many more than five sessions including cognitive-behavioral therapy (CBT) and motivational interviewing. Although there is a wide variation in brief intervention activities, there are a number of essential principles to delivery; brief interventions should obviously be short and should be deliverable by health professionals without specialist training and who are working in busy health care settings. Brief interventions are often based on a fundamental set of ingredients summarized by the acronym FRAMES (see Box 30.1).

BOX 30.1

FRAMES

Feedback on the client's risk for behavior

Responsibility The individual is responsible for change

Advice Advises reduction or gives explicit direction to change

Menu Provides a variety of options for change

Empathy Emphasizes a warm, reflective, understanding approach

Self-efficacy Encourages optimism about changing behavior

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Again, given the variability in activity, it is important to explain that brief interventions are *not* merely traditional treatments (psychiatric or psychological) carried out in a short timescale; they have more specific properties than that. Brief interventions are techniques that a variety of health professionals (physicians, nurses, pharmacists, health workers, drug workers, social workers, psychiatrists, etc.) can easily incorporate into their practice in a variety of cultural settings, populations, and health care systems.

Brief interventions, particularly for alcohol and tobacco, are supported by a large literature on their efficacy and cost-effectiveness with a wealth of trials and meta-analyses indicating that both opportunistic brief interventions delivered by generalists and brief treatment delivered by addiction specialists are efficacious as a secondary prevention and as a treatment strategy, respectively.

Opportunistic brief intervention is made up of interventions typically designed for and evaluated among individuals not seeking help for substance abuse problems who are identified by opportunistic screening in primary health care settings. Such individuals often have less severe problems and lower motivation for change. These interventions are typically shorter, less structured, less theoretically based, and delivered by a nonspecialist.

Brief treatment has typically been evaluated among individuals seeking or being persuaded to seek treatment for substance abuse problems. These interventions are usually longer, more structured, theoretically based, and delivered by a specialist. As brief interventions are now increasingly being evaluated in the context of illicit drug use, the distinction between generalist and specialist delivery is becoming increasingly blurred although the evidence for brief interventions in nontreatment seekers is stronger than those in treatment settings. Brief interventions are also highly cost-efficient due to the minimal cost of the intervention and the breadth of scope for prevention of more serious and costly problems. Brief interventions are particularly effective in the field of substance use.

Definition of Extended Brief Interventions

An extended brief intervention typically takes 20–30 min to deliver and can involve a small number of repeat sessions. It is essentially a condensed form of "motivational interviewing" in which an attempt is made to elicit, rather than impose, an increase in motivation to change behavior. More specifically, extended brief intervention is based on generic principles of health behavior change described by Rollnick and colleagues. The level of training required to carry out this form of brief intervention effectively is substantially

greater than that for simple advice and should involve an emphasis on experiential learning.

Brief Interventions Theory

Brief interventions are firmly grounded in theory from the field of psychology, which is concerned with understanding, predicting, and changing human behavior. Different theories are relevant to the context for brief interventions and its content or delivery mode.

In general terms, the principles of brief interventions are broadly based on social cognitive theory, which is drawn from the concept of social learning by Albert Bandura. Consequently, brief interventions address, in a structured format, an individual's knowledge, attitude, and skills in relation to behavior so as to encourage behavior change for subsequent health benefit.

In terms of therapeutic application, brief interventions in pioneering research were based on principles of CBT, which was itself closely linked to the social learning perspective. CBT is a talk-based treatment designed to make individuals change how they think (cognitive) and what they do (behavior). Unlike some other therapies it focuses on "here and now" problems and difficulties instead of focusing on causes or symptoms in the past.

Recently in brief interventions research and practice there has been a move away from condensed CBT toward adaptations of motivational interviewing (MI). MI is a patient-centered interviewing style with the goal of resolving conflicts regarding the pros and cons of change, enhancing motivation, and encouraging positive changes in behavior. The interviewer style is characterized by empathy and acceptance, with an avoidance of direct confrontation. Any statement associated with positive behavior change that the patient brings up in the discussion are encouraged so as to support self-efficacy and a commitment to take action. Although within the time constraints for brief interventions, particularly in general health and social care settings, it is not possible to carry out MI, the general ethos and some of the techniques of MI can be adapted for this purpose. Adapted or condensed versions of MI are often referred to as BCC or adapted motivational interventions.

The transtheoretical (stages of change) model has been widely used to inform the context for brief intervention activities. Initially developed to describe the stages through which people progress in smoking cessation, this model has since then proved influential in guiding treatment across a range of addictive behaviors. Individuals are characterized as belonging to one of six internal "stages" depending on the individual's awareness of a problem and their readiness to change behavior to address this problem. The stages consist of

precontemplation (not thinking about change for at least 6 months), contemplation (planning to change in the next 6 months), preparation (planning to change in the next month), action (changing behavior within the last 6 months), maintenance (having changed for more than 6 months), and termination (permanently changed behavior). Individuals progress through these stages sequentially and it may take several cycles around the stages of change (i.e. relapses) before a sustained recovery is achieved. The model also proposed that different self-change strategies or "processes of change" are involved in moving between different stages and that different stages are associated with different beliefs about a problem. It argued that brief interventions to promote change should be designed so that they are appropriate to an individual's current stage. Although the theory has provided a heuristic model, evaluations to date have not supported its use in improving treatment outcomes.

Interventions for Alcohol

More than a hundred clinical trials have been conducted to evaluate the efficacy and cost-effectiveness of alcohol screening and brief interventions in both nontreatment- and treatment-seeking populations. There is now a very strong evidence base supporting the effectiveness of brief alcohol interventions in reducing alcohol-related problems. Many systematic reviews and meta-analyses have reported beneficial outcomes of brief interventions, compared to control conditions, in terms of reductions in hazardous and harmful drinking. In 2007, a review focusing on primary care identified 29 controlled trials of brief interventions, which included over 7000 patients. This review found that brief interventions produced an average reduction of seven standard drinks (UK = 8 g ethanol) per week and there was no significant benefit of longer (more intensive) interventions compared to shorter input.

Primary Care Settings

In terms of strength of the evidence and relevance to practice, the most obvious setting for early identification of alcohol-related risk and brief intervention to reduce excessive drinking is primary health care. This setting represents most people's first point of contact with health services in the majority of countries worldwide. Primary care generally refers to general practice-based health care with a relatively large distribution of health centers or doctor's surgeries across a wide geographical area. However, primary care can be defined as all immediately accessible, general health care facilities that treat a broad range of possible presenting problems, and which can be accessed by a wide range of patients on

demand, and not as the result of a referral for specialist care. Thus, emergency care (accident and emergency departments) can also be considered to be part of primary care.

The most recent review of brief interventions in primary care settings reported a significant reduction in weekly drinking at 1-year follow-up compared to a range of control conditions (such as assessment only, treatment as usual and written information). The magnitude of this effect was an average reduction of 4-5 standard drinks per week. In addition, the review found no significant benefit of increased treatment exposure during brief interventions. Thus, although spending extra time and/or delivering extra sessions did produce some additional reduction in alcohol consumption, this addition was not statistically superior to shorter single-session input. Moreover, there was no significant benefit of extended psychological intervention compared to brief intervention on weekly drinking outcomes. Thus, in primary care contexts, short focused input appears to be the most effective approach to alcohol risk reduction work.

The review considered both the countries that brief intervention trials were based in and the characteristics of patients in these trials. It was clear that the majority of this work had been conducted in the United States and other English-speaking countries, although there was a growing body of work emerging in the Mediterranean countries of Europe and in Scandinavia. However, there was no published research from developing or transitional countries. In addition, the majority of participants in the brief alcohol intervention trials were middle-aged males and there was insufficient work in women, young people, and individuals from black and other minority ethnic backgrounds. Thus, there is a need for more research in the developing world and in different types of drinkers.

Other Medical Care Settings

There is now abundant international evidence that brief interventions delivered in other medical settings are efficacious in leading to reduced alcohol consumption. A comprehensive systematic review of this evidence considered 34 randomized controlled trials carried out in generalist settings among individuals not seeking treatment for alcohol problems. Small to medium aggregate effects were seen consistently across different follow-up points. At follow-ups of between 3 and 6 months inclusive, the effect for brief interventions compared to control conditions was significantly larger when patients showing more severe alcohol problems were excluded from the analysis. Studies conducted in the "real world" conditions of general practice show somewhat less benefit than in those carried out under optimal research

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conditions, but they nevertheless support the effectiveness of brief interventions. Equally impressive are the findings of randomized clinical trials carried out in emergency departments, with several large studies in the United States and the United Kingdom showing the positive effects of brief interventions. In general hospital wards, both patients and staff have more time available for screening and brief intervention than in primary care. Research in general hospital wards has been less extensive and evidence for the effectiveness of brief interventions is inconclusive at present, although there seems no good reason in principle why they should not also be effective there.

College Settings

Meta-analyses have consistently reported that students who received brief interventions in educational settings subsequently reduced their drinking behavior compared to control conditions who typically received assessment only. The key elements of the brief interventions were MI approaches and/or personalized feedback on alcohol consumption typically with a normative component. Such brief interventions typically achieved small to medium effect sizes across multiple measures of alcohol consumption including quantity, frequency, and intensity of drinking. The effects of brief interventions seemed to peak in the shorter term and then diminish over time. Indeed, it has been noted that relatively few of the reduced drinking effects seemed to persist beyond 6 months following the intervention. Thus, it is clear that booster or repeated brief intervention sessions may be needed in college populations to help sustain positive changes in drinking behavior. However, while reductions in alcohol-related problems often took longer to emerge, they were reported in longer term follow-up of 1 year to 18 months.

For example, the college drinker's checkup (CDCU) was developed as both a Windows and web-based brief motivational intervention for heavy drinking college students. The CDCU first screens for heavy drinking. Students who screen positive are given personalized feedback and invited to use the rest of the program, which takes about 35 min. The modules include the following:

- A decisional balance exercise to begin the process of considering the "not so good" things they've experienced from their heavy drinking.
- A comprehensive assessment of drinking and drug use, alcohol-related problems, and risk factors for future alcohol-related problems.
- Personalized feedback includes quantity and frequency compared to their gender specific fellow students at their University, blood alcohol content

feedback, and feedback on how their frequency of alcohol-related problems compared to other, same gender students at their school.

 A final module, Consider Your Options, helps students resolve their ambivalence about changing and develop a plan of action to reduce their drinking and risk for alcohol-related problems.

The results of two randomized clinical trials have demonstrated the effectiveness of the CDCU with heavy drinking college students. Heavy drinking students who used the CDCU reduced their drinking by 43–55% at follow-ups to 12 months.

Another example, Brief Alcohol Screening and Intervention of College Students (BASICS) is a preventive alcohol intervention program for college students of 18–24 years old. It is aimed at students who drink alcohol heavily and have either experienced or are at risk for alcohol-related problems such as poor class attendance, missed assignments, accidents, sexual assault, and violence. BASICS is designed to help students make better alcohol-use decisions. The program

- Reduces the adverse effects of alcohol consumption.
- Promotes reduced drinking.
- Promotes healthier choices among young adults.
- Provides important information and coping skills for risk reduction.

BASICS is conducted over the course of only two 50-min interviews, and these brief, limited interventions prompt students to change their drinking patterns. Before or after the first interview, the student receives a self-report questionnaire to complete. From the questionnaire and the first interview, information is gathered about the student's alcohol consumption pattern, personal beliefs about alcohol, understanding of social alcohol norms, and family history. The second interview, which occurs approximately 1 week after the initial interview, provides the student with personalized feedback on myths about alcohol's effects, facts on alcohol norms, ways to reduce future risks associated with alcohol use, and a menu of options to assist in making changes. As a harm reduction approach, BASICS motivates students to reduce risky behaviors. It can be implemented in a variety of settings including university health and mental health centers, residential units, and administrative offices. Students can be identified through routine screening or through referral from medical, housing, or disciplinary services. BASICS has been evaluated and found to be effective with nontreatment-seeking students in large, traditional university settings but may be tailored for use with young adults in other settings such as the military.

Interventions for Tobacco

Brief interventions were first developed in the smoking cessation field. A study carried out by Russell et al. (1979) revealed that a small proportion (5.1%) of patients had stopped smoking 1 year after their general practitioner provided a simple brief intervention. This intervention comprised brief advice to quit smoking plus a leaflet with additional information to help patients to achieve their goals. While the results from this study appeared modest from a clinical perspective, the authors estimated that such a simple intervention could easily be delivered by physicians to all smokers who consulted; if implemented by all physicians in the United Kingdom, this could potentially result in over half a million smokers quitting each year. They claimed that this figure could not be matched even if the number of specialist smoking cessation services were doubled.

This move toward interventions in nontreatmentseeking populations was perhaps the key principle supporting the development of brief interventions. The potential impact of brief interventions from a public health perspective was huge and coincided with a growing interest in secondary prevention around this time. A model for brief interventions, derived from this pioneering study, continued to be used within the field of smoking cessation; however, it was further applied to other areas of public health. In particular, brief interventions were applied to excessive alcohol consumption in 1983 as coincidental research had highlighted that lower intensity interventions were often as effective as more intensive treatments coupled with moderate alcohol consumption being accepted as a valid treatment goal. Brief interventions for excessive alcohol consumption have subsequently proved successful in a wide range of published studies.

There have also been over 41 controlled trials of brief interventions for smoking cessation. Pooled data from 17 trials of brief advice versus no advice or usual care have shown that brief interventions result in significant increase in smoking cessation among patients. Brief interventions are shown to be even more effective if combined with nicotine replacement therapy. It has been concluded that when health practitioners provide brief interventions for smoking it increases the likelihood that the patient will successfully quit and remain a nonsmoker 12 months later.

The 5 A's, developed by the US Public Health Service, represent a set of clinical practice guidelines for treating tobacco use and dependence in patients. Activities can be divided among the clinical staff, for example a receptionist can provide patients with a questionnaire that asks if the patient uses tobacco, a physician can advise the patient to quit and prescribe pharmacotherapy, a nurse can help the patient create

a quit plan, and a case manager can refer the patient to intensive counseling and provide follow-up. Successful intervention begins with identifying users and appropriate interventions based upon the patient's willingness to quit. The five major steps to intervention are the 5 A's: Ask, Advise, Assess, Assist, and Arrange.

Ask: Systematically identify and document tobacco use status (current, former, never) for every patient on his/her first clinical visit. Update tobacco use status at least annually.

Advise: In a clear, strong, and personalized manner, urge every tobacco user to quit.

Assess: Establish if the tobacco user is willing to quit. Provide a motivational intervention to all users unwilling to quit and repeat at each visit. Diagnose and treat underlying disorders.

Assist: For users willing to quit provide counseling, resources, and pharmacotherapy to help them quit. Arrange: Schedule follow-up, either in person or on the phone. Provide relapse prevention intervention for all former tobacco users.

Interventions in Other Settings

Unlike smoking, excessive alcohol consumption is associated with social as well as health problems, which means that interventions sometime occur outside of the health context. Prevalence of excessive alcohol consumption is higher amongst those in contact with the criminal justice system. It should be possible to implement brief interventions within the criminal justice system – in prisons, probation settings, and even police stations. Evaluation of brief interventions in a variety of criminal justice settings is ongoing.

Electronic forms of brief intervention can modify behavior compared to controls who generally receive screening or assessment only. However, it is not clear whether electronic forms of brief intervention are as effective as those delivered by therapists since there are conflicting accounts across different trials. One potential source of conflicting findings could be the heterogeneous nature of interventions, which often contain multiple components. Hence, it is difficult to ascertain which components are effective.

Other settings where research studies have shown some positive effects of brief intervention include somatic outpatient clinics, general population health screening work, and workplace or occupational settings. However, more research is needed before we could conclude that brief intervention in these settings was robustly evidence based.

Despite less evidence for the effectiveness of interventions for illicit drug use in nonmedical settings, the CONCLUSIONS 297

evidence for brief alcohol interventions in nonmedical settings may guide the development of brief interventions for illicit drug use.

Interventions for Benzodiazepines

While only six randomized controlled trials have evaluated brief interventions to reduce benzodiazepine use, all six studies produced positive effects. Brief interventions, consisting of a physician's letter, consultation offer, simple advice, and/or self-help booklet, significantly reduced benzodiazepine use compared to control groups. A systematic review with meta-analysis of brief interventions (e.g. giving simple advice in the form of a letter or meeting to a large group of people) and systematic discontinuation (defined as treatment programs led by a physician or psychologist) found both to be significantly more effective than treatment as usual. Using different inclusion and exclusion criteria, a more recent systematic review with meta-analysis assessing the effectiveness of treatment approaches to assist benzodiazepine discontinuation also concluded that interventions were more effective than routine care. Brief interventions in this review consisted of a letter outlining the need to reduce benzodiazepine use, sometimes accompanied by a self-help booklet.

CONCLUSIONS

Research on interventions for alcohol and tobacco has accumulated rapidly during the past two decades. There is now a very large literature on the effectiveness of brief interventions including both opportunistic brief interventions delivered by generalists and brief treatment delivered by addiction specialists. Not only are the procedures generally effective with a variety of population groups, they can be delivered by a variety of health care providers. Less evidence is available regarding brief interventions for other drug users, but several studies show positive effects. There is no reason in principle why some of the findings from the alcohol and tobacco field should not be explored. It could possibly be argued that illicit drug use disorders usually show such a high level of dependence, and/or involve such a strong commitment to a deviant lifestyle that brief interventions are unlikely to be successful. Needless to say, however, these assumptions should be tested and there will almost certainly be exceptional subgroups that may well respond to brief intervention. As indicated above, one example of generalization to substances other than alcohol and tobacco is work on the effectiveness of forms of brief interventions directed against long-term benzodiazepine use in primary health care populations. Research indicates the global efficacy of brief interventions for illicit and licit drugs in the general population.

SEE ALSO

Brief Feedback-Focused Interventions, Motivational Enhancement Approaches, Cognitive Behavioral Therapies, Behavioral Treatments for Smoking, Screening and Assessment of Substance Use Disorders in Youth and Young Adults, Screening and Brief Alcohol Intervention for Adolescents and Young Adults in Primary Care and Emergency Settings

List of Abbreviations

AUDIT alcohol use disorders identification test

BASICS Brief Alcohol Screening and Intervention of College

Students

BCC behavior change counseling
CBT cognitive-behavioral therapy
CDCU college drinker's checkup
DAST drug abuse screening test

FTND Fagerström test for nicotine dependence
FTQ Fagerström tolerance questionnaire
GGT gamma-glutamyl transferase
MAST Michigan alcoholism screening test
motivational interviewing

Glossary

Behavior change counseling adapted or condensed version of motivational interviewing.

Binge drinking episodic excessive drinking. There is currently no worldwide consensus on how many drinks constitute a "binge," but in the United States, the term is often taken to mean consuming five or more standard drinks (male), or four or more drinks (female), in about 2 h for a typical adult. In the United Kingdom, binge drinking is defined as drinking more than twice the daily limit, that is, drinking eight units or more for men or six units or more for women.

Brief interventions a range of clinical activities focused on the use of a talk-based therapeutic approach aimed at changing certain health-limiting behaviors (usually smoking, heavy drinking, or other drug use) and their associated problems.

Cognitive-behavioral therapy a talk-based treatment designed to make individuals change how they think (cognitive) and what they do (behavior).

Dependent drinking when a person meets diagnostic criteria for alcohol dependence.

Harmful drinking when a person drinks over the recommended weekly amount and has experienced health problems directly related to alcohol and will typically meet criteria for alcohol abuse.

Hazardous drinking when a person drinks over the recommended weekly limit or binge drinks. Individuals may not yet have any health problems directly related to alcohol, but are increasing the risk of experiencing problems in the future.

Motivational interviewing a patient-centered interviewing style with the goal of resolving conflicts regarding the pros and cons of

- change, enhancing motivation, and encouraging positive changes in behavior.
- **Primary health care settings** all immediately accessible, general health care facilities that treat a broad range of possible presenting problems, and which can be accessed by wide range of patients on demand, and not as the result of a referral for specialist care.
- **Screening** tool to determine if a patient may be at risk or experiencing early stage harm from alcohol, tobacco, or drug use.
- Secondary health care settings health care provided by hospital clinicians for a patient whose primary care was provided by the general practitioner or other health professional who first diagnosed or treated the patient.
- **Standard drinks** a simple way of remembering alcohol strengths. One standard drink is one half-pint of ordinary strength beer, larger or cider (284 ml, 3.5% ABV); one pub measure of spirits (25 ml, 40% ABV); one standard glass of wine (125 ml, 8% ABV); one small glass of sherry (50 ml, 20% ABV). Also referred to as alcohol units.
- The transtheoretical model developed to describe the stages through which people progress in cessation across a range of addictive behaviors.

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Relevant Websites

- www.alcohollearningcentre.org.uk Alcohol learning centre.
- http://www.inebria.net/ INEBRIA (International Network on Brief Interventions for Alcohol Problems).
- http://www.niaaa.nih.gov/ National Institute on Alcohol Abuse and Alcoholism (NIAAA).
- www.sips.iop.klc.ac.uk Screening and intervention program for sensible drinking.
- http://www.tobacco-control.org The Tobacco Control Resource Centre.
- http://www.surgeongeneral.gov/tobacco/tobaqrg.htm Treating Tobacco Use and Dependence, Quick Reference Guide for Clinicians.
- http://www.who.int/topics/substance_abuse/en/ World Health Organization, Substance Abuse.
- http://www.who.int/topics/tobacco/en/ World Health Organization, Tobacco.
- http://www.gencat.cat/salut/phaseiv/index.htm World Health Organization Collaborative Project on Identification and Management of Alcohol-related Problems in Primary Health Care: Phase IV.

31

Screening and Assessment of Comorbidity

Sharon Dawe*, Genevieve Dingle^{\$}, Natalie J. Loxton^{\$}
*Griffith University, Nathan, QLD, Australia *University of Queensland, St Lucia, QLD, Australia

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THE ISSUE OF COMORBIDITY

Comorbidity is a widely used term that refers to the co-occurrence of two or more mental disorders as defined by the Diagnostic and Statistical Manual of the American Psychiatric Association or International Classification of Diseases (ICD-10). There is considerable comorbidity between substance use disorders and other mental health problems. In people with substance use disorders the most common disorders seen are the anxiety and mood disorders (Hides, Diagnostic Dilemmas in Comorbidity). While figures vary across studies, a third to half of people with a substance use disorder would meet diagnostic criteria for another mental disorder in the previous 12 months. Assessing additional co-occurring disorders in people with a substance use disorder is of particular importance given that the presence of two or more disorders is associated with poorer treatment outcome and greater service utilization. Indeed, the more disorders a person has the greater the impact will be on their ability to function. Finally, the likelihood of keeping an individual in treatment for an optimal period is influenced by whether co-occurring disorders are addressed as part of an integrated treatment approach.

However, it is not simply the presence of another disorder that is of concern. For many people, a substance use disorder may be accompanied by feelings of dysphoria and anxiety that impact on quality life and daily functioning. Such symptoms may not meet diagnostic criteria at the point of first contact with a treatment service, but certainly pose a risk of further exacerbation if not recognized and then addressed within a broader treatment plan.

IDENTIFYING HOW DISORDERS ARE RELATED

The time course and associated symptoms of cooccurring disorders need to be carefully assessed when a person presents with an array of symptoms that could be substance related and also influenced by the presence of another disorder. The possibilities that need to be considered are as follows:

 Are the symptoms due to either withdrawal or intoxication? If so, comorbidity – a second disorder – is not present. For example, "feeling edgy and restless" could be a symptom of amphetamine intoxication,

- alcohol withdrawal or of an anxiety disorder; while "low energy and fatigue" could be a sign of withdrawal from amphetamines or a symptom of depression. If symptoms are substance-related, these symptoms should abate relatively quickly following withdrawal. *See* Diagnostic Dilemmas in Comorbidity for a more detailed discussion.
- 2. Does the substance abuse cause the co-occurring mental disorder/symptoms? If so, the latter are sometimes referred to as substance-induced disorders. Once again, the symptoms of the co-occurring disorder typically cease within a matter of weeks after substance use has stopped.
- 3. Does the substance abuse occur only when the mental health symptoms are present? For example, a person who has social anxiety may drink alcohol prior to a social event. As time progresses there is greater reliance on alcohol (exacerbating alcohol problems).
- 4. Do the co-occurring substance use and mental health symptoms have mutually synergistic effects? This mutual determinism can occur regardless of the causal relationship at the start. So, in addition to the examples given, the first episode of disorder may appear substance-induced, but that may increase the risk of a subsequent independent episode.
- 5. There may be several disorders present that may not be causally related. For example, a person may have a long-standing alcohol problem and then be exposed to a traumatic event. At presentation there would then be two independent disorders, alcohol abuse and posttraumatic stress disorder (PTSD). The former may be exacerbated by the latter.

PURPOSE AND STRUCTURE OF THE CHAPTER

Fundamental to the delivery of effective treatment is the need to identify those who are either at risk of developing a co-occurring disorder or those who have an existing disorder that requires treatment. This chapter provides an overview of the issues surrounding the screening and assessment of a range of co-occurring disorders and describes measures to assess both comorbid mental disorder/s in people with a substance use disorder and comorbid substance use disorders in people with mental disorders. This consists of an overview of: (1) screening measures, i.e. those who are intended to flag that a disorder may be present, (2) diagnostic measures, i.e. those who lead to a formal diagnosis within the current diagnostic nomenclature of the Diagnostic and Statistical Manual (DSM-IV-TR) and the International Classification of Diseases (ICD 10), and (3) symptom measures that allow for the measurement of particular symptoms that may or may not meet formal diagnostic criteria. Within each of these three categories we review key instruments that measure general mood states such as anxiety and depression, emotional well being or psychological health. We further include instruments that assess PTSD and personality disorders as these distinct disorders are prevalent in people with substance use disorders. Finally, we review instruments that are designed to measure psychotic symptoms.

PSYCHOMETRIC ISSUES TO CONSIDER WHEN SELECTING A MEASURE OF COMORBIDITY

There is considerable "behind the scenes" work undertaken before a measure is considered to be scientifically robust. The field of study concerned with the development and testing of psychological measures is psychometrics and involves a series of steps that first begins by defining the construct or concept that is being measured such as depression. In the case of self-report instruments or structured interviews, questions are developed around these concepts and scored as present or absent, or rated on a scale with end points reflecting extremes such as "never" or "not at all" to "always" or "all of the time." It is then important to determine whether this measure has predictive validity. In the case of depression, for example, does the reduction in score on this measure predict improvement over the course of treatment such as a decrease in sadness and hopelessness and an increase in energy level and whether the measure converges with other measures of the same construct (convergent validity)? The accuracy of an instrument is assessed by how well it detects the presence of a disorder (sensitivity) and absence of a disorder (specificity). The validity of an instrument is constrained by its reliability. Inter-rater reliability assesses whether two independent raters would reach the same score or diagnosis (and is relevant to instruments requiring interviewers to observe or rate symptoms); internal consistency is the extent instrument's items correlate with each other and form a total score (typically measured by Cronbach's alpha) and its test-retest reliability measures how stable its scores are over time.

SCREENING FOR MENTAL DISORDER IN PEOPLE WITH ADDICTIVE DISORDERS

Screening instruments are best thought of as a way of "flagging" that there are other important problems that

may need either or both (1) further assessment and/or (2) inclusion in a treatment plan. They are brief, easily administered, and scored and developed for use across a range of settings. There are several well validated and widely used measures for general psychological functioning and well being that can be easily administered. The following are some examples.

The General Health Questionnaire (GHQ) is one of the most widely used measures and is particularly sensitive to the presence of psychological problems in individuals presenting in primary care settings. The GHQ28 and GHQ12, with 28 and 12 items, respectively, are well validated and found to be sensitive to the presence of mental health problems such as anxiety, depression, somatic complaints, and social withdrawal. The GHQ has been translated into 38 languages. The widespread use of the GHQ enables comparisons to be made across different populations as well as having well established cut-off scores that indicate "caseness."

A similar instrument that was developed by Kessler and colleagues at Harvard Medical School is the Kessler-10 (K10) and the shorter 6-item version (K6). The K10 was originally designed to form the mental health component in the annual United States National Health Interview Survey. Since then, it has been included in many other epidemiological surveys including the United States National Health Interview Survey and the American Indian Services Utilization, Psychiatric Epidemiology, Risk and Protective Factors Project. The K6 was also in the Australian National Indigenous Health Survey in 2004–2005. The Kessler screens for the presence of psychological distress in the preceding 30 days and has items that cover behavioral, emotional, cognitive, and psychological difficulties which fall into four distinct categories: negative effect, nervousness, lethargy, and agitation. The *K10* has strong psychometric properties and is a good predictor of mental illness. Like the GHQ, it has been translated into many different languages, and these versions are available to download from the Internet.

A well-validated screening measure for PTSD is the *Primary Care Posttraumatic Stress Disorder Screen*. This measure consists of four items that measure the main symptom clusters of PTSD in the last month: reexperiencing, numbing, avoidance, and hyperarousal. Each item on the PC-PTSD is administered with the opening statement, "In your life, have you had any experience that was so frightening, horrible, or upsetting that in the past month you..." Items are scored as yes (1) or no (0) and individual scores are summed to provide an overall score ranging from 0 to 4. This measure has been shown to have strong psychometric properties and has cut-off scores that provide important information on the likelihood of a person needing further assessment of trauma-related symptoms.

There are many people with substance use problems who also have long-standing personality problems that have been found to impact on treatment outcome. For those whose substance use meets diagnostic criteria for abuse or dependence, the estimates for concurrent personality disorder fall between a quarter and half the substance use treatment population (compared with an approximately 10% in the general population). There are relatively few screening instruments developed to flag personality disorders. One that shows promise is the Standard Assessment of Personality – Abbreviated Scale (SAPAS). This clinician-administered scale consists of eight items that are scored as present (1) or absent (0). The SAPAS is quick to administer and derives a single score. A score of three or more may need to be followed up with a more detailed structured interview for personality disorders. The SAPAS tends to be more sensitive to the presence of paranoid, dependent, avoidant, and borderline personality disorders, and is less sensitive to antisocial personality disorder. Given the high rates of antisocial diagnoses typically found in substance abuse treatment settings, clinicians within inpatient substance abuse treatment clinics may also use additional screens.

An alternative to the SAPAS is the *Iowa Personality Disorder Screen (IPDS)*. A mini-structured interview, the IPDS consists of 11 items designed to test each of the 11 DSM-IV axis II disorders. A score of 3 from the following suggests further follow-up: (1) marked shifts in mood, (2) actions directed toward immediate satisfaction, (3) reluctance to confide in others, (4) excessive social anxiety, (5) unwillingness to get involved unless certain of being liked, (6) lack of stable image, and (7) prone to overemphasize importance.

In situations in which a self-report measure is desired to screen for possible personality disorders, clinicians may wish to use the *DSM-IV and ICD-10 Personality Questionnaire (DIP-Q)*. Unlike the SAPAS and the IPDS, the DIP-Q is a questionnaire completed by the client. However, this is a lengthy device with 151 yes/no items plus further rating scales of impairment and ratings of global functioning. As with the SAPAS and the IPDS, the DIP-Q has been validated in substance use treatment samples and has been found to correlate highly with treatment staff ratings of personality.

The final diagnostic category that is worth screening for is the schizophrenia spectrum disorders. While psychotic disorders can be considered to be low prevalence disorders, when present they have considerable impact on treatment course and outcome. *The Psychosis Screener* is one of the several instruments that have been developed to screen for the presence of a psychotic illness such as schizophrenia. This measure was originally developed as screening for psychotic disorders in an epidemiological study of mental health and well

being in Australia. It consists of seven items, although three of these are only asked if the previous question is answered "yes." Its items are drawn, in part, from the *Composite International Diagnostic Interview (CIDI)*. A score of 1 indicates that there may be psychotic symptoms that require further assessment (Table 31.1).

SCREENING FOR ADDICTIVE DISORDER IN PEOPLE WITH MENTAL DISORDER

There have been several reviews of assessment instruments to identify addictive disorder in people who experience a mental disorder – see examples in the further reading. These instruments may be separated into screening instruments (e.g. AUDIT, SDS, MAST, CAGE, DAST), consumption patterns (Timeline Followback), level of dependence (SADQ, SODQ), collateral reports and urine screens, and measures of substance related problems (e.g. DrInC).

Most of these are client self-report measures. However, the AUS/DUS are five-item clinician-administered screens, and the Addiction Severity Index is regarded as a gold standard in substance-related interviews. A new self-report measure, the DrugCheck Problem List accurately predicts substance use disorder in people with psychosis. The problem list identifies areas to address in further assessment and in treatment.

DIAGNOSIS OF COMORBIDITY

A mental disorder is diagnosed when a set of clearly specified criteria for the presence of a disorder has been met within the current diagnostic classification systems: The Diagnostic and Statistical Manual of Mental Disorders (currently in its fourth revision, and draft fifth revision – see website listed at the end of the chapter) and Chapter V: Mental and Behavioral Disorders, of the ICD-10. However, diagnosing both substance use problems and other mental disorders is plagued by difficulties in that symptoms frequently overlap. For this reason, diagnostic assessment should ideally occur following a period of abstinence, or at least when the person is not intoxicated or experiencing substance induced withdrawal. A general rule of thumb is to allow 2–4 weeks since cessation of use in order ensure that there are no confounding effects of either intoxication or substance withdrawal. In services that do not provide this time for assessment, multiple assessments over time can be helpful.

The primary purpose of a diagnosis is to provide clear descriptive categories that allow for more effective treatment planning and patient management. When diagnoses are necessary, the use of structured clinical interviews to differentiate between comorbid substance misuse disorders and other mental disorders is strongly recommended, as structured interviews are both more accurate and have greater inter-rater reliability than the traditional unstructured diagnostic interview. Indeed, structured interviews are generally considered the "gold standard" of diagnostic assessment. However, they do not typically provide an index of symptom severity, which is important for assessment of changes after treatment. In addition, they are considerably more time-intensive than the screening instruments and other self-report measures, and require training in the administration and scoring of the clinical interview.

There are a number of well-validated structured diagnostic interviews that are based on the DSM. The Psychiatric Research Interview for Substance and Mental Disorders (PRISM) was developed specifically for the assessment of comorbid psychiatric diagnoses in people with substance abuse, including an assessment of 20 DSM-IV axis I disorders and 2 axis II disorders: antisocial personality disorder and borderline personality disorder. The interview begins with recording heavy drug and alcohol use across the lifetime. In this way, it is possible to plot the course of symptoms that occur within the context of substance use by taking into account the potential effects of intoxication or withdrawal. A disorder is considered to be substanceinduced if (1) all DSM criteria are met, (2) the symptoms occur entirely during a period of heavy substance use or within the first 4 weeks of cessation of use, (3) the substance used is related to the nature of the symptoms shown, and (4) the symptoms are greater than the expected effects of intoxication or withdrawal. There is growing evidence that the PRISM is the most reliable diagnostic instrument when there is comorbidity. However, in common with other diagnostic interviews, the PRISM requires training and establishment of reliability, and takes some time to administer.

The Structured Clinical Interview for DSM Diagnosis (SCID-CV) has been widely used in psychiatric research for many years. While it is not as reliable as the PRISM in determining whether the condition is substance induced, it is still considered to be one of the gold standard instruments. The SCID is organized around disorder classes, which allows the researcher or clinician to tailor a diagnostic assessment. An example question for the diagnosis of a depressive episode is: "In the past month, has there been a period of time when you were feeling depressed or down for most of the day nearly everyday?" - where the clinician rates the patient with a "+" or "0," followed by prompts for further descriptive information as required. The SCID can be administered in pencil and paper form or in computerized form; there are versions for clinicians (SCID-CV) and for researchers (SCID-RV) with an online resource

 TABLE 30.1
 Screening Measures for Comorbidity

Screening measures: author and date	Description	Cut off scores
(a) General mental health		
General Health Questionnaire (GHQ): Goldberg, 1972	Designed to screen for psychological distress in the general population. Measures depression, anxiety, somatic symptoms, and social withdrawal. Two versions: a short 12-item version and a 28-item version. Translated across a range of languages.	Cut off available for both. "caseness" GHQ28 = 4, GHQ12 = 3.
Kessler 10, K-6: Kessler, 1996; Andrews and Slade, 2001	Designed to screen for depression and anxiety in the previous 30 days. Consists of 10 items on 5- point rating scales. Translated across a range of languages.	K10 $10-15 = low$; $16-21 = moderate$; $22-29 = high$; $30-50 = very high$ psychological distress.
(b) Trauma/PTSD		
Primary Care PTSD screen (PC-PTSD): Prins et al., 2004; Kimerling et al., 2006	PC-PTSD is a four-item yes/no rated scale to detect PTSD: reexperiencing, numbing, avoidance and hyper-arousal in the past month.	Cut off score of 3 indicates further assessment.
(c) Personality disorders		
Standard Assessment of Personality — Abbreviated Scale: (SAPAS): Moran et al., 2003; Hesse and Moran, 2010	Eight yes/no items deriving a single score with a follow-up question. The SAPAS is a general screen for the presence of a personality disorder. This measure is more sensitive to paranoid, dependent, avoidant, and borderline personality and less sensitive to antisocial personality disorders.	Cut off of 3 indicates the probability of a personality disorder.
Iowa Personality Disorder Scale (IPDS): Langbehn et al., 1999; Casillas and Clark, 2002	An alternative to the SAPAS, the IPDS is a 11-item mini-structured interview that screens for each of the 11 personality disorders in the DSM-IV. Items 1—6 are general screening questions, items 4—8 assess social anxiety and instability.	Cut off of 2–3 for items 1–6; cut off of 2 for items 4–8.
DSM-IV and ICD-10 Personality Questionnaire (DIP-Q): Hesse, 2005	A 151-yes/no item self-report questionnaire with an additional five-item impairment and distress scale and a 100-point global functioning scale as used in the DSM-IV. This questionnaire is based on DSM-IV and ICD-10 axis II criteria. Takes approximately 20 min to complete. Computer scoring recommended.	Cut off for diagnosis require the specified number of criteria as per the DSM/ICD plus a score >1 on the distress scale and global functioning <70.
(d) Psychosis		
Psychosis screener: Degenhardt et al., 2005	Derived from the CIDI the psychotic screener has seven items in total with three only asked if previous questions are positively answered. Items cover delusions of control, thought interference, and passivity, delusions of reference or persecution, grandiose delusions, and whether respondent reports ever receiving a diagnosis of schizophrenia.	Cut off of one indicates likely psychotic case.
(e) Substance use in people with a mental illne	rss	
AUDIT: Saunders et al., 1993	The alcohol use disorders identification test is a 10-item self-report measure those screens of drinking at hazardous and harmful use. Rated on a 4-point Likert type scale, the AUDIT provides a possible score of 0–40. The AUDIT has been validated on a wide range of samples from across the world. The AUDIT assesses quantity and frequency of drinking, binge drinking, alcohol dependency symptoms, and negative consequences from drinking.	Scores of 8 or above suggest hazardous drinking. Scores of 13 or above indicate harmful drinking. Lower cut off has beer recommended for women and adolescents.

TABLE 30.1 Screening Measures for Comorbidity—cont'd

Screening measures: author and date	Description	Cut off scores
SDS: Gossop et al., 1995	The severity of dependence scale is a five-item self-report measure that assesses the degree of psychological dependence on a range of drugs. The SDS focuses on anxiety regarding use, impaired control over drug use and excessive preoccupation with drug use. Unlike other measures of drug use severity the SDS does not assess physical symptoms such as withdrawal and tolerance.	Cut off differ across drug of use: 4 for amphetamine, 3 for cannabis and 6 for benzodiazepine.
AUS/DUS: Drake et al., 1996	The alcohol use scale (AUS) and drug use scale (DUS) are five-item clinician administered screens with items based on the DSM-IV criteria for alcohol and drug use disorders during the past six months.	Patients are assigned a score from $1 = no$ use, $2 = use$ with impairment, $3 = abuse$, $4 = dependence$, to $5 = dependence$ with institutionalization.
DrugCheck Problems list: Kavanagh et al., 2011	The drugcheck problem checklist (PL) predicts substance use disorder in people with a psychosis. It has 12 items rated No (0), 1 (A bit) or 2 (A lot); with eight items adapted from the Problem Drinking Questionnaire, and four items assessing psychological impact of substance use. The problem list identifies areas to address in further assessment and in treatment.	A cut off score of 2 indicates the presence of a DSM-IV abuse or dependence with 97% sensitivity and 84% specificity.

site. Although clinically experienced interviewers tend to achieve better inter-rater reliability and overall diagnostic accuracy than novice interviewers, both groups are able to achieve and maintain high levels of reliability and diagnostic accuracy.

A companion interview for diagnosing axis II disorders, the Structured Clinical Interview for DSM-IV Personality Disorders has been developed. This measure covers 11 DSM-IV personality disorders in addition to two personality disorders no longer included in the DSM-IV (depressive and passive aggressive). The SCID-II has been validated across a range of client populations including those with drug and alcohol use disorders. The SCID-II also includes a questionnaire for the client to complete prior to the interview. This "brief screen" takes approximately 20 min to complete. The clinician is then able to follow-up with any endorsed items. The SCID-II is regarded as one of the "gold standards" for assessing axis II pathology. However, structured interviews such as the SCID-II are lengthy and require specialist training. In large part, these limitations have led to the development of shorter, brief screens such as those discussed in the previous section, such as the SAPAS and the IPDS.

The *CIDI*, developed by the World Health Organization, is also a structured symptom interview that provides DSM-IV and ICD-10 diagnoses. As with the SCID it can be administered in either paper and pencil or computer-administered forms; the latter can be completed by patients themselves if they are able to understand the nature and purpose of the questions. A

short form of the CIDI (CIDI-SF) has been developed that can be administered as a screener to rule out nondisordered cases rather than as a diagnostic assessment instrument as it tends to overestimate the rate of diagnoses. The CIDI is supported by 10 centers around the world, where standardized training programs are provided. There is a data entry and scoring program to derive diagnoses.

A third brief structured interview is the *The Mini-International Neuropsychiatric Interview – Version 6* (*M.I.N.I.6*). The M.I.N.I. is a short diagnostic structured interview developed in the United States and Europe, with "Yes/No" items designed to generate positive diagnoses for 23 axis I disorders in the Diagnostic and Statistical Manual-IIIR and IV. There are clinician-rated (M.I.N.I.-CR) and patient-rated (M.I.N.I.-PR) versions.

The structured interviews provided by the SCID, CIDI and M.I.N.I.6 cover all diagnoses contained in the DSM and ICD, and it is possible to use particular sections of each instrument to check for the presence of one diagnosis only. However, there are a number of other diagnostic schedules for specific disorders. These are often slightly longer instruments, and in some instances provide more accurate diagnostic classification of individual, targeted disorders. *The Clinician Administered PTSD Scale (CAPS)* is a structured clinician-administered interview designed to assess the 17 PTSD symptoms identified in the DSM-IV and associated features such as guilt over acts, survivor guilt, gaps in awareness, depersonalization, and derealization. The CAPS includes standardized questions to determine the

TABLE 30.2 Diagnostic Interviews for Comorbidity

Diagnostic interviews: author and date	Description
PRISM: http://www.columbia.edu/~dsh2/prism/	Extensive structured interview covering axis I and some axis II disorders (antisocial personality and borderline personality disorder). Current gold standard for differentiation of primary psychotic disorder and schizophrenia disorders. Best used in research settings.
Structured Clinical Interview for DSM Disorders (SCID): Spitzer et al., www.scid4.org	Clinician administered structured interview with modules for various disorder classes. Online or hard copy versions available, and SCID-II for personality disorders (see below).
Composite International Diagnostic Interview (CIDI): Andrews and Peters, 1998.	A structured symptom interview that yields diagnoses according to both the DSM-IV and ICD-10 diagnostic criteria. Available in either hard copy or computerized versions.
Mini International Neuropsychiatric Interview: (MINI): Sheehan et al., 1998, Mordal et al., 2010	Interview with yes/no items designed to generate positive diagnoses for 23 axis I disorders in the DSM-IV. There are clinician-rated (MINI-CR) and patient-rated (MINI-PR) versions.

frequency and intensity of each symptom over the past month, using standard prompt questions and explicit, behaviorally anchored rating scales. The CAPS has been found to be both reliable and valid in a number of different populations (Table 31.2).

ASSESSMENT OF SYMPTOMS

Some of the screening measures reviewed above are also used as symptom measures to track progress across time. Other measures that tend to be longer are also available to monitor change across time. One of the most widely used of these in the substance misuse field is The Addiction Severity Index (ASI), which has been in use for over 25 years. The ASI is a semi-structured interview that assesses the frequency of substance use and areas of everyday functioning that are also affected by substance misuse i.e. poor physical health, distress, family/social environment, employment/financial problems, and legal difficulties. Each item is assessed with reference to two time frames: lifetime and current (past 30 days). The instrument is sensitive to treatment effects and can be used to monitor individuals across several admissions. The ASI is the most widely used instrument in US substance abuse clinics, and is used increasingly in other countries. It has been made freely available in the public domain, promoting its use and increasing the rich source of information on cross cultural applicability and validity. There are also shorter versions available which tend to be used by treatment agencies rather than researchers. The ASI-Lite, is made up of 111 items and can be administered in approximately 30-40 min.

Another frequently used measure is the *Health of the Nation Outcome Scale (HoNOS)*. This is a clinician-rated

instrument with 12 items that measure behavior, impairment, symptoms, and social functioning on a five-point scale (0 = no problem, 1 - 4 = minor problem to very severe problem) in the previous two weeks. There are versions designed for adults, children, and older adults. While the HoNOS appears psychometrically sound, there have been concerns regarding accuracy of symptom description, complexity of social items, and the subjective nature of terminology used. In addition, the measure does not appear to be sufficiently sensitive to cultural differences. As with other clinician-rated instruments, training and ongoing monitoring of interrater reliability are needed to ensure ratings are accurate.

There are also many self-report instruments that can be used to track symptom course for the mood and anxiety disorders. Those that are widely used include The Beck Depression Inventory (BDI), a 21-question selfreport inventory, the Speilberger State Trait Anxiety Inventory, and the Depression Anxiety and Stress Scale. All are also well validated and have been shown to be sensitive to treatment gains. The Adult Wellbeing Scale, although less well known, has been recommended as a key measure of parental functioning under the framework for the assessment of children, Department of Health, UK. In addition to these measures are a number of instruments developed to assess the severity of psychotic symptoms. One of these is *The Brief Psychiatric* Rating Scale. This is administered by a clinician or researcher to measure psychiatric symptoms such as depression, anxiety, hallucinations, and unusual behavior associated with psychosis. Finally, the Posttraumatic Stress Symptom Scale Self-Report (PSS-SR) is a selfreport version of the structured interview for PTSD. The 17 items on this scale are identical in content to the interview, but contain simplified wording. The

TABLE 30.3 Description of Symptom Measures

Symptom measures: author and date	Description	Norms and cut-off scores
(a) General mental health		
The Addiction Severity Index: McLellan et al., 1992, 2006; Makela, 2004. http://www.tresearch.org/resources/instruments.htm	A semi-structured interview of frequency of substance use and associated problems, lifetime and current (past 30 days).	Extensive normative data available, accessible through websites and publications (e.g. McLellan et al., 2006)
Health of the Nation Outcome Scale (HoNOS): Wing et al., 1996	A semi-structured interview consisting of 12 items assessing psychosocial functioning of respondents in treatment for a range of disorders. Uses a five point rating scale covering the previous 2 weeks.	Both adult and adolescent/child (Health of the nation outcome scale for children and adolescents; HoNOSCA) norms are available.
(b) Mood disorders		
Beck Depression Inventory-II: Beck et al., 1996	The Beck Depression Inventory (BDI, BDI-IA; BDI-II) is a 21-question multiple choice self-report inventory, with items rated from 0–3 according to frequency in past week.	Cut off score on the BDI-11: 0–13 (minimal depression), 14–19 (mild depression), 20–28(moderate depression), 29–63 (severe depression)
The Speilberger State Trait Anxiety Inventory: Speilberger, 1983	The STAI comprises two 20-item scales: the state measure assesses how respondents feel "right now, at this moment," and the Trait measure targets how respondents "generally feel." The scale has been used in thousands of studies and translated to over 30 languages.	Both percentile ranks and standard (<i>T</i>) scores are available for male and female adults in three age groups (19–39, 40–49, 50–69). Norms also available for high school students.
The Adult Well Being Scale: Snaith, 1978	18 item measure of adult well being with four subscales: depression anxiety, outward irritability, and inward irritability	Scoring available on website framework for the assessment of children, UK.
(c) Psychoses		
Brief Psychiatric Rating Scale: (BPRS) Overall and Gorham, 1962; Leucht et al., 2005	The BPRS is a rating scale in which a clinician or researcher may use to measure psychiatric symptoms such as depression, anxiety, hallucinations, and unusual behavior. Each symptom is rated 1–7 and depending on the version between a total of 18–24 symptoms are scored.	Norms are available for a range of diagnostic samples.
(d) Trauma/PTSD		
Posttraumatic Stress Symptom Scale Self Report (PSS-SR): Foa et al., 1993, 1997, 1999	Is a 17 item self-report version of Foa's structured interview for PTSD. The questions correspond to DSM-IV symptoms so that the measure permits diagnosis of the disorder. Subscale scores are calculated by summing symptoms in the reexperiencing (four items), avoidance (seven items), and arousal (six items) clusters.	Cut off score of 13 indicates likelihood of PTSD. Norms available for men and women who have suffered a traumatic event.

questions correspond to DSM-IV symptoms so that the measure permits diagnosis of the disorder. The PSS-SR is intended for use with individuals who have a known assault history. If the background information is unknown, the PSS-SR should be used in conjunction with a trauma screen (Table 31.3).

SUMMARY AND CONCLUSIONS

In summary, epidemiological and clinical studies indicate that people with a substance misuse problem typically

also experience a range of other mental disorders or psychological problems. These may be separate diagnoses and may or may not predate the substance misuse problem. However, as there is growing consensus that it is important to treat both problems in an integrated manner, it is necessary to determine the most efficient method for assessing for co-occurring symptoms/disorders. We have presented a range of measures that may be selected to screen for the presence of a disorder, be used to determine if diagnostic criteria are met for the disorder and finally to measure symptom changes over time. Awareness and consideration of the full range of

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factors that may contribute to substance use problems is the first important step in treatment planning.

SEE ALSO

Diagnostic Dilemmas in Comorbidity, Implications of Comorbidity for Clinical Practice, Treatment for Co-occurring Substance Abuse and Mental Health Disorders

List of Abbreviations

2100 01	
ASI	Addiction Severity Index
AUS	alcohol use scale
CAPS	Clinician Administered PTSD Scale
CIDI	Composite International Diagnostic Interview
DIP-Q	DSM-IV and ICD-10 Personality Questionnaire
GHQ	General Health Questionnaire
ICD-10	International Classification of Diseases
IPDS	Iowa Personality Disorder Screen
PRISM	Psychiatric Research Interview for Substance and Mental
	Disorders
PSS-SR	Posttraumatic Stress Symptom Scale Self-Report
PTSD	posttraumatic stress disorder

Glossary

SAPAS

SCID

Convergent validity the extent to which a measure is associated with other measures of the same construct.

Structured Clinical Interview for DSM Diagnosis

Standard Assessment of Personality - Abbreviated Scale

Cronbach's alpha an index of internal consistency of a questionnaire or scale.

Cut-off scores scores on a measure that best identifies correctly between individuals likely to have a disorder and individuals unlikely to have a disorder.

Inter-rater reliability the extent of agreement between two or more raters on measures that require a judgmental score/diagnosis.

Norms a summary of measure scores including typical means for various clinical and nonclinical populations obtained from large, representative samples.

Predictive validity the extent to which scores on a measure are predictive of future behavior and emotions assessed by the measure.

Psychometrics the field of study concerned with the development and testing of psychological measures.

Reliability the extent to which a measure consistently assesses a disorder or symptoms of a disorder.

Sensitivity the accuracy of correctly detecting the presence of a disorder.

Specificity the accuracy of correctly identifying the absence of a disorder.

Test–retest reliability the extent to which scores on a measure change across time in the absence of treatment.

Validity the extent to which a measure accurately assesses the construct that was designed to measure.

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http://www.dh.gov.uk - Adult Wellbeing Measure, see Framework for the assessment of children in need and their families.

http://whqlibdoc.who.int/hq/2001/who_msd_msb_01.6a.pdf – Alcohol Use Disorders Inventory.

http://psych.org/MainMenu/Research/DSMIV/DSMV.aspx – American Psychiatric Association. DSM-5: The Future Manual.

http://www.psychiatrictimes.com/clinical-scales/schizophrenia/ – Brief Psychiatric Rating Scale.

http://psych.org/MainMenu/Research/DSMIV.asp – Diagnostic and Statistical Manual.

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Diagnostic Dilemmas in Comorbidity

Leanne Hides

Queensland University of Technology (QUT), Brisbane, QLD, Australia

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INTRODUCTION

The high rates of comorbid mental health and substance use disorders and the poor clinical, functional, and treatment outcomes associated with them make the accurate diagnosis of comorbid disorders an important clinical priority. However, a number of diagnostic dilemmas associated with the presence of comorbid disorders have hindered our understanding of the etiology of comorbid disorders and our ability to effectively treat them. This chapter begins by discussing the prevalence of common comorbid disorders. The diagnostic dilemmas created by comorbid disorders and issues with the reliability, validity, and clinical utility of current systems of psychiatric nomenclature's approach in diagnosing comorbid disorders will then be briefly reviewed. A number of alternative models for understanding comorbid disorders will be briefly discussed, followed by suggestions for how research can improve our understanding of comorbid disorders.

COMMON COMORBID DISORDERS

Alcohol and cannabis are the most commonly used licit and illicit drugs in the world. Affective and anxiety disorders are also highly prevalent worldwide. Data

from the United States National Comorbidity Survey-Replication indicated that 26.2% met criteria for a mental health disorder in the past 12 months, including anxiety (18.1%), mood (9.5%), impulse control (8.9%), and substance use disorders (3.8%). Similar 12-month prevalence rates of mental health disorders (20%) were reported in the Australian National Survey of Mental Health and Wellbeing (NSMHWB) indicating that 14.4% had an anxiety disorder, 6.2% had an affective disorder, and 5.1% had a substance use disorder. Depression is now the leading global cause of years lost to disability and alcohol and drug use disorders rank in the top 10 most disabling conditions in the developed world. Alcohol is a major risk factor for chronic disease and injury and is responsible for 3.8% of all deaths and 4.6% of global disability-adjusted life-years worldwide.

Epidemiological data consistently indicate that mental health and substance use disorders frequently co-occur. The 2010 Australian National Drug Strategy Survey reported recent drinkers who drank at least once a week (>4 standard drinking units) were more likely to be diagnosed with a mental illness (13.6%) than low risk drinkers (11.1%). Cannabis users in the previous 12 months (18.7%) or in the previous month (20.5%) were also more likely to have been diagnosed with mental illness than nonusers (11.3%).

Comorbidity is not random, and some disorders cooccur much more frequently than others. Substance use disorders are particularly prevalent among individuals with bipolar disorder, with population estimates of a 12-month prevalence rate of 33%. Large-scale international surveys have found consistently high rates of cannabis use in psychotic populations. For example, the Australian NSMHWB found that cannabis-dependent individuals were 11 times more likely to screen positively for psychosis. Community studies conducted in the United States and Australia found that individuals with alcohol dependence are 3-4 times more likely to have a concurrent anxiety or affective disorder compared to the general population. Cannabis dependence has been associated with between 3 and 6 times the risk of a comorbid mood or anxiety disorder.

Even higher rates of comorbid disorders are found within treatment settings. Between 30 and 50% of individual presenting to alcohol/drug or mental health treatment services meet criteria for comorbid substance use and depression disorders. High rates of comorbid alcohol and anxiety disorders (15–45%) have also been documented, with comorbid alcohol and social anxiety or posttraumatic stress disorder (PTSD) the most common. Of particular concern are the high rates of comorbid cannabis use and psychotic disorders, with recent studies reporting rates ranging from 40 to 74%.

PSYCHIATRIC NOMENCLATURE AND COMORBIDITY

Such high levels of comorbid disorders pose a significant challenge to diagnostic systems such as the Diagnostic and Statistical Manual (DSM) and the International Classification of Diseases (ICD). These diagnostic systems were developed to improve the reliability of clinical diagnoses and enhance treatment planning and outcomes. However, clinical diagnoses may be unreliable due to five sources of error variance. This includes subject variance, in which individuals have different diagnoses at different times, occasion variance in which individuals may be in different stages of the same condition at different times, and observation variance due to clinicians noticing different things about the same patient. The two largest sources of unreliable diagnoses are information variance, which occurs when clinicians have different sources of information, and criterion variance, when clinicians vary diagnostic criteria. These sources of diagnostic variance are even more pronounced among individuals with comorbid disorders, as clinicians need to identify two or more comorbid disorders, based on a complex history, typically provided by an acutely unwell patient over a short timeframe, with little collateral information available.

The diagnosis of comorbid mental health and substance use issues is further complicated by variability in the nature of the relationship between the disorders (see Models of Relationships between Substance Use and Mental Disorders). First, comorbid mental health and substance use disorders may represent two or more independent conditions with their own clinical course, treatment needs, and outcomes. Second, there may be an interaction between mental health and substance use disorders. Substance use may contribute to the onset, course, and relapse of mental health problems, such as the growing evidence for the influence of cannabis use on the onset, course, and relapse of psychosis. Third, substance use may develop secondary to a mental health condition in an attempt to alleviate the symptoms of the disorder or the side effects of psychiatric medications. For example, the relief of depression and anxiety symptoms are the commonly reported reasons for substance use among a range of comorbid populations. Finally, mental health symptoms may develop as a consequence of substance use. For example, substance users often present with a depressed mood as well as a number of other symptoms of major depressive disorder (MDD) including anhedonia, poor sleep, and feelings of hopelessness, suicidal ideation, and intent. The relationship between mental health and substance use disorders may also be bidirectional, where the disorders interact to mutually influence the course and outcomes of each disorder. For example, while cannabis use has been strongly associated with psychotic symptom severity and relapse, there is also evidence that individuals may increase their cannabis use in response to exacerbations in psychotic symptoms. Thus, after identifying the presence of comorbid disorders, clinicians must develop an understanding of the relationship between the mental health and substance use disorders in order to develop a case formulation and treatment plan.

The multiaxial format of both the ICD and the DSM allows for the recording of comorbid disorders as well as other presenting problems on multiple domains. Traditionally, comorbidity was defined according to primary and secondary disorders, in which the primary disorder was usually defined by chronology. However, this approach provides little information on the relationship between the comorbid disorders. While several suggestions for improving the recording of comorbid disorders have been made, including the use of asterisks and arrows, or the use special axes (as in the Chinese classification of mental disorders) to denote the potential relationship between comorbid disorders, there has been little uptake of these ideas.

The role of substance-induced disorders (SID) in the high prevalence of comorbid disorders also requires consideration, as some of the observed relationships between mental health and substance use disorders may be the result of drug intoxication and withdrawal. For example, the resemblance of the intoxication and withdrawal effects of substances such as cannabis and stimulants to the symptoms of psychosis (e.g. persecutory ideas) make it difficult to differentiate substance induced from primary psychotic symptoms. Cannabisinduced psychotic disorder is characterized by the presence of persecutory delusions, anxiety, emotional variability, and depersonalization, while the common symptoms of stimulant-induced psychosis include persecutory delusions, distorted body image, misperception of people's faces and tactile hallucinations (bugs under skin). Substance-induced depression disorders may also develop during alcohol intoxication or withdrawal, or during withdrawal from cannabis, sedatives, and anxiolytics. The presence of SID has also been associated with intoxication with cocaine, hallucinogens, inhalants, opiates, PCP, sedatives, hypnotics, and anxiolytics.

The prevalence of SID varies across different categories of substances and mental health disorders. For example, up to 40% of alcohol-dependent and 65% of stimulant-dependent individuals will develop SID. Forty-four percent of 386 psychotic patients were found to have a substance-induced psychosis (SIP), while the remaining 56% had primary psychotic disorder (PPD) with concurrent substance use. Cannabis-induced psychosis (19%) was the most common type of SIP, followed by alcohol- (17%) and cocaine-induced psychosis. Similarly, another study found 30% of 1193 alcoholdependent adults diagnosed with MDD had an SID. A comparatively lower rate (2.4%) of 320 alcoholdependent adults with anxiety disorders in the same study had a SID, but this is likely to be an underestimate as generalized anxiety disorder and PTSD were not assessed.

The addition of diagnostic criteria for SID to DSM-IV sought to improve the diagnostic reliability of comorbid disorders, by providing information on the specific timeframes and conditions necessary to distinguish substance-induced from primary disorders among individuals with substance use. For example, a DSM-IV diagnosis of SIP is made when psychotic symptoms only occur during periods of heavy substance use, and exceed the expected effects of intoxication or withdrawal. In contrast, a PPD is diagnosed if a full psychotic syndrome (including schizophreniform, schizophrenia, schizoaffective disorder, etc.) is established before substance use onset, if the symptoms are in excess of what would be expected for the type or amount of substance used, or if symptoms persist for more than 4 weeks after the cessation of acute intoxication or withdrawal.

However, the DSM criterion for SID is difficult to apply in clinical practice. The accurate diagnosis of substance induced from primary disorders in the context of substance use relies on clinicians being able to reliably differentiate (1) the expected effects of drug intoxication and withdrawal, (2) mental health disorders occurring during period of active substance use, and (3) mental health disorders that are independent from substance abuse. Clinicians rarely have the opportunity to observe patients during sufficient periods of abstinence (>4 weeks) to accurately differentiate these three conditions. The criteria offer little guidance on the frequency, severity, and duration of psychotic symptoms or substance use required to meet the criteria for an SID. The 4-week timeline also contradicts data relating to the clearance of substances such as cannabis in urine (46–77 days after last consumption). It is also unclear how clinicians are supposed to establish the independence of mental health symptoms from substance use, among substance users. Finally, the term substance-induced is also misleading, as it implies causation, whereas DSM specifies that a diagnosis of SID be used when it is not possible to establish the independence of the psychotic symptoms from substance use.

STRUCTURED CLINICAL INTERVIEWS

A number of structured diagnostic interviews have been developed to improve the reliability of psychiatric diagnoses. However, many of these instruments were not developed specifically to assess comorbid mental health and substance use disorders.

For example, the Structured Clinical Interview for DSM (SCID) differentiates primary from SID by determining (1) if the onset of mental health symptoms preceded alcohol or drugs use and (2) if the mental health symptoms are greater than the extent expected from the effects of the substance itself. This process can be problematic, however, as guidelines on the expected effects of the substances are not provided, nor are specific questions to determine the temporal relationship between mental health symptoms and substance use. These diagnostic issues are highlighted by the results of several studies finding that the SCID has poor levels of inter-rater reliability among substance users. Other diagnostic instruments, such as the Composite International Diagnostic Interview (CIDI), suffer from the same definitional limitations as the SCID and have only moderate levels of reliability among substance users.

Several diagnostic instruments have been designed specifically to differentiate substance induced from primary disorders and improve the reliability of comorbid diagnoses. The Semi-structured Assessment for the Genetics of Alcoholism (SSAGA), developed for use in population-based studies, provides current and lifetime diagnoses of mental health and substance use disorders, classified as independent, completely co-occurring, or a mixture between the two. The SSAGA takes between 45 min and 4 h to administer and uses a timeline approach to gather detailed information on the chronology of mental health and substance use disorders. A final diagnosis is determined by a clinician following a diagnostic review of all available data sources. The SSAGA has high levels of inter-rater reliability for diagnosing substance use and mental health disorders, but its ability to differentiate substance induced from primary mental health disorders is yet to be determined.

The Psychiatric Research Interview for DSM-IV Substance and Mental Disorders (PRISM) is a valid and reliable measure of current and lifetime DSM-IV substance use, affective (including depressive and bipolar disorders), anxiety, and psychotic disorders, as well as antisocial personality disorder. The PRISM differentiates SID from primary disorders by (1) obtaining a lifetime timeline of periods of heavy substance use and abstinence, (2) determining the temporal relationship of psychotic symptoms and substance use, and (3) providing guidelines for differentiating primary disorders from SID and from the expected effects of intoxication and withdrawal. The PRISM has shown good to excellent test-retest reliability for diagnosing mental health and substance use disorders, as well as differentiating PPD from SIP in two studies of substanceabusing patients. PRISM diagnoses for SIP and schizophrenia have also been shown to have significantly better concordance with diagnoses derived using longitudinal, expert, all data (LEAD) criteria and the SCID. However, the PRISM requires intensive clinical training to administer and takes approximately 2 h.

Thus, structured clinical interviews such as the SSAGA and PRISM can assist with the accurate diagnosis of comorbid disorders by differentiating substance induced from primary mental health disorders. However, these measures are lengthy, and require considerable clinical judgment and intensive training to administer. They also provide little assistance with determining the nature and direction of the relationship between primary mental health and substance use disorders.

Nevertheless, structured clinical interviews like the PRISM can provide a number of hints for improving the reliability of comorbid diagnoses. The development of a timeline of the onset, course and patterns of drug and alcohol use, and psychiatric symptoms over time can facilitate understanding of comorbid disorders. This is particularly effective if the timeline assessment of drug and alcohol use is conducted prior to the timeline assessment of mental health symptoms. The

substance use assessment should include information on the age of onset of regular (weekly) use, patterns of heavy or binge use (at least 4 days a week for a month or 3 days straight), as well as periods of abstinence or minimal use of at least a months duration.

Several indicators of an SIP have been identified in the clinical research literature, which may assist clinician's with the differentiation of substance induced from primary psychotic disorders (with concurrent substance use). Individuals with an SIPD are more likely to have a concurrent substance use disorder and a parental history of substance use, but are less likely to have a family history of psychosis than those with a PPD. SIPD have also been associated with less severe positive and negative symptoms, the presence of visual hallucinations in particular.

Consideration should also be given to the timing of the initial psychiatric assessment, as SID will be most prevalent during drug intoxication or withdrawal. This requires clinicians to be aware of the common signs and length of intoxication and withdrawal from a range of substances. It is also important to note that the first few weeks of abstinence are likely to be associated with the experience of a range of depression-related symptoms.

The assessment of comorbid disorders requires clinicians to take a longitudinal perspective to develop an understanding of the relationships between these disorders over time. The collection of collateral information from multiple sources can also assist with this process. The results of the assessment should be used to develop a biopsychosocial case formulation and treatment plan to ensure the individual receives the most appropriate and effective treatment available.

VALIDITY OF COMORBID DIAGNOSES

A number of the diagnostic issues associated with comorbid disorders may be associated with the validity of the diagnostic categories themselves. Diagnostic validity is demonstrated if one of the two conditions is met. First, if the defining characteristic of the category is a syndrome, then this syndrome needs to be an entity with distinct boundaries that clearly separate it from normality as well as other disorders. Second, if the defining characteristic of the category has a biological basis, this must be clearly differentiated from other disorders that may indeed be conditions with a similar syndrome. Psychiatry is especially prone to problems with diagnostic validity, as most diagnoses are based on a combination of symptoms and there is rarely a genuine discontinuity between the threshold symptoms of a disorder and normality (e.g. most people experience an occasional depressed mood). In addition, there are few (if any) biological tests that are sensitive and specific enough to establish a psychiatric diagnosis. The presence of comorbid mental health and substance use disorders makes diagnostic validity a particularly challenging issue to address.

Problems with the validity of the diagnostic criteria do not necessarily threaten their value. In psychiatry, there has been an increasing emphasis on the clinical utility of a diagnostic category in recent years, defined as the extent to which it provides distinct information about the etiology, risk factors, course, treatment, and outcomes of a diagnosis, compared to other diagnoses. Research evidence has consistently demonstrated the negative prognostic value of comorbid disorders. For example, comorbid substance use and depression disorders have been associated with more severe depressive symptoms, suicidal ideation, poorer social functioning, and increased service utilization. Relapses and remissions in depressive and substance use disorders among individuals with both disorders have been found to adversely influence the course of the other disorder. Cannabis use has been associated with higher rates of psychotic relapse among individuals with first episode and established psychoses, as well as poorer treatment attendance and medication adherence. There is also preliminary evidence for the clinical utility of SIP, as it is characterized by a higher level of substance use, less severe positive, negative, and general symptoms at initial presentation as well as higher rates of symptom remission over a 12-month follow-up period. Thus, while comorbid diagnoses have been associated with a range of negative outcomes the extent to which different combinations of comorbid disorders have a distinct etiology, clinical course, and outcomes is yet to be determined.

ALTERNATIVE MODELS OF COMORBIDITY

If comorbid diagnoses lack clinical utility and do not have a distinct clinical course and outcomes compared to other disorders, alternative approaches to comorbid mental health and substance use disorders would need to be considered. One approach argues that comorbid disorders are an artifactual by-product of the overlap between the symptoms of several disorders in the current DSM and ICD diagnostic systems. Two potential solutions have been proposed. One involves increasing the specificity of current diagnostic criteria. Another involves "lumping" diagnostic categories together into fewer more broadly defined categories. However, the current diagnostic classification systems were developed to be as simple and broadly applicable as possible to facilitate communication between clinicians and researchers. It is unclear whether redefining or reclassifying diagnostic criteria for mental health and substance

use disorders will overcome the diagnostic issues associated with comorbid disorders, or just create diagnostic issues of their own. It may also be premature to change current diagnostic criteria at a stage when we are only just beginning to understand the genetic, neurobiological, environmental, and psychological etiology of many mental health and substance use disorders.

A number of alternative models for understanding comorbid mental health and substance use disorders have been provided. One approach involves the development of more dimensional models of psychiatric nosology, in which variation in symptoms is considered to be continuous. This model is based on increasing evidence that psychotic symptoms are continuously distributed between the general population and individuals with psychotic disorders. There is also increasing evidence for the clinical utility of dimensional models of depression over categorical models. Substance use disorders are also better represented as a single dimension of dependence rather than separate diagnoses of substance abuse and dependence.

While dimensional models of comorbid disorders are yet to be developed, a number of dimensional models of mental health and substance use disorders have been proposed. One option retains the current categorical diagnoses of mental health and substance use disorders, and examines the size and the direction of the relationship between the comorbid disorders. "Symptom network models," which conceptualize comorbidity as a network of symptoms of distinct disorders, which are directly (possibly causally) related to one another, could also be applied to the development of dimensional models of comorbidity. It has been argued that such a network approach more accurately reflects the reality of comorbidity, as it allows for (1) multiple etiological processes that interact in causing symptoms, (2) interindividual differences in the manner in which a constellation of symptoms is contracted, (3) direct relations between overlapping symptoms, and (4) inequality of symptoms. However, the reliability, validity, and clinical utility of any of these alternative models of comorbidity are vet to be tested.

A number of advances in statistical modeling including latent class analysis (for categorical data), latent class factor analysis (for both dimensional and categorical measures), and factor mixture analysis have made it possible to quantitatively develop new dimensional models of comorbidity as well as compare these to categorical DSM and ICD diagnoses. These statistical approaches focus on identifying variability both within the individual as well as interindividual differences in the trajectories of mental health symptoms and substance use over predefined periods of time. Mapping changes in the trajectories of both substance use and mental health symptoms (i.e. modeling the

association between latent growth curves for substance use and symptoms) will help us to ascertain the clinical validity of current DSM diagnosis, as well as develop alternative categorical diagnostic and/or dimensional models of comorbidity.

SUMMARY AND CONCLUSIONS

Clinicians are faced with the reality of the diagnostic dilemmas created by comorbid mental health and substance use disorders everyday. The presence of comorbidity requires a comprehensive assessment aimed at developing a biopsychosocial formulation of the comorbid disorders. This requires an understanding of the relationship between the comorbid disorders in terms of whether they are independent entities or interactive. If an interaction between the comorbid disorders is identified, it is important to determine both the nature and direction of the relationship between them. This is complicated by the fact that comorbid relationships may be bidirectional and vary over time.

Increased concerns about the validity of the DSM and ICD diagnostic systems have resulted in an increased focus on the clinical utility of diagnostic categories. While comorbid disorders have consistently been associated with a range of negative outcomes, the extent to which different combinations of comorbid disorders have distinct outcomes is yet to be determined.

A number of alternative models for understanding comorbid disorders have been proposed. The first involves the development of dimensional models of psychiatric nosology in which variation in symptoms is considered to be continuous. The second retains the diagnosis of mental health and substance use disorders, and examines the size and the direction of the relationship between them, while the third proposes the development of new symptom network models of comorbidity, which focus on the direct relationships between the symptoms of comorbid disorders. However, these alternative models of comorbid mental health and substance use disorders are yet to be developed or tested.

There is much to learn about comorbid disorders. Future research aimed at developing alternative models for understanding comorbid disorders is urgently required to determine if these new approaches overcome the diagnostic dilemmas of the current systems of psychiatric nosology. Studies comparing the reliability, validity, and clinical utility of categorical and/or dimensional approaches to comorbid disorders would be most useful at this time. This will require large prospective studies, which systematically map the course of substance use and mental health symptoms, using a combination of structured clinical interviews

(e.g. PRISM) and dimensional measures (e.g. Brief Psychiatric Rating Scale, Timeline Followback Method) and frequent follow-up (at least monthly).

SEE ALSO

Screening and Assessment of Comorbidity, Treatment for Co-occurring Substance Abuse and Mental Health Disorders, Implications of Comorbidity for Clinical Practice, The Treatment of Depressed Alcoholics, Treatment of Anxiety in Substance-Using Patients, Pain and Addiction

List of Abbreviations

DSM Diagnostic and Statistical Manual ICD International Classification of Diseases

MDD major depressive disorder

NSMHWB National Survey of Mental Health and Wellbeing

PPD primary psychotic disorder PTSD posttraumatic stress disorder

PRISM Psychiatric Research Interview for DSM-IV Substance

and Mental Disorders

SCID Structured Clinical Interview for DSM

SID substance-induced disorder SIP substance-induced psychosis

SSAGA Semi-structured Assessment for the Genetics of

Alcoholism

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Treatment for Co-occurring Substance Abuse and Mental Health Disorders

Kim T. Mueser*, Robert E. Drake\$, Douglas L. Noordsy**

*Center for Psychiatric Rehabilitation, Boston, MA, USA *Dartmouth Psychiatric Research Center, Rivermill Commercial Center, Lebanon, NH, USA **Dartmouth Medical School, Lebanon, NH, USA

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HISTORICAL TREATMENT OF CO-OCCURRING DISORDERS

The historical division in the training of clinicians and the treatment of people with substance use or psychiatric disorders resulted in two approaches to the treatment of co-occurring disorders that predominated until recent years. These two approaches, *parallel treatment* and *sequential treatment*, each have their own significant limitations, as described below. Traditional treatment approaches to treating co-occurring disorders are becoming increasingly obsolete as they are gradually replaced by more nuanced and effective interventions that integrate the treatment of both disorders.

Parallel treatment is when the substance use and psychiatric disorder are treated at the same time by different clinicians who are usually working for different agencies. There are several problems associated with this approach. Although in theory people should be receiving treatment for both their disorders in parallel

treatment approaches, in practice this often fails to occur, for a number of reasons. First, some North American health insurance policies make it difficult or impossible for people to obtain both psychiatric and substance use disorder services provided by different agencies at the same time. Second, people with co-occurring disorders who are receiving treatment from one provider often fail to follow through on referrals for treatment for their other disorder. For example, people with a substance use disorder may not pursue a treatment referral for their psychiatric disorder because of the stigma of mental illness, and either denial or minimization of the effects of this disorder on their life and well-being. Similarly, people receiving treatment for a psychiatric disorder often do not follow through on referrals for treatment of their substance use problems because they lack motivation to seek such treatment, or are unaware of the effects of their substance use on their psychiatric disorder and life. Third, even when people do receive both types of treatment, the services are often poorly

integrated, and sometimes addiction and mental health professionals give inconsistent or even contradictory messages.

In the *sequential treatment* approach, first one disorder is treated or stabilized followed by the treatment of the second disorder. Sequential treatment approaches are often predicated on the assumption that a "primary" disorder can be identified, and the treatment of that disorder may obviate the need to treat the other, or "secondary" disorder. There are several problems with this approach. It is often difficult or impossible to identify which disorder is primary and which is secondary. Cooccurring disorders frequently develop within a relatively narrow time period, making it difficult to accurately determine which came first. Furthermore, delaying treatment in order to attempt to distinguish which disorder is primary often does not yield more conclusive evidence, and can lead to further deterioration in functioning. However, the most significant limitation of sequential treatment is that it fails to take into account the fact that each disorder tends to worsen the other, making it difficult to successfully treat either one alone. For example, it can be difficult or impossible to pharmacologically stabilize a person with bipolar disorder who is actively abusing substances without attending to their substance use. Similarly, addressing substance use problems in a person with poorly controlled symptoms of schizophrenia can also pose a major challenge.

INTEGRATED TREATMENT

The limitations of parallel and sequential treatment approaches to co-occurring disorders have led to the development and growing adoption of integrated treatment approaches. Integrated treatment is defined as when both the psychiatric and substance use disorders are treated at the same time, by the same clinician or same team of clinicians, who assume responsibility for integrating the treatment of both disorders. In addition to the integration of mental health and substance abuse services, effective programs also share several other common characteristics, including comprehensiveness, motivational enhancement, harm-reduction orientation, low stress treatment environment, and pharmacological treatment. These components are briefly described below.

Comprehensive Assessment and Treatment

Substance use disorders in people receiving treatment for a major mental illness are frequently not detected, and hence treatment is often not provided. Similarly, psychiatric disorders are frequently not detected in people receiving treatment for substance use disorders. Effective integrated treatment requires routine screening for substance use disorders in people receiving psychiatric services, and screening for mental illness in people receiving addiction treatment services. Psychometrically valid assessment instruments have been developed for detecting psychiatric and substance use disorders in these populations.

When a co-occurring disorder has been detected, comprehensive assessment is necessary in order to better understand the nature of each disorder and how the disorders interact with one another. Comprehensive assessment of substance use disorders includes obtaining information about the types of substance used, routes of administration, the situations in which use is most common, the pattern of use over time, and the consequences of substance use. Comprehensive assessment of psychiatric disorders involves the identification of characteristic symptoms and specific psychiatric diagnoses, the individual's awareness and involvement in the management of the disorder, and its functional consequences in areas such as work, school, social relationships, and independent living. Understanding the individual's socio-environmental context is also a critical feature of comprehensive assessment, including social support, housing, legal problems, and medical illnesses and related treatment needs.

Developing an understanding of how psychiatric and substance use disorders interact can lead to more effective treatments. For example, an individual with schizophrenia may use alcohol in social situations to feel more comfortable and facilitate contacts with others, suggesting that social skills training may help the individual learn more effective skills for meeting and getting closer to people, and resisting offers to use substances from other people. Similarly, someone with posttraumatic stress disorder (PTSD) may use alcohol in an attempt to cope with the hyperarousal symptoms and sleep difficulties related to their PTSD, suggesting that in addition to overall treatment of their PTSD the person may benefit from learning relaxation and sleep hygiene skills to reduce their susceptibility to using alcohol to cope with these symptoms.

Individuals with co-occurring disorders often experience complex problems, and integrated treatment programs need to have services that address the broad range of needs. For example, common problems in people with co-occurring disorders include housing instability, family conflict, unemployment, health problems, legal problems, and an exploitive social network. Comprehensive treatment requires attention to all of these problem areas if sobriety is to be successfully achieved and maintained, and if psychiatric symptoms are to be stabilized or remission of symptoms sustained. Interventions such as supported housing, family psychoeducation, medical and legal services, supported

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employment, and skills training may be critical to addressing these needs.

Motivation-Based Treatment

People with co-occurring disorders often lack motivation to pursue and follow-up on treatment for one, if not both, of their disorders. Integrated treatment needs to enhance and harness motivation to work on these problems. In order to gear treatment to the individual's level of motivation, their motivation to change must be understood.

One useful concept for understanding the role of motivation in behavior change is the stages of change. The stages of change concept posits that changes in health behavior (such as substance abuse) occur over a period of discrete stages, with each stage reflecting a different degree of motivation and readiness to change. At the pre-contemplation stage, the individual is not even thinking about changing. At the contemplation stage, the individual is considering the possible advantages and disadvantages of change. In the preparation stage, the person has made a decision to change and is undertaking preparatory steps. During the action stage, the person is actually making desired changes. In the maintenance stage, change has successfully been made, and efforts focus on maintaining the behavior change.

The stages of change concept has been adapted to provide a clinical heuristic for treating substance use disorders in people with major mental illness-stages of treatment. This framework may also be useful for harnessing motivation to work on psychiatric illness in people receiving treatment for their substance use disorder. Each stage is characterized by a different level of motivation to change, and a different treatment goal, with multiple options available for achieving each treatment goal. Matching the treatment goal and interventions to the individual's level of motivation to change, or stage of treatment, optimizes treatment effectiveness and minimizes dropout from treatment. Each of the four stages of treatment is described below, including the goal of each stage and examples of treatment options.

Engagement Stage

In the engagement stage of treatment, the client is not involved in treatment with the clinician or treatment team who can provide integrated care for their disorders. Therefore, the goal of this stage is to develop a therapeutic relationship with the client, defined as meeting with the individual on a regular basis. This goal can be achieved through strategies such as assertive outreach into the community, practical assistance to address basic living needs (e.g. housing and food),

assistance in resolving the crisis (e.g. social network support and medical problem), or legal constraints (e.g. court mandated treatment).

Persuasion Stage

The client enters the persuasion stage when he or she has been successfully engaged in treatment, but continues to actively abuse substances. The goal of this stage is to help the individual understand that he or she has problems related to substance abuse, and to instill motivation for working on these problems. A wide range of strategies can be helpful in increasing insight and motivation for working on substance abuse. Effective pharmacological treatment can reduce severe symptoms that may contribute to substance use in some individuals and facilitate awareness of the effects of substance use. Motivational interviewing, which involves helping people articulate personal goals and values, and then exploring the effects of substance use on those priorities in order to draw attention to the problem can often instill motivation to work on substance abuse in order to make personally desired changes in one's life. Psychiatric rehabilitation methods such as social skills training, supported employment, and teaching skills for coping with symptoms can address common motives for using substances, such as socialization, having something interesting to do, and coping with symptoms, thereby reducing reliance on substances for getting basic needs met and increasing willingness to work on substance abuse.

Active Treatment Stage

When the client is motivated to reduce his or her use of substances or to become abstinent, as indicated by repeated attempts to cut down, successful reduction in use, or abstinence, they enter the active stage of treatment. The goal of this stage is to help the individual further reduce the use of substances and to prolong the periods of abstinence. A wide range of interventions can be helpful at this stage. Individuals often benefit from cognitive-behavioral therapy groups aimed at increasing coping skills and social skills related to urges to use and situations involving substance use. Self-help programs such as Alcoholics Anonymous, or special self-help programs designed for people with co-occurring disorders such as Dual Recovery Anonymous, may be useful in providing support and inspiration about the benefits of longterm sobriety. Social network interventions, such as family work, may facilitate garnering support for sobriety, and helping individuals change substance use habits that may be inadvertently or deliberately reinforced by family members. Pharmacological interventions such as naltrexone or acamprosate may be useful in reducing cravings to use substances.

Relapse Prevention Stage

When an individual's substance use has not been problematic for an extended period of time (e.g. 6 months), he or she begins the relapse prevention stage of treatment. The goals of this stage are to prevent relapses and to extend the recovery to other areas of functioning. Developing a *relapse prevention plan* for dealing with high-risk situations for using substances can be provided in this stage. Extending the recovery to other areas of functioning involves focusing greater attention on important domains such as work, social relationships, school, and health, which in the long run may protect the individual from relapses back into substance use.

Harm-Reduction Philosophy

Many people with co-occurring disorders have limited motivation for treatment and are not willing to set abstinence as a goal regarding their substance use. Despite this, the numerous negative consequences of co-occurring disorders make it incumbent upon professionals to take steps toward engaging and initiating treatment with these individuals. A harm-reduction philosophy focuses first on efforts to reducing the most harmful consequences of substance use on an individual's health, safety, well-being, or living situation. Successfully addressing some of these consequences can be crucial to establishing a therapeutic relationship with the individual, which can then be used to instill motivation to work on substance use reduction and abstinence, as described above in the persuasion stage of treatment. Common harm-reduction strategies include helping people obtain clean needles, providing vaccinations to protect them against hepatitis B, teaching safe sex practices to individuals who trade sex for drugs or money, and identifying places where substances can be used that have reduced risks of victimization.

Low Stress Treatment

Individuals with co-occurring disorders are often highly sensitive to the effects of interpersonal stress, which can precipitate symptom relapses, and contribute to exacerbations of substance abuse. Therefore, maintaining a low stress treatment environment is a common feature of integrated treatment programs for co-occurring disorders. Low stress treatment involves minimizing heated interpersonal exchanges and face-to-face confrontations that historically have been a common feature of substance abuse treatment approaches. Maintaining a low stress treatment environment does not mean that individuals are not confronted with the self-defeating aspects of their own behavior. However, insight into these contradictions, and

motivation to change, is instilled by gentle probing and prompting of the individual in an empathic and understanding manner. In the context of a good working relationship with the clinician, the exploration of apparent contradictions or ambivalent feelings regarding substance use, mental illness, and their interactions, and combined with identifying and increasing self-efficacy for achieving personal goals, is often sufficient for motivation to change to take root.

Pharmacological Treatment

Following the principles of integrated treatment, pharmacological treatment should also focus on managing both the psychiatric and substance use disorders simultaneously. This approach primarily involves engaging the person with co-occurring disorders in a collaboration on identifying the most useful treatments for managing each disorder, while remaining mindful of potential effects on the other disorder. While many evidence-based treatments for psychiatric and substance use disorders tend to have little direct impact on the other disorder, stabilizing each disorder facilitates global stability and improved treatment outcomes. There are some risks of destabilization to be aware of, such as prescribing potentially addictive medications (e.g. benzodiazepines and opiates), or medications that may exacerbate psychotic, mood, or cognitive symptoms (e.g. amphetamines, benzodiazepines and anticholinergics). There is also some potential for medications prescribed for one disorder to be somewhat helpful in managing the other.

Numerous psychotropic agents have been studied for their potential to help reduce substance use. This evidence base is limited by methodological factors such as small sample sizes and naturalistic designs. The few randomized, controlled trials generally show weaker effects. For example, desipramine had been suggested to suppress cocaine use, but a well-controlled study failed to demonstrate a significant effect. Selective serotonin reuptake inhibitors have been suggested to help reduce substance craving, but have not demonstrated substantial impact on substance use outcomes. There is some evidence that lithium might help reduce alcohol use, but a controlled trial failed to demonstrate significant benefit. On the other hand, bupropion has been clearly demonstrated to help reduce tobacco use, and this finding is well replicated among people with schizophrenia. Valproate treatment has been associated with significant reduction in alcohol use among people with bipolar disorder. Numerous small studies have also suggested that various second-generation antipsychotic medications may be associated with reduction in substance use among individuals with schizophrenia. The strongest evidence involves clozapine, and a recent RESEARCH 321

controlled trial demonstrated some advantages of clozapine over antipsychotic treatment as usual among people with schizophrenia.

Research on the neurobiology of addiction among people with psychiatric disorders has implications for pharmacotherapy. There is growing evidence that the altered activity in the mesocorticolimbic circuitry associated with schizophrenia impairs brain reward responsiveness, creating vulnerability to addiction to substances that can activate brain reward responses exogenously. Brain reward responses, which stimulate repetition of behavior, are mediated by dopaminergic neurons in this circuit. Consistent with this model, psychotropic agents that produce potent dopamine blockade appear to be associated with poorer reward responses, greater substance self-administration in animals, and poorer substance use outcomes among people with schizophrenia. On the other hand, some agents with modest dopamine antagonistic effects (e.g. clozapine) have been associated with reduction in substance use. Antagonism of the norepinephrine alpha 2 receptor, which facilitates greater norepinephrine output, appears to improve signal detection in the mesocorticolimbic circuit as well. This may help to explain why clozapine, which has the highest ratio of alpha 2 to dopamine 2 receptor antagonism of currently available antipsychotics, appears to have the most appreciable effects on substance use behavior. Pharmacologic enhancement of brain reward response among people with mental illness may also facilitate their engagement in inherently reinforcing recovery activities such as physical exercise or work. While further work is needed to confirm this model, it could help to inform future directions in medication development.

Most medications that have demonstrated efficacy in the treatment of people with substance use disorders have had at least limited study among people with co-occurring disorders. This body of work generally finds that these agents are safe and well tolerated and have similar effects among people with co-occurring disorders, although the magnitude of these effects is often attenuated. A recent study failed to find beneficial effects of acamprosate on drinking outcomes among people with schizophrenia and alcohol use disorders, but this is consistent with a large trial among people with primary alcohol use disorders. Disulfiram inhibits dopamine-beta-hydroxylase, an enzyme responsible for the metabolism of dopamine. While higher dopamine levels might be helpful for brain reward response, there are several case reports of psychotic symptoms among individuals treated with disulfiram. Studies of disulfiram among people with co-occurring disorders treated with antipsychotic medications have shown good tolerability, suggesting that antipsychotic treatment may adequately protect against this potential risk. On the other hand, bupropion has been demonstrated to improve negative symptoms among people with schizophrenia in controlled trials. Methadone has been associated with some improvements in negative symptoms in case reports among people with schizophrenia. Improvements in anxiety among some individuals treated with naltrexone have also been observed.

Pharmacologic management of anxiety is a particular challenge among people with co-occurring disorders. People with co-occurring disorders who are prescribed benzodiazepines are more likely to abuse them than individuals who are not prescribed these medications. Medications with low abuse potential, such as the sero-tonergic antidepressants, buspirone, and some antipsychotics, may be helpful with anxiety without exacerbating substance use disorders. Psychotherapy, skills training, and physical exercise may also be effective interventions for anxiety management.

Finally, prescribers should be aware of potential drug interactions between psychotropic medications and substances of abuse, and engage people with cooccurring disorders in an informed discussion about these risks. Cocaine use may stimulate cardiac arrhythmias, which might be facilitated by medications that prolong the cardiac QTc interval. Sedating medications that have potential to suppress level of consciousness and respiratory drive could interact additively with alcohol, opiates, or barbiturates. Alcohol use during disulfiram treatment results in adverse reactions. Using a shared decision-making approach and documenting clear informed consent for medication treatment despite the potential for interaction with substances that the individual may use may help to reassure clinicians about their liability risks, and highlight the individual's responsibility for managing their health risks. The decision-making discussion can highlight the importance of prioritizing effective treatment for the co-occurring disorders, and the role that stabilization can play in achieving desired outcomes.

RESEARCH

Research on the treatment of people with cooccurring disorders has progressed rapidly over the last 20 years. People with these disorders value several recovery outcomes: managing their mental illnesses and addictions, avoiding institutionalization (i.e. hospitalization, incarceration, homelessness, and nursing homes), living in independent housing, having a job, and having friends who support their recovery. Many people do achieve recovery goals within each of these outcome domains. Recovery often takes years, and these outcome domains are only weakly associated with one another over time, suggesting that people take different pathways to recovery, pursuing different goals, paces, and sequences.

Effective interventions involve integrating mental health and addiction treatments with needed psychosocial services and supports. The optimal vehicle for delivering integrated treatments is the multidisciplinary team, typically including care managers, addiction specialists, medical professionals, supported employment specialists, and peers in recovery.

Treatment research has established effective interventions for each of the domains. Supported housing models, such as housing first, and care management models, such as assertive community treatment, especially when combined, help people to avoid institutionalization and to maintain independent housing in the community. Supported employment (often combined with supported education for younger clients) helps people to find and succeed in competitive employment (and schooling). Professionally led dual recovery groups and attending peer support groups in the community help people to establish new social networks of people who support abstinence and recovery. Research shows that these basic outcomes - housing, employment, and friends who support recovery - often precede recovery from addiction and, for many people, are necessary steps in the process.

Learning to manage psychiatric symptoms is also possible and often precedes recovery from addiction. A large number of interventions are effective in symptom management. For most people, symptom management via a combination of pharmacological and psychosocial strategies is optimal, and may generate synergistic interactions between treatment modalities. People learn to use medications effectively and develop strategies to avoid relapses and to cope with residual symptoms. Specific interventions address specific types of symptoms, for example, antipsychotic medications for psychotic symptoms and cognitive-behavioral or exposure-based treatments for posttraumatic stress disorder symptoms. The illness management and recovery program draw together many of these interventions in a coherent package.

Recovery from addiction also can be speeded or enhanced by evidence-based interventions. The strongest evidence (controlled trials) supports three types of interventions: professionally led dual recovery groups, residential treatments, and contingency management. Different models of group interventions and residential programs are effective, but all effective programs integrate mental health and addiction interventions. Contingency management, the systematic use of rewards to reinforce abstinence, is largely a research-based intervention at this point.

Research-based interventions must of course be delivered in the context of trusting therapeutic relationships, often termed *working alliances*. The art of co-occurring disorder treatment entails engaging the client in such a relationship, understanding the client's individual needs (i.e. specific problems, goals, strengths, stage of recovery, and so on), blending appropriate interventions into a coherent plan through a process of shared decision making, and supporting the client over months and years while he or she is working toward recovery. Interventions can only be effectively delivered within such an interpersonal context.

CONCLUSIONS

Co-occurring psychiatric and substance use disorders are the norm rather than the exception, and clinicians need to be prepared to assess and treat both disorders. Traditional approaches to treating co-occurring disorders, including parallel and sequential models, have proved ineffective due to either the inability to engage people in treatments for both disorders or the failure to address the interactions between the disorders. Integrated treatment, characterized by the concurrent treatment of both disorders, by the same clinician or team of clinicians, is widely accepted as the treatment of choice, and is supported by a growing research literature. In addition to combining treatments for both psychiatric and substance use disorders and addressing their interactive nature, effective integrated treatment programs share a number of other common features, including comprehensive assessment and treatment, motivationbased treatment, a harm-reduction philosophy, minimization of treatment-related stress, and pharmacological treatmant. Until recently, the outlook for people with co-occurring disorders was bleak, with one or both disorders insufficiently treated, and individuals suffering frequent relapses, functional impairment, and premature mortality. There is now good reason for hope and optimism, as integrated approaches to the treatment of mental health and substance use problems are rapidly becoming the standard in the field, improving the quality of life of most individuals, and making their recovery from both disorders a true possibility.

SEE ALSO

Evaluating Treatment Efficacy, Evidence-Based Treatment, Dissemination of Evidence-Based Treatment into Practice, Diagnostic Dilemmas in Comorbidity, Screening and Assessment of Comorbidity, Implications of Comorbidity for Clinical Practice, Motivational

FURTHER READING 323

Enhancement Approaches, Cognitive Behavioral Therapies, Contingency Management, PTSD and Substance Abuse Treatment, The Treatment of Depressed Alcoholics, Medications for Comorbid Bipolar Disorder and Addiction, Treatment of Anxiety in Substance-Using Patients, Comorbid Addictions and Schizophrenia

Glossary

- **Co-occurring disorders** the co-occurrence of a substance use disorder and a psychiatric disorder.
- Parallel treatment the concurrent treatment of co-occurring disorders by different treatment providers addressing the psychiatric and substance use disorder, usually working for different agencies and systems.
- PTSD posttraumatic stress disorder
- **Sequential treatment** the treatment of co-occurring disorders by first treating either the psychiatric or the substance use disorder, followed by the treatment of the other disorder.
- **Integrated treatment** the concurrent treatment of co-occurring disorders by the same clinician or clinical team, who assume responsibility for integrating the treatment for both disorders.

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34

Implications of Comorbidity for Clinical Practice

David J. Kavanagh

Institute of Health & Biomedical Innovation, Queensland University of Technology, Brisbane, QLD, Australia

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In the past, co-occurring substance use and mental health problems have often been missed, because related screening and assessment has not been routine. When co-occurrence has been identified, affected people have often been excluded from services, or were referred to other agencies without assistance to ensure that they arrived and received help. If they did receive treatment, it was often focused on a single problem domain, or was offered by different agencies, which frequently were in

different locations, had differing priorities, policies and procedures, and did not share record systems or communicate effectively in other ways. As a result, treatment plans often missed key elements or had conflicting goals and demands. Practitioner training typically focused on either addictive disorders or other mental health problems, and graduates lacked skills and confidence in dealing with problems outside their focal domain. Despite international attempts to improve services for people with

co-occurring problems, many of the issues remain. However, we now have more information on comorbidity and its management, and on ways to disseminate sound, evidence-based care. This knowledge can guide our development of services that are more responsive to these co-occurring problems. Principles or observations about co-occurring disorders and their implications for practice are summarized in Table 34.1.

PEOPLE WITH CO-OCCURRING DISORDERS HAVE A RIGHT TO EQUAL ACCESS TO QUALITY CARE

The historical situation described above clearly violated the basic right of people with co-occurring

TABLE 34.1 Principles and Observations on Comorbidity Practice and Their Implications for Services

Principle or observation	Implications for services
People with co-occurring disorders have a right to equal access to quality care	Underpins all the implications that follow
Co-occurring disorders are common and often have a profound impact	Screening for co-occurring problems should be routine A boutique service is impractical: existing agencies must address the issue Universal interventions must be capable of large-scale implementation
Tobacco smoking is endemic and affects morbidity, mortality, and functioning	Assessment and interventions should include tobacco smoking
Co-occurring problems are often multiple and closely interlinked	Treatments should address the multiple issues of concern Closely interrelated problems require integrated treatments A single health agency to assist an individual is typically needed Strengths, resources, and functional sources of pleasure should be included in assessment and intervention
Better policies and practices for co-occurring disorders require organizational change	Co-occurring disorders must be core business for the organization and practitioners Effective comorbidity practice should be recognized and rewarded Required skills must be present or taught, and cues to use them provided A culture supporting the use of the intervention should be fostered

Note: These estimates are based on the results from Kavanagh, D. J., & Connolly, J. M. (2009). Interventions for co-occurring addictive and other mental disorders (AMDs). Addictive Behaviors, 34, 838-845.

disorders to an equal access to the same quality of care as if they had a single problem. The moral imperative presented by this right of access is the guiding assumption underpinning all the recommendations that follow.

CO-OCCURRING DISORDERS ARE COMMON AND OFTEN HAVE A PROFOUND IMPACT

In Western countries, 25–30% of people with a mental disorder also have a substance use disorder at some time in their lives. In the landmark US Epidemiologic Catchment Area (ECA) study in 1980–84, this corresponded to 2.7 times the risk of a substance use disorder if the person had a mental disorder. In antisocial personality disorder (84%, OR = 29.6), bipolar I disorder (61%, OR = 5.3), and schizophrenia (47%, OR = 4.6), the lifetime prevalence and increased risks were particularly high. Mental disorders are also common in people with substance use disorders. In the ECA study, the lifetime rate of a mental disorder in people with an alcohol use disorder was 37% (OR = 2.3) or 53% (OR = 4.5) in people with another substance use disorder.

Since rates of substance use disorders in the community as a whole are higher among men, and depression and anxiety are more common in women, there are gender differences in risk that reflect these overall trends. Generally, problematic substance use is also more common in younger people. Exact proportions of affected people change across countries, over time, and in specific religious or ethnic groups, with many indigenous groups at particularly high risk of both substance misuse and mental disorder or distress. Community rates of both substance-related and other mental health problems increase even further when subclinical conditions are included.

Treatment settings have greater rates of comorbidity than the general community, especially where crisis care is delivered. This is partly because co-occurring issues have synergistic effects on functioning and distress, and crises that trigger demands for treatment can occur from either problem. In many agencies, this means that a substantial majority currently has a co-occurring substance-related problem.

Not only are co-occurring disorders common tragically, but they also pose substantially increased risks of morbidity and mortality. Substance use increases the risk of illness and fatality from a variety of causes, some directly related to the substance and its metabolism (e.g. overdose, withdrawal, and vitamin depletion), some as a consequence of psychological or lifestyle impacts (e.g. suicide, injury, being a victim of assault, and hyperthermia), and some related to illegal supply (e.g. toxic additives).

Co-occurring disorders also tend to have profound and widespread impact on the functioning and quality of life of the individual and their family. Even mild forms of co-occurring disorders can have a powerful functional impact: for example, any substance use at all by someone with severe mental disorder who is unemployed can entail missing meals, going into debt, having housing problems, or foregoing highly valued opportunities for rehabilitation or employment. If cognition, impulse control, motivation, and social skills are substantially impaired, adding intoxication can take the person from marginally appropriate to dysfunctional behavior, with significant and lasting consequences. Families experience economic impacts (e.g. financial burdens of housing, medical care and other support, lost work time, and property stolen to support substance use), as well as emotional hardship and disruption to their social and recreational activities.

While the functional impacts of co-occurring disorders are often substantial, the companion disorders are often of mild or moderate severity, partly, because less severe problems are much more common in the general community. So, although the relative risk of bipolar disorder or schizophrenia increases to a greater extent than anxiety disorders in people with addictive disorders, anxiety and unipolar depression are most commonly seen. This observation offers some optimism in approaching co-occurring disorders. For example, a study by Green and colleagues showed that some people with even very severe mental disorders spontaneously reduce consumption of cannabis use in the month after they experience a negative effect from it. This suggests that even this group may often have existing skills in self-control that they can exercise if sufficiently motivated.

Together with the moral imperative to provide equal access to service, these observations have important implications for agencies addressing mental health or substance use.

Screening for Co-Occurring Problems Should Be Routine

In assessments and reviews of mental health problems, protocols should include questions about all substance use, with brief screening for associated problems, followed by more detailed assessment of affected areas. Similarly, assessments and progress reviews of people with substance use problems should routinely include screening for psychological distress and disorder, with a full symptomatic assessment being conducted where indicated. Universal screening needs to be brief and easily implemented within the agency's standard assessment protocol if it is to be feasibly undertaken without significantly increasing costs per patient. Fortunately, brief screening tests are available to assist (*see* Screening and Assessment of Comorbidity).

A Boutique Service Is Impractical: Existing Agencies Must Address the Issue

Some agencies have nominated a staff member or group of staff to deal with co-occurring disorders. However, if specialist practitioners have to assess and provide ongoing management for patients with cooccurring disorders, the high incidence of these problems either means that they will soon be swamped with referrals (preventing others from receiving treatment), or selecting only some for special attention. There is some merit in devoting specialist time to a subgroup that presents greater challenges for care, as long as that does result in better outcomes. However, a consequence is that a large group would then miss out on that attention, unless the specialist staff became the primary practitioner group. Given the moral imperative of equity of access to care, agencies may be better advised to give specialists in co-occurring disorders the roles of consultants or trainers rather than case managers, so their expertise becomes spread throughout the organization and all affected people can receive appropriate treatment.

Universal Interventions Must Be Capable of Large-Scale Implementation

The most readily implemented minimum standard for a universal intervention to address co-occurring disorders is a treatment that is effective for many affected people, but minimizes additional contact time. There are several potential forms this treatment can take: one to two focused sessions, brief segments within case management sessions, or computerized or webbased intervention with or without therapist coaching. A recent trial of treatments for alcohol and depression by Baker and colleagues found that 10-session interventions had greater impact on outcomes at some points of time, but effects from a single, integrated session were also strong. A small number of sessions are particularly well suited to contexts where ongoing treatment may be impractical – for example, in emergency rooms. Within ongoing, case management short segments about cooccurring problems can be included within routine sessions. Brief segments over several sessions are particularly suited to people who have problems with attention and memory, such as people with psychosis.

Efficiencies in delivery may also be increased by supporting the use of computer- or Internet-based interventions. These programs can be applied in various ways - for example, as stand-alone adjunctive or primary treatments (where staff may just encourage their use and monitor progress), or with varying degrees of staff support as required. These approaches allow high-fidelity, multicomponent interventions to be delivered inexpensively. When used within treatment sessions, they also build practitioners' skills and confidence in delivering treatment for co-occurring problems - a training strategy that incurs little or no cost to the agency. Both computerized and web-based treatments have shown strong results in co-occurring depression and substance use problems. In fact, one study by Kay-Lambkin and colleagues found that a computerized treatment for substance use and depression ("SHADE"), which had a few minutes of therapist contact at the start and end of each session, was as effective as giving the same treatment strategies in a face-to-face format. Increased availability of smart phones and of phonebased applications is progressively allowing additional ways to practice skills, cue their application, and monitor changes in the natural environment, while minimizing service costs.

Brief treatments are typically preceded by a triage, so that more severely affected people are streamed to more intensive treatment (e.g. people with severe cognitive deficits and risk of self-harm or people with severe substance dependence). Agencies may also offer a form of "stepped care," where more intensive skills training or supportive treatment is offered in cases where brief interventions do not produce optimal results.

TOBACCO SMOKING IS ENDEMIC AND AFFECTS MORBIDITY, MORTALITY, AND FUNCTIONING

The frequencies of substance use in mental disorders that were quoted earlier in this chapter do not include smoking, which is endemic in serious mental disorder: For example, a 1997 Australian community survey of people with psychosis found that 74% currently smoked tobacco (over three times the community prevalence at the time). After suicide, tobacco smoking is the most important contributor to the increased morbidity and early mortality seen in people with serious mental disorders. Smoking also has important impacts in the shorter term: when people are on low incomes, its cost has a substantial impact on money available for both leisure and for essentials such as housing and food.

There are also pragmatic reasons to address smoking in conjunction with other substance use. Almost all people with serious mental disorder who smoke cannabis also smoke tobacco, and users with limited money often cut cannabis with tobacco. Where community-wide campaigns to stop smoking have been implemented, patients can often be more easily engaged initially in an attempt to quit tobacco than to stop using cannabis. Attempts to become more healthy by stopping smoking can sometimes then be generalized to cannabis and other substance use.

Despite the cogency of these arguments, we have found it easier to convince staff of mental health services that they should address illegal drug use or problematic drinking than to convince them of the need to assess and manage tobacco smoking. Cannabis, amphetamines, hallucinogens, cocaine, and excessive drinking have obvious mental health impacts, and are also readily seen as important foci by substance use services. Tobacco smoking is commonly seen as the province of the family doctor. However, people with severe mental disorder or with multiple substance use are less likely to attend a family physician regularly, and may need more support to stop smoking than others. Omission of smoking from issues to be assessed and addressed by specialist services is, therefore, particularly problematic.

Assessment and Interventions Should Include Tobacco Smoking

Routine screening should include whether the person smokes, and how many cigarettes they smoke each week. Motivational interventions for smoking should be offered, and reengagement after lapses encouraged. Because many people with co-occurring disorders are on very low incomes, financial subsidies for nicotine replacement therapy will often be needed.

CO-OCCURRING PROBLEMS ARE OFTEN MULTIPLE AND CLOSELY INTERLINKED

Co-occurring disorders are often referred to as a dual diagnosis. However, multiple substances are commonly used, and the psychological problems often include more than one type of mental disorder – including personality disorders, or subclinical features of other problems (e.g. social anxiety). Physical problems are also commonly experienced, including poor oral health (which is exacerbated by smoking). More than one situational problem is often present (e.g. social, forensic, housing, and employment issues).

Some problems can be secondary to others, so that someone only has psychotic symptoms when they are using substances. When the companion problem is truly secondary, there may really be only one disorder. However, the relationship is often more complex: While two or more problems may seem to resolve when one

problem is addressed, if an untreated problem becomes worse, it may still increase the risk of relapse in the treated one. So, depression often resolves after treatment for alcohol dependence, but if the person becomes depressed once more, they tend to be at greater risk of relapse in alcohol misuse. Furthermore, a problem may initially be triggered by substance use, but then develops a momentum of its own (e.g. amphetamine use may trigger psychosis, but later psychotic episodes may occur even when the person is abstinent). Indirect associations can also be seen: For example, one study found that the mechanism by which cannabis use triggered a later psychotic episode in that sample appeared to be conflict within the family (which was greater in people with more cannabis use).

Interlinkage between problems is often present, so that exacerbations of each problem may exacerbate the other(s). Close mutual associations between mental health status and substance use appear especially common in people with psychosis; substance use by this group is often triggered by worsening symptoms, but more consumption also puts them at greater risk of psychotic symptoms. These observations also have important implications.

Treatments Should Address the Multiple Issues of Concern

Close interlinkage of problems implies that the interventions that are used should impact on all that are required to obtain and maintain change. If as in the example above, conflict with the person's immediate family is a trigger for later symptomatic relapse, it is important to monitor whether the relationships improve as cannabis use comes under greater control, or whether family intervention for that issue is needed. Furthermore, the vulnerability to conflict suggests that care should also be taken to avoid generating distress within the therapeutic relationship (e.g. by using confrontation). If exacerbations of depression appear to have triggered alcohol use by an individual in the past, even if depression improves after the alcohol treatment, then vulnerability may need to be addressed.

Closely Interrelated Problems Require Integrated Treatments

Comparisons of outcomes from integrated treatment of co-occurring problems by a single agent and parallel or sequential treatment of problems clearly favor integrated treatment for people with psychosis. In the case of depression and anxiety, the evidence is less clearcut. Sustained long-term outcomes appear to require that treatment of the substance-related problem(s) is provided.

One trial on people with both excessive alcohol use and depression demonstrated substantial recovery in depression at 12 months, regardless of whether treatment comprised a single integrated session, gave additional treatment focused on alcohol or depression, or provided extended integrated treatment for both problems. Women had faster short-term recovery in alcohol and depression if they received either integrated or depression-focused treatment, but the latter gave weaker alcohol outcomes for them at 12 months. Men had stronger short-term alcohol-related outcomes from extended treatment that focused on alcohol or on both problems. The central importance of the substancerelated treatment is consistent with other research showing that the alcohol-related treatment is often equally effective in people with and without depression. However, the differential response of women suggests that it may also be important to address depression to maximize the speed of recovery.

Having multiple treatment goals does not necessarily mean that the treatment is more complex for the patient, or requires more sessions. A sensitive treatment for cooccurring disorders often involves negotiating targets that address both problems at once rather than burdening the person with a complex set of concurrent behavioral goals. Creative interweaving of treatment elements can then offer positive outcomes for each area. Examples include increasing pleasurable time with non-substance-using friends to improve the person's mood and reduce their substance use, and helping the person find highly valued housing or employment that precludes heavy substance use. Even when one issue is the primary focus of current treatment (e.g. substance control), relationships with others are explicitly addressed (e.g. negative mood as a trigger for drinking and as an outcome of binges).

A Single Health Agency to Assist an Individual Is Typically Needed

Integrated treatment is difficult to achieve in practice. As noted at the start of this chapter, mental health and substance use are commonly addressed by different agencies, whose staff have correspondingly different training and expertise. In consequence, a common service model for co-occurring disorders involves multiple agencies, each of which treats a different aspect of the person's problem in parallel or sequentially. As already mentioned above, these models potentially result in inconsistent treatment or treatment that is insufficiently sensitive to the co-occurring problem. Affected people may miss treatment for one or more

problems altogether, partly because the low severity of the most common co-occurring problems means that people who need help often do not meet priority criteria for the companion agency (e.g. severe mental disorder or severe substance dependence).

Where multiple agencies duplicate assessments, interventions, or monitoring regimes, also waste staffing resources and unnecessarily increase costs for affected people and their families. More people may be effectively treated within a particular budget if fewer agencies are involved, overlaps in functions or duties are minimized, and interagency communication is effective and efficient. Ideally, this would include sharing of patient records. Since these features are difficult to attain, a single agency with primary responsibility for integrated care provides the greatest assurance that required treatment will be received; delays minimized; harmful treatment interactions; duplication, or miscommunication avoided; and costs contained.

Which agency should therefore take responsibility in an individual case? There is a risk that uncertainty about this issue could result in each agency consigning the person to the other, resulting in exclusion from service. A heuristic is provided by the 2×2 "quadrant" model proposed by Ries and Miller in 1993 and further explicated by the US Substance Abuse and Mental Health Administration in a 2002 report to Congress. The model describes the severity of the psychiatric disorder and substance use disorder on two dimensions, categorized as low versus high. People with low-severity problems in both domains are seen as being best treated by the general health system (e.g. in primary care). Those with severe psychiatric problems and low-severity problems with substance use are typically seen as being the responsibility of mental health services, and those with severe substance misuse and relatively mild mental health problems are seen as being best managed by alcohol and other drug services. This would leave just one quadrant with a potential need for multiple services: those with high-severity problems in both areas. Health service organizations need to negotiate which agency will have the lead responsibility for this group, calling in assistance from other agencies when needed. In most cases, we suggest that the lead agency will need to be mental health, since that agency is usually better able to provide the level of assertive follow-up, supported care, and engagement of multiple other agencies that this group often requires.

The quadrant model clearly needs operationalization (i.e. with clear guidelines on what diagnosis, measure, or dimensional cutoffs are used), if it is to have practical use in agency decision making. Also, it is based on a conceptualization of the problems as dual disorders, and omits consideration of agencies apart from primary care, substance use, and mental health ones. As already

stated, these restrictions frequently oversimplify the true situation. The task of clarifying decision rules still requires negotiation between agencies and is likely to differ across jurisdictions, depending on the roles that particular agencies have. The quadrant model also needs further testing, to show that its application does improve treatment access and outcomes.

Strengths, Resources, Functional Sources of Pleasure Should Be in Assessment and Treatment

The number and severity of problems in this group sometimes capture attention of practitioners, and both assessment and treatment often focus exclusively on behaviors that need to be controlled or problems that require solution. The emphasis on symptoms and deficits potentially leaves people demoralized, and the complex array of needs can be overwhelming for all parties.

We know that negative mood undermines confidence in being able to make changes, and that sustained changes need to be rewarded, yet much of what we are trying to achieve has at best, a delayed net benefit, and at worst, can leave the person feeling worse off. Assessing and building the strengths, resources, and capabilities of the person increase confidence, which encourages the person to start and persist in their attempt in the face of difficulties. Assessments need to seek out areas that are unaffected or represent significant achievements, summarizing them, showing their relevance to the current challenges, and encouraging the person to rehearse them. Of special importance are ones that show an ability to delay or forego short-term comfort for the sake of greater long-term benefits - for example, maintaining attendance at work or school, practicing a musical instrument, looking after pets, paying rent, and paying off debts. These islands of achievement highlight resources, sources of social support and personal skills, and often give strategies to address current problems.

A focus on behaviors that need to be controlled means that some current sources of pleasure or relief (at least in the short term) may be lost (e.g. positive effects of intoxication, a leisure activity that relieves boredom or distracts from negative rumination, or contact with substance using friends – who in some cases are the only people outside the family and other patients who accept them as they are). To maintain change, new sources of pleasure and reward may be needed: highly valued relationships, opportunities for training or employment, and new housing options. While addressing problems sometimes allows these positive changes to occur, they may not do so without therapeutic

support. For example, the person may be highly socially anxious or lack skills in forming relationships. A focus on improving quality of life and inclusion of its measurement in monitoring of outcomes will help ensure that practitioners and patients address goals that both see as central.

BETTER POLICIES AND PRACTICES FOR CO-OCCURRING DISORDERS REQUIRE ORGANIZATIONAL CHANGE

Even if we continue to have separate agencies for substance misuse and other mental disorders, as well as ones to deal with other health or social problems, there is much that can be done to improve services and make them more integrated and easier to access. However, this typically requires changes to organizations and the way practitioners work. There is now a substantial body of research and theory about the effective diffusion of innovations throughout organizations, and we can also be guided by what we know about individual's behavior change. Some of these principles are applied to co-occurring disorders below. Overall, the evidence shows that both top-down and bottom-up supports of the change through the organization are needed for optimal uptake.

Co-Occurring Disorders Must Be Core Business for the Organization and Practitioners

A corollary of the need for existing agencies to take responsibility for co-occurring disorders is that they must acknowledge that co-occurring disorders represent core business. That in turn requires that this principle is captured by the agency's mission, addressed in its policies, and reflected in the duty statements of individual staff. Policies need to be translated into procedures or guidelines that clearly communicate how they are translated into routine practice, are publicly supported by senior managers, and are widely promulgated throughout the organization. The organization's budget must also reflect this priority, providing sufficient staffing for it, including after-hours coverage where required, and consultants with specialist expertise to support use of the interventions by other staff. In some cases, additional prescribers will be needed to ensure that appropriate pharmacological interventions are available. Other resources for specific intervention components may also be required (e.g. space for support groups, cars for assertive follow-up of vulnerable patients, supported housing, computers and fast Internet links for electronic interventions within clinics, facilities to send text messages to remind about

appointments, cue coping strategies, etc.). Resources to cue high-fidelity use of the practices (e.g. forms, electronic record systems, charts, or computerized tools to use in sessions, brochures, cue cards, etc.) are typically also needed, which in turn involves investment in their development, organizational approval, production, and regular updating (e.g. including new drugs or slang terms, and adapting to new technologies).

Similarly, individual practitioners need to view the assessment and management of co-occurring disorders as being core to their role. Where specialist mental health services have a history of being split from services for alcohol and other drug use, staff have tended to see their role only through the narrow lens of their subspecialty. We have found it useful to describe co-occurring disorders as a subtype of "complex presentations": Practitioners are used to dealing with complexity, and more easily acknowledge it as core business than if the discourse is framed in terms of problems they initially see as the province of another agency.

Effective Comorbidity Practice Should Be Recognized and Rewarded

Just as patients need to see a clear net benefit from changing their behavior, the incentive balance for practitioners needs to favor implementation of sound procedures to address co-occurring disorders. If the procedures are seen as incurring cost for little benefit (e.g. effort, time, or financial cost to learn new skills, extra duties, more time for consultations, perceived restriction of practitioner choice, etc.), they are unlikely to be implemented. One aspect of ensuring a high level of implementation is to minimize these costs (e.g. by showing how existing skills can be applied to co-occurring disorders).

Positive incentives for uptake are also needed. A strong motivator of uptake of the required practices is to systematically collect data on their use, and then give individuals and teams information comparing their own performance with the performance target (or the average or top performance of the overall group). An incentive for uptake by individual staff is provided by routinely including co-occurring problems in case review meetings, and praising attempts to assess and address them. Inclusion of work on co-occurring disorders in performance reviews of staff at all levels is also highly motivating.

Ultimately, both practitioners and organizations are motivated by demonstrably better patient outcomes. Tracking and summarizing positive changes in a patient's admissions, substance use, symptoms, functioning, or quality of life can help to keep motivation high, even when some other patients appear to have

gained limited benefit or (as commonly is the case) their outcomes are at least initially unstable. A corollary is that outcomes should be systematically monitored, so that staff are aware of positive changes, and organizations can report on improved outcomes across their serviced population. Reductions in use of high-cost services by individual patients (e.g. inpatient or afterhours interventions) can be especially motivating for managers, since that can substantially impact on organizational costs and on numbers who can be treated within existing budgets.

Incentives should not exclusively rely on external rewards for optimal uptake. Individual staff should be encouraged to develop goals for learning and using assessments and interventions for co-occurring problems, to solve problems with their application, and notice their own achievements. Effective self-regulation makes them less reliant on the continued integrity of organizational monitoring and reward systems.

Required Skills Must Be Present or Taught, and Cues to Use Them Provided

If co-occurring disorders are adequately covered in the initial training of practitioners in addiction, mental and general health, additional training to assess and manage comorbidity may be able to focus just on local procedures and on advances in practice. In the meantime, other strategies are needed to increase the knowledge, skills, and confidence of front-line staff.

In both mental health and substance use agencies, some effective strategies that are amenable for use on a large scale are already in the skills repertoire of staff. Examples related to assessment are the ability to establish trust and rapport, to take a detailed history, examine triggers and effects of exacerbations, and review contexts, coping strategies, and supports that were associated with periods of better status. Intervention examples include development and maintenance of motivation for agency attendance and behavioral change, and effective goal setting, planning, and problem solving.

Some other strategies are relatively easy to communicate, for example the need to use multiple methods to accurately determine consumption (e.g. daily frequency and amount, frequency and amount of purchases, and weekly cost); the use of a "Timeline Followback" (a day-by-day review of recent events to cue recalled consumption); or helping the person identify pleasurable, non-substance-using activities that can help to boost their mood. Some more demanding areas of knowledge and skills can be supported by other resources (e.g. information on the effects and management of withdrawal from a specific drug, or information

about potential drug interactions can be provided) or given by other specialist staff on the team (e.g. pharmacotherapy for mental health symptoms, management of withdrawal, or long-term support of abstinence).

Low-intensity interventions for co-occurring substance misuse typically involve motivational interviewing or brief advice, plus goal setting, planning, and problem solving for issues that are likely to arise in early phases of initiating behavior change. In addition to pharmacotherapy for depression, several brief psychological strategies have significant impact, including behavioral activation (to increase pleasurable activity and daily achievements). Problem solving, goal setting, and planning (e.g. to address situational stressors) are applicable to both depression and anxiety. Longer treatments with application to both addictive and mental disorders include mindful meditation, which assists users to reduce rumination and related distress.

Where additional skills are needed, one-off workshops by themselves appear to have limited impact: while short-term increases in knowledge and skill can often be demonstrated, unless they are then consolidated in everyday practice, the gains may then be lost. In order for that consolidation to occur, the context must allow it – for example, the new practice may initially take a little longer until it is mastered, and this additional time must be able to be accommodated. Mentoring or supervision may be needed to assist the practitioner to use it effectively and solve problems with its use, and practitioners may need to be cued so they remember to use it (e.g. by items to be checked in patient records of assessment and treatment). Strategies to increase ongoing fidelity may also be required - for example, checklists for key steps in the assessment or intervention.

A Culture Supporting the Use of the Intervention Should Be Fostered

"Champions" can develop enthusiasm for comorbidity practice in the organization. Whether they are within management or among practitioners, they model the use of skills in dealing with co-occurring disorders, provide incidental learning, and reward use of the practices by others. However, excessive reliance on champions in the longer term is dangerous, as their loss can mean that use of the intervention collapses.

A focus on staff who are already keen to use the intervention ("early adopters") appears useful; it avoids unproductive conflict with staff who are initially resistant to comorbidity practices, and allows a critical mass of mutually reinforcing users to develop. We have found that provision of mentoring to this group results in

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significantly improved rates of screening and intervention for co-occurring disorders being recorded in patient files. Active engagement of staff in development and updating of support materials is another useful strategy; it both increases commitment to their use and helps to consolidate their understanding of the strategies.

CONCLUSION

There is no "silver bullet" to meeting the complex needs of people with co-occurring disorders, and ensuring stable positive outcomes. However, adopting sound practices that ensure detection of co-occurring problems and access to the best-known treatments is both an excellent start and a moral necessity.

SEE ALSO

Diagnostic Dilemmas in Comorbidity, Treatment for Co-occurring Substance Abuse and Mental Health Disorders

List of Abbreviations

ECA Epidemiologic Catchment Area OR odds ratio

Glossary

- **Antisocial personality disorder** a disorder that produces pervasive disruptions in interpersonal functioning and is characterized by features such as aggression, deceitfulness, impulsivity, reckless disregard for others, and a lack of remorse.
- **Bipolar disorder** a disorder with mania (elevated or irritable mood, often with increased activity and impulsivity), or alternating mania and depression which may have psychotic features that are consistent with that mood (e.g. grandiose delusions in mania).
- **Incentives** these are expected and valued benefits from engaging in a behavior. They increase the likelihood of that behavior occurring.
- Integrated treatment this treatment is adjusted to take account of the presence of co-occurring problems, and addresses them all. It is typically conducted by a single practitioner or team, and is contrasted with parallel or sequential treatment for different problems, usually by different agencies.
- **Odds ratio** the increased chance that a person from a particular group shows a feature (in this case a disorder) in comparison with other people.
- **Psychosis** a type of disorder that affects brain processes and is marked by features such as attentional difficulties, delusional beliefs, disorganized speech, and disturbances in perception (e.g. hallucinations). Speech may be disorganized, or be limited in amount or content, and motivation may also be affected.
- Schizophrenia a psychotic disorder (see above), which is not dominated by mood features. Emotional expression, speech, and motivation may be significantly impaired, and disorganized behavior or immobility seen. It cannot be due to another disorder (e.g. intoxication), causes significant functional disruption, and is

distinguished from similar disorders by its duration (in the *Diagnostic and Statistical Manual* of the American Psychiatric Association, persisting disturbance for at least 6 months, including at least a month of acute symptoms).

- Quadrant model of substance misuse and psychiatric problems a guide for decisions on which service should lead the management of an individual with co-occurring disorders. It is a 2×2 matrix, based on the severity of the psychiatric and addictive problems.
- **Timeline Followback** a day-by-day review of events or activities over recent weeks or months to cue recall of consumption.

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Relevant Websites

http://www.dualdiagnosis.org.au/ The link has-Australian and international resources on comorbidity and policy or service development, including toolkits for clinicians.

http://www.ontrack.org.au The link includes–programs for people with co-occurring alcohol and depression issues, and for psychosis-like experiences (including ones triggered by substance use).

http://www.samhsa.gov/ The link has-resources on comorbidity.

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Medications to Treat Addictions: Nicotine Replacement

Aryeh I. Herman, Mehmet Sofuoglu

Yale University, VA Connecticut Healthcare System, West Haven, CT, USA

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INTRODUCTION

Cigarette smoking is the leading cause of preventable death in the developed world. Cigarette smoking results in 435 000 premature deaths in the United States and 5 million deaths worldwide. Half of cigarette smokers die as a result of smoking related diseases, including lung cancer, coronary heart disease, stroke, and chronic obstructive pulmonary disease. The economic cost of cigarette smoking is enormous: over \$158 billion annually in the United States alone. Approximately 80% of smokers wish to quit and 40% attempt to quit each year. Unfortunately, without treatment, less than 5% of smokers are able to achieve abstinence lasting more

than 1 year. These data appear daunting and discouraging; however, longitudinal epidemiological data are more optimistic. In the United States, smoking rates have steadily dropped during the past four decades from 42.4% in 1965 to 19.8% in 2009. The decline in smoking prevalence is largely the result of a massive anti-smoking campaign targeting both smoking initiation as well as smoking cessation. While the prevention of smoking initiation is vital for long-term reduction of tobacco-related illnesses and deaths, there will be a delay of several decades before the prevention strategies bear fruit. Thus, current efforts to improve smoking cessation rates will likely provide more immediate results. Currently, there are effective medications to aid smokers

in quitting smoking including nicotine replacement therapy (NRT), bupropion, and varenicline. These pharmacological treatments increase the success rate of smoking cessation by two- to threefold compared to quit attempts without any treatments. In this section, we review the first pharmacotherapy developed for the treatment of tobacco addiction, NRTs. First, we overview nicotine's role in tobacco addiction. Then a brief history of NRTs will be provided, followed by their clinical use. We will also review the use of NRTs in special populations of smokers and genetic factors influencing the efficacy of NRTs.

ROLE OF NICOTINE IN TOBACCO ADDICTION

Nicotine is thought to be the main addictive chemical in tobacco smoke. After inhalation of a cigarette puff, nicotine in smoke particles diffuses readily into pulmonary veins. Nicotine is then carried to the arterial circulation and rapidly enters the brain tissue in less than a minute after its delivery. In the brain, nicotine binds to nicotinic cholinergic receptors (nAChRs). The nAChRs are ligand-gated ion channels that facilitate the release of several neurotransmitters in the brain, including dopamine (DA), serotonin, noradrenaline, acetylcholine, γ-aminobutyric acid (GABA), and glutamate. Increased release of these neurotransmitters mediates multiple effects of nicotine on mood, cognition, and the neuroendocrine and cardiovascular systems. Following a rapid delivery of nicotine to smokers, as with smoking or intravenous route, nicotine induces subjective effects of euphoria and drug liking, and increases blood pressure, heart rate, and plasma levels of cortisol, ACTH, and norepinephrine. Nicotine, especially in abstinent smokers, increases level of arousal and performance on attention tasks. With repeated nicotine exposure, as in light to heavy smoking, nAChRs desensitize, thereby resulting in diminished effects of nicotine (i.e. tolerance). At the same time, the number of nAChRs increase (upregulation). This nAChR desensitization and upregulation lead to tolerance development, which is thought to be crucial in nicotine dependence as well as tobacco withdrawal upon cessation of nicotine intake.

The nAChRs are pentameric combinations of 12 subunits ($\alpha 2$ – $\alpha 10$ and $\beta 2$ – $\beta 4$). The two most commonly expressed nAChRs in the brain are $\alpha 4\beta 2$ nAChR and $\alpha 7$ nAChR types. The $\alpha 4\beta 2$ nAChRs have a high affinity for nicotine and desensitize at low concentrations of nicotine, within the range of those found in the blood of smokers. Stimulation of $\alpha 4\beta 2$ nAChRs that are found in dopamine cell bodies and presynaptic terminals increases dopamine release both in the nucleus

accumbens and prefrontal cortex. For the addictive effects of nicotine, dopamine release in the nucleus accumbens, mediated by $\alpha 4\beta 2nAChRs$, is especially critical. Dopamine release in the prefrontal cortex contributes to cognitive-enhancing effects of nicotine.

The α 7nAChRs, similar to NMDA type glutamate receptors, are highly permeable to calcium, which allows them to enhance neurotransmitter release (e.g. glutamate) and modulate synaptic plasticity. The α 7nAChRs located in the hippocampus and the prefrontal cortex have been studied in relation to cognitive processes including attention and memory tasks. Compared to the α 4 β 2nAChRs, α 7nAChRs have low affinity for nicotine and do not desensitize at low nicotine concentrations. This delayed desensitization of α 7nAChRs has been suggested to maintain dopaminergic activity after the α 4 β 2nAChRs are desensitized, thereby contributing to nicotine reward and addiction.

Nicotine is extensively metabolized in the liver to cotinine largely by CYP2A6 enzyme. Cotinine is widely used as a marker for exposure to nicotine. Because of its long half-life (about 16 h), cotinine is useful to verify abstinence in cigarette smokers. For smokers who are receiving NRTs, cotinine is not useful to verify abstinence, which is generally assessed with exhaled carbon monoxide levels.

HISTORY OF NRT

The idea for using NRT for treatment purposes was conceived based on the findings that nicotine administered intravenously or orally reduced the number of cigarettes smoked by smokers. In the 1960s, Dr Claes Lundgren observed that Swedish submariners were able to cope when unable to smoke cigarettes by using smokeless tobacco. In 1973, two Swedish researchers, Ohlin and Westling, hypothesized that pure nicotine could be used for the purpose of tobacco withdrawal. Ohlin and Westling reasoned that using NRT is feasible and appropriate "if it is accepted that the tar and carbon monoxide are the most noxious components of tobacco smoke (Ohlin and Westling, p. 191)." The difficulty that the researchers encountered was that a suitable nicotine delivery system was not available. Fernö, Liehtneekert, and Lundgren developed a chewing gum that released nicotine at a slow rate when chewed. In a seminal paper in 1973, Ohlin and Westling reported that during a 1-week double-blind study smokers receiving nicotine gum smoked less cigarettes than those receiving a placebo gum. During the 6-month follow-up phase all subjects were offered nicotine-containing chewing gum. The researchers reported that the number of nonsmokers then remained fairly constant in the "initial-nicotine group" while it increased in the NRT FORMULATIONS 339

"initial-placebo group." These pioneering studies began a cascade of research studying whether nicotine administration in a variety of delivery systems could aid as potential smoking cessation treatments.

MECHANISM OF ACTION

Though a definitive mechanism of action has not been identified, several possible mechanisms have been proposed to explain the therapeutic efficacy of NRTs as pharmacological aids for smoking cessation. Initially, NRTs were thought to be a "substitution" treatment, similar to methadone treatment for opioid addiction. Opioid dependent individuals on methadone treatment display significantly reduced opioid reinforcement as a result of tolerance to opioid effects. Unlike methadone treatment, NRTs have limited efficacy in reducing nicotine reinforcement and smoking behavior changes minimally in unmotivated smokers who are treated with clinically used doses of NRTs. A likely mechanism is the attenuation of tobacco withdrawal severity by NRT treatment. Following cessation of cigarette smoking, smokers experience a range of withdrawal signs and symptoms including anger, anxiety, dysphoric mood, difficulty in concentrating, impatience, insomnia, weight gain, and restlessness. These symptoms start within hours and last up to 2–4 weeks following abstinence from smoking. Smokers also experience powerful cravings for smoking, sometimes precipitated by cues related to smoking. Cigarette smoking rapidly relieves these symptoms. It is important to emphasize that the relationship between withdrawal severity and relapse to smoking is not straightforward. Smokers may relapse to smoking without experiencing severe withdrawal and some smokers may not relapse in spite of experiencing withdrawal symptoms. However, withdrawal severity during early abstinence predicts relapse to smoking. It has been suggested that the NRTs' effectiveness in relieving tobacco withdrawal makes it easier to abstain from smoking, improving the success rate of smokers trying to quit.

NRT FORMULATIONS

Five NRT products have been marketed in the United States: nicotine patch, nicotine chewing gum, nicotine lozenge, nicotine nasal spray, and nicotine vapor inhaler. While the vapor inhaler and nasal spray are only available by prescription, nicotine gum, patch, and lozenge can be purchased over-the-counter (OTC). The NRTs are classified as short-acting (gum, lozenge, inhaler, and spray) and longer-acting (patch) products. The short-acting NRTs are especially effective in acute

management of tobacco withdrawal and cigarette craving. For NRT treatment, an important consideration is titration of the dose of longer-acting products based on the smoker's nicotine intake. In clinical practice, this is roughly determined by the number of cigarettes smoked per day (CPD).

Nicotine Patch

The nicotine patch is currently available OTC in 16- or 24-h delivery systems. The nicotine patch delivers nicotine at a relatively steady rate transdermally. The steadystate blood nicotine levels with patch treatment are about half those found in an average smoker. The 24-h delivery system is available in 7-, 14-, or 21-mg doses. Smokers who smoke more than 10 CPD begin with a 21-mg/day nicotine patch for the first 4 weeks and switch to 14 mg/day on weeks 5 and 6, and to 7 mg/day on weeks 7 and 8. Neither longer term (>8 weeks) nor a higher dose (>21 mg day $^{-1}$) of nicotine patch improves efficacy over the standard treatment. Some evidence suggests that highly dependent smokers may benefit from higher nicotine doses and longer treatment duration. The nicotine patch has many advantages including ease of administration, few side effects (skin irritation, nausea, vomiting, sweating, mood, and sleep disturbances), and once-daily dosing, all of which may lead to better compliance. For nicotine patch use, smokers are instructed to place a new patch on a relatively hairless location, typically between the neck and waist at the start of each day. It is recommended to rotate the site of application to reduce local skin irritation. Smokers who experience sleep disturbances are recommended to remove the 24-h patch before bedtime or use the 16-h patch, which is designed for use while the smoker is awake. Nicotine patches, however, do not alleviate craving episodes for smoking.

Nicotine Gum

Nicotine polacrilex gum is available OTC in 2- or 4-mg doses. With nicotine gum administration, nicotine is absorbed through buccal mucosa, reaching peak plasma nicotine concentrations within 15–30 min, as compared to within 1–2 min after smoking. Smokers who are heavily dependent (>25 CPD) are recommended to start with the 4-mg pieces. The initial recommended dose is one piece every 1–2 h in the first 6 weeks, one piece every 2–4 h between weeks 7 and 9, and one piece every 4–8 h between weeks 10 and 12. The gum should be used for up to 12 weeks with no more than 24 pieces to be used per day. Smokers are instructed to chew the gum intermittently for about 30 min or until the taste dissipates. The main side effects of gum include nausea,

burping, hiccups, and jaw fatigue. Acidic beverages such as coffee and juices should be avoided before and after the use of nicotine gum because they decrease the absorption of nicotine.

Nicotine Lozenge

Similar to nicotine gum, the lozenge is available OTC in 2- or 4-mg doses of nicotine. The pharmacokinetic properties of lozenge are similar to nicotine gum, except that lozenge delivers about 25% more nicotine than the same dose of nicotine gum, as some nicotine is retained in the gum, and the lozenge is dissolved completely. The 4-mg dose is preferred for highly dependent smokers (those who smoke their first cigarette <30 min after waking up). Smokers are advised to use at least nine lozenges per day in the first 6 weeks for a total duration of up to 12 weeks. The lozenge use should not exceed 20 lozenges per day. Nicotine lozenges may be particularly well-suited for smokers who wear dentures, have temporomandibular joint pain, or prefer not to chew gum.

Nicotine Nasal Spray

Nicotine nasal spray is available by prescription only. Nicotine nasal spray delivers nicotine faster than the other NRTs, achieving peak plasma levels between 5 and 10 min after delivery, perhaps leading to a better efficacy in relieving acute cravings in comparison to gum or lozenge. The nasal spray comes in a multidose container with a pump that delivers 0.5 mg of nicotine per 50-µl squirt. The dose of nasal spray varies depending on the individual level of dependence and severity of symptoms. The usual recommended dose is 1–2 doses for 8 weeks, with a minimum of 8 doses per day and a maximum of 40 doses per day. Gradual tapering is recommended between 9 and 14 weeks. Smokers who use nasal spray are more than twice as likely to have long-term abstinence from cigarette smoking as compared with placebo treatment. Nasal spray may cause nasal burning, itching, and irritation, and adherence rates tend to be lower than those for other forms of NRT.

Nicotine Inhaler

The nicotine inhaler contains a vaporized cartridge of nicotine placed in a plastic container with the mouth-piece similar to that used in the treatment of asthma. The nicotine aerosol is inhaled and absorbed through the buccal mucosa rather than through the lungs, as in smoking. Peak levels of nicotine are reached 15 min after delivery. The nicotine comes in individualized 10-mg

cartridges, of which 4 mg are delivered and 2 mg are absorbed. However, puffs are highly variable and dependent on factors such as consistency of delivery between puffs as well as air temperature. Recommended dosage is 6–16 cartridges per day, with a treatment duration up to 6 months. Smokers are instructed to taper dosage during the final 3 months of treatment. The nicotine inhaler can cause local irritation, such as a burning sensation in the throat, coughing, sneezing, dizziness, nausea, and indigestion. These side effects may compromise compliance with heavy use and may reduce the efficacy of an inhaler.

ABUSE LIABILITY OF NRTS

Given the addictiveness of nicotine delivered via cigarette smoking, an important consideration is the abuse liability of NRTs. For drugs of abuse, addictiveness is also influenced by the speed and dose of delivery such that large amounts of the drug delivered rapidly is more addictive than lower doses delivered slowly. This is also true for NRTs. Nicotine gum, lozenge, spray, or vapor inhaler provides faster delivery than nicotine patch. Nicotine delivered via patch does not produce any psychoactive effects. Similarly, nicotine, 1-2 mg, delivered via gum or lozenge produces much lower level of reinforcement than the same amount delivered via smoking. Faster delivery systems, like nicotine vapor inhaler and spray, although much less than cigarette smoking, have greater abuse potential than other NRTs. In clinical practice, only a few smokers continue using NRTs longer than their recommended use. In one prospective study, among smokers trying to quit smoking, those who continue using NRTs at week 15, beyond the 12 weeks of recommended use, were 2% for patch, 7% for gum and inhaler, and 10% for spray. These figures are consistent with the rate of nicotine delivery from these NRT products, those with faster nicotine delivery having a greater abuse liability.

EFFICACY OF NRTS

Overall, the efficacy of NRTs has been tested in more than 100 clinical trials in over 35 000 smokers. The meta-analyses of these clinical trials demonstrate the efficacy of NRTs in helping individuals quit smoking. However, because there are different preparations of NRT, their effectiveness may also vary. In 2008, a large meta-analysis investigating 83 studies was conducted to determine relative efficacies of NRT for smoking cessation. As summarized in Table 35.1, all NRTs, compared to placebo, significantly improve smoking abstinence rates at 6 months following quit date.

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TABLE 35.1 Comparison of Nicotine Replacement Therapy (NRT) Preparations

Preparation	Dosage	Schedule	Precautions and adverse effects	OR* (95% CI) versus placebo
Nicotine chewing gum	2 mg (≤25 cigarettes per day) 4 (>25 cigarettes per day)	Week 1–6: 1 piece 1–2 h Week 7–9: 1 piece 2–4 h Week 10–12: 1 piece 4–8 h	Dentures, acidic beverages, sore throat, nausea, burping, hiccups, jaw fatigue	1.5 (1.2–1.7)
Nicotine patch	7 mg 14 mg 21 mg	Most smokers Weeks 1–6: 21 mg Weeks 7–9: 14 mg Weeks 10–12: 7 mg	Local skin irritation, contact sensitization, vivid dreams, headache, insomnia	1.9 (1.7–2.2)
Nicotine nasal spray	0.5 mg (1 spray into each nostril = 1 dose)	Weeks 1–8: 8–40 doses per day Weeks 9–14: taper down	Hot peppery spray sensation in back of throat, sneezing, cough, watery eyes, runny nose	2.3 (1.7–3.0)
Nicotine inhaler	4 mg (1 cartridge delivers 4 mg over 80 inhalations)	Months 1–3: 6–16 cartridges per day Months 4–6: taper	Headache, cough, mouth/ throat irritation, dizziness, nasal congestion, hiccups, nausea, vomiting	2.1 (1.5–2.9)
Nicotine lozenge	2 mg (>30 min to first cigarette) 4 mg (≤30 min to first cigarette)	Weeks 1–6: 21 mg day ⁻¹ Weeks 7–9: 14 mg Weeks 10–12: 7 mg	Hiccups, heartburn, nausea, vomiting, diarrhea	2.1 (1.6–2.6)

^{*} Odds ratio compared with placebo 6 months post-quit.

NRT COMBINATION TREATMENTS

NRT combination strategy entails combining two NRTs to improve the outcomes for smoking cessation. The rationale for this strategy is that the slow nicotine delivery via nicotine patch, while reducing the severity of tobacco withdrawal symptoms, does not relieve episodes of craving for cigarettes. Combining nicotine patch with a faster delivery NRT like gum or spray provides relief from breakthrough cravings. The most commonly studied combination is nicotine patch plus nicotine gum. Several studies support the added benefit of this combination than either treatment alone. Combination of nicotine patch with other rapid delivery NRT products has been less well studied. A recent clinical trial of five smoking cessation pharmacotherapies (nicotine lozenge, nicotine patch, sustained-release bupropion, patch + nicotine nicotine lozenge, bupropion + nicotine lozenge) found that only the combination of nicotine patch plus nicotine lozenge significantly improved smoking cessation at 6 months post-quit. These findings are consistent with a recent meta-analysis in which nicotine patch (>14 weeks) and one NRT (gum or spray), relative to placebo treatment, increased the success rate of smoking cessation by 3.6 times.

In addition to combination of two NRTs, NRTs can also be combined with other smoking cessation medications. For example, combination of NRT with bupropion increases the success rate of cessation more than either treatment alone. The safety and efficacy of NRT and varenicline combination remains to be evaluated in controlled studies.

REAL-WORD EFFECTIVENESS OF NRTs

Some questions have been raised about the efficacy of NRT in real-world use, especially for those that are available OTC including nicotine patch and gum. A large survey study from California questioned the effectiveness of NRT in long-term smoking cessation by demonstrating that those who attempted to stop smoking using NRT were no more likely to remain abstinent for 6 months or more than those who did not use NRTs. One particular flaw of this survey was its retrospective nature, which may introduce systemic bias. It is possible that smokers may recall quit attempts if they purchase NRTs, than other short-lived attempts without the use of NRTs. In addition, smokers who purchase NRTs may believe that they may not be able to quit on their own and be more dependent on tobacco. Given these limitations, cross-sectional population-based studies may not be a good way to assess treatment effectiveness of NRTs.

SPECIAL POPULATIONS

One of the difficulties of applying clinical trial data into general treatment settings is that the composition of the sample in clinical trials may not mirror the diversity of patients seen in clinical settings. Ethnicity, gender, age, medical co-morbidities, presence of other addictions or psychiatric disorders, and level of smoking may influence the efficacy of NRTs.

Ethnicity

Ethnic minorities represent more than one-third of the US population, with Hispanic/Latino Americans and African Americans as the largest minority groups. In a large 1996 California Tobacco Survey, Latino, Asian, and African Americans were more likely to attempt smoking cessation than Caucasian smokers but had equivalent smoking cessation rates. Additionally, smokers from minority racial/ethnic groups reported lower utilization of NRTs, lower rates of physician advice, and physician assistance to quit smoking. These disparities remain even after correcting for sociodemographic factors and smoking history. Overall, NRTs seem to be effective in African Americans and Hispanics, although the relative efficacy of NRT in racial/ethnic groups is less well understood.

Gender

In the United States, the rate of smoking among women is significantly lower than that for men (34.5% versus 22.5%). In general, women maintain their nicotine addiction with lower levels of nicotine intake than men, even after controlling for the number of cigarettes smoked. Evidence also suggests that women may be more sensitive to the behavioral effects of nicotine. Many studies have demonstrated that NRTs are effective in women smokers. Although some studies suggest that NRTs may be less effective in women than in men, gender-specific guidelines for NRT treatment remains to be developed.

Pregnancy

Rates of smoking during pregnancy are about 13%, reflecting the fact that about half of the women are able to quit during pregnancy. Unfortunately, among those who quit smoking during pregnancy, 40–52% relapse within 2 weeks and 70–80% resume smoking within 1 year of childbirth. In addition to the health risk associated with smoking in postpartum women, second-hand exposure is also a significant health risk for newborns. In pregnant smokers, NRTs seem to be safe and increase birth weight. However, the efficacy of NRTs, as well as any other first-line medications, remains to be determined in pregnant and postpartum smokers. Behavioral treatments are preferred for pregnant and postpartum smokers.

Adolescents

Accumulating evidence suggests that adolescence is a period of greater vulnerability to nicotine addiction, with more than 80% of dependent smokers starting smoking before the age of 18. In the United States, every day, about 4000 teenagers smoke their first cigarette, with one-third becoming daily smokers. Unfortunately, only 4% of teenage smokers successfully quit smoking each year. The efficacy of NRTs, or any other smoking cessation pharmacotherapies, has not been demonstrated in adolescent smokers. Clearly, further research is needed to develop effective pharmacotherapies for teenage smokers.

Older Adults

Older adults, age 50 or older, who quit smoking are likely to benefit from smoking cessation by decreasing their likelihood of cancer, coronary heart disease, stroke, and chronic obstructive pulmonary disease. Even smokers who are in poor health can reduce the risk for imminent mortality, reverse respiratory difficulties, decrease disability levels, and increase quality of life through smoking cessation. Studies have demonstrated that nicotine patch is safe and ought to be offered to older smokers who are motivated to quit smoking.

Psychiatric Disorders

Individuals with psychiatric co-morbidity, including those with other addictions, compared with those without co-morbidity, consume more cigarettes, are more dependent on tobacco, and are less likely to quit smoking. High rates of smoking have been observed in individuals with schizophrenia (44–88%), depression (40–60%), bipolar disorder (55–70%), and panic disorder (19–56%). Similarly, smoking rates are high in those with cocaine (80%), methamphetamine (>90%), opioid (>80%), and alcohol use (70–80%) disorders. Smokers who receive treatments for other addictions represent a unique opportunity to target both tobacco and other addictions. The efficacy of NRTs in smokers with psychiatric co-morbidities has not been well studied. For example, preliminary studies suggest that schizophrenic smokers may benefit from NRT combined with bupropion. Further research is needed to establish clinical guidelines for NRT use in smokers with psychiatric disorders.

Medical Comorbidities

Smokers with medical conditions including cancer, diabetes, cardiac disorders, COPD, and asthma particularly benefit from quitting smoking. Unfortunately,

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smoking cessation is difficult to achieve in smokers with medical co-morbidities: over 50% of smokers resume smoking within 6 months after having a heart attack and 58% of smokers continue to smoke after a new cancer diagnosis. The safety of NRTs has been demonstrated in smokers with medical co-morbidities including those with coronary artery diseases. Although the efficacy of NRTs needs to be further examined in many of the medial co-morbid conditions, the clinicians should not hesitate to provide smoking cessation treatment in smokers. Evidence suggests that smokers with co-morbidities may require longer treatment with NRTs and may benefit from combination treatments. Further controlled studies will help to develop more effective guidelines for NRTs in smokers with medical co-morbidities.

Light Smokers

Light smokers, those who smoke less than 10 cigarettes day ⁻¹, comprise about 25% of smokers in the United States. Light smokers, like heavier smoker, have difficulty in quitting smoking. Since light smokers have traditionally been excluded from clinical trials, there is little information regarding the effectiveness of NRTs in this group. One study suggested that light smokers had better outcomes with nasal spray than placebo, while another study did not find differences between the 2 mg and placebo gum for smoking cessation outcomes. Further research examining the efficacy of NRTs in light smokers is needed. This is especially important given the increasing number of light smokers, perhaps due to increasing cigarette cost and restrictions on smoking.

PERSONALIZED MEDICINE WITH NRTs

In recent years, an active area of research has been to identify individuals who will respond favorably to smoking cessation medication including the NRTs. This approach is especially important for tobacco addiction, where treatment success rates are low and smokers show significant individual differences in their tobacco addiction including amount of use, and severity of tobacco withdrawal and craving. The overall goal of this "personalized medicine" approach is to be able to choose the most effective medication and the dose with least side effects based on the genetic makeup of individual smokers. Most of the pharmacogenetic studies conducted with NRTs have focused on genes related to nicotine reward and nicotine metabolism.

As mentioned before, several neurotransmitters play an essential role in mediating the rewarding effects of nicotine and some have been examined as potential moderators of NRT responses. Among them are genetic variation in the mu opioid receptor (OPRM1), a4 subunit of nAChR (CHRNA4), dopamine D2 receptor, dopamine and serotonin transporter, catechol-O-methyltransferase (COMT), and dopamine beta-hydroxylase (DBH) enzymes. Although, there have been initial promising findings, they remain inconclusive.

Other studies have focused on the genetic variation in nicotine metabolism. In one study, the rate of nicotine metabolism was predictive of treatment response to nicotine patch but not to nasal spray. Those with slower nicotine metabolism were more likely to quit smoking at the end of the trial and at 6-month follow-up. These examples support the promise of pharmacogenetic approaches to improve the effectiveness for NRT treatment of tobacco addiction.

SEE ALSO

Non-nicotine Medications

List of Abbreviations

CPD cigarettes smoked per day
GABA γ-aminobutyric acid
nAChRs nicotinic cholinergic receptors
NRT nicotine replacement therapy

OTC over-the-counter

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Non-Nicotine Medications

Bahar Haji-Khamneh*, Tony P. George*,\$

*Centre for Addiction and Mental Health (CAMH), Toronto, ON, Canada \$University of Toronto, Toronto, ON, Canada

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INTRODUCTION

Cigarette smoking is the leading cause of preventable death in developed countries and it is spreading rapidly throughout the developing world. Currently, an estimated 1.1 billion people smoke cigarettes worldwide and approximately 4 million deaths occur annually due to smoking-related illnesses such as lung cancer and cardiovascular disease. If the prevalence of cigarette smoking continues to climb in developing countries, the annual death toll from smoking-related morbidity will rise to a staggering 10 million by the year 2030. In the United States, smoking-related morbidity accounts for upwards of \$400 billion per year in health-care costs. Furthermore, though the prevalence of smoking in the United States has nearly decreased in half since 1965, mortality rates remain above 400 000 annually without

any observed decline over the past 10 years. This is true despite increased focus on prevention strategies such as the institution of various social policies and educational programs aimed at curbing the initiation of smoking by adolescents. This speaks to the importance of developing effective interventions for treating current smokers – especially those who have not been able to quit with available treatments.

Over 70% of current smokers report the desire to quit; however, the observed long-term (1 year) quit rate is a mere 6%. Nicotine replacement therapies (NRTs), such as the gum, the patch, and the inhaler, which are designed to reduce nicotine withdrawal by delivering nicotine through methods other than smoking, are the most widely accessible pharmacological treatment options available. While NRTs substantially improve quit rates in the short run, more than 85% of individuals

relapse within 6–12 months. This finding highlights the limitations of NRTs and the need for the development of more effective long-term pharmacological treatment strategies for smoking cessation. Over the past decade, non-nicotine medications have shown great effectiveness in treating nicotine dependence and are the focus of this chapter.

NEUROBIOLOGY OF NICOTINE AND TOBACCO

Nicotine

Nicotine is the principal reinforcer found in tobacco smoke and has been strongly implicated in mediating tobacco dependence. Like most other drugs of abuse, nicotine has been shown to stimulate the release of the neurotransmitter dopamine in the mesolimbic reward pathway. The mesolimbic reward pathway comprises midbrain dopaminergic neurons that originate in the ventral tegmental area (VTA) and project to the nucleus accumbens (NAc). Nicotine acts on several neurotransmitter systems including dopamine, norepinephrine, serotonin, glutamate, gamma aminobutryic acid (GABA), and endogenous opioid receptors; and its primary site of action in the central nervous system (CNS) is the nicotinic acetylcholine receptor (nAChR), which is located pre-synaptically on these neuronal types. nAChRs in the CNS are pentameric ligand-gated ion channel complexes composed of two α and three β subunits, forming a pore. There are seven types of α and three types of β subunits found in the CNS that allow for considerable diversity among nAChRs in terms of sites of action and activation response. Highaffinity β2-containing nAChRs desensitize to a greater degree than the low-affinity α7-containing nAChRs in response to treatment with nicotine. While β 2containing nAChRs are located on the GABAergic inputs to VTA dopamine neurons, α7-containing nAChRs are located on the glutamatergic inputs to the VTA dopamine neurons. Thus, after activation with high concentrations of nicotine, the β2-containing receptors on GABAergic neurons desensitize to a greater extent than the α7-containing nAChRs on glutamatergic neurons, resulting in reduced inhibition of dopaminergic projections to the NAc. Accordingly, there is relatively more excitation of glutamatergic neurons compared to GABAergic neurons, resulting in increased VTA dopaminergic firing and dopamine release in the NAc. While nAChRs desensitize quickly (i.e. within milliseconds) in response to nicotine activation, they re-sensitize after overnight abstinence. This heightened sensitivity may explain why most smokers report the first cigarette in the morning to be the most satisfying.

The role of nAChRs and related transmitter systems in the psychopharmacologic effects of nicotine/tobacco implicates numerous targets for the development of non-nicotine medications.

NON-NICOTINE PHARMACOTHERAPIES

In this section, we review FDA-approved (i.e. bupropion and varenicline) as well as some nonapproved (e.g. topiramate, baclofen) non-nicotine pharmacotherapies for nicotine dependence.

Bupropion

Sustained-release bupropion (Zyban®), initially used for treating major depression as Wellbutrin®, was the first FDA-approved non-nicotine first-line pharmacological intervention for treating nicotine dependence.

Mechanism of Action

The exact mechanism of action of bupropion in treatment of tobacco dependence is still not clearly understood. However, multiple mechanisms have been proposed as mediating bupropion's anti-smoking effects.

One of the proposed mechanisms is the attenuation of withdrawal symptoms. Dopamine and norepinephrine are the main neurotransmitters that have been implicated in mediating these effects. Bupropion has been found to block the reuptake of dopamine and norepinephrine in the mesolimbic reward pathway, which is believed to contribute to the mitigation of withdrawal symptoms such as irritability and negative affect. Chronic administration of bupropion has been found to increase dopamine release in the NAc. Norepinephrine transmission in the NAc also has an impact on dopamine flow during nicotine withdrawal and bupropion may mitigate the anhedonic effect of nicotine withdrawal through norepinephrine reuptake inhibition. Thus, given that dopamine plays a central role in motivational and reward-related processes, it is likely that bupropion mitigates the unpleasant effects of withdrawal by boosting dopamine release within the NAc. There is also some evidence that the mechanism by which bupropion enhances synaptic availability of norepinephrine may not be the inhibition of reuptake, but the enhancement of the firing rate of noradrenergic neurons. Whichever the precise mechanism of action, norepinephrine is linked to dopamine release in the reward system and bupropion's action on both of these neurotransmitters is thought to be important to attenuating withdrawal symptoms and aiding smoking cessation.

In addition to the blockade of reuptake associated with withdrawal attenuation and reward replacement, bupropion also plays a role in decreasing satisfaction from smoking. Bupropion administration has been associated with reduced smoking satisfaction and psychological reward. Chronic bupropion administration has been shown to decrease smoking, and decreases smoking satisfaction in those who continued to smoke during bupropion treatment. While it may seem counter-intuitive at first glance, acute bupropion administration has been associated with increased ad-lib smoking behavior. However, this unexpected increase in smoking behavior is likely due to decreased satisfaction from smoking, which has been most strongly linked to bupropion's antagonistic properties toward the highaffinity nAChRs. Thus, both acute and chronic bupropion mitigate the rewarding properties of nicotine, likely through the blockade of nAChRs.

In summary, increased dopamine release in the mesolimbic pathway mimics the action of nicotine, thereby reducing nicotine withdrawal. The increase in concentration of norepinephrine is also thought to attenuate withdrawal symptoms. There is also some evidence that bupropion can act as an antagonist for high-affinity nAChRs. This is thought to reduce some of the reinforcing effects of nicotine. However, further research is required to clarify the link between neurobiology of bupropion and the resulting behavioral correlates, in facilitating smoking cessation.

Clinical Studies

Several pivotal studies helped establish bupropion's efficacy as a smoking cessation aid. A double-blind four-arm placebo-controlled trial by Hurt and colleagues was the first large study (N = 615) to demonstrate the efficacy of bupropion in treatment of smoking cessation. This study showed that bupropion as compared to placebo leads to a twofold increase in abstinence rates at 7 weeks of treatment. At the end of the treatment, the abstinence rate for subjects receiving placebo was 19% as compared with 28.8% in the 100 mg group, 38.6% in the 150 mg group, and 44.2% in the 300 mg group. This advantage was maintained 45 weeks following the end of treatment. This study also established the recommended dose of bupropion as 300 mg/day (150 mg bid), since the best smoking cessation outcomes and a favorable side-effect profile were observed in the 300 mg/day group. Subsequent analysis revealed no effect of past history of major depression on treatment response. Additional analyses showed that lower smoking rate, longer periods of previous abstinence, and male gender were among the important predictors of successful outcome. A large (N = 893) multicenter follow-up study by Jorenby and colleagues corroborated these results for 9 weeks of bupropion treatment and further demonstrated that bupropion is superior to NRT for achieving abstinence.

Bupropion was also evaluated as a means for smoking relapse prevention in abstinent smokers. Hays and colleagues conducted an open-label study (N = 784) investigating the effects of prolonged bupropion administration on relapse prevention. This study showed that treating smokers who had successfully quit by the seventh week of treatment and continued to receive bupropion as opposed to placebo for an additional 45 weeks achieved greater abstinence rates at the end of the 52-week treatment phase of the trial (55.2% versus 42.3%). However, these gains were not present at the 6-month or the 1-year follow-up visits. The study did show, however, that bupropion as compared with placebo delayed the median time to relapse (156 days versus 65 days). Thus, bupropion was shown to be efficacious in short-term cessation and demonstrated some utility in delaying relapse.

Common Adverse Effects

The most common adverse effects associated with bupropion include insomnia, dry mouth, and nausea. These effects are generally well tolerated and usually subside with continual use.

Serious Adverse Events

Seizures are the most common serious adverse events associated with bupropion. While seizures were not commonly reported in clinical trials, a number of cases have been reported in post-marketing surveillance studies. Depression is the most frequently encountered psychiatric effect; however, since nicotine withdrawal is commonly associated with depressive symptoms, the direction of causality is unclear. Other psychiatric side effects include unusual changes in behavior, worsening of depression, and onset of suicidal ideation. In 2009, the Food and Drug Administration requested the manufacturers to add a black box warning on the prescribing information, highlighting the risk of serious psychiatric side effects.

Use in Special Populations

Bupropion has been evaluated for use in a number of special populations, including those with psychiatric co-morbidity, patients with cardiovascular disease, and ethnic minorities.

The prevalence of smoking is elevated in people with a number of co-morbid psychiatric conditions. Rates of smoking are significantly higher in patients with schizophrenia, major depression, and other mood disorders. Given the high prevalence of smoking in psychiatric populations, much attention has been given to establishing the efficacy and safety of bupropion in these populations. Over the past decade, numerous studies have

been conducted to test the efficacy and safety of bupropion in patients with schizophrenia. Evins and colleagues conducted a 12-week double-blind placebocontrolled trial of bupropion added to high-dose NRT (i.e. combination of transdermal nicotine patch and nicotine polacrilex gum) and weekly group cognitive behavioral therapy for smoking cessation in patients with schizophrenia (N = 51). They found that compared with patients on placebo+NRT, patients on bupropion+NRT had a higher rate of smoking reduction at week 12 and 24, a lower expired air carbon monoxide during treatment and follow up, and a greater continuous abstinence rate at week 8 prior to NRT tapering. However, abstinence rates were not significantly different between groups at week 12. In a similar study, George and colleagues conducted a 10-week doubleblind placebo-controlled trial of bupropion in combination with the transdermal patch for smoking cessation in patients with schizophrenia (N = 58). Findings from this trial corroborated previous findings that short-term continuous abstinence rates were greater for patients on bupropion+NRT than those on placebo+NRT, and long-term abstinence rates were consistent with previous findings. No worsening of psychiatric symptoms was observed in either of these trials for patients on bupropion+NRT. Taken together, these and other trials of bupropion in patients with schizophrenia suggest that bupropion is well tolerated in smokers with schizophrenia and that while it is effective in smoking cessation and reduction during treatment, these effects are not sustained in the long term. Bupropion has also been tested for efficacy in populations with depression. While bupropion appears to have only moderate success in patients with depression, it appears to be a safe treatment option as no significant side effects or drug-drug interactions have been noted to date. Further studies regarding the efficacy and safety of bupropion in other psychiatric populations are

Since smoking cessation following myocardial infarction significantly reduces the risk of death in patients with cardiovascular disease, bupropion has been evaluated as a treatment option for patients with cardiovascular disease. These studies suggest that similar to the pattern observed in the general population, bupropion increases short-term abstinence rates but is not as successful in sustained long-term abstinence. Bupropion is safe for use in this population.

Bupropion has also been tested for use in ethnic minorities. Not only do smoking rates vary by ethnicity, but abstinence rates are also significantly different among ethnic minorities in North America. For example, while 70% of all smokers express the desire to quit, African Americans who smoke fewer cigarettes and have more frequent quit attempts than Caucasian smokers report

significantly lower abstinence rates. Research into the efficacy of bupropion for smoking cessation suggests that while bupropion is associated with increased abstinence rates among ethnic minorities such as African Americans, Hispanic Americans, and Indian Americans, quit rates are still significantly lower compared with Caucasian samples. Further research is required to determine the relative contribution of metabolic differences and environmental factors to the observed differences in efficacy between different ethnicities.

Bupropion has also been evaluated as an aid to smoking cessation in adolescents. Randomized placebo-controlled trials have shown that while at 150 mg/day bupropion in combination with the patch does not increase abstinence rates relative to placebo in combination with the patch, bupropion treatment at 300 mg/day in combination with individual counseling does improve short-term abstinence. However, short-term abstinence rates are lower than those observed in adults, and adolescents relapse soon after discontinuation of medication.

Varenicline

Varenicline, a synthetic derivative of a naturally occurring nAChR partial agonist cytisine, is the most recently approved pharmacological aid for smoking cessation. It is currently the most effective monotherapy available, as it nearly triples the odds of achieving long-term abstinence at 12 months after the beginning of treatment.

Mechanism of Action

In order to understand varenicline's mechanism of action, a brief review of nicotine's action in the mesolimbic reward system is necessary. The addictive characteristic of nicotine can at least be partly contributed to the stimulation of $\alpha 4\beta 2$ -containing nAChRs, which in turn result in increased stimulation of dopaminergic neurons in the VTA (see above). Varenicline has a high affinity for the $\alpha 4\beta 2$ type of receptor, which results in modulation of dopaminergic neurons of the VTA. It is hypothesized that a partial agonist whose affinity for the $\alpha 4\beta 2$ nAChR is greater than nicotine's would bind them selectively, thereby antagonizing (i.e. reducing the availability of binding sites for) nicotine. The natural nAChR partial agonist cytisine seemed the most promising candidate at the time. However, its low bioavailability and poor ability to cross the blood-brain barrier rendered it only minimally effective for treating smoking cessation. Thus, scientists began making structural changes to cytisine with the aim of arriving at a compound with more suitable biochemical properties.

Studies have shown that the increase in dopamine in response to varenicline exposure ranged from 35 to 60%

of the response to nicotine exposure. That is, due to its partial agonist properties, varenicline stimulates dopamine release at a significantly lower concentration than nicotine, itself a full agonist. It has been suggested that stabilization of dopamine levels in response to varenicline treatment in smokers may help curb craving and withdrawal symptoms associated with smoking cessation or reduction. At the same time, since the dopamine release is significantly reduced, the rewarding effects of nicotine are also attenuated to a large extent. In line with this theory, rates of abstinence increase over the first few weeks of varenicline treatment. This suggests that the reduction in rewarding properties of smoking associated with varenicline may actually facilitate the initiation of abstinence, rather than attenuating withdrawal symptoms after abstinence has already been reached. This reduction in dopamine release also limits varenicline's potential for abuse and dependence.

Clinical Studies

The initial Phase II trials of varenicline aimed to investigate its safety and efficacy as a smoking cessation aid. Taken together these studies identified the optimal dosing regimen as 2.0 mg/day and showed that titration of the medication over the first week improves its tolerability. The Phase III trials aimed to determine the efficacy and safety of varenicline compared to other existing pharmacotherapies. Two identical randomized double-blind placebo-controlled studies by Gonzales and colleagues and Jorenby and colleagues, compared the efficacy of varenicline directly to bupropion and placebo. A total of 2045 smokers were randomized to receive either varenicline, bupropion, or placebo. Both studies yielded almost identical outcomes for continuous abstinence for weeks 9-12. Abstinence rates for varenicline (study 1: 44.4%, study 2: 44.0%) at the end of the 12-week trial were significantly higher compared to bupropion (study 1: 29.5%, study 2: 30%) and both drug treatments were associated with significantly higher abstinence rates compared to placebo (study 1: 17.7%, study 2:17.7%). Continuous abstinence rates for the follow-up period (weeks 9-52) were lower for all groups. However, participants in the varenicline group continued to show a higher abstinence rate (study 1: 22.1%, study 2: 23.0%) compared to bupropion (study 1: 16.4%, study 2: 15.0%) and placebo (study 1: 8.4%, study 2: 10.3%). The continuous abstinence rate was statistically significant in study 1 (p < .0001) but only showed a trend toward significance in study 2 (p = .064). These studies established the superiority of varenicline to bupropion after 12 weeks of treatment. The effects of varenicline on long-term abstinence and prevention of smoking relapse were tested by Tonstad and colleagues using a 12-week open-label phase followed by randomization to an additional 12 weeks of either varenicline or placebo. Only participants who had achieved abstinence for at least the last week of the open-label treatment phase were randomized. Of the 1926 participants, 64.1% achieved 7-day point-prevalence abstinence at the end of the open-label phase and 1206 were randomized. Results showed that participants taking varenicline were 2.5 times more likely to continue abstaining during weeks 13–24 and 1.5 times more likely during weeks 13–52, compared to the placebo group. Taken together, these studies demonstrated that varenicline is an efficacious pharmacotherapy for smoking cessation, that it is more effective than bupropion, and that its long-term use is also effective in reducing relapse.

Common Adverse Events

The most frequent adverse events reported with varenicline use include nausea, abnormal dreams, and insomnia. Phase III trials revealed that nausea mainly occurred in the first week of treatment and its prevalence was highest in week 2.

Serious Adverse Events

Since its approval in 2006, some concerns have emerged regarding the risk of serious neuropsychiatric symptoms in patients using varenicline. As of July 2009, the FDA requires manufacturers of varenicline to add new black box warning highlighting the risk of various neuropsychiatric symptoms to their prescribing information. These symptoms were determined based on post-marketing surveillance data received by the FDA and include changes in behavior, hostility, agitation, depressed mood, suicidal thoughts and behavior, and attempted suicide.

Post-marketing adverse event reports are continuously monitored by the FDA and from May 2006 to December 2007 there were 227 cases of suicidality associated with varenicline, 28 of which were fatal. Fifty percent of these cases were of individuals with preexisting mental illness whereas approximately 25% had no documented psychiatric history. Gunnell and colleagues conducted a large cohort study in the United Kingdom (N = 80660) showing that NRTs were associated with a greater risk of self-harm than both varenicline and bupropion. However, the risk of suicidal thoughts was elevated by 43% in participants treated with varenicline. Contrary to the concerns of FDA, a cause-and-effect relationship cannot be conclusively established as smoking doubles the risk of suicidality. Furthermore, prevalence of smoking is much greater in patients with mental illness, who also have a higher risk of suicidality than the general population. Thus, further research into patients who experience suicidality while taking vareniciline is required to identify the risk factors of suicidality for varenicline treatment (Table 36.1).

TABLE 36.1 Approved Smoking Cessation Pharmacological Treatments

Medication	Mechanism of action	Dosing details	Effectiveness rating	Odds ratio of smoking abstinence (in comparison to placebo)
Varenicline	Acts as a partial nAChR agonist, reducing cravings and withdrawal symptoms while also reducing the reinforcing effects of nicotine	1 mg twice daily following a 1-week titration period	1	2.33*
Bupropion	Acts by inhibiting DA and NE reuptake to reduce withdrawal symptoms while its nAChR antagonism reduces reinforcing effects of nicotine	150 mg twice daily following a 3-day titration period	1	2.1*

^{*} Cahill, K. Stead, L.F., Lancaster, T., 2008. Nicotine receptor partial agonists for smoking cessation. Cochrane. Database of Systematic Reviews, 3, CD006103.

OTHER NON-NICOTINE PHARMACOTHERAPIES

Other medications have been tested for safety and efficacy in treating smoking cessation. However, none of these medications have yet been approved by the FDA.

Nortriptyline

Nortriptyline is a second-generation tricyclic antidepressant and its main indication is the treatment of major depression. It is currently a second-line treatment for treating smoking cessation due its history of adverse events when used for depression, though smoking cessation trials have not reported serious adverse side effects. Nortriptyline's mechanism of action in aiding smoking cessation does not appear to be related to its antidepressant effects. Its effect on noradrenergic neurons may substitute for the noradrenergic action of nicotine. Another possible mechanism contributing to its anti-smoking effects may be its property as a weak nAChR antagonist. However, its exact mechanism of action for smoking cessation is unclear. A 2004 study by Hall and colleagues investigating the effect of longterm nortriptyline treatment in conjunction with smoking cessation counseling (N = 160) showed that while short-term abstinence rates were higher compared with placebo, short-term treatment (i.e. 8 weeks) with nortriptyline resulted in high relapse rates. By contrast, extended treatment (i.e. 52 weeks) increased long-term abstinence rates significantly for both placebo and nortriptyline groups compared with those receiving nortriptyline or placebo for a shorter duration. All in all, randomized clinical trials of nortriptyline have shown that compared to placebo, nortriptyline treatment doubles the odds of achieving smoking cessation and results in higher continuous abstinence rates for at least 6 months.

Rimonabant

Rimonabant, a selective endocannabinoid (CB1) receptor antagonist, was initially developed as an anti-obesity drug. However, since the endogenous cannabinoid system (mediated by CB1 receptors) in the brain is known to play a part in nicotine reward, rimonabant was investigated as a potential aid to smoking cessation. Three large clinical trials involving smokers and guitters have been conducted. Rimonabant was found to increase abstinence rates at high dosages only, and in a relapse prevention trial smokers who quit were more likely to stay abstinent in the treatment group relative to placebo. Weight gain was also significantly lower in the rimonabant quitters. Though these results appear promising and the reported adverse events were low, some concern has emerged over the prevalence of depression and suicidal thoughts in people taking this medication for weight control. Rimonabant was withdrawn from the European market in 2007, and was given a letter of nonapproval in the United States.

Topiramate

Topiramate is a synthetic anti-convulsant and is most commonly prescribed for the treatment of migraines, epilepsy, and bipolar disorder. Though the exact mechanism of action of topiramate is unclear, it is known to antagonize AMPA (α -amino-3-hydroxy-5-methyl-4-iso-xazolepropionic acid)/kainate subtype of glutamate receptor. This receptor has been implicated in the

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expression of established addiction and this property has been exploited as a means of curbing nicotine addiction. Findings from small pilot studies suggest that topiramate may have some modest effects on facilitating short-term smoking cessation and reduction. However, larger trials are required to determine its efficacy in smoking cessation. Research on patients with alcohol dependence has shown that topiramate treatment is associated with increased smoking reduction and spontaneous abstinence rates. A secondary analysis of topiramate for smoking cessation in patients with schizoaffective disorder found no difference across treatment groups. There is also some evidence that topiramate may in fact increase nicotine craving and reward. Taken together, the evidence suggests that the efficacy of topiramate for smoking cessation is mixed at best, though it may have some utility in smokers with alcohol dependence.

Selegiline

Selegiline hydrochloride is a selective irreversible inhibitor of MAO-B subtype, which is responsible for the metabolism of neurotransmitters such as dopamine involved in the reward pathway. Selegiline may facilitate smoking cessation by inhibition of nicotine metabolism or by mimicking the effects of cigarette smoke on MAO. Selegiline demonstrated moderate success in smoking cessation treatment in preliminary studies and was found to be safe and well tolerated. However, large-scale trials failed to demonstrate an advantage for selegiline as compared with placebo in smoking cessation. For example, Weinberger and colleagues conducted a double-blind placebocontrolled randomized trial to determine the efficacy and safety of selegiline as a smoking cessation aid. Subjects received either selegiline (5 mg twice daily) or placebo in addition to brief smoking cessation counseling. No significant improvements were observed in 7-day point prevalence abstinence rates or continuous 4-week abstinence rates at the end of the trial. Other recent large trials have corroborated these negative results and therefore this medication is no longer being actively pursued as a potential treatment for smoking cessation.

Naltrexone

Naltrexone is an opioid antagonist mainly used for treatment of alcohol and opioid dependence. Findings on the efficacy of naltrexone on treating nicotine dependence have been equivocal. However, naltrexone may augment the effect of NRTs on craving and attenuate weight gain associated with smoking cessation.

Baclofen

Baclofen, an agonist at gamma-amino-butyric acid-B (GABA_B) receptors, reduces the surge in dopamine produced by various drugs in the NAc. Animal studies have shown that Gamma-vinyl GABA, another GABA receptor agonist, reduces both acquisition and expression of nicotine-induced conditioned place preferences and decreases self-administration of nicotine in rats. However, this compound is not well tolerated and baclofen appears to be a safer alternative for clinical treatment of nicotine dependence. Preliminary double-blind placebo-controlled pilot trials of baclofen for smoking reduction in smokers who are contemplating quitting suggest that baclofen may be effective in attenuating cravings and facilitating smoking reduction. Baclofen merits further investigation in larger controlled trials.

Nicotine Vaccine

The latest advance in the search for an effective intervention for smoking cessation involves immunotherapy techniques in the form of nicotine vaccination. The vaccine induces the production of antibodies which bind to the nicotine molecule. These antibodies are too large to cross the blood–brain barrier, reducing the distribution of nicotine in the brain and preventing nicotine from producing its addictive effects. Nicotine vaccine is currently in Phase III clinical trials and preliminary findings are encouraging. These findings suggest that the nicotine vaccine is well tolerated and can be effective in boosting continuous abstinence rates when sufficient levels of antibody concentration are reached (Table 36.2).

CONCLUSION

Our increasing understanding of the neurobiology of tobacco dependence has provided a wide range of pharmacological targets for the development of non-nicotine medications. The prototypes for non-nicotine medications include FDA-approved pharmacotherapies such as sustained-release bupropion and varenicline. Interestingly, the mechanism of action of these approved agents involves at least in part action at the receptors for nicotine. Other promising medication target sites related to the pharmacodynamic actions of nicotine include dopamine, GABA, glutamate, and endogenous opioids. One very promising non-nicotine therapy targets the pharmacokinetics of nicotine (e.g. nicotine vaccines). Over the next few years we can expect to see the development of non-nicotine medications related to the actions of nicotine and its associated neurotransmitter systems.

TABLE 36.2 Nonapproved Smoking Cessation Pharmacological Treatments

Medication	Mechanism of action	Dosing details	Effectiveness rating	Odds ratio of smoking abstinence (in comparison to placebo)
Nortriptyline	Acts as a weak nAChR antagonist and blocks reuptake of NE; exact mechanism of action still unclear. Side effects limit utility	75–100 mg daily following a 10–28- day titration period	1–2	2.1*
Rimonabant	Acts as an endocannabinoid antagonist that may contribute to nicotine reward by affecting dopamine release. Side effects limit utility	Not approved, tested at 5 and 20 mg day ⁻¹ in Phase III studies	2	1.61\$
Topiramate	Acts by antagonizing AMPA glutamate receptors, leading to inhibition of dopamine release in the reward system	Dosage used varied from 50–225 mg daily across studies	3	1.14^{\dagger}
Selegiline	Acts as a Monoamine Oxidase Inhibitor, increasing monoamine (e.g. DA, NE) levels	10 mg daily in BID dosing following a 7-day titration period	3	1.17^{\dagger}
Naltrexone	Acts by antagonizing endogenous opioid peptide receptors, augmenting the effect of NRT on craving and attenuate weight gained associated with smoking cessation	50 mg daily	3	0.94^{\dagger}
Baclofen	Acts as a GABA agonist, reducing the surge of DA in the reward system	60 mg daily following a 12-day titration period	2	NA^{\ddagger}
Nicotine Vaccine	Acts by inducing the production of nicotine anti-bodies too large to cross the blood-brain barrier	NA \S 100 μg Nicotine-Qβ	2	1.7 [¶]

^{*} Hughes, J.R., Stead, L.F., Lancaster, T., 2005. Nortriptyline for smoking cessation: a review. Nicotine & Tobacco Research 7(4), 491–499.

Note: Effectiveness rating: 1 = strong evidence to support efficacy; 2 = moderate evidence to support efficacy; 3 = little evidence to support efficacy.

SEE ALSO

Medications to Treat Addictions: Nicotine Replacement, Vaccines for Addictive Disorders

List of Abbreviations

CNS central nervous system
GABA gamma aminobutryic acid
NAc nucleus accumbens

nAChR nicotinic acetylcholine receptorNRTs nicotine replacement therapiesVTA ventral tegmental area

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^{\$} Cahill, K., Ussher, M., 2007. Cannabinoid type I receptor antagonists (rimonabant) for smoking cessation. Cochrane Database of Systematic Reviews 3, CD005353.

[†] Calculated based on data presented in existing randomized placebo-controlled trials to date.

[‡] No data exists for randomized placebo-controlled trials of baclofen at the time of this publication.

[§] Dosing information and odd ratios provided for the nicotine vaccine is based on one randomized placebo-controlled trial of nicotine-Qβ only (see §).

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37

Alcohol Detoxification

Gabriel Rubio, Guillermo Ponce

Hospital Universitario 12 de Octubre, Madrid, Spain

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CONCEPT

The alcohol withdrawal syndrome (AWS) consists of symptoms and signs arising in alcohol-dependent individuals, typically within 6–48 h of consumption of their last drink (Table 37.1). Although AWS occurs intentionally in those seeking abstinence, it may arise unexpectedly in an alcohol-dependent patient, after an admission to hospital. Although alcohol withdrawal is common and usually mild, the abrupt cessation of alcohol consumption by a patient with alcohol dependence may lead to delirium tremens (DTs) and withdrawal seizures.

EPIDEMIOLOGY AND CLINICAL MANIFESTATIONS

The prevalence of alcohol withdrawal in the general population is low (<5%). However, in the setting of

medical practice, this figure is higher, with the prevalence of alcohol abuse or dependence reaching 20% of hospital inpatients and up to 40% of patients attending accident and emergency departments.

The spectrum of withdrawal symptoms and the time range for the appearance of these symptoms after cessation of alcohol use are listed in Table 37.2. Generally, the symptoms of alcohol withdrawal relate proportionately to the amount of alcoholic intake and the duration of a patient's recent drinking habit. Most patients have a similar spectrum of symptoms with each episode of alcohol withdrawal.

Uncomplicated AWS

In those patients with physiologic dependence on alcohol, the clinical manifestations of alcohol withdrawal begin within 6–24 h after the last drink, sometimes arising before the blood alcohol level has

TABLE 37.1 Symptoms and Signs of Alcohol Withdrawal Syndrome

Anxiety Tremor Headache Disorientation Agitation

Delirium Hallucinations (tactile, visual, auditory) Insomnia Anorexia, nausea, vomiting

Diaphoresis Hyperreflexia Tachycardia Hypertension Seizures Low-grade fever

Hyperventilation

returned to zero. Early withdrawal signs and symptoms include anxiety, sleep disturbances, vivid dreams, anorexia, nausea, and headache. Physical signs include tachycardia, elevation of blood pressure,

TABLE 37.2 Course of Untreated Alcohol Withdrawal Syndrome

Signs/ Symptoms	Phase I	Phase II	Phase III or DTs
Heart rate	100-110 bpm	110–120 bpm	120 bpm
Increased systolic blood pressure	10-20 mmHg	10-20 mmHg	30–40 mmHg
Tachypnea	20-22 bpm	22-28 bpm	28 bpm
Diaphoresis	+	++	+++
Tremor	+	++	+++
Hyperreflexia	+	++	+++
Emotional lability	+	++	+++
Anxiety	+	++	+++
Seizures	0	+	0
Hallucinations	0	+	+++
Percentage of patients passing each stage whether the syndrome is untreated	75-80%	10-25%	5-10%
Time of appearance of symptoms after cessation of alcohol use (hours)	6—12	12–24 (hallucinations) 24–48 (seizures)	48-72

hyperactive reflexes, sweating, and hyperthermia. A tremor, best brought out by extension of the hands or tongue, may appear. This tremor has a rate of six to eight cycles per second and appears on electromyography to bean exaggeration of normal physiologic tremor. For up to 90% of patients, withdrawal does not progress beyond the mild to moderate symptoms described previously, peaking between 24 and 36 h and gradually subsiding.

Hallucinations

In mild alcohol withdrawal, patients may experience perceptual distortions of a visual, auditory, and tactile nature. Lights may seem too bright or sounds too loud and startling. A sensation of "pins and needles" may be experienced. In more severe cases of withdrawal, these misperceptions may develop into frank hallucinations. Visual hallucinations are most common and frequently involve some type of animal life. Auditory hallucinations may begin as unformed sounds (such as clicks or buzzing) and progress to formed voices. In contrast to the auditory hallucinations of schizophrenia, which may be of religious significance, these voices often are of friends or relatives and frequently are accusatory in nature. Tactile hallucinations may involve a sensation of bugs or insects crawling on the skin. In milder cases of withdrawal, the patient's sensorium is otherwise clear and the patient retains insight that the hallucinations are not real. In more severe withdrawal, this insight may be lost.

Alcohol Withdrawal Seizures

Grand mal seizures are another manifestation of alcohol withdrawal. Withdrawal seizures occurred in around 11–33% of the patients enrolled in prospective controlled studies. Withdrawal seizures usually begin within 8-24 h after the patient's last drink and may occur before the blood alcohol level has returned to zero. Most are generalized major motor seizures, occurring singly or in a burst of several seizures over a period of 1–6 h. Although 3% of withdrawal seizures evolve into status epilepticus, alcohol withdrawal has been found to be a contributing cause in up to 15% of status epilepticus patients. Seizures peak 24 h after the last drink, corresponding to the peak of withdrawal-induced electroencephalogram (EEG) abnormalities, which include increased amplitude, a photomyoclonic response, and spontaneous paroxysmal activity. These EEG abnormalities are transient, in keeping with the brevity of the convulsive attacks. Except for this brief period after withdrawal, the incidence of EEG abnormalities in patients with withdrawal seizures is not greater than in the normal population. The risk of withdrawal seizures appears to be in part genetically determined and is increased in patients with a history of prior withdrawal seizures or in those who are undergoing concurrent withdrawal from benzodiazepines or other sedative-hypnotic drugs. There also is evidence that the risk of seizures increases as an individual undergoes repeated withdrawals. This association has been described as a "kindling effect."

Alcohol Withdrawal Delirium

DTs is one of the most severe clinical complications of the AWS. In the classic cases of withdrawal delirium, the manifestations of withdrawal steadily worsen and progress into a severe life-threatening delirium accompanied by an autonomic storm.

DTs generally appears within 72–96 h after the last drink. In their classic presentation, DTs is marked by all the signs and symptoms of mild withdrawal but in a much more pronounced form (marked tachycardia, tremor, diaphoresis, and fever). The patient develops global confusion and disorientation to place and time. The patient may become absorbed in a separate psychic reality, often believing himself or herself to be in allocation other than the hospital, and misidentifies staff as personal acquaintances. Hallucinations are frequent, and the patient may have no insight into them. Without this insight, they can be extremely frightening to the patient, who may react in a way that poses a threat to his own or the staff's safety. Marked psychomotor activity may develop, with severe agitation in some cases or continuous low level motor activity in others. Severe disruption of the normal sleep-wake cycle also is common and may be marked by the absence of clear sleep for several days. The duration of the delirium is variable, but averages 2-3 days in most studies. In some cases the delirium is relatively brief, lasting only a few hours before the patient regains orientation. In other cases, the patient remains delirious for several days or weeks before the confusion clears. It is known that many cases of delirium during alcohol withdrawal occur without the autonomic storm associated with classically described DTs. Although the terms alcohol withdrawal delirium and DTs are often used interchangeably, many cases of delirium in alcohol withdrawal are mild and transient.

Risk Factors for the Development of Complicated AWS

Many clinical findings have shown that severe clinical manifestations early in the course are predictive of the development of seizures and delirium. Other risk factors for complicated withdrawal include a history of prior DTs or withdrawal seizures. Marked autonomic

hyperactivity, commonly measured as elevated heart rate on admission, elevated blood alcohol level of 100 mg dl⁻¹ or higher at the time of admission, serum electrolyte abnormalities, and medical comorbidity, particularly infection, are other clinical findings associated with an increased rate of DTs or severe withdrawal. Characteristics that have not been useful in triaging patients include amount of daily intake, duration of heavy drinking, age, and gender.

ASSESSMENT OF AWS: ALCOHOL WITHDRAWAL SCALES AND BIOMARKERS

Because alcohol withdrawal involves a constellation of nonspecific finding, efforts have been made to develop structured withdrawal severity assessment scales to objectively quantify the severity of withdrawal. The most extensively studied and best known scale is the Clinical Institute Withdrawal Assessment-Alcohol-Revised (CIWA-Ar) (Table 37.3). The CIWA-Ar has well-documented reliability, reproducibility, and validity based on comparisons to ratings of withdrawal severity by experienced clinicians. The CIWA-Ar requires 2–4 min to complete and has proved useful in a variety of settings, including detoxification units, psychiatric units, medical/surgical wards, and intensive care units. The CIWA-Ar allows rapid documentation of the patient's signs and symptoms and provides a simple summary score that facilitates accurate and objective communication among staff. A score of 9 indicates mild withdrawal, a score of 10-18 moderate withdrawal, and a score of >18 severe withdrawal. A careful analysis of symptoms recorded using withdrawal scales found that patients segregated into distinct clinical groups. Approximately 20% had no significant withdrawal symptoms. Another 20% had only vegetative (physical) signs, such as tremor and sweating, but no psychologic symptoms. The largest group, approximately 40%, had both vegetative and mild to moderate psychologic symptoms, primarily anxiety. The last group, about 20% of patients, had both vegetative and severe psychologic symptoms with either disorientation, delirium, or hallucinations. As indicated previously, relatively few patients in alcohol withdrawal experience the adrenergic and clinical manifestations of DTs. The Luebeck alcohol withdrawal risk scale (LARS) is a rating system developed to predict the severity of withdrawal.

When a history is unobtainable or unreliable, and suspicion is present for alcohol dependence, biochemical markers of heavy alcohol consumption are modestly helpful in clarifying the diagnosis. Gamma glutamyl transferase and carbohydrate-deficient transferrin are both sensitive markers for alcohol overuse, particularly when tested as a combination. Other nonspecific

TABLE 37.3 Clinical Institute Withdrawal Assessment-Alcohol-Revised (CIWA-Ar)

Patient	Date	_//		Time: : : (24-hour clock, midnight = 00:00)
	y	m d		(24-hour clock, midnight = 00:00)
Pulse or heart rate, taken for 1 minu	ite:		_ Bl	ood pressure:/
NAUSEA AND VOMITING — A Have you vomited?" Observation 0 no nausea and no vomiting 1 mild nausea with no vomiting 2 3 4 intermittent nausea with dry heave 5 6 7 constant nausea, frequent dry heave	• es			k to your stomach?
•				of Observed as
TREMOR — Arms extended and 0 no tremor 1 not visible, but can be felt fingerti 2 3 4 moderate, with patient's arms extended 5	p to fing	-	1 ара	irt. Observation.
7 severe, even with arms not extend	led			
PAROXYSMAL SWEATS — Ob 0 no sweat visible 1 barely perceptible sweating, palm 2 3 4 beads of sweat obvious on foreher 5 6 7 drenching sweats	s moist	on.		
ANXIETY — Ask "Do you feel no 0 no anxiety, at ease 1 mildly anxious 2	ervous?	" Obse	rvati	ion.
3 4 moderately anxious, or guarded, s 5	o anxiet	y is inf	erred	
6 7 equivalent to acute panic states as schizophrenic reactions	seen in	severe	delir	ium or acute
AGITATION — Observation.				
0 normal activity 1 somewhat more than normal activ 2 3	rity			
4 moderately fidgety and restless 5 6				
7 paces back and forth during most thrashes about	of the in	terviev	, or	constantly
TACTILE DISTURBANCES — a sensations, burning sensations, nu under your skin?" Observation. 0 none 1 very mild itching, pins and needles, but 3 moderate itching, pins and needle 4 moderately severe hallucinations 5 severe hallucinations 6 extremely severe hallucinations 7 continuous hallucinations	s, burning or	or do	you i	feel bugs crawling on or

AUDITORY DISTURBANCES — Ask "Are you more aware of sounds around you? Are they harsh? Do they frighten you? Are you hearing anything that is disturbing to you? Are you hearing things you know are not there?" Observation.

0 not present

- 1 very mild harshness or ability to frighten
- 2 mild harshness or ability to frighten
- 3 moderate harshness or ability to frighten
- 4 moderately severe hallucinations
- 5 severe hallucinations
- 6 extremely severe hallucinations
- 7 continuous hallucinations

VISUAL DISTURBANCES — Ask "Does the light appear to be too bright? Is its color different? Does it hurt your eyes? Are you seeing anything that is disturbing to you? Are you seeing things you know are not there?" Observation.

0 not present

- 1 very mild sensitivity
- 2 mild sensitivity
- 3 moderate sensitivity
- 4 moderately severe hallucinations
- 5 severe hallucinations
- 6 extremely severe hallucinations
- 7 continuous hallucinations

HEADACHE, FULLNESS IN HEAD — Ask "Does your head feel different? Does it feel as if there is a band around your head?" Do not rate for dizziness or lightheadedness. Otherwise, rate severity.

0 not present

- 1 very mild
- 2 mild
- 3 moderate
- 4 moderately severe
- 5 severe
- 6 very severe
- 7 extremely severe

ORIENTATION AND CLOUDING OF SENSORIUM — Ask "What day is this?

Where are you? Who am I?"

- ${f 0}$ oriented and can do serial additions
- 1 cannot do serial additions or is uncertain about date
- 2 disoriented for date by no more than 2 calendar days
- 3 disoriented for date by more than 2 calendar days
- 4 disoriented for place and/or person

Total CIWA-Ar score:	Maximum possible score: 67

biomarkers of alcohol consumption can reflect the effect of alcohol on different body tissues (mean corpuscular volume, alanine aminotransaminase, and aspartate aminotransferase). The measurement of direct ethanol metabolites, such as ethyl sulfate, may serve as biomarkers of recent ethanol intake in the future. Homocysteine levels are elevated in nonabstinent alcoholics and levels are associated with alcohol withdrawal seizures. Homocysteine and a product of its metabolism, homocysteic acid, may overstimulate *N*-methyl-D-

aspartate (NMDA) receptors, leading to a reduction in seizure threshold. In addition, homocysteine levels have been shown to be significantly higher in patients actively drinking with a history of withdrawal seizures than in those actively drinking without a history of seizures, and thus a homocysteine level has been thought to be a useful biomarker of risk for alcohol-withdrawal seizures. However, difficulty in defining a cut-off value that will allow adequate sensitivity and specificity has hampered its clinical usefulness.

PATHOPHYSIOLOGY

Alcohol has an effect on multiple neurotransmitter systems in the brain (see Table 37.4). Acute alcohol ingestion has an inhibitory effect at NMDA receptors, reducing excitatory glutamatergic transmission, and has an agonistic effect at gamma-aminobutyric acid type-A (GABA_A) receptors. During prolonged exposure to alcohol, NMDA receptors are upregulated and GABA_A receptors are downregulated, leading to tolerance. The roles are reversed during abstinence, with enhanced NMDA receptor function, reduced GABAergic transmission and dysregulation of the dopaminergic system, leading to many of the symptoms and signs of AWS. Although GABA levels increase in both plasma and Cerebrospinal fluid during withdrawal, symptoms of withdrawal still evolve due to downregulation of GABA_A receptors during prior prolonged alcohol exposure. GABAA and GABAB mechanisms are also critical for the development of anxiety symptoms that are induced by repeated ethanol intoxications and withdrawal. Altered numbers and functions of NMDA and GABA_A receptors resulting from chronic alcohol exposure may be partly responsible for alcohol withdrawal seizures.

In addition, voltage-dependent calcium influx modulates neurotransmitter release and expression of genes that regulate production of NMDA and GABA-receptor proteins; the continued presence of alcohol increases voltage-operated calcium channel expression and contributes to alcohol tolerance and AWS. Dopaminergic transmission is enhanced during AWS and may play a role in hallucination formation; increased dopamine receptor-binding density has also been observed. The potential importance of the amygdala and the striatum

in the pathophysiology of alcohol withdrawal has also been suggested by persisting high levels of cyclic guanosine monophosphate in these regions. Neurons in the deep layers of the superior colliculus are also an important part of the neural network that initiates ethanol withdrawal seizures. Increased noradrenergic activity has been observed in early AWS, which contributes to sympathetic overdrive during withdrawal. However, the role of serotonin is less certain, but levels have been noted to be lower than controls at various stages of AWS.

MANAGEMENT OF AWSs

In most patients with mild to moderate withdrawal symptoms, outpatient detoxification is safe and effective and costs less than inpatient treatment. However, certain patients should be considered for inpatient treatment regardless of the severity of their symptoms. Relative indications for *inpatient alcohol detoxification* are as follows: history of severe withdrawal symptoms, history of withdrawal seizures or DTs, multiple previous detoxifications, concomitant psychiatric or medical illness, recent high levels of alcohol consumption, pregnancy, and lack of a reliable support network.

General Principles

The primary goals of the treatment of AWSs are to first assure clinical stability of the patient and secondarily encourage on going treatment (e.g. rehabilitation) of a patient's alcohol consumption. The first step in managing a patient with alcohol withdrawal is to perform an assessment for the presence of medical and psychiatric problems. Chronic alcohol intake is associated with the

TABLE 37.4 Neurobiology of Acute Alcohol Actions and Alcohol Withdrawal

	Acute effects		Alcohol withdrawal syndrome		
	Pharmacodynamic action	Clinical effects	Biological effects	Clinical effects	
NMDA	_	Sedation, amnesia	+++	Seizures	
$GABA_A$	+	Sedation, activation, euphoria, anxiolysis		Anxiety, neuronal irritability	
NE	_	Anxiolysis	+++	Anxiety	
5-HT-3	+	Anxiolysis, nausea		Insomnia, depression	
DA	+	Activation, euphoria	++	Psychotic symptoms	
Opioids	+	Euphoria		Craving	
Muscarínic	_	Amnesia	++	Tremor	
Adenosine	+	Incoordination/sedation	Lower response	?	
Ca++ channels	_	Inhibition	+++	Cell damage	

 $NMDA = N - methyl - D - aspartate; GABA = Gamma\ aminobutyric\ acid,\ NE = Norepinephrine,\ 5 - HT = serotonin,\ DA = dopamine;\ (+) = Activation,\ (-) = Stimulation.$

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development of many acute and chronic medical problems. The clinician needs to determine whether there are acute conditions that require hospital treatment or chronic conditions that may alter the approach to management of withdrawal because they could be exacerbated significantly by the development of withdrawal or its treatment. Pertinent *laboratory tests* generally include complete blood count, electrolytes, magnesium, calcium, phosphate, liver enzymes, urine drug screen, pregnancy test (when appropriate), and Breathalyzer or blood alcohol level. Others, depending on suspected co-occurring conditions, may include skin test for tuberculosis, chest X-ray, electrocardiogram, and tests for viral hepatitis, other infections, or sexually transmitted diseases.

General management also involves maintaining adequate *fluid balance* correction of electrolyte deficiencies, correction of thiamine deficiency, and attendance to the patient's nutritional needs. Patients in early withdrawal often are overhydrated so that aggressive hydration usually is not necessary unless there have been significant fluid losses from vomiting or diarrhea. Supportive care and reassurance from health care personnel are important elements of comfortable detoxification and help to facilitate continuing treatment. Supportive nonpharmacologic care is an important and useful element in the management of all patients undergoing withdrawal. Simple interventions such as reassurance, reality orientation, monitoring of signs and symptoms of withdrawal, and general nursing care are effective.

Pharmacologic Management of Uncomplicated Withdrawal Syndrome

The medical literature on the pharmacologic management of alcohol withdrawal has been recently reviewed in several meta-analysis. These reviews of the evidence indicate that the cornerstone of pharmacologic management of withdrawal is the use of benzodiazepines.

Benzodiazepines

Benzodiazepines are pharmacologically cross-tolerant with alcohol and have the similar effect of enhancing the effect of GABA-induced sedation. A specific benzodiazepine receptor site has been identified on the GABA-receptor complex. It is believed that the administration of benzodiazepines alleviates the acute deficiency of GABA neurotransmitter activity that occurs with sudden cessation of alcohol intake. Well-designed studies consistently have shown that benzodiazepines are more *effective* than placebo in reducing the signs and symptoms of withdrawal. Meta-analysis of prospective placebo-controlled trials of patients

admitted with symptomatic withdrawal has shown a highly significant reduction in seizures, with a risk reduction of 7.7 seizures per 100 patients treated, as well as in delirium, with a risk reduction of 4.9 cases of delirium per 100 patients treated. Trials comparing different benzodiazepines indicate that all are similarly efficacious in reducing signs and symptoms of withdrawal. However, longer-acting agents such as diazepam and chlordiazepoxide may be more effective in preventing seizures. Longer-acting agents may also contribute to an overall smoother withdrawal course, with a reduction in breakthrough or rebound symptoms. On the other hand, pharmacologic data and clinical experience suggest that longer-acting agents can pose a risk of excess sedation in some patients, including elderly persons and patients with significant liver disease. In such patients, shorter-acting agents such as lorazepam or oxazepam may be preferable. Another consideration in the choice of benzodiazepine is the rapidity of onset. Certain agents with rapid onset of action (such as diazepam, alprazolam, and lorazepam) demonstrate greater abuse potential than do agents with a slower onset of action (such as chlordiazepoxide and oxazepam). This consideration may be of relevance in an outpatient setting or for patients with a history of benzodiazepine or other substance abuse. However, when rapid control of symptoms is needed, medications with faster onset offer an advantage. A final consideration in the choice of benzodiazepine is cost, as these agents vary considerably in price. Given the evidence of equal efficacy, if a particular agent is available to a practitioner or program at a lower cost, cost is a legitimate factor to consider. Studies have indicated that nonbenzodiazepine sedative-hypnotics are also effective in reducing the signs and symptoms of withdrawal, but non-benzodiazepine agents have not been as extensively studied, and the size of studies with them is not adequate to draw conclusions as to their degree of effectiveness in reducing seizures and delirium. Benzodiazepines have a greater margin of safety, with a lower risk of respiratory depression, as well as overall lower abuse potential than do the nonbenzodiazepine agents. Phenobarbital, a long-acting barbiturate, is still used by some programs, as it is long-acting, has welldocumented anticonvulsant activity, is inexpensive, and has low abuse liability.

Determining the Dosing Schedule

Three treatment schedules have been used on AWS: a fixed dose, symptom-triggered, and a front-loaded regimen (see Fig. 37.1).

FIXED DOSE

In general, these regimens start with a standard dose (such as chlordiazepoxide 50 mg every 6 h), which is

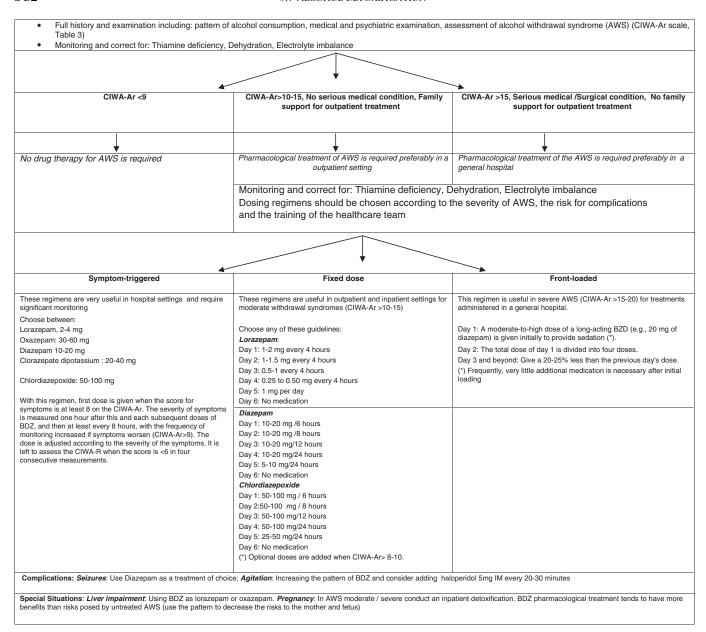


FIGURE 37.1 Algorithm for management of uncomplicated alcohol withdrawal syndrome.

then reduced over the next 5–7 days. Most include an "as required" option to treat breakthrough symptoms. In the majority of studies examining the effectiveness of various medications for withdrawal, the medications were given in *fixed amounts* and were effective in controlling most of the alcohol withdrawal manifestations.

SYMPTOM-TRIGGERED

This type of regimen tailors treatment to the person's requirements as determined by the severity of their withdrawal signs and symptoms. Patients are regularly assessed and monitored, either using clinical experience, and questioning alone, or with the help of a designated questionnaire such as the CIWA-Ar. Pharmacotherapy is

provided only when symptoms cross a threshold of severity. Well-designed studies have demonstrated that this approach is as effective as fixed-dose therapy but leads to the administration of significant less medication and a significantly shorter duration of treatment. Symptom-triggered therapy also facilitates the delivery of large amounts of medication quickly to patients who evidence rapidly escalating withdrawal and thus reduces the risk of undertreatment that may arise with the use of fixed doses. For programs specializing in the management of addiction, use of a symptom-triggered approach with the utilization of a severity scale offers significant advantages. However, there may be situations in which the provision of fixed doses remains

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appropriate. For example, with patients admitted to general medical or surgical wards, the nursing staff may not have the training or experience to implement the regular use of scales to monitor patients. In certain patients, such as those with severe coronary artery disease, the clinician may wish to prevent the development of even minor symptoms of withdrawal.

FRONT-LOADED

The loading dose regimen provides a large dose of long-acting pharmacotherapy at the start of the treatment regimen and then provides it on an "as required" basis after this. The scheme aims to induce a state of mild sedation in the patient to avoid complications such as withdrawal seizures and prevent progression to DTs. When front-loading and fixed-dosing regimes were compared, subjects treated with loading-dose schedules required lower amounts of medication.

Route of Administration

In all cases, medications should be administered by a route that has been shown to have reliable absorption. Therefore, the benzodiazepines should be administered orally or, when necessary, intravenously. An exception is lorazepam, which has good intramuscular and sublingual absorption. In the past, intramuscular administration was commonly used. However, for most agents intramuscular absorption is extremely variable, leading to problems when rapid control of symptoms is necessary and also with delayed appearance of over sedation when large amounts are administered. The use of intravenous benzodiazepines with rapid onset, such as diazepam, has been shown to provide more rapid control of the patient's symptoms. Treatment should allow for a degree of individualization so that patients can receive large amounts of medication rapidly if needed.

Anticonvulsants

Carbamazepine has been widely used in Europe for alcohol withdrawal and has been shown to be equal in efficacy to benzodiazepines for patients with mild to moderate withdrawal. Fixed, tapering doses of carbamazepine are without significant toxicity when used in 5- to 7-day protocols for alcohol withdrawal and are associated with less psychiatric distress, a faster return to work, less rebound symptoms, and reduced posttreatment drinking. When compared with placebo, there is significantly less use of benzodiazepines for breakthrough symptoms. Carbamazepine does not potentiate the central nervous system and respiratory depression caused by alcohol and has no abuse potential. Although the clinical evidence is smaller, tapering doses

of sodium valproate could be used in similar fashion. Both of these medications may also be used as adjuncts to benzodiazepine-based regimens in patients who have a history of recurrent withdrawal seizures, with prominent mood lability during withdrawal or with concurrent benzodiazepine withdrawal. However, studies of adequate size to assess the efficacy of these agents in preventing withdrawal seizures or delirium are not yet available. They are available only in oral form, making it difficult to titrate doses rapidly for the more symptomatic or rapidly worsening patient. For these reasons, patients treated with carbamazepine or sodium valproate should be monitored using withdrawal scales and receive benzodiazepines should more severe withdrawal symptoms emerge. Both these agents have interactions with other drugs and have hepatic and hematologic toxicities, and thus must be used carefully, if at all, in patients with certain comorbid medical and psychiatric disorders.

The routine use of *phenytoin* has been advocated as a method to prevent the occurrence of withdrawal seizures, and there is some evidence from early trials that it may be effective for this purpose. However, more recent, methodologically sound trials have failed to show evidence that phenytoin is effective in preventing recurrent withdrawal seizures. Moreover, studies have shown that appropriately used benzodiazepines are extremely effective in preventing withdrawal seizures and that the addition of phenytoin does not lead to improved outcomes, so its use has been largely abandoned. Anticonvulsants such as *gabapentin* and *vigabatrin*, *topiramate*, *oxcarbacepine*, *and zonisamide* have been used for the treatment of AWS because they have fewer side effects and a better safety profile than carbamazepine and sodium valproate.

Other Agents

Beta-adrenergic blocking agents, such as atenolol and propranolol, as well as centrally acting alpha-adrenergic agonists, such as clonidine, are also effective in ameliorating symptoms in patients with mild to moderate withdrawal, primarily by reducing the autonomic system manifestations of withdrawal. However, these agents do not have known anticonvulsant activity, and the studies to date have not been large enough to determine their effectiveness in reducing seizures or delirium. Beta blockers pose a particular problem in this regard because delirium is a known, albeit rare, side effect of these drugs. In addition, there is concern that selective reduction in certain manifestations of withdrawal may mask the development of other significant withdrawal symptoms and makes it difficult to utilize withdrawal scales to guide therapy.

Neuroleptic agents (haloperidol, tiapride, amisulpride) have shown some effectiveness in reducing the signs and symptoms of withdrawal and for a time were used

extensively for that purpose. However, these agents are less effective than benzodiazepines in preventing delirium and actually lead to an increase in the rate of seizures. Neuroleptic agents are widely used to calm agitated patients and are useful for this purpose in the setting of alcohol withdrawal as well. They should not be used alone, but always in conjunction with a benzodiazepine; moreover, neuroleptic agents with less effect on the seizure threshold, such as haloperidol, should be selected. *Tiapride*, a benzamide with D2 and D3 antagonist activity, reduces hyperhidrosis, agitation, and tremor during alcohol withdrawal and may be a useful adjunct to other agents used in the treatment of AWS.

There is currently limited evidence to support the use of baclofen, amisulpride, and gamma-hydroxybutyric acid in the management of AWS

It has long been recognized that magnesium levels often are low during alcohol withdrawal, but routine administration of magnesium, either oral or intramuscular, for withdrawal is no longer recommended.

Despite the relative lack of evidence of oral and intravenous alcohol for the management of alcohol withdrawal, several hospitals continue to use intravenous or oral alcohol in the management of alcohol withdrawal. Intravenous alcohol infusions require close monitoring because of the potential toxicity of alcohol. As a pharmacologic agent, ethyl alcohol has numerous adverse effects, including its well-known hepatic, gastrointestinal, and neurologic toxicities as well as its effects on mental status and judgment. Given the proven efficacy and safety of other agents, the use of oral or intravenous alcohol for alcohol detoxification is generally discouraged.

COMPLICATIONS OF AWS

Alcohol Withdrawal Seizures

Patients with alcohol withdrawal seizures raise a number of management issues. It is important to recognize that not all seizures in alcohol-dependent patients are the result of withdrawal. In epidemiologic studies, the rate of epilepsy and seizures rises in parallel with the amount of an individual's alcohol intake. Alcohol-dependent patients are at higher risk for seizures unrelated to withdrawal. A careful history of the temporal relationship of alcohol intake to the seizure should be obtained, and the diagnosis of withdrawal seizure should be made only if there is a clear history of a marked decrease or cessation of drinking in the 24–48 h preceding the seizure. All patients who present with their first seizure warrant a thorough neurologic examination and brain imaging, with lumbar puncture and EEG being appropriate in many cases. Patients who are known to have a history of withdrawal seizures and who present with a seizure that can be attributed

clearly to withdrawal may not require a full repeat evaluation. If the seizure was generalized and without focal elements, and if a careful neurologic examination reveals no evidence of focal deficits, there is no suspicion of meningitis and there is no history of recent major head trauma, additional testing has an extremely low yield and may be safely omitted. There is a 6- to 12-h period during which there is increased risk of seizures. Withdrawal seizures often are multiple, with a second seizure occurring in one case out of four. For the patient who presents with a withdrawal seizure, rapid treatment is indicated to prevent further episodes. The parenteral administration of a rapid-acting benzodiazepine such as diazepam or lorazepam is effective. Several studies have shown that phenytoin is no more effective than placebo in preventing recurrent seizures. Initial treatment should be followed by oral doses of longacting benzodiazepines over the ensuing 24–48 h. Early studies indicated that a withdrawal seizure placed the patient at increased risk for progression to DTs, so close monitoring is warranted.

Delirium Tremens

DTs is a severe disorder that should be treated in an impatient setting. Older studies showed a mortality rate of up to 30% in DTs but, with modern care, mortality has been reduced to 1%. The principles of successful treatment involve adequate sedation and meticulous supportive medical care. Such patients require close nursing observation and supportive care, which frequently necessitates admission to an intensive care unit. Careful management of fluids and electrolytes is important, given the patient's inability to manage his or her own intake and the presence of marked autonomic hyperactivity. Delirium often is encountered in patients admitted for acute medical problems whose alcohol dependence was not recognized and whose withdrawal was not adequately treated. A high index of suspicion for the development of infection – whose presenting signs may be masked by fever, tachycardia, and confusion of the underlying delirium – is essential, as is careful management of coexisting medical conditions. The use of cross-tolerant sedative-hypnotics has been shown to reduce mortality in DTs and is recommended. However, such medications have not been shown to reverse the delirium or reduce its duration.

The goal is to sedate the patient to a point of light sleep. This will control the patient's agitation, preventing behavior posing a risk to himself or herself and to staff, and allow staff to provide necessary supportive medical care. Examples of treatment regimes used for DTs patients are given in Fig. 37.2. The use of intravenous benzodiazepines with rapid onset, such as diazepam, provides more rapid control of the patient's

COMPLICATIONS OF AWS 365

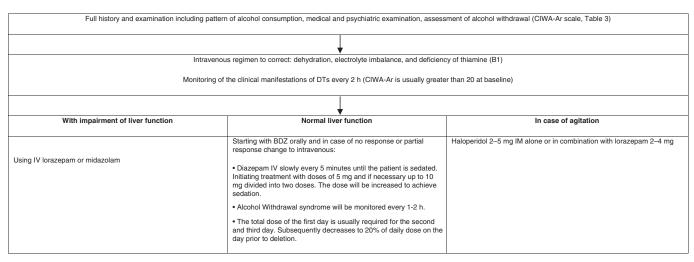


FIGURE 37.2 Algorithm for management of delirium tremens (DTs).

symptoms. The main complication of therapy with diazepam is respiratory depression. Whenever this approach is used, providers should have equipment and personnel immediately available to provide respiratory support if needed. One advantage of diazepam is that its peak onset occurs within 5 min of intravenous administration. This allows the provider to deliver repeat boluses and titrate sedation quickly without a fear of a delayed appearance of over sedation. Once established, delirium can be expected to last for a number of hours, so diazepam offers another advantage in that its longer half-life helps maintain sedation with less chance of breakthrough agitation. Large doses of benzodiazepines may be needed to control the agitation of patients in DTs, with hundreds and even thousands of milligrams of diazepam or its equivalent used over the course of treatment. The practitioner should not hesitate to use whatever amounts are needed to control the agitation, while keeping in mind the possible build up of long-acting metabolites especially in patients with impaired hepatic function or the elderly.

There have been reports of the use of continuous intravenous drips of short-acting agents such as loraze-pam or midazolam. Existing evidence suggests that this approach is no more effective than the use of boluses of longer-acting agents and is very expensive. In the agitated patient, benzodiazepines can be supplemented with the addition of neuroleptic agents such as haloperidol. As has been discussed, such agents should not be used alone. Also, neuroleptic agents with less effect on seizure threshold, such as haloperidol, should be used. In patients whose withdrawal is not readily controlled with oral benzodiazepines and who are beginning to demonstrate signs of agitation, intramuscular administration of a combination of lorazepam and a neuroleptic such as haloperidol often is effective in calming the

patient, thus avoiding the need to use intravenous administration.

Thiamine Deficiency and Wernicke Encephalopathy

Alcohol-dependent patients are at risk for thiamine deficiency, which may lead to Wernicke disease and the Wernicke-Korsakoff syndrome. Wernicke disease is an illness of acute onset characterized by the triad of mental disturbance, paralysis of eye movements, and ataxia. This encephalopathy is a neurologic emergency that should be treated by the immediate parenteral administration of thiamine, with a dose of 50 mg intravenously and 50 mg intramuscularly. Delay in provision of thiamine increases the risk of permanent memory damage. The provision of intravenous glucose solutions may exhaust a patient's reserve of B vitamins, acutely precipitating Wernicke disease. Therefore, intravenous glucose should always be accompanied by the administration of thiamine in the alcohol-dependent patient.

Electrolyte Disturbance and Dehydration

Hyponatraemia is frequently seen in chronic alcoholics, particularly beer drinkers, due to intake of a large volume of fluid. In most cases, this is chronic and is best treated with restoring normal hydration and resumption of a normal diet while abstaining from alcohol. Attempts to correct the electrolyte disturbance with saline (particularly hypertonic saline, 3% sodium chloride) may result in central pontine myelinolysis (CPM), which is thought to be triggered by rapid osmotic shifts in the brain causing

complement-mediated oligodendrocyte toxicity. The clinical features of this are irreversible and severe, so prevention is critical. There is some evidence to suggest that slow correction of chronic hyponatremia minimizes the risk of CPM. Most reported cases of osmotic demyelination occurred after rates of correction exceeding 12 mmol/24 h, although cases have also been reported after corrections of 9-10 mmol/day. General recommendations include slow correction, no more than 8-10 mmol/l of correction in any 24-h period, and if severe symptomatic hyponatremia occurs, to obtain specialist advice prior to more rapid correction or use of hypertonic saline. Deficiencies in serum potassium, magnesium, and phosphate are often seen in this setting due to poor nutrition and secondary to vomiting and should be carefully corrected along with dehydration.

List of Abbreviations

AWS alcohol withdrawal syndrome

CIWA-Ar Clinical Institute Withdrawal Assessment-Alcohol-Revised

CPM central pontine myelinolysis

DTs delirium tremens EEG electroencephalogram

GABA_A gamma-aminobutyric acid type A LARS Luebeck alcohol withdrawal risk scale

NMDA N-methyl-D-aspartate

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38

Disulfiram for Alcohol and Other Drug Use

Karin E. Kerfoot, Ismene L. Petrakis Yale University, New Haven, CT, USA

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INTRODUCTION

Disulfiram, also known as tetraethylthiuram disulfide, is a thiuram derivative which has been used since the 1800s as an accelerator in rubber manufacturing. Its potential effect on alcohol consumption was noted by an American physician, E.E. Williams, in his 1937 letter to the editor of the Journal of the American Medical Association (JAMA). As a Connecticut chemical plant physician, he became aware that workers grinding tetramethylthiuram disulfide were no longer able to tolerate alcohol. These men experienced flushing, rapid pulse, palpitations, and "a terrible fullness in the face, eyes, and head" on ingestion of any type of alcohol and subsequently became "involuntary total abstainers." Williams postulated that if it was not harmful to humans, disulfiram might lead to "the cure for alcoholism," but no further developments came of his observations.

Several years later, Danish researchers Jens Hald and Erik Jacobsen were conducting research on disulfiram for the treatment of parasitic infections. By chance, they independently discovered the effect of combining alcohol with disulfiram when they ingested alcohol during their investigations into the human tolerance of disulfiram. Together with psychiatrist Oluf Martensen-Larsen, they went on to conduct much of the initial clinical research investigating disulfiram for the treatment of alcoholism. For several subsequent decades, the large majority of clinical research and use of disulfiram was focused on the treatment of alcohol dependence. More recently, disulfiram's potential utility in other populations, including the dually diagnosed (patients with both a primary psychiatric disorder and a substance use disorder) and those with cocaine use disorders, has received increasing attention.

EFFECTS OF DISULFIRAM

Pharmacology

Disulfiram is almost completely absorbed from the gastrointestinal tract after oral ingestion. It is metabolized by the liver and excreted renally, though up to 20% can pass unchanged in the feces. It is lipid soluble and has an estimated half-life of 60–120 h. Because of

the long half-life of disulfiram and its metabolites, it may take 7–14 days before disulfiram is totally eliminated from the body, after the last dose is taken.

Alcohol is metabolized in the human liver by a multistep process (*see* Fig. 38.1). Alcohol is first converted to acetaldehyde by the enzyme alcohol dehydrogenase (ADH). Acetaldehyde is then metabolized to acetate by a second enzyme, aldehyde dehydrogenase (ALDH). Acetaldehyde causes unpleasant symptoms such as flushing, elevated heart rate, nausea, headache, and visual disturbance, among others, and is likely one of the main causes of the cluster of symptoms commonly referred to as the "hangover." Disulfiram inhibits aldehyde dehydrogenase and in doing so causes an accumulation of acetaldehyde, which has the aforementioned toxic effect in the body.

In addition to its inhibition of ALDH in the liver, disulfiram is known to have other pharmacological effects in humans. Disulfiram inhibits dopamine beta-hydroxylase in the central nervous system. Dopamine beta-hydroxylase is an enzyme that normally converts dopamine to norepinephrine. Thus, disulfiram can increase dopamine levels in the brain, accompanied by relative decreases in norepinephrine. When exposed to thiol groups following absorption, disulfiram is reduced in the blood to diethyldithiocarbamate (DDC). This metabolite of disulfiram, DDC, is a potent copper chelator and can impact the activity of enzymes such as monooxygenases, amine oxidase, cytochrome oxidase, microsomal carboxylesterase, and plasma cholinesterase, which are copper dependent.

Combination with Ethanol

The result of combining alcohol with disulfiram is often referred to as the disulfiram–ethanol reaction. Accumulation of acetaldehyde by disulfiram produces a variety of unpleasant symptoms that become magnified in intensity and consequence with increasing concentrations. Mild disulfiram–ethanol reactions commonly consist of flushing, diaphoresis, and headache. Moderate reactions are characterized by nausea,

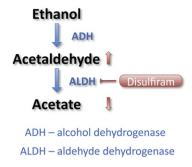


FIGURE 38.1 Inhibition of alcohol metabolism by disulfiram.

vomiting, increases in heart rate, palpitations, difficulty breathing, and decreased blood pressure. The most severe reactions can result in respiratory depression, cardiac arrhythmias, congestive heart failure, myocardial infarction, cardiovascular collapse, loss of consciousness, seizures, and death.

The patient should generally wait at least 12–24 h after consumption of alcohol (depending on blood alcohol concentration) before starting disulfiram. Besides refraining from drinking while taking disulfiram, one should also avoid any products containing alcohol. This includes many cold syrups, tonics, and mouthwashes. It is also advised that patients not use topical preparations which contain alcohol, such as perfume and after-shave lotion (Table 38.1).

Side Effects

In the absence of alcohol, disulfiram at clinically appropriate doses (125–500 mg daily) is generally fairly well tolerated. Common side effects are relatively minor and include headache, drowsiness, dermatitis, and a metallic aftertaste. Electrocardiogram changes can be seen, in addition to hyper- or hypotension. Disulfiram has also been associated with peripheral neuropathy, confusion, and optic neuritis. Effects on the liver include elevations in liver enzymes and, in rare cases, potentially fatal hepatotoxicity. Fortunately, disulfiraminduced hepatotoxicity is usually reversible if the medication is stopped early in the course of illness. Most cases of disulfiram-induced hepatitis occur within 4-6 weeks after starting the medication and resolve gradually over several weeks. Monitoring of liver function is recommended in all patients receiving disulfiram. In general, disulfiram is not recommended for use in patients with cardiovascular or cerebrovascular disease, significantly abnormal liver functioning, or in pregnant/ nursing women. It is also not recommended for use in patients with impaired cognitive status, who would be unable to understand the disulfiram-ethanol reaction.

Over the years, there have been several reports of disulfiram causing psychiatric symptoms, including delirium, depression, anxiety, mania, and psychosis. At least some of these symptoms have been attributed to the relative increase in dopamine and decrease in norepinephrine produced by disulfiram's inhibition of dopamine beta-hydroxylase. However, it should be noted that the reports of such symptoms were primarily made several decades ago, when clinical dosing of disulfiram was much higher (1–3 g) and the definitions of the psychiatric symptoms were not standardized. For example, the term "psychosis" was applied not only to hallucinations and delusions, but also to anxiety and depression. Current clinical dosing (125–500 mg daily)

TABLE 38.1 General Clinical Guidelines for the Use of Disulfiram

Wait at least 12-24 h after drinking before starting disulfiram.

Never take disulfiram while intoxicated.

Wait at least 7–14 days after taking disulfiram before consuming alcohol.

Alcohol should be avoided in all forms, including alcoholic beverages, vinegars, sauces, after-shave lotions and colognes, perfume, mouthwash, and alcohol-containing medications, such as some cough syrups.

Disulfiram may cause drowsiness. Caution should be used with respect to driving and performance of tasks which require alertness.

Carry identification which documents current use of disulfiram.

If signs of serious liver disease develop (loss of appetite, yellowing of the eyes/skin, dark-colored urine, light-colored stools, nausea, lethargy), seek medical attention immediately.

Disulfiram should not be used when pregnant or intending to become pregnant.

Store disulfiram in a safe location, out of reach of children.

is not thought to confer significant risk for major psychiatric symptoms.

Interactions with Other Medications

Disulfiram is known to interact with certain medications, particularly those metabolized by the cytochrome P450 system. Co-administration of disulfiram with amitriptyline has been associated with confusion and psychosis. Disulfiram decreases the body's clearance of such medications as desipramine, diazepam, chlordiazepoxide, phenytoin, caffeine, and cocaine. In combination with warfarin, disulfiram can potentiate warfarin's anticoagulant effect. Disulfiram inhibits the metabolism of theophylline. Concurrent use of disulfiram and monoamine oxidase (MAO) inhibitors is not recommended.

Other

Interestingly, disulfiram-induced inhibition of aldehyde dehydrogenase is mirrored in nature. Among humans, there is known to be genetically determined variability in aldehyde dehydrogenase. Alcohol sensitivity experienced by some Asians (e.g. flushing, tachycardia, nausea following the consumption of alcohol) is thought to be highly influenced by functional polymorphisms in the genes for alcohol dehydrogenase (ADH1B on chromosome 4) and aldehyde dehydrogenase (ALDH2 on chromosome 12). The ALDH2*2 allele is

prevalent in Asian populations but is otherwise extremely rare. Heterozygotes have a significantly lower rate of alcohol dependence in comparison to those without the allele, and alcohol use disorders are close to absent in individuals who are homozygous for ALDH2*2.

DISULFIRAM IN ALCOHOL USE DISORDERS

Disulfiram (Antabuse) was approved by the US Food and Drug Administration (FDA) for the treatment of alcohol dependence in 1951 and was the first medication to be given this indication. It remained the only FDAapproved medication for the treatment of alcohol dependence for several decades, until the approval of oral naltrexone in 1994. Disulfiram's utility in the treatment of alcohol use disorders primarily relies on "psychological deterrence," with patients ceasing consumption of alcohol in order to avoid the unpleasant disulfiram-ethanol reaction. Disulfiram is considered an "antidipsotropic" agent (one that prevents drinking) and is still referred to as an "aversive" agent. Though no longer done in current clinical practice, patients receiving disulfiram many years ago were initially administered both disulfiram and alcohol, creating an in vivo experience of aversive conditioning with the intent to eliminate drinking. This was not particularly successful, so more recently disulfiram is prescribed to help individuals avoid consuming alcohol. While taking disulfiram, its potential to foster complete abstinence from alcohol is unique among agents used to treat alcoholism and confers both great strength and weakness to the medication.

Numerous studies examining the clinical use of disulfiram have been published over a span of several decades. Early studies largely reported quite positive results. Unfortunately, many suffered from significant limitations, including lack of blinding, no monitoring of treatment adherence, inadequate follow-up periods, lack of comprehensive treatment plans, and nonrandomization. The majority of studies did not include control groups, and only very limited conclusions could be drawn from the first decades of study.

Taken as a whole, the accumulation of published literature has been equivocal in its support for disulfiram as an effective treatment for alcohol dependence. The largest and most frequently cited trial was a multi-site, Veterans Affairs (VA) cooperative study which included 605 veterans. Participants were randomly assigned to receive (1) 250 mg of disulfiram with 50 mg of riboflavin, (2) blinded 1 mg of disulfiram with 50 mg of riboflavin, or (3) no disulfiram with 50 mg of riboflavin. The inclusion of riboflavin was utilized to measure medication

adherence. The second group, who received only 1 mg of disulfiram in a blinded fashion, was included in order to confer the psychological threat of a disulfiram—ethanol reaction, without occurrence of the actual experience. All subjects in the study were given counseling.

Disappointingly, all three groups in the study showed similar outcomes, including total abstinence and time to first drink. Among those who drank and had a complete set of assessment interviews, those in the 250-mg disulfiram group, reported significantly fewer drinking days than either of the other two groups, which led to the suggestion that disulfiram may help reduce drinking frequency after relapse. Compliance with the drug regimen (in all three groups) was the best predictor of positive outcome (abstinence). However, only 20% of patients who completed the study were medication compliant. Though impressive in its scope, this study was limited by its lack of any systematic procedures known to enhance medication compliance, such as supervised use, administration by a significant other, or behavioral contracting.

Data from several smaller trials utilizing supervised disulfiram administration have produced some positive results. In a randomized, placebo (vitamin C)-controlled trial involving 126 alcohol-dependent patients, the disulfiram-treated group had a significantly higher number of abstinent days, decreased mean weekly alcohol intake, and lower total alcohol consumption over a 6-month period compared to the vitamin C group. Two-thirds of the disulfiram group requested to continue the treatment at the end of the study. Other studies have found increased rates of abstinence and "significant periods of sobriety" in the context of supervised disulfiram use.

It has been repeatedly shown that techniques known to improve medication compliance, such as incentive-driven interventions and supervised disulfiram treatment, are associated with improved outcomes, including decreased alcohol consumption and achievement of abstinence. Based on these findings, it is strongly recommended that disulfiram use should be supervised and prescribed within a comprehensive treatment program. A small body of literature suggests that court mandates may also improve adherence with disulfiram therapy.

In attempting to address issues with compliance, investigations have been conducted on the use of disulfiram implants. The technique of subcutaneous disulfiram implantation was first introduced in the 1960s. Implants were intended to release disulfiram at a consistent rate and sufficient dose to invoke the disulfiramethanol reaction if the patient consumed alcohol. However, the effectiveness of disulfiram implants remains in doubt. Many studies utilizing disulfiram implants have suffered from methodological flaws.

Furthermore, significant concerns regarding the implants themselves have arisen, including insignificant absorption and/or inadequate release of drug, infections, and other adverse physiological consequences. Disulfiram implants are not currently licensed for use in the United States.

The relationship between medication compliance and the effectiveness of disulfiram treatment is admittedly complex. It has been suggested that patients who are able to maintain compliance with disulfiram likely represent a more motivated, treatment-adherent subset of individuals whose success in achieving abstinence may not be attributable to the drug itself. These patients are hypothesized to be more likely to achieve positive outcomes, regardless of the treatment prescribed. Furthermore, a patient's willingness to take a medication, such as disulfiram, which confers the risk of a significantly unpleasant bodily experience, is likely indicative of a heightened level of determination.

It is possible that disulfiram may be more useful in patients with certain characteristics. Though the literature on this topic has been unable to draw definite conclusions, patients who are older (over 40), socially stable, highly motivated, and able to tolerate treatment relationships have been shown to be more likely to benefit from disulfiram treatment. Additional predictors of positive response include longer drinking histories and Alcoholics Anonymous (AA) involvement.

Disulfiram may be particularly useful in the abstinence initiation phase of treatment, given its likelihood of eliminating impulsive drinking. However, it is not useful in preventing alcohol consumption planned in advance (allowing for premeditated nonadherence with the medication). The total prohibition of drinking fostered by disulfiram may also reduce preoccupation with alcohol, as craving has been shown to be related to perceived availability of substances.

In summary, the use of disulfiram in the treatment of alcohol dependence has garnered mixed results to date. However, there is evidence that disulfiram can be useful in reducing alcohol consumption and increasing rates of abstinence, particularly in the context of supervised use and among motivated individuals. Despite its potential utility, however, disulfiram is infrequently prescribed and, even then, often used for brief periods of time only. The exact reasons for this are unclear, though likely multifactorial. Patient acceptance can be hampered by fear of side effects or the disulfiram-ethanol reaction itself. Many patients are ambivalent about taking medication which dictates abstinence rather than allowing for occasional consumption. Physicians may be uncomfortable prescribing disulfiram due to lack of knowledge and experience with the medication, and many lack sufficient time/resources to comprehensively manage these patients. Additional factors include doubts about pharmacotherapeutic effectiveness, concern that medication might reduce motivation for psychosocial treatment and mutual-help group attendance, and cost. In spite of the high prevalence of alcohol dependence and its consequences, disulfiram remains underutilized.

COMPARISONS AND COMBINATIONS WITH OTHER AGENTS

In addition to disulfiram, three other medications have received FDA approval for the treatment of alcohol dependence: oral naltrexone, acamprosate and, most recently, an extended-release injectable form of naltrexone (Vivitrol). Naltrexone, an opioid antagonist, gained FDA approval for the treatment of alcohol dependence in 1994. In clinical studies, naltrexone has been shown to reduce both alcohol use and "craving." In decreasing the positive reinforcement associated with alcohol consumption, naltrexone has been associated with significant decreases in heavy drinking. Acamprosate (calcium acetylhomotaurinate) was approved for use in the United States in 2004. Though its exact mechanism of action is unclear, studies suggest that acamprosate may alter neuronal excitability at the N-methyl-D-aspartate glutamate receptors and/or facilitate the function of gamma-aminobutyric acid-A receptors. In doing so, acamprosate is thought to reduce protracted withdrawal symptoms which contribute to relapse.

There are few published studies directly comparing disulfiram with these agents. In a pilot study which looked at patients with both alcohol and cocaine dependence, disulfiram (250 mg per day) was found to be superior to naltrexone (50 mg per day) in reducing the frequency and quantity of alcohol consumption, in addition to lowering cocaine use. In a later study, 254 dually diagnosed patients (with an Axis I psychiatric disorder and comorbid alcohol dependence) were randomly assigned to one of four groups: (1) 50 mg of naltrexone, (2) placebo alone, (3) 250 mg of (open-label) disulfiram and (blinded) naltrexone, or (4) (open-label) disulfiram and (blinded) placebo. Individuals treated with an active medication sustained significantly more consecutive weeks of abstinence and reported less craving than those treated with placebo, but neither disulfiram nor naltrexone was more effective than the other. There was no advantage found in the combination of the two medications. A more recent double-blind placebocontrolled trial (N = 208) found that patients with cooccurring cocaine and alcohol dependence who received disulfiram (alone or in combination with naltrexone) were most likely to achieve combined abstinence from cocaine and alcohol. In contrast to the previous study, combination treatment with disulfiram and naltrexone resulted in the highest achievement of three consecutive weeks of abstinence from both substances.

In a Swiss study investigating acamprosate (assigned randomly versus placebo) and disulfiram (as an "optional" medication chosen by patients) for the treatment of chronic or episodic alcohol dependence, similar outcomes were seen with each medication. Patients who received concomitant administration of the two medications showed the highest cumulative abstinence duration. However, potentially confounding factors included both the optional nature of receiving disulfiram and increased contact with treatment providers among disulfiram patients, due to the practice of daily handout of disulfiram in Switzerland.

In addition to contrasting medications, these studies also highlight the recent interest in combining medications for the treatment of alcohol dependence. Given their different mechanisms of action, it has been hypothesized that each medication may make a unique contribution within treatment, thus enhancing overall outcomes if administered in combination. For example, prescribing a medication that decreases craving for alcohol may enhance a patient's ability to maintain adherence with disulfiram and benefit from its administration.

Once again, investigations utilizing combination treatment have been small in number and have produced mixed results. Other than those studies already described, an additional trial looking at the combination of disulfiram and naltrexone suggested possible support for combination treatment. Patients were randomly assigned to receive (1) naltrexone (25 mg) and disulfiram for 6 months, followed by 6 months of disulfiram or (2) disulfiram for 1 year. At the end of 1 year, 73% of the combination treatment group was abstinent from alcohol compared to 34% of the disulfiram-only group. At 2 years, 40% of the combination group remained abstinent, in comparison to no patients in the disulfiram-only group. Unfortunately, a naltrexone-only group was not included in the study, making it difficult to assess the actual benefit of combination therapy.

To date, the combination of disulfiram with either naltrexone or acamprosate has not resulted in additional patient safety concerns, including the occurrence of adverse hepatic effects. However, data remain sparse. Pharmacotherapeutic combination treatment for alcohol dependence remains an area in need of future study.

DISULFIRAM IN COCAINE USE DISORDERS

It has been observed that there is a unique association between alcohol and cocaine dependence. Data from the Epidemiological Catchment Area study indicated that 85% of subjects who met criteria for cocaine dependence also met criteria for alcohol abuse or dependence. Co-occurrence of alcohol and cocaine dependence has been associated with increased severity of dependence, decreased treatment retention, and poorer outcomes when compared to either disorder on its own.

The association between alcohol and cocaine dependence is likely caused by multiple factors. Alcohol may be used to attenuate negative effects of acute cocaine use or withdrawal. Alcohol consumption may lead to initial or increased cocaine use, through disinhibition and impairment of judgment. When repeatedly used together, co-administration may become conditioned. There is also evidence that alcohol inhibits cocaine metabolism. Furthermore, co-ingestion of the two drugs results in the formation of cocaethylene (CE), a centrally active metabolite. The pharmacological effects of CE are similar to those of cocaine itself, but CE causes less elevation in heart rate and has a longer halflife than cocaine. In animal studies, CE has been shown to be more reinforcing and less anxiogenic than cocaine. This may help to explain why the combination of cocaine and alcohol has been reported to prolong cocaine-induced "highs," reduce paranoia and anxiety, lessen hyperactivity, and attenuate sleep disturbance.

In the early 1990s, two groups reported a positive impact of disulfiram in decreasing both alcohol and cocaine use among patients with co-occurring alcohol and cocaine use disorders. Subsequently, a larger study was conducted investigating disulfiram and three forms of manual-guided psychotherapy in the treatment of cocaine dependence and concurrent alcohol abuse or dependence. Administration of disulfiram was associated with better treatment retention and longer duration of abstinence from both alcohol and cocaine. In a 1-year follow-up study, the initial benefits of disulfiram on both cocaine and alcohol use were sustained. Furthermore, study participants continued to reduce their cocaine (but not alcohol) use after treatment ended.

Two papers published in 2000 examined the impact of disulfiram on cocaine use in patients addicted to both cocaine and opioids. One study recruited individuals maintained on methadone, while in the other, participants were maintained on buprenorphine. In these studies, disulfiram was associated with decreased cocaine use and increased cocaine abstinence. Alcohol consumption was minimal for all subjects across studies. Both sets of authors concluded by supporting the potential efficacy of disulfiram in treating cocaine dependence among methadone/buprenorphine-maintained opioid addicts.

Most recently, a randomized, placebo-controlled, double-blinded trial with 121 participants examined disulfiram, cognitive behavior therapy, and interpersonal psychotherapy in the treatment of patients with cocaine dependence, with or without alcohol dependence. Those who received disulfiram reduced their cocaine use significantly more than those who received placebo. Positive effects of disulfiram were most pronounced in patients who did not have alcohol dependence at baseline or who completely abstained from alcohol consumption during the study. These results provided support for the concept that disulfiram has an impact on cocaine use that is independent of its effect on reducing alcohol intake.

The manner in which disulfiram may exert a direct effect on cocaine use is somewhat unclear. Given disulfiram's role in the central inhibition of dopamine beta-hydroxylase, the medication is known to increase dopamine concentrations. The use of cocaine in the presence of disulfiram then leads to further increases in dopamine. This may induce or exacerbate psychosis in certain individuals. Furthermore, disulfiram impedes the metabolism of cocaine through inhibition of plasma and microsomal carboxylesterases and plasma cholinesterase. It has been suggested that the combination of disulfiram and cocaine may result in an unpleasant "high." In altering the pleasurable effects of cocaine, leading to aversive and less reinforcing effects, cocaine use may be decreased.

Given the high rates of comorbidity with alcohol use disorders, investigation of disulfiram for the treatment of cocaine dependence needs to be approached with appropriate caution and patient education. Patients should be made aware of the potential consequences associated with alcohol consumption while taking disulfiram. Furthermore, the possibility of cocaine toxicity in the setting of disulfiram treatment has been raised. To date, however, disulfiram has been used safely in the investigational treatment of cocaine-dependent populations, with only mild adverse effects reported. At present, there are no FDA-approved medications for the treatment of cocaine dependence.

DISULFIRAM IN THE DUALLY DIAGNOSED

There are currently no FDA-approved medications for the specific treatment of dually diagnosed individuals (patients with both a primary psychiatric disorder and a substance use disorder). Early reports suggested that disulfiram may precipitate or worsen psychosis, in addition to causing delirium, depression, anxiety, and mania. However, in the context of lowered disulfiram dosing and more standardized definitions of psychiatric symptoms, a growing number of recent studies have suggested that disulfiram can be used safely in patients with comorbid psychiatric disorders.

CONCLUSIONS 373

One recent large-scale placebo-controlled study compared disulfiram and naltrexone, alone and in combination, for the treatment of alcohol dependence in a veteran population with a heterogeneous set of comorbid mental disorders. The majority of participants were taking psychotropic medications at the time of study entry, and many were on more than one. There were no significant differences in serious adverse effects between groups and the study suggested that monitored use of disulfiram could be conducted safely in dually diagnosed individuals, even within the setting of concurrent use of psychotropic medications. In further analyses looking specifically at alcohol-dependent patients with comorbid posttraumatic stress disorder (PTSD), psychotic spectrum disorders, or depression, there were no significant increases in adverse effects associated with the use of disulfiram.

Notably, individuals with PTSD who were treated with disulfiram showed significantly more improvement in several symptoms of PTSD and it was suggested that such patients may respond particularly well to disulfiram. It has been hypothesized that the noradrenergic system may mediate both symptoms of hyperarousal in PTSD and the increased risk for substance abuse seen in these patients. Therefore, medications which dampen this response may be particularly effective in treating patients with comorbid PTSD and alcohol dependence. Disulfiram's central inhibition of dopamine beta-hydroxylase, resulting in increased levels of dopamine and decreased synthesis of norepinephrine, may alleviate symptoms of PTSD and decrease alcohol consumption by attenuating the vulnerability to stress-induced relapse.

Among patients with a psychotic spectrum disorder, there was no evidence that disulfiram at a dose of 250 mg daily caused a worsening of psychotic symptoms. Furthermore, patients with psychotic spectrum disorders were medication compliant and no more likely than nonpsychotic patients to consume alcohol with disulfiram. Of note, these study patients were thought to be highly motivated, clinically stable, adequately treated with psychotropic medication, and had only mild psychotic symptoms. Thus, these results may not be generalizable to the larger dual diagnosis population, particularly those who are less motivated, more unstable, and severely ill.

Effective medication treatment of alcohol dependence in patients with psychotic spectrum disorders may be particularly beneficial for several reasons. Alcohol-dependent patients with psychotic disorders may have greater reluctance to participate in self-help groups, such as AA, in which most members do not have comorbid psychiatric disorders. Furthermore, negative symptoms in psychotic disorders may undermine patients' motivation. In contrast, the use of pharmacotherapy is

usually familiar to dually diagnosed patients and generally requires less new learning than psychosocial treatments. Dose scheduling can often be readily integrated into existing treatment. Based on the small body of literature currently available, monitored use of disulfiram is thought to be safe and appropriate in dually diagnosed individuals.

CONCLUSIONS

Over several decades of research and clinical experience, disulfiram has remained an important, yet underutilized, treatment option within the addictions field. Despite some equivocal findings in the treatment of alcohol dependence, disulfiram's efficacy in the setting of supervised use has repeatedly received support. For many years, disulfiram represented the only medication approved by the FDA for the treatment of alcohol dependence. In spite of the recent addition of such medications as naltrexone and acamprosate, disulfiram continues to make a unique contribution, given its mechanism of action, reliance on "psychological deterrence," and ability to foster complete abstinence. The possibility that it may be particularly useful in patients with certain characteristics and in specific stages of treatment suggests that sophisticated prescribing may enhance disulfiram's benefit. Its combination with other agents and treatment modalities, either in parallel or in succession, may represent another avenue to maximize positive outcomes.

Though the majority of disulfiram research and utilization has taken place in the treatment of alcohol dependence, a growing body of literature has recently emerged supporting its use in the treatment of cocaine dependence and dually diagnosed individuals. The possibility of its use in additional patients, such as those with pathological gambling, has also been raised. It is hoped that additional study will help to maximize the benefit to be derived from this unique medication.

SEE ALSO

Improving Medication Use in Addictions Treatment, Implications of Comorbidity for Clinical Practice, Pharmacotherapy of Cocaine Dependence, Naltrexone and Opioid Antagonists for Alcohol Dependence, Acamprosate for Alcohol Dependence

List of Abbreviations

ADH alcohol dehydrogenase
ALDH aldehyde dehydrogenase
CE cocaethylene

DDC diethyldithiocarbamate PTSD posttraumatic stress disorder

VA Veterans Affairs

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Naltrexone and Opioid Antagonists for Alcohol Dependence

Helen M. Pettinati*, William D. Dundon*, María José Casares López^{\$}
*Center for the Studies of Addiction, Philadelphia, PA, USA *University of Oviedo, Asturias, Spain

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INTRODUCTION

It has been increasingly recognized by many in the treatment community that alcohol dependence is a medical illness. Surprisingly, few clinicians have utilized medications as a frontline treatment or even as an adjunct to treatment for alcohol dependence. For instance, a 2007 study from the US Veterans Health Administration reported that only 3% of veterans with an alcohol use disorder received a medication approved by the Food and Drug Administration (FDA) for alcohol

dependence. In this same study, of those who had a co-occurring psychiatric disorder, 52.6% received an antidepressant, most commonly a selective serotonin reuptake inhibitor (SSRI), while only 4.3% received a medication for their alcohol use disorder. Furthermore, alcohol-dependent individuals with no co-occurring psychiatric disorder were six times more likely to receive an SSRI than any of the FDA-approved medications for alcohol dependence.

In the United States, there are four medications approved by the FDA for the treatment of alcohol

dependence. Two of the naltrexone medications are different formulations - daily oral naltrexone tablets (ReVia®, Depade®), and a long-acting monthly injection (Vivitrol®). These medications are believed to reduce alcohol craving and blunt the rewarding properties of alcohol by blocking the opioid receptors in the brain. The other two medications are acamprosate and disulfiram. Acamprosate is thought to modulate the glutamate system and promote abstinence by alleviating aversive symptoms related to protracted alcohol withdrawal. Disulfiram interferes with the metabolism of alcohol creating an intense aversive state including flushing, nausea, and headache when the person drinks alcohol. This chapter, however, primarily focuses on the use of naltrexone and other opioid antagonists for the treatment of alcohol dependence.

DEFINITION OF THE PROBLEM

Alcohol use disorders comprise the disorders of alcohol dependence and alcohol abuse. Alcohol dependence is a chronic, relapsing disorder characterized by diminished control over the consumption of alcohol resulting in significant personal, social, and occupational consequences. The Diagnostic and Statistical Manual of Mental Disorders of the American Psychiatric Association defines alcohol dependence as a cluster of three to seven specific symptoms occurring in the same 12-month period that cause significant distress or impairment for the individual. The symptoms can include the physiological manifestations of tolerance and withdrawal, as well as more behavioral signs including the persistent desire to stop or cut down alcohol consumption, drinking more or longer than intended, drinking despite knowledge that alcohol is causing physical or psychological problems, spending too much time consuming alcohol or recovering from drinking, or impairment to important social, occupational, or recreational activities. Alcohol abuse is characterized by at least one of four symptoms that include failure to fulfill major role obligations, physically hazardous use, recurrent legal problems, and recurrent social or interpersonal problems. In 2000, the cost of alcohol dependence and alcohol abuse to the US economy was approximately \$185 billion per year. However, only 26% of those diagnosed with lifetime alcohol dependence based upon a national epidemiological survey ever received treatment either from professionals or from self-help groups (e.g. Alcoholics Anonymous). Furthermore, while it has been increasingly recognized by many in the treatment community that alcohol dependence is a medical illness, the majority of medical clinicians have failed to respond to the compelling evidence from controlled studies of efficacy derived with opioid antagonists in treating alcohol dependence. The need for improving education and patient access to pharmacological treatment options while discovering new treatments is an undeniable problem.

EPIDEMIOLOGY

Alcohol use disorders affect a large segment of the population in the United States. The results of the recent National Epidemiologic Survey on Alcohol and Related Conditions reveal that lifetime prevalence of any alcohol use disorder is 30.3%. For men, 42.0% will meet criteria for alcohol abuse or dependence at some time in their lives. In keeping with the focus of this chapter, the remaining prevalence statistics will be reported for alcohol dependence only.

The lifetime prevalence of alcohol dependence in adults in Western countries ranges from 7 to 12.5%. In the United States, the 12-month prevalence (the percentage of adults with alcohol dependence in a 12-month period) is 3.8%. Men have a higher rate of alcohol dependence than women, with a lifetime rate of 17.4% versus 8.0% and a 12-month prevalence of 5.4% versus 2.3%. Within the United States, the race/ethnicity prevalence varies considerably, with Native Americans having the highest lifetime rate (20.1%), followed by Caucasians (13.8%), Hispanics (9.5%), African Americans (8.4%), and Asians (6.0%). Lifetime prevalence decreases by age cohort with 18–29 year olds reporting a 17.3% prevalence, 30-44 year olds reporting a 15.4% prevalence, 45-64 year olds reporting a 11.0% prevalence, and those 65 and older reporting a 3.4% prevalence. There are also differences based upon region of the country with those in the West and Midwest reporting higher lifetime rates (15.1 and 15.0%, respectively) than those in the Northeast and the South (10.6 and 10.3%, respectively).

In the United Kingdom, according to a 2000 national survey of those 16–74 years old (total sample size n=8580), 7% of the total sample were assessed as being dependent on alcohol (ICD-10 criteria). Men had a higher rate of alcohol dependence than women, with a 12-month prevalence of 7.5% versus 2.1%. In Spain, estimates of "problematic drinking" have ranged from 3.4 to 7.2%. In other countries reporting ICD-10 or DSM-IV criteria, the lifetime prevalence rates for men and women (respectively) were Germany: 10.5 and 3.7%; Finland: 6.5 and 1.5%; Slovakia: 9.4 and 1.1%. In China, the rate of past year alcohol dependence was 5.2% (total), 9.2% (males), and 0.6% (females).

MEDICAL APPROACHES TO TREATMENT

More than a decade ago, McLellan and colleagues proposed a paradigm shift for the conceptualization and treatment of alcohol and other drug dependencies. The prevailing view among policy makers and many in the treatment community had been that alcohol and other drug dependencies were primarily social and moral problems rather than medical illnesses. Treatments focused on acute cures or were relegated to forensic interventions. The authors demonstrated the similarities of these disorders to other chronic medical illnesses (such as type 2 diabetes and hypertension) in terms of diagnosis, genetic heritability, role of personal responsibility, pathophysiology, and response to treatment. By understanding alcohol dependence as a chronic medical illness, treatment in the primary care arena could become normative, with more difficult cases being referred to specialty care, as is typical of other chronic diseases. Frontline treatments would entail screening, diagnosis, brief interventions, medication management, and referral to specialty addiction counseling when indicated. Within this perspective, health care coverage for alcohol dependence would embrace a chronic disease model, supporting continuing care and achieving parity with other medical illnesses. In the past decade, considerable advances using this model have been made. Two new medications were approved by the FDA, and medical management protocols for treating alcohol dependence have been developed and tested. The Mental Health Parity and Addiction Equity Act of 2008, which went into effect in 2010, requires group health plans that cover 50 or more employees and offer both medical and mental health benefits to ensure that the mental health and substance abuse benefits are no more restrictive than the medical and surgical benefits. In addition, the Patient Protection and Affordable Care Act, was signed into law on March 23, 2010. Under this law, mental health coverage is considered an essential health benefit. As such, insurance companies are required to provide coverage that is equal to that provided for any other medical condition. Thus, with supportive legislation and a modern conceptualization, the field may be more open to accepting alcohol dependence as a medical illness.

NEUROBIOLOGY OF ALCOHOL DEPENDENCE AND THE ROLE OF THE ENDOGENOUS OPIOID SYSTEM

Alcohol affects all of the major neurotransmitter systems of the brain through complex, direct, or indirect processes. For example, it is hypothesized that lower doses of alcohol stimulate dopamine release via the glutamate system, and higher doses facilitate the gamma-aminobutyric acid (GABA) system and inhibit glutamate, consequently, suppressing dopamine release. This process contributes in part to the biphasic response to alcohol of early arousal followed by later sedation.

Our understanding of these mechanisms is incomplete but comes from animal models, human laboratory studies, human imaging studies, and human clinical trials. Acute exposure to alcohol facilitates GABA transmission and noradrenergic, serotonergic, dopaminergic, opioidergic, and endocannabinoid signaling while it inhibits glutamergic functioning. Chronic exposure to alcohol results in neuroadaptational changes that apparently underlie compulsive use of alcohol and the loss of consumptive control seen in alcohol dependence.

It is well established that all substances of abuse (including alcohol) facilitate dopamine release in the reward regions of the brain. The reward center includes the mesolimbic dopamine pathway with dopaminergic neurons projecting from the midbrain ventral tegmental area to the amygdala, hippocampus, nucleus accumbens, and prefrontal cortex. Alcohol is believed to have a direct impact on dopamine release in the nucleus accumbens but also impacts the dopamine system through the opioid system. Alcohol consumption increases the release of endogenous opioid peptides. The effects of opioids on reward are due in part to their ability to regulate dopamine release in the terminal regions of the reward pathway. Opioid peptides and other agonists at mu and delta opioid receptors increase extracellular dopamine levels in the nucleus accumbens. In addition, there is evidence that opioid reward also involves dopamine-independent mechanisms. Opioids can activate opioid receptors located postsynaptically to dopamine terminals in the nucleus accumbens. Given these actions, it is logical to consider medications with opioid-antagonist properties for the treatment of alcohol dependence.

OPIOID ANTAGONISTS FOR THE TREATMENT OF ALCOHOL DEPENDENCE

Oral Naltrexone

Naltrexone is an antagonist at the mu, delta, and kappa opioid receptors and was initially investigated for the treatment of opiate dependence. Oral naltrexone received FDA approval for opiate-dependence treatment in 1984 and injectable, long-acting naltrexone received FDA approval in October 2010. Early preclinical studies also demonstrated the potentiality of naltrexone for treating alcohol dependence. Based upon these findings, Dr Charles O'Brien initiated open label studies of naltrexone at the Philadelphia Veterans Affairs Medical Center in 1983. Subsequently, he and Volpicelli conducted a placebo-controlled clinical trial in chronic alcohol-dependent patients. Naltrexone significantly reduced rates of relapse to heavy drinking,

compared with placebo, with minimal side effects. These results were replicated by O'Malley and colleagues at Yale University in an independent study. These two important studies provided the basis for the FDA approval of oral naltrexone in 1994 for the treatment of alcohol dependence in the United States. Naltrexone has been approved for treatment of alcohol dependence in Canada, Australia, and a number of other countries in Europe and Asia.

Pharmacology and Mechanism of Action

Taken orally, naltrexone is quickly absorbed and undergoes first-pass metabolism in the cytosol system in the liver. Naltrexone is then converted to several metabolites. The major metabolite of naltrexone is 6-β-naltrexol, which is also an opioid antagonist and independently reduces alcohol drinking in a rat model. The mean serum elimination half-life after chronic administration of a 50 mg daily dose is 9.7 h for naltrexone and is 11.4 h for 6-β-naltrexol. PET studies show significant blocking of brain mu receptors for more than 72 h after a single 50 mg dose. By blocking the opioid receptors, naltrexone is believed to reduce the reinforcing effects of alcohol. Animal studies and human laboratory studies have shown that naltrexone reduces the reinforcing properties of alcohol. Human laboratory studies and clinical trials have shown that naltrexone reduces alcohol craving. In one human laboratory study, nontreatmentseeking alcohol-dependent subjects were randomly assigned to pretreatment with naltrexone or placebo. Subsequently, subjects were given a priming drink of alcohol and then were given a choice to consume more alcohol or earn money. The naltrexone-treated subjects reported less craving for alcohol at baseline, no change in craving score after the priming dose, drank less alcohol, and reported less alcohol craving overall during the experiment. In contrast, the placebo-treated subjects reported more alcohol craving at baseline, their craving significantly increased after the priming drink, they drank more alcohol, and reported more craving for alcohol during the experiment. Alcohol-dependent participants in human clinical trials randomly assigned to receive naltrexone have also reported less craving for alcohol than those receiving placebo.

Safety Profile

The safety profile of naltrexone provides a significant advantage for treatment of alcohol dependence. Traditionally, chronic drinkers were denied medications (except for detoxification) due to safety concerns over the potential interaction of most medications with alcohol. Naltrexone neither potentiates alcohol effects on motor skills or cognition nor does it reduce seizure threshold. Furthermore, naltrexone overdose has not resulted in any fatalities and it has no known abuse potential.

Fewer than 15% of patients report side effects with naltrexone. Nausea and vomiting are more commonly reported, while headache, low energy, anxiety, depression, rashes, and decreased alertness are less common. These side effects typically resolve spontaneously after a few doses, or with reduction of the daily dosage. Dysphoria has been reported by a few patients with opiate addiction and by a few normal volunteers who were given naltrexone. It is hypothesized that these reports may be indicative of a mild opiate "withdrawal-like" reaction in some patients that occurs when naltrexone abruptly blocks opioid receptors that are in an activated condition, possibly due to stress or substance intake. However, most studies have not found evidence of dysphoria or other mood changes with the recommended dose of naltrexone when treating alcohol-dependent patients.

There is a "black-box" in naltrexone's package insert warning of possible hepatocellular injury when taken in approximately seven times the recommended daily dose. It also warns against prescribing naltrexone in cases of acute hepatitis or liver failure. The warnings of hepatotoxic effects were derived from early studies, which prescribed dosages of up to 350 mg day⁻¹ for obesity and dementia. There are no reports of hepatotoxicity at the recommended daily dosage of 50 mg. Indeed, liver enzyme levels in alcohol-dependent patients typically are lowered with naltrexone treatment (relative to placebo), presumably due to reduced alcohol intake while in treatment. There appears to be a much greater risk of hepatotoxicity from chronic excessive alcohol drinking than from treatment with naltrexone at the recommended dosage.

The original manufacturer of naltrexone (DuPont Pharma) conducted a large safety study (~570 alcohol-dependent patients) and concluded that the medication was safe under a variety of circumstances. Naltrexone has also been studied for use in several other medical disorders, including obesity, bulimia, dementia, autism, self-injurious behavior seen in autism, and mental retardation.

Summary

Over 50 randomized, controlled trials with nearly 7000 alcohol-dependent patients have been published examining the efficacy of opioid antagonists for alcohol dependence. While not all studies have demonstrated an advantage over placebo, the results of several reviews (including two meta-analyses) clearly indicate the superiority of naltrexone over placebo in reducing relapse rates to heavy drinking, as well as in other drinking indices. The next section highlights the Combined Pharmacotherapies and Behavioral Interventions (COMBINE) study as the best example of this research, which, to date, is the largest pharmacological study of alcohol dependence.

The COMBINE Study

The COMBINE study was conducted from 2001 to 2004 at 11 academic research sites across the United States. This study enrolled 1383 patients with alcohol dependence who were randomized into 9 groups. Eight groups of patients received a new type of Medical Management (MM) intervention given with 16 weeks of naltrexone (100 mg day⁻¹ and placebo), or acamprosate (3 g day⁻¹ and placebo), or both naltrexone $(100 \text{ mg day}^{-1})$ and acamprosate (3 g day^{-1}) , or two placebos, with or without weekly sessions of a combined behavioral intervention (CBI) provided by behavioral health specialists. Medical professionals provided MM, which primarily focused on enhancing medication adherence and alcohol abstinence. A ninth group received CBI only (no MM, medications or placebo pills). After completing the 16 weeks of treatment, patients were evaluated after 1 year, and all patient groups showed substantial reduction in drinking. The baseline rate of percent days abstinent of 25.2% improved to 73.1% by the end of treatment. Percent days abstinent was significantly higher for those patients taking naltrexone with CBI (77.1%) or without CBI (80.6%), compared to those with placebo and no CBI (75.1%). One year after completing treatment, these between-group effects were similar but no longer significant. For the percentage of patients who relapsed to heavy drinking, those taking naltrexone had a better outcome than those taking placebo (68.2% versus 71.2%). This advantage for naltrexone persisted at the 1-year follow-up evaluation. The investigators also calculated the percentage of patients who achieved a good clinical outcome during the last 8 weeks of the trial. Those patients taking naltrexone with CBI or without CBI fared better than those with placebo and no CBI (74%, 74%, and 58%, respectively). One year after treatment, these between-group effects were similar but no longer significant. Interestingly, there was no advantage in taking acamprosate alone or in combination with naltrexone compared to placebo at any time during or after treatment.

Issues of Medication Adherence

In the COMBINE study, the mean medication adherence rate was excellent (86%), likely due in part to the MM intervention, which focuses a patient on treatment adherence. There were similar adherence rates for individual medication groups and for those with and without CBI. However, not all naltrexone studies have demonstrated good adherence rates and those with low rates typically were associated with reduced efficacy. One of the earliest naltrexone trials found an effect only when considering the patients that were 90% adherent.

Medication nonadherence is problematic for all chronic medical illnesses. Nearly 50% of adults evidence some problems with medication adherence. Nonadherence may be unintentional (forgetfulness or misunderstanding the medication regimen) or intentional (related to side effects, cost, or symptom improvement). Medication nonadherence rates may be higher in alcohol-dependent patients than in other patient populations for a variety of reasons. In the alcohol-treatment community, there has been a bias against medication interventions that may influence patient adherence. Furthermore, by blocking the euphoric effects of alcohol, some patients may terminate medication usage because they want to re-experience the reinforcing effects of alcohol. In addition, since the opioid antagonists selectively impact the reward centers, they neither relieve other distressing psychiatric symptoms nor provide a sense of well-being or relief. Thus, it is widely accepted that nonadherence is a major barrier to successful treatment outcome, particularly when treating alcohol dependence. Some major naltrexone trials have been published that have demonstrated that the benefits of naltrexone are evident only in patients who are reliable in taking their study medication every day. Although there may be no demonstrable advantage for naltrexone in the study sample as a whole, a clear advantage for naltrexone emerges when outcome data are based only on patients who received an adequate exposure to the medication.

Injectable Naltrexone

Injectable naltrexone formulations were designed to improve medication adherence, minimize fluctuations in plasma levels, increase bioavailability, and minimize side effects. Long-acting formulations of naltrexone were developed by encapsulating naltrexone into injectable, biodegradable polymer microspheres. Naltrexone is released continuously, achieving a stable therapeutic level that is low enough to reduce side effects. Furthermore, an intramuscular injection avoids the first-pass metabolism of the oral version, increasing bioavailability.

While at least three injectable formulations have been tested, only one is FDA-approved for the treatment of alcohol dependence (Vivitrol®, Alkermes, Inc., Cambridge, Massachusetts, USA). This formulation is given as a monthly injection. The safety and efficacy of longacting naltrexone has been demonstrated in four randomized clinical trials. The largest trial on injectable naltrexone (Vivitrol®) is a 6-month multicenter trial (24 sites) with 624 patients randomized to monthly injections of 190 mg or 380 mg or a matched volume injectable placebo. Compared to placebo, there was a dose–response reduction in heavy drinking, but the

differential treatment response from placebo reached statistical significance only in the higher dose group (380 mg). The primary outcome variable was the event rate of heavy drinking, which proved to be 25% lower among patients who received 380 mg extended-release naltrexone compared to patients who received placebo (p = 0.03). Significant treatment interactions were shown for gender and pretreatment status of abstinence. Extended-release naltrexone was most effective in men and in patients who entered the study with at least 14 days of abstinence. Pettinati and colleagues also demonstrated that extended-release naltrexone was associated with improvements in quality of life, specifically in the domains of mental health, social functioning, general health, and physical functioning.

Other Opioid Antagonists

Nalmefene is the only other opioid antagonist that has been extensively studied for treating alcohol dependence. It is licensed for the treatment of alcohol dependence in various countries but not in the United States and there are several ongoing Phase III trials in Europe. While nalmefene has a similar chemical structure to naltrexone, it is purported to have improved opioid receptor binding, improved bioavailability, and less of a risk for liver toxicity than naltrexone. While these purported benefits have not been independently verified, human laboratory studies demonstrated that it was comparable to naltrexone in reducing alcohol craving and reward stimulation in nontreatment-seeking alcohol-dependent patients. Some randomized trials have supported the efficacy of nalmefene. For instance, a multicentered, placebo-controlled 28-week trial conducted in Finland randomized 403 treatment-seeking heavy drinkers to 20 mg of nalmefene per day or to placebo in a 3:2 ratio. Patients were instructed to take the medication 1-2 h before drinking when drinking seemed imminent. After 2 weeks the dose could be adjusted upward to 40 mg day⁻¹ or downward to 10 mg day⁻¹, based upon treatment response and tolerability. Patients received a brief medical intervention that focused on medication adherence. Patients receiving nalmefene demonstrated reductions in heavy drinking and improvements in liver function tests compared to those receiving placebo. Despite support from this trial, another multicenter trial conducted in the United States did not support the efficacy of nalmefene. Eleven sites participated in this trial, randomizing 270 alcohol-dependent patients to 5, 20, or 40 mg of nalmefene in a double-blind comparison to placebo. As is typically found, patients demonstrated reduced drinking, craving, and improvement on liver function tests during the course of the trial, but there were no significant differences between the active medication and placebo groups. Thus, despite the promise of nalmefene, currently there is insufficient clinical evidence to support its use in the United States for treating alcohol dependence.

FUTURE DIRECTIONS

Subtypes of Alcohol Dependence: The Impact of Individual Characteristics on Treatment Response

The population of alcohol-dependent patients represents considerable diversity in etiology, manifestation of the illness, and response to treatment. There is a rich tradition of attempts to identify more homogeneous subgroups of alcohol dependence and match treatments to patient characteristics. This same tradition has influenced the use of naltrexone for alcohol dependence treatment. While the efficacy of naltrexone has been repeatedly demonstrated in groups of patients, individual patients vary widely in their response to opioid antagonists. Not all clinical trial studies have reported an advantage of naltrexone over placebo for alcohol treatment, including a large, multi-site Veterans Affairs study. Interestingly, a reanalysis of these data identified three subgroups based upon the drinking trajectories during the trials with different outcomes. Compared to patients randomized to be treated with placebo, naltrexone patients were more likely to be "abstainers" and less likely to be "consistent drinkers." However, the likelihood of being classified as a "sporadic drinker" was not influenced by naltrexone. This study represents the advantage of considering more homogenous subgroups of alcohol-dependent patients when predicting treatment response to specific pharmacotherapies.

Another promising line of research has focused on genetic factors that may impact naltrexone treatment response. A number of functional polymorphisms have been studied in the gene encoding for the mu opioid receptor, OPRM1. Particular interest has been focused on Asn40Asp polymorphism, such that individuals with one or two copies of the Asp40 allele report greater subjective feelings of intoxication, stimulation, sedation, and euphoria, compared to those homozygous with the Asn40 allele. Furthermore, in a retrospective analysis combining three clinical trials, patients with the Asp40 allele who took naltrexone demonstrated a 3.5 times better response, preventing relapse to heavy drinking. The COMBINE study replicated these findings, showing an advantage in the percent days abstinent, percent days of heavy drinking, and the percentage of patients with a good clinical outcome for the subset of patients receiving only naltrexone and FUTURE DIRECTIONS 381

MM. However, a third clinical trial did not find an association of improved drinking outcomes with naltrexone in those with the Asp40 allele.

Another typology has been proposed by Babor and colleagues who defined Type A and Type B alcoholdependent patients. Type A alcohol dependence is characterized by late-onset problem drinking, few childhood risk factors, lower severity of alcohol dependence, little drug use, few alcohol-related problems, little concomitant psychopathology, and a relatively promising prognosis with traditional alcohol-dependence treatment. Type B alcohol dependence, by comparison, is characterized by an early age of onset of alcohol problems, more childhood risk factors, higher severity of dependence, more evidence of polydrug use, a higher degree of concomitant psychopathology, and a poorer prognosis after treatment. This typology has been particularly promising in distinguishing response to specific SSRI treatment for alcohol dependence. For individuals with Type A alcohol dependence, SSRI treatment may be beneficial, whereas for Type B patients SSRIs may be contraindicated. One study has looked at response to naltrexone treatment using the Babor typology. In a secondary analysis of the COMBINE study data, Type A patients receiving naltrexone and MM (but not CBI) showed improved drinking outcome versus those taking placebo. Interestingly, no benefit over placebo was seen in the Type B patients, although this had been initially hypothesized, given the relationship between Type B characteristics and serotonin depletion.

Other promising typologies have been proposed by investigators such as Cloninger, Lesch, and Mann. Of particular interest, the ongoing German project "PREDICT" seeks to categorize patients according to different types of alcohol craving and evaluate the effectiveness of naltrexone and acamprosate. According to the specific mechanism of action of both substances, patients with high "reward" craving are assumed to benefit more from naltrexone, whereas patients with "relief" craving should benefit more if treated with acamprosate. The study shares several components with the COMBINE study (e.g. the same medications, inclusion and exclusion criteria, use of MM and CBI) that facilitates a direct comparison between the German and US studies. In the original design, 430 patients were to be randomized to naltrexone, or acamprosate, or placebo in a 2:2:1 ratio. Patients received medication for 12 weeks in conjunction with MM, which is extended to 6 months. Patients who relapsed were re-randomized to either MM or CBI while remaining on the same medication. The trial is in the data analysis phase. To date, there are insufficient data to support that any of these different typologies provide a reliable, replicable classification for predicting treatment outcomes with specific pharmacotherapies. However, research efforts are ongoing.

Some investigators have proposed that naltrexone may not be efficacious for all populations. For instance, a secondary analysis of the COMBINE study data suggested that naltrexone may be most efficacious for individuals of European descent who inherited a particular polymorphism. Other investigations have questioned the efficacy of naltrexone for the treatment of women, although almost always these studies are underpowered for testing medication effects in women. A full exploration of these issues is beyond the scope of this chapter but there is general consensus in the field that naltrexone is efficacious for many African Americans and many women. Discrepancies in the findings of some studies may be a function of samples size, or too few studies that a priori planned to test these subgroups. Furthermore, the FDA has not restricted the use of naltrexone for these populations. Nonetheless, future research is needed on the study of such subgroups and their response to opioid antagonists, such as naltrexone.

Combining Naltrexone with Other Pharmacotherapies to Improve Treatment Response

Naltrexone and Acamprosate for the Treatment of Alcohol Dependence

Given the variability in etiology and progression of alcohol dependence and limited response to treatment for any of the available medications, it is reasonable to try combining medications if they have different but complementary mechanisms of action. Acamprosate, approved by the FDA in 2006, is thought to decrease relapse rates by its action on the glutamate system, whereas naltrexone targets the opioid system. Two randomized, placebo-controlled trials have compared the results of oral naltrexone, acamprosate, both naltrexone and acamprosate to a double placebo. In a single-site trial, 160 patients received medication and weekly psychosocial treatment for 12 weeks. All three treatment groups demonstrated better relapse rates than the placebo groups. The patients receiving the combination of naltrexone and acamprosate fared significantly better than patients who received acamprosate alone but not better than those who received naltrexone alone (time to the first drink and time to first heavy drink). In the multi-site COMBINE study described earlier, naltrexone, but not acamprosate, showed an advantage in longer times to first heavy-drinking day and higher rates of percent days abstinent. Acamprosate was not shown to be effective, either alone or in combination with naltrexone. Thus, although safe and well tolerated, there is insufficient evidence to date to

recommend adding acamprosate to naltrexone for the treatment of alcohol dependence.

High-Dose Naltrexone with and without Disulfiram for the Treatment of Alcohol Dependence and Co-Occurring Cocaine Dependence

High rates of comorbidity exist among alcohol and cocaine populations. Up to 60% of patients seeking treatment for cocaine dependence are also dependent on alcohol. Alcohol+cocaine-dependent patients suffer more addiction-related consequences, greater psychosocial problems, and higher rates of recidivism than patients addicted to alcohol or cocaine alone. Furthermore, these patients are particularly difficult to treat. Commonly, the use of one substance leads to the use of the other. In addition, concurrent use of cocaine and alcohol notably yields cocaethylene, an active metabolite associated with more lethality and toxicity than cocaine alone. From a neurobiological perspective, addiction to both alcohol and cocaine is further complicated because these agents have different and additive effects on reward-related glutamate and GABA neurons. Thus, this treatment-refractory population may require a pharmacological approach, to supplement traditional counseling, which effectively targets the potentially different neurobiology of the combination of cocaine and alcohol dependencies. It is reasonable to explore the efficacy of naltrexone for treating alcohol- and cocaine-dependent patients, because drinking alcohol can trigger cocaine use. In addition, there is some evidence that naltrexone may have a direct effect on reducing the compulsive use of cocaine, without respect to alcohol.

While two double-blind, placebo-controlled studies of 50 mg day⁻¹ of naltrexone did not reduce alcohol nor cocaine use in co-occurring cocaine+alcohol-dependent outpatients, an open-labeled trial of 150 mg day⁻¹ showed promise. Pettinati and colleagues conducted a series of naltrexone studies using higher daily doses to treat this population. In a 12-week clinical trial, 164 patients (stratified by gender) were randomized to 150 mg of naltrexone or placebo and to either cognitive behavioral therapy or a type of medical management. The higher than typical daily dose of naltrexone (i.e. 150 mg day⁻¹) was associated with gender differences in response to treatment. For men, there was a reduction in the amount of use and severity in treatment on both cocaine and alcohol. However, women dependent on both cocaine and alcohol did not appear to benefit from the daily dose. In another trial, disulfiram (250 mg day⁻¹) was added to a treatment regimen of 100 mg day⁻¹ of naltrexone. Two hundred and eight patients were randomized to receive disulfiram, naltrexone, the combination, or placebo for 11 weeks while participating in twice-weekly individual cognitive behavioral therapy (CBT). While the primary analyses demonstrated no differences among groups in abstinence from cocaine or alcohol, secondary analyses revealed that patients taking the disulfiram–naltrexone combination were most likely to achieve three consecutive weeks of abstinence from cocaine and alcohol than were the placebo-treated groups. These studies suggest that higher doses of naltrexone may show some promise with this treatment-resistant population.

Naltrexone and Sertraline for the Treatment of Alcohol Dependence and Co-Occurring Depression

The co-occurrence of alcohol dependence and depression is highly prevalent and difficult to treat. High severity in one disorder is associated with high severity in the other, and each disorder carries a significant risk for the development of the other. The persistence of depression during abstinence from alcohol is a risk factor for relapse to heavy drinking, and alcohol dependence prolongs the course of depression. Two independent reviews of controlled trials concluded that antidepressants alleviated depression but had little effect on reducing drinking. Because antidepressants alone do not typically appear to affect drinking in depressed alcohol-dependent patients, a medication such as naltrexone that directly affects drinking may be a necessary adjunct to antidepressant therapy for successful treatment. Pettinati and colleagues randomly assigned 170 depressed alcohol-dependent patients to sertraline (200 mg day⁻¹), naltrexone (100 mg day⁻¹), the combination of sertraline plus naltrexone, or double placebo while receiving weekly CBT during a 14-week clinical trial. In this study, more depressed alcoholdependent patients treated with the combination of sertraline plus naltrexone significantly delayed relapse to heavy drinking than patients taking single-medication treatments or placebo. Furthermore, the sertraline plus naltrexone combination produced a higher alcohol abstinence rate than the other groups. Secondary drinking analyses supported these findings and there were fewer serious adverse event reports in the medication combination group than the other groups. While all treatment groups showed a clinical reduction in depressive symptoms, those receiving the medication combination (sertraline plus naltrexone) tended not to be depressed in the last 3 weeks of treatment than those in one of the other three treatment groups. The findings from this study suggest that patients with both alcohol dependence and depression would benefit from the combination of an antidepressant and a medication for alcohol dependence.

Other Promising Medications for the Treatment of Alcohol Dependence

While the focus of this chapter has been on the use of opioid antagonists, it is important to mention other SUMMARY 383

promising medications for the treatment of alcohol dependence that are currently under investigation but are not FDA-approved for alcohol dependence. Indeed, some of these medications may complement the pharmacological effects of naltrexone and may be targets for combination therapies.

Topiramate is an anticonvulsant that has been used to treat alcohol withdrawal. It facilitates the GABA system at the GABA_A receptors and has demonstrated efficacy for the treatment of alcohol dependence in at least three double-blind, placebo-controlled clinical trials. Its use may be hampered by the side-effect profile which includes fatigue, paresthesia, weight loss, headache, taste perversion, nausea, and dizziness. However, a slow titration schedule can minimize the occurrence of adverse events and drop out from adverse events.

Baclofen is a muscle relaxer and antispastic agent used in the treatment of multiple sclerosis. As a selective GABA_B receptor agonist, it directly and indirectly inhibits dopaminergic neurons by which baclofen is believed to suppress alcohol reinforcement. Baclofen appears to be well tolerated and safe for patients with compromised liver function. Preclinical data, open-label studies, and two randomized placebo-controlled trials in Europe support its use for alcohol-dependence treatment. However, at least one well-controlled trial in the United States did not demonstrate efficacy.

Quetiapine is an atypical antipsychotic with both dopaminergic and serotonergic activity. In a recent 12-week double-blind, placebo-controlled trial of quetiapine, alcohol-dependent patients taking quetiapine were more likely to remain completely abstinent compared to placebo-treated patients. Interestingly, reduction in drinking and in craving for alcohol was seen in the Babor Type B patients but not in the Babor Type A patients. Currently, a single-site and multi-site trials are underway to further explore the potential of quetiapine for the treatment of alcohol dependence.

Ondansetron is a serotonin-3 (5-HT3) receptor antagonist with support from preclinical and human laboratory studies for the treatment of alcohol dependence. Three double-blind, placebo-controlled trials demonstrated improvements in drinking outcomes, particularly for those with Babor Type B alcohol dependence.

SUMMARY

Charles O'Brien has described naltrexone as an optimal medication for the treatment of alcohol dependence because it has been shown to be efficacious, highly specific to opiate receptors, with no abuse potential, and a tolerable side-effect profile. This chapter reviews the latest literature on the use of opiate antagonists for the treatment of alcohol dependence, focusing

primarily on naltrexone. Alcohol-use disorders cause substantial morbidity and mortality. Alcohol is the third leading cause of preventable death in the United States according to the Centers for Disease Control and Prevention. Lifetime prevalence of alcohol dependence is higher in men (17.4%) than women (8.0%); however, only 26% of those diagnosed with lifetime alcohol dependence have received some type of treatment (professional or self-help groups).

One goal of the authors of this chapter was to promote an understanding of alcohol dependence as a chronic medical illness amenable to frontline treatment by primary care and specialty clinicians. Surprisingly, few clinicians have utilized medications to treat alcohol dependence, despite the fact that there are four medications approved by the FDA. Oral naltrexone (50 mg daily) was approved in 1994 and a long-acting, injectable formulation (380 mg monthly) was approved in 2006. Injectable naltrexone was designed to improve medication adherence, minimize fluctuations in plasma levels, increase bioavailability, and minimize side effects. The two other FDA-approved medications are disulfiram and acamprosate, both of which are oral formulations requiring daily pill taking.

Alcohol affects all of the major neurotransmitter systems of the brain through complex, direct, or indirect processes. Alcohol and other drugs of abuse facilitate dopamine release in the reward regions of the brain. Alcohol impacts the dopamine system through the opioid system. Given this, it was logical to want to test medications with opioid-antagonist properties as treatments of alcohol dependence. Naltrexone is an antagonist at the mu, delta, and kappa opioid receptors and was initially investigated for the treatment of opiate dependence.

Another opioid antagonist, nalmefene, has been studied extensively. Despite its use in other countries, there is currently insufficient clinical evidence to support its use in the United States. Overall, 50 randomized, controlled trials with nearly 7000 alcohol-dependent patients have been published examining the efficacy of opioid antagonists for treating alcohol dependence. While not all studies have demonstrated an advantage of these medications compared with placebo, the results of several reviews (including two recently published meta-analyses) clearly indicate the superiority of naltrexone over placebo in reducing relapse rates to heavy drinking and other drinking indices.

The population of alcohol-dependent patients represents considerable diversity in etiology, presentation of the illness, and response to treatment. There is a rich tradition of attempts to identify more homogeneous subgroups of alcohol dependence and match treatments to patient characteristics. A promising line of research has focused on genetic factors that may

impact naltrexone-treatment response. Individuals with one or two copies of the Asp40 allele who took naltrexone demonstrated a 3.5 times better response in relapse to heavy drinking than those homozygous to the Asn40 allele. Other promising typologies have been proposed by Babor, Cloninger, Lesch, and Mann among others.

To address the limited response to any treatment by many alcohol-dependent patients and to address cooccurring illnesses, numerous studies have combined naltrexone with other medications. Acamprosate has been added to naltrexone in two clinical trials a single-site trial and the multi-site COMBINE study. Although safe and well tolerated, there is insufficient evidence to date to recommend adding acamprosate to naltrexone for the treatment of alcohol dependence. Higher doses of naltrexone with and without disulfiram have shown some promise for the treatment of alcohol dependence and co-occurring cocaine dependence. Combining sertraline with naltrexone was efficacious for the treatment of alcohol dependence and co-occurring depression in one clinical trial. Finally, topiramate, baclofen, quetiapine, and ondansetron are under investigation for the treatment of alcohol dependence and may be targets for combination therapies with naltrexone.

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SEE ALSO

Evaluating Treatment Efficacy, Evidence-Based Treatment, Improving Medication Use in Addictions Treatment, Cognitive Behavioral Therapies, Multisystemic Therapy for Adolescent Substance Use, Acamprosate for Alcohol Dependence, Disulfiram for Alcohol and Other Drug Use, Anticonvulsant Medications for the Treatment of Alcohol Dependence, The Treatment of Depressed Alcoholics

List of Abbreviations

CBI combined behavioral intervention CBT cognitive behavioral therapy

COMBINE Combined Pharmacotherapies and Behavioral

Interventions

GABA gamma-aminobutyric acid MM Medical Management

SSRI selective serotonin reuptake inhibitor

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Relevant Websites

http://www.niaaa.nih.gov – National Institute on Alcohol Abuse and Alcoholism.

http://www.nida.nih.gov - National Institute on Drug Abuse. http://www.rsoa.org - Research Society on Alcoholism.

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Acamprosate for Alcohol Dependence

Barbara J. Mason, Amanda E. Higley
The Scripps Research Institute, La Jolla, CA, USA

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ALCOHOL DEPENDENCE

Alcohol-use disorders, which include both alcohol abuse and dependence, make up one of the most prevalent categories of substance-use disorders affecting more than two billion people worldwide. The Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM-IV) characterizes alcohol dependence as a maladaptive pattern of drinking leading to clinically significant impairment, as manifested by a compulsion to drink, a lack of control over the amount of alcohol consumed, and continued drinking despite a realization of the problems associated with it. Alcohol dependence is a chronic relapsing disorder that has several stages that contribute to excessive drinking and dependence. Chronic heavy alcohol use can drive the neuroadaptive changes in stress and reward pathways associated with dependence and the resulting negative affective states and alcohol craving when alcohol use is discontinued. These latter symptoms comprise a syndrome referred to as protracted abstinence.

Protracted abstinence is a state that involves symptoms of anxiety, irritability, hostility, dysphoria, insomnia, fatigue, and craving and is hypothesized to be driven by dysregulation in stress and reward systems in the central nervous system (CNS) that persist long past acute withdrawal from alcohol. Clinical literature has indicated that protracted abstinence symptoms of craving, negative affect, and sleep disturbances are strongly correlated with relapse to compulsive drinking. For example, one study found that 94% of alcohol-dependent subjects experienced anxiety following cessation of drinking, and 82% of these patients reported an alleviation of this symptom after alcohol use. Relapse, or the return to alcohol abuse following periods of abstinence, is one of the principle characteristics of dependence on alcohol. Given that one of the most challenging aspects of recovering from alcohol dependence is to not relapse to heavy drinking after acute withdrawal, a recent Betty Ford consensus panel identified complete abstinence, as opposed to "controlled drinking," as the most reliable way for dependent individuals to avoid relapse and its associated problems.

NEUROBIOLOGY OF ALCOHOL DEPENDENCE AND PROTRACTED ABSTINENCE

Neurobiological approaches to alcohol dependence have suggested that it develops in a process of homeostatic adaptation to chronic high doses of alcohol that increases the set point for reward. The process is thought to include several neurotransmitter systems including gamma-aminobutyric acid (GABA) which is involved primarily with protective inhibitory effects and glutamate which is involved primarily with endogenous excitability. These neurotransmitter systems modulate internal states associated with positive and negative affect, states which are implicated in clinical vulnerability to relapse and protracted abstinence. The neural substrates and neuropharmacological mechanisms for the negative motivational effects of withdrawal from alcohol may involve not only disruption of the same neural systems implicated in the positive reinforcing effects of alcohol, but also recruitment of brain stress systems. During the withdrawal/negative affect stage, negative reinforcement mechanisms are in effect rather than positive reinforcement mechanisms. As such, individuals will often take the addictive substance to relieve protracted withdrawal states such as anxiety, irritability, or dysphoria, or to self-medicate the negative affect or general malaise. Acute withdrawal from alcohol dependence includes decreased dopaminergic activity, activated glutamatergic systems, an activated pituitary adrenal stress response, and activated amygdala corticotrophin-releasing factor (CRF). However, repeated cycles of relapse and withdrawal lead to a blunted pituitary adrenal response and a sensitized extrahypothalamic CRF stress system response in the amygdala. One goal of medications development for alcohol dependence is to reverse or compensate for such pathological effects.

A critical issue in the development of treatments for alcohol dependence is that relevant targets be based on an empirical understanding of the neurobiology of dependence. There is a substantial need for discovering innovative ways to provide more information on the neurobiology of alcohol dependence as well as to discover more effective pharmacotherapies for alcohol dependence.

MEDICATIONS TO TREAT ALCOHOL DEPENDENCE

Three medications are currently approved for the treatment of alcohol dependence – disulfiram,

naltrexone, and acamprosate. The first two medications, disulfiram and naltrexone, attempt to reduce pathological alcohol use by reducing the rewarding value of alcohol. Both drugs, however, have been characterized by problems with high rates of noncompliance and a return to pathological drinking when the drug is discontinued. Current research indicates that acamprosate has a unique mechanism of action, which may have implications for its therapeutic use. In contrast to disulfiram, which causes aversive behavior through negative physical effects, or naltrexone, which tempers the pleasurable effects of alcohol, acamprosate acts to normalize dysregulated brain systems caused by chronic alcohol use and withdrawal thereby decreasing an alcoholic's "need" to drink.

OVERVIEW OF ACAMPROSATE

Acamprosate is a safe and well-tolerated pharmacotherapy for alcohol dependence that has been studied in numerous clinical trials worldwide. Its safety and efficacy have been evaluated in more than 6500 outpatients participating in 23 double-blind, placebocontrolled clinical trials conducted in 15 countries. It has been used to treat alcohol dependence in over 1.5 million patients since its introduction in Europe in 1989 and is currently available in most European and North American countries, Australia, and parts of South America, Asia, and Africa. A recent survey of pharmacies found that acamprosate is now the most widely prescribed therapeutic agent for the treatment of alcoholism in the United States. It is available as a 333 mg tablet, and the recommended dosage regimen is two 333 mg tablets taken three times a day which may be prescribed in a blistercard. Clinical trials have typically shown that acamprosate is effective in maintaining abstinence in recently detoxified patients, especially when patients are motivated to be abstinent. Overall, acamprosate has been consistently associated with greater beneficial effects on measures of alcohol abstinence compared with placebo. Specifically, patients treated with acamprosate achieve greater rates of complete abstinence, longer times to first drink and/ or increased duration of cumulative abstinence when compared with placebo.

Acamprosate is a synthetic taurine analog that acts centrally to restore the normal activity of glutamatergic neurotransmission altered by chronic alcohol exposure. Its mechanism of action involves normalizing the dysregulation of brain *N*-methyl-D-aspartic acid (NMDA)-mediated glutamatergic neurotransmission that occurs in alcohol dependence, thus attenuating one of the physiological mechanisms that may prompt drinking relapse.

MECHANISM OF ACTION OF ACAMPROSATE

Acamprosate is an analog of amino acid neurotransmitters such as taurine and homocysteic acid which have modulatory effects on brain NMDA receptors. Recent evidence has demonstrated that acamprosate binds to a specific spermidine-sensitive site that modulates the NMDA receptor in a complex way acting as a "partial co-agonist" at the NMDA receptor, such that low concentrations enhance activation when receptor activity is low, and high concentrations inhibit activation when receptor activity is high. In other words, at low levels of endogenous activity, the drug works as an agonist, whereas at high levels of endogenous activity, the drug works like an antagonist because it "competes" with the endogenous ligand. Thus, partial agonists serve a more modulatory role than a pure agonist or antagonist would. This may be particularly relevant to the success of acamprosate as a pharmacotherapy given that chronic exposure to ethanol results in an upregulation of NMDA receptors and an upregulation in the density of voltage-dependent calcium channels such that abstinence from alcohol induces a surge of excitatory neurotransmitters such as glutamate, which in turn activates the NMDA receptors. These alcoholrelated changes in NMDA receptors are posited to contribute to the symptoms associated with protracted abstinence, such as craving and disturbances in sleep and mood. Conversely, acamprosate promotes the release of taurine in the brain. Taurine is a major inhibitory neuromodulator/neurotransmitter and an increase in taurine availability contributes to a decrease in the earlier-described hyperexcitability. Therefore, it has been hypothesized that acamprosate may promote abstinence by minimizing or negating some of the physiological changes produced by chronic heavy ethanol exposure and withdrawal that may underlie symptoms associated with relapse, such as craving, anxiety, and insomnia. Further support for this hypothesis is provided by polysomnography studies that found acamprosate reversed alcohol-related changes in sleep architecture in humans.

CLINICAL EFFICACY OF ACAMPROSATE

The safety and clinical efficacy of acamprosate have been studied in more than 6500 alcohol-dependent outpatients in 23 randomized, placebo-controlled trials conducted in Europe, Asia, North and South America, and Australia. Efficacy measures for the majority of the studies were the rate of complete abstinence (defined as zero drinks during the entire study) and the

percentage of abstinent days over the study duration. An increase in abstinence rates with acamprosate was confirmed in the majority of studies (18 of the 23 trials reported positive outcomes for acamprosate relative to placebo) as well as in meta-analyses of acamprosate clinical trials. All five meta-analyses concluded that abstinence rates were significantly higher in acamprosatetreated patients than in those treated with placebo with small to moderate, but significant effects in maintaining abstinence in alcohol-dependent patients. A recent meta-analysis found a relative benefit of acamprosate for abstinence rates to be 1.33 at 3 months, 1.50 at 6 months, and 1.95 at 12 months. Compliance rates tend to average around 85% across studies with a meta-analysis reporting a significant effect of acamprosate on compliance rates relative to placebo. Treatment durations of randomized trials ranged from 2 months to 1 year with 13 of 23 trials being greater than or equal to 6 months in duration. Patients typically underwent inpatient detoxification prior to randomization. However, the two US studies reported that only 2.3 and 7.7% of patients received inpatient detoxification prior to randomization. Most studies required abstinence at baseline for approximately 5 days (range of 3–32 days), with the exception of three studies, conducted in the United Kingdom, the United States, and Korea, that did not have an abstinence requirement at initiation of study medication. Based on the postdetoxification "normalizing" mechanism of action described earlier, it is not surprising that the three studies without an abstinent requirement at baseline did not show an effect of acamprosate on abstinence in the Intention-To-Treat (ITT) populations. Acamprosate is not indicated for the induction of abstinence but rather for the maintenance of abstinence in alcohol-dependent patients who have been withdrawn from alcohol. In addition, post hoc analyses of the US study data that controlled for baseline differences in outcome-related variables, including goal of total abstinence and stage of readiness to change, showed a significantly higher percentage of abstinent days with acamprosate versus placebo in the ITT population (58.2%, 2 g day acamprosate; 62.7%, 3 g day acamprosate; 52.3%, placebo). Furthermore, even greater treatment effects were observed in the subgroup of 241 patients having a baseline goal of abstinence (70.0%, 2 g day acamprosate; 72.5%, 3 g day acamprosate; 58.1%, placebo), suggesting that motivation to be abstinent may be an important determinant of treatment success with acamprosate.

Two randomized, controlled trials initiated doubleblind treatment simultaneously with the start of detoxification to determine if, relative to placebo, acamprosate would provide an advantage in reducing withdrawal symptoms or the dose of anxiolytic required to manage withdrawal symptoms. No effect of acamprosate on parameters relevant to acute withdrawal was found. However, the safety of the combination was supported, with the advantage that patients had achieved a steady-state dose of acamprosate at the conclusion of inpatient detoxification.

In addition to the maintenance of abstinence, clinical evidence suggests that acamprosate may help patients regain abstinence after a relapse. Pooled data from three European trials evaluated 587 patients who relapsed to drinking; 13% of relapsed patients treated with acamprosate were able to regain and maintain abstinence through study end compared to 5% with placebo. A post hoc analysis of 15 acamprosate trials showed that compared to placebo, continued acamprosate treatment during relapse episodes significantly decreased the quantity and frequency of alcohol consumption. Therefore, continued acamprosate treatment during periods of relapse may reduce the severity and duration of relapse.

A number of posttreatment follow-up studies have shown the effects of acamprosate to be sustained for periods of up to 1 year after the last dose. At the end of the 48-week posttreatment follow-up period to a 48-week trial conducted in Germany, 39.9% of the remaining patients who had been treated with acamprosate remained abstinent, compared to 17.3% of the placebo-treated patients. Similarly, a significant difference in complete abstinence at the end of a 52-week post-treatment follow-up period was also reported following a 52-week randomized, controlled trial in Austria. It is possible that the 1-year length of treatment in these trials may have had some bearing on the robustness of post-treatment effects.

Clinical histories of alcohol-dependent adults typically show age of onset of alcohol abuse to occur in the teenage years, underscoring the importance of early intervention for alcoholic adolescents. A prospective, 3-month randomized, controlled trial was conducted in 26 adolescents with alcohol dependence. Acamprosate (1332 mg day) significantly increased the percentage of abstinent days on study relative to placebo and was well tolerated in this cohort of alcohol-dependent adolescents.

ACAMPROSATE EFFECTS ON SLEEP

Sleep disturbances are another challenge often faced by recently detoxified patients and have been shown to persist for up through 4 years of complete abstinence. These alcohol-related alterations in sleep architecture have been shown to be a strong predictor of relapse, since recovering individuals often self-medicate with alcohol to improve sleep. The sleep disturbances associated with alcohol dependence include prolonged sleep onset latency, decreased sleep efficiency, shorter sleep duration, and reduced amounts of slow wave sleep when compared to healthy controls. Several recent studies suggest that acamprosate may normalize the underlying neurobiological mechanisms of sleep that are disrupted by alcohol. For example, compared to placebo, acamprosate demonstrated clinically significant improvements in polysomnographic parameters of sleep in alcohol-dependent individuals during the 2 weeks following alcohol withdrawal. There are no prospective assessments of sleep in the clinical trials reported to date. However, adverse events assessments from these studies show that acamprosate does not disrupt sleep.

SAFETY AND TOLERABILITY OF ACAMPROSATE

The safety profile of acamprosate appears quite favorable. The adverse event most commonly reported more frequently in acamprosate-treated patients with respect to placebo-treated patients is diarrhea (16 versus 10%). It is typically depicted as transient and of mild or moderate severity. Patients taking concomitant medications had similar adverse events in acamprosate and placebo groups, as did acamprosate-treated patients with versus without liver disease. Notably, concomitant use of alcohol has no effect on the pharmacokinetics of acamprosate, suggesting patients can safely continue acamprosate through a period of relapse. Acamprosate has not been found to affect vital signs or clinical laboratory values. No differences are found between acamprosate and placebo groups in the rate of discontinuations due to adverse events (8% of acamprosate versus 6% of placebo patients discontinued from trials of 6-month duration; 7% of patients in both groups discontinued from trials of duration greater than 6 months).

Since its approval in Europe in 1989, there have been no identified health risks of acamprosate use in more than 1.5 million patients. Additionally, the only adverse symptom reported following acute overdose of acamprosate was diarrhea, with no reports of hypercalcemia. A risk of hypercalcemia should be considered in chronic overdose only. Acamprosate is assigned a Category C labeling in pregnancy. The animal reproduction studies demonstrated some teratogenic effects in rat fetuses at doses comparable to the human dose and in rabbit fetuses at doses approximately three times the human dose. In the rat, these malformations included hydronephrosis, malformed iris, retinal dysplasia, and retroesophageal subclavian artery; hydronephrosis was also observed in the rabbit. To date, there are no adequate well-controlled studies of acamprosate use in pregnant women; therefore, acamprosate should only be used FURTHER READING 389

during pregnancy if the potential benefit justifies the potential risk to the fetus.

DRUG-DRUG INTERACTIONS

Acamprosate is not metabolized by the liver and is not likely to cause clinically significant pharmacokinetic drug-drug interactions through inhibition of the cytochrome P450 enzyme system. When combined with diazepam, disulfiram or alcohol, the pharmacokinetic profile of acamprosate was not modified. This lack of interaction is important due to the potential concomitant use of these drugs in patients with alcohol dependence. In addition, acamprosate does not influence the kinetics of imipramine or its metabolite desipramine. Results of pharmacokinetic studies in humans reported that co-administration of naltrexone increased the rate and extent of acamprosate absorption. However, a complete absence of negative interactions on measures of safety and cognitive function suggests that no adjustment in acamprosate dosage is required when co-administered with naltrexone. To date, no pharmacokinetic studies of acamprosate have been conducted in patients who are receiving renally excreted medications, such as lithium, or drugs that bind to the NMDA receptors; thus, a potential for drug-drug interactions of such combinations remains unknown.

CONCLUDING REMARKS

The major therapeutic challenge to successful management of alcohol dependence is the maintenance of abstinence and prevention of drinking relapse. Prevention of relapse has the potential to reduce hospitalization and rehabilitation costs, as well as alcoholrelated loss of productivity in the workplace. Over the past two decades, numerous well-controlled clinical trials have found that acamprosate, in combination with psychosocial support, is a safe and well-accepted therapy. Acamprosate has been demonstrated to increase abstinence rates and reduce the risk of return to drinking in alcohol-dependent patients significantly more than placebo across 18 of 23 randomized, placebo-controlled trials. Given its excellent safety record and the positive results of a majority of clinical trials, it is not surprising that it is now the most widely prescribed drug therapy in the treatment of alcoholism. Pharmacoeconomic studies both in Europe and in the United States have demonstrated the potential costsaving benefits of prescribing acamprosate as an adjunct to psychosocial support compared with nonpharmacological techniques alone. Based on these findings, it appears that acamprosate is an important advancement in the treatment of alcohol dependence.

Acamprosate can be viewed as a prototype of a neuromodulatory approach in the treatment of alcohol dependence. More specifically, earlier drugs used a punishment model (as in the case of disulfiram) or an antagonist approach to decrease the reinforcing value of alcohol (as in the case of naltrexone). Rather, acamprosate appears to work by ameliorating some key underlying changes in neurochemistry caused by chronic heavy alcohol intake and withdrawal, thus restoring homeostasis to those systems. Importantly, acamprosate's neuromodulatory (indirect) approach is associated with less serious side effects and superior compliance rates among patients relative to disulfiram and naltrexone. It is our opinion that the neuromodulatory approach exemplified by acamprosate will provide a heuristic framework for developing more efficient and effective pharmacotherapies for alcohol dependence.

SEE ALSO

International Policies to Reduce Alcohol Consumption and Related Harms, Naltrexone and Opioid Antagonists for Alcohol Dependence

List of Abbreviations

CRF corticotrophin-releasing factor ITT Intention-To-Treat NMDA N-methyl-D-aspartic acid

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Anticonvulsant Medications for the Treatment of Alcohol Dependence

Nassima Ait-Daoud

University of Virginia, Charlottesville, VA, USA

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INTRODUCTION

Considerable progress has been made in the understanding of the specific neurotransmitter systems and brain pathways involved in alcohol drinking. An important pathway that provides extensive neuromodulation to the reward pathway (the cortico-mesolimbic dopamine (CMDA)) is the excitatory glutaminergic system, which is correspondingly modulated by inhibitory inputs from gamma-aminobutyric acid (GABA) neurons. Chronic alcohol ingestion results in an increased sensitization of glutamate receptors and enhanced activity at voltage-sensitive calcium channels as well as reduced GABA-A (GABA_A) function. This has led to an increased scientific interest in the development of pharmacotherapy targeting these particular systems to avoid the direct postsynaptic blockage that is likely to lead to neuroadaptation. Repeated alcohol ingestion also leads to a process of neuronal "sensitization" which causes increased neurophysiological response with future use also known as kindling. This phenomenon resets a lower "trigger" for continued alcohol use. A pharmacological agent that would block this kindling phenomenon and prevent the summative effects of each drinking episode may interrupt this process of sensitization. Medications with antiglutaminergic and/or GABAergic function may have therapeutic potential for the treatment of alcohol dependence.

Anticonvulsant drugs by virtue of their sedative-like activity and nonaddictive property are ideal agents to consider for the treatment of acute alcohol withdrawal symptoms while transitioning care into an outpatient setting. In fact, anticonvulsants such as carbamazepine, gabapentin, and topiramate have been safely used in the treatment and prevention of alcohol withdrawal. Sleep disturbances are among the most common complaints of alcoholics during the protracted withdrawal phase. Other withdrawal symptoms include anxiety, dysphoria, and irritability. These symptoms may last for weeks to months after the cessation of drinking and increase the risk for alcohol relapse. It is possible that the continuation of agents that were effective in the treatment of acute withdrawal into this protracted withdrawal period could alleviate some of these symptoms and lead to lower relapse rates. Given the cross tolerance that alcoholics often have to sedative/hypnotic GABAergic drugs, the use of anticonvulsant medication offers the advantages of safety, mood stabilization, and lack of addictive properties that make them a significant tool to use in the treatment for alcohol dependence.

In this review, we focus on the anticonvulsant agents that have been evaluated for the treatment of alcohol dependence with an overview of their mechanism of actions.

PHARMACOLOGICAL TREATMENTS FOR ALCOHOL DEPENDENCE

Carbamazepine

Among anticonvulsant agents evaluated for efficacy in alcohol dependence, some studies have found that carbamazepine treatment might reduce drinks per drinking day and time to first drink after withdrawal. The mechanism of action of carbamazepine remains unknown, although data from rats and mice suggest that it is chemically related to the tricyclic antidepressants and it appears to exert its anticonvulsant properties by reducing the polysynaptic response and blocking post-tetanic potentiation. The rationale for carbamazepine use in treating alcohol dependence is based on its potential to suppress withdrawal-induced kindling in limbic structures and to affect improvement in symptoms such as sleep disturbances, anxiety, and mood instability, which are common in the protracted withdrawal syndrome. However, the exact mechanism by which carbamazepine might reduce alcohol consumption remains unknown

A study by Kranzler and colleagues in 1995 evaluated the efficacy of carbamazepine in a 12-week, placebocontrolled trial of relapse prevention in 40 cocainedependent male subjects. Assessments of alcohol use and alcohol history were conducted at study entry, at the end of the 12-week treatment period, and at 3 months posttreatment. Assessment tools included the addiction severity index and the Timeline Followback assessment method. The results of the study showed that carbamazepine did not affect cocaine use but the number of days of alcohol use declined in both the carbamazepine- and placebo-treated groups. There were no between-group differences in either measure during the active treatment period. At 3 months posttreatment, the placebo-treated group resumed their pretreatment severity of drinking while the carbamazepine-treated subjects maintained a lower drinking frequency. The addiction severity index alcohol score increased slightly for placebo-treated subjects during follow-up and was consistent with the finding that placebo-treated subjects drank on significantly more days during the posttreatment period than did the carbamazepine-treated subjects. It is important to note that the participants were not alcohol-dependent subjects and, therefore, the effect occurred in the context of mild to moderate alcohol drinking and the reduction in drinking days among carbamazepine-treated subjects occurred only during the posttreatment so the clinical significance of these results is unclear.

In another study conducted by Mueller and colleagues in 1997, 29 subjects were enrolled in a 12-month doubleblind placebo-controlled pilot study evaluating the efficacy of carbamazepine for the treatment of alcohol dependence in recently detoxified alcoholics. Assessments were conducted at baseline and bimonthly for a 12-month follow-up period. Subjects were contacted monthly by phone and twice a month in person for 12 months after discharge. Due to the large drop out rate (46% of the treatment group) after the first 120 days, outcome measures were evaluated at 120 days, the time point at which at least 50% of subjects reported taking the medication. Despite the small sample size at 120 days, survival analysis revealed that during the first few months, carbamazepine showed a nonsignificant trend toward increasing mean time to first drink (P = 0.23) and a significant reduction in time to return to heavy drinking (>5 drinks day⁻¹ for men and >4 drinks day⁻¹ for women) compared with placebo (P = 0.04). Mueller and colleagues proposed that their findings were consistent with the kindling model of alcoholism. The kindling model suggests that the repeated withdrawal episodes occurring in alcohol dependence result in long-lasting neuronal and neurochemical changes in the brain that ultimately alter the response to ethanol, so that successive withdrawal episodes are increasingly severe and, therefore, rendering any attempt to quit drinking even more difficult. Agents such as carbamazepine, which might interrupt the kindling process, would prevent the summative effects of each drinking episode, so its chronic administration would reduce more extensive or uncontrolled heavy use once drinking had occurred, as was demonstrated in this study.

Adverse effects of carbamazepine, particularly in the initial stages of therapy, include dizziness, drowsiness, ataxia, and gastrointestinal disturbances, such as nausea and vomiting. Carbamazepine should be dispensed with caution to patients with a history of blood disorders or with cardiac, hepatic, or renal disease. Photosensitivity reactions have been reported and transient leucopenia is common and usually resolves with continued therapy. However, in rare cases, blood disorders including agranulocytosis, aplastic anemia, thrombocytopenia, and purpura have been reported. Carbamazepine is metabolized by CYP3A4, therefore interactions with other drugs that induce, inhibit, or

compete for CYP3A4 are relatively common, which may limit its use.

Valproate

Valproate sodium is an antiepileptic agent with unknown therapeutic mechanism of action, although it is believed to exert its effect by increasing the concentrations of GABA in the brain.

In a small (N = 16) pilot study conducted by Longo and colleagues in 2002 comparing the safety and efficacy of the anticonvulsant agent valproate (divalproex sodium) with standard benzodiazepine detoxification for alcohol withdrawal and relapse prevention, 16 alcohol-dependent patients were randomized to either standard benzodiazepine detoxification, valproate detoxification, or valproate detoxification plus 6-week maintenance. The results showed that at the 6-week follow-up, 4 out of 5 patients (80%) in the valproate maintenance group were completely abstinent compared with the detoxification-alone group (4 out of 11 patients, or 45%), and none relapsed to daily or heavy drinking. Despite the small sample size, this study indicated that valproate might have utility as a postdetoxification relapse-prevention agent.

Another study by Brady and colleagues in 2002 provided additional support for the use of valproate as an agent for alcohol-relapse prevention. This was a 12-week, double-blind, placebo-controlled trial of divalproex in 31 alcohol-dependent subjects. The study was based on the idea that the continued use of an agent, such as divalproex, which is effective in alcohol withdrawal, might be effective in treating protractedabstinence syndrome. Drinking decreased significantly in both the placebo and the active medication groups. However, in the divalproex group a significantly smaller percentage of individuals relapsed to heavy drinking, but there were no significant differences in other alcohol-related outcomes. There was a significantly greater reduction in the irritability scale of the anger, irritability, and aggression questionnaire and a trend toward greater reduction in indirect hostility subscales of the Buss-Durkee hostility index in the active medication group compared with placebo (P = 0.009).

More recently, Salloum and colleagues studied in 2005 the efficacy of valproate in the treatment of bipolar alcohol-dependent patients in a 24-week, double-blind, placebo-controlled, randomized parallel-group trial. Fifty-nine participants who were alcohol dependent, actively drinking in the past month and had a concurrent acute episode of bipolar 1 disorder (manic, mixed, or depressed) were enrolled in the study. All participants received their usual treatment, including lithium carbonate and were randomized to receive valproate or placebo as adjunctive therapy. The valproate group

had a significantly lower proportion of heavy drinking days (HDDs; P=0.02) and a trend toward fewer drinks per HDD (P=0.055) than the placebo group. Furthermore, higher valproate serum concentration significantly correlated with improved alcohol use outcomes. In summary, valproate might be a promising medication for treating alcohol-dependent patients with comorbid bipolar disorder.

Valproate is usually well tolerated with most common adverse events including somnolence, headache, nausea vomiting, hair loss, rash, and thrombocytopenia: there is an FDA black box warning for hepatotoxicity, teratogenicity, and pancreatitis linked to the use of valproate. Hyperammonemia has been reported in association with valproate therapy and may be present despite normal liver function tests. Most adverse events are dose related and require close monitoring.

Topiramate

Topiramate exerts its anticonvulsant effects through blockade of voltage-dependent Na $^+$ and L-type high voltage-gated Ca $^{++}$ channels and facilitation of GABAergic neurotransmission via GABAa; additionally, it inhibits the activity of the $\alpha\text{-amino-3-hydroxy-5-methylisoxazole-4-propionic acid (AMPA) and kainate subtypes of glutamate receptors as well as carbonic anhydrase (CA)-II and CA-IV, and enhances <math display="inline">K^+$ conductance.

The rationale for topiramate as treatment for alcohol dependence is based on its neurochemical activity. Topiramate might antagonize alcohol's reinforcing effects by suppressing the dopamine release in the midbrain ventral tegmental area (VTA) via facilitation of GABA activity and inhibition of glutamate function. The midbrain VTA dopamine pathways that project to the nucleus accumbens are believed to mediate the craving and rewarding effects associated with alcohol use. In chronic alcoholics who have increased hippocampal and cortical glutamate binding sites, dopaminergic neurotransmission might be facilitated and brain reward enhanced. Thus, the rationale for topiramate as treatment for alcohol dependence might stem from an ability to increase GABAergic activity and suppress CMDA activity after alcohol intake.

Johnson and colleagues tested this hypothesis in 2003 in a randomized, double-blind, 12-week controlled proof-of-concept study. One hundred and fifty alcoholdependent men and women were enrolled in this study. Topiramate and placebo were both administered on an escalating schedule beginning at 25 mg day⁻¹ at week 1 and increased by 50 mg day⁻¹ each week until a dose of 300 mg day⁻¹ was reached at week 8. The 300 mg day⁻¹ dose was then maintained from week 8 to 12. Participants

were encouraged to attempt drinking cessation but were not required to be abstinent in order to participate. All participants received weekly, standardized, brief behavioral medication compliance enhancement treatment focusing on medication and visit compliance only. At the end of the 12-week course of treatment, both the topiramate and placebo groups showed lower self-reported and objective drinking measures than at baseline. Over the 12-week treatment period, topiramate treatment was significantly more effective than placebo in improving self-reported drinking outcomes, including drinks per day (P = 0.000 6), drinks per drinking day (P = 0.000 9), percentage of HDDs (P = 0.000 3), and percentage of days abstinent (P = 0.000 3). Additionally, topiramate treatment resulted in a greater reduction in log plasma gamma-glutamyl transferase ratio, an objective measure of drinking (P = 0.004 6). The significant differences between topiramate and placebo on self-reported drinking measures were apparent at week 6 while the dose was about 200 mg, while differences in objective measures were observed at week 8. The probability of non-abstinence decreased over time in the topiramatetreated group and was significantly lower than in the placebo group (P = 0.003). Topiramate treatment also produced a significantly greater reduction in subscale scores in the Obsessive Compulsive Drinking Scale (OCDS) craving factors, including drinking obsessions (P = 0.003 1), automaticity of drinking (P = 0.001 0), and interference due to drinking (P = 0.000 3), compared with placebo. The alcohol consumption subscale was not included in the analysis due to its colinearity with the other self-reported drinking measure, the Timeline Followback. There was no evidence for a differential response between early-onset and late-onset alcoholics on any of the six primary outcome measures.

The topiramate-treated group reported more frequent adverse events, including dizziness (topiramate versus placebo, 28.0% versus 10.7%, P = 0.007), paresthesia (topiramate versus placebo, 57.3% versus 18.7%, P < 0.001), psychomotor slowing (topiramate versus placebo, 26.7% versus 12.0%, P = 0.023), memory impairment (topiramate versus placebo, 18.7% versus 5.3%, P = 0.012), and weight loss (topiramate versus placebo, 54.7% versus 26.7%, P = 0.001). Approximately 4% of topiramate-treated subjects and 7% of those in the placebo group discontinued their participation in the study due to adverse events. This study suggests a possible role of topiramate in reducing drinking and promoting abstinence in alcohol-dependent adults. Topiramate treatment had robust effects on self-reported drinking outcomes that were supported by decreases in an objective measure of drinking. Additionally, topiramate treatment significantly reduced craving as measured by the drinking obsessions, automaticity of drinking, and interference due to drinking subscales of the OCDS. Due to the fact that the craving and drinking reductions occurred contemporaneously, it is tempting to speculate that an important mechanism of action for topiramate is as an anti-craving medication. Nevertheless, it cannot be discounted that it was simply the marked reduction in drinking that occasioned the decrease in craving.

The pharmacokinetic profile of topiramate offers advantages over traditional anticonvulsants such as carbamazepine. Absorption of orally administered topiramate tablets is rapid and nearly complete, with peak plasma levels reached within 2 h of dosing following a 400-mg oral dose. Its pharmacokinetic profile is linear across the range of therapeutic doses. Since the extent to which topiramate is absorbed is not affected by its administration with food, it can be taken either as tablets or as sprinkled granules with meals without affecting plasma levels.

Due to its poor binding to plasma proteins (9–17%), topiramate is unlikely to be displaced by highly protein-bound drugs, thus limiting the likelihood for its interaction with other drugs. Furthermore, because topiramate is eliminated predominantly in the urine, with an elimination half-life of approximately 21 h, and is not metabolized extensively in humans (~20%), topiramate will not exacerbate the hepatic-enzyme-inducing properties of alcohol.

In a 14-week, double-blind, randomized, placebocontrolled multisite trial, 378 alcohol-dependent men and women aged 18-65 years were enrolled. Participants were seen weekly for 14 weeks and received weekly compliance enhancement intervention. Effects of topiramate up to 300 mg per day versus placebo were evaluated on drinking outcomes. Treating all dropouts as relapse to baseline, topiramate was superior to placebo at reducing percent HDDs from baseline to week 14 - mean difference of 8.44, 95% confidence interval 3.07-13.80 (P=0.002). Prespecified mixed model analysis also showed that topiramate compared with placebo decreased percent HDDs - mean difference = 16.19, 95% confidence interval 10.79–21.60 $(P < 0.000 \ 1)$ – and all other drinking outcomes (P < 0.000 1 for all comparisons). Adverse events more common with topiramate versus placebo included: paresthesia – 50.8% versus 10.6%; taste perversion – 23.0% versus 4.8%; anorexia – 19.7% versus 6.9%; and difficulty with concentration – 14.8% versus 3.2%.

Another study has shown that topiramate may be more effective than oral naltrexone for treatment of alcohol dependence. A 6-month naturalistic, randomized, open-label, trial of topiramate 200 mg versus naltrexone 50 mg, with assessments at enrollment and after 3 and 6 months of treatment was conducted by Flores and colleagues in 2008. One hundred and two alcohol-dependent patients were enrolled in the study.

Both topiramate and naltrexone groups received psychological relapse prevention therapy. At the end of the trial both groups showed substantial reduction in their drinking. Topiramate was better at reducing alcohol-related cravings throughout the study and at the 6-month evaluation, patients taking topiramate had significantly lower scores on the OCDS (all subscales) and Europe Addiction Severity Index (EuropASI) for medical, alcohol, family, social, and psychiatric subscales. More patients taking topiramate remained in the abstinence and the moderate drinking groups.

These results provide strong evidence that topiramate is efficacious for the treatment of alcohol dependence even when compared with an FDA approved drug. Cognitive side effects represent the biggest barrier to its widespread use. Most adverse events could be minimized using a slow titration. The importance of slow titration of topiramate is demonstrated by the small clinical trial by Alapati in 1999. This study reviewed the side-effect profile of topiramate at two starting doses as adjunctive therapy for partial seizures in 84 adult patients. Forty-two patients were started on a 25-mg dose of topiramate with a dose escalation of 25 mg week⁻¹, and 42 patients received an initial dose of 50 mg with a dose escalation of 50 mg week⁻¹. The observed adverse events included neurocognitive effects, such as psychomotor slowing, word-finding difficulty, and speech or language difficulties, and psychiatric side effects, such as psychosis or altered perception, depression, agitation, and altered behavior. The incidence of these side effects, as well as the rate of discontinuation, was lower in the group who were started on the 25-mg dose and titrated slowly than in those who initially received 50 mg day⁻¹.

Levetiracetam

Levetiracetam is an anticonvulsant that binds to a synaptic vesicle protein, SV2A, which is believed to impede nerve conduction across synapses. It therefore inhibits burst firing without affecting normal neuronal excitability, which suggests that it may selectively prevent hypersynchronization of epileptiform burst firing and propagation of seizure activity. On a biochemical level, levetiracetam could block ethanol-seeking behavior by inhibiting α -amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid (AMPA) receptors, and reduce excitability associated with alcohol withdrawal by attenuating the negative allosteric effects of zinc and f3-carboline on brain GABA and glycine receptors.

Evidence supporting the clinical efficacy of levetiracetam for alcohol dependence has been suggested in three small, open-label preliminary studies. In a study reported by Mariani and Levin in 2008, three patients with alcohol dependence and anxiety disorders were treated with levetiracetam IR: 1000–1500 mg twice daily. The percentage of HDDs and anxiety scores decreased by at least 50% for each of the three patients over the 6–8 weeks of the trial. In another study conducted by Krebs and colleagues in 2006, 15 patients seeking treatment for alcohol detoxification received 2000 mg of levetiracetam IR per day. Levetiracetam was found safe and efficacious in the treatment of alcohol withdrawal. In a more recent open-label pilot study by Sarid-Degal and colleagues in 2008 with the aim to assess the efficacy and safety of levetiracetam for the treatment of alcohol dependence, a maximal dose of 2000 mg was administered daily for 10 weeks to 20 alcohol-dependent subjects. Patients were titrated up to 1000 mg twice daily over a period of 3 weeks, and then maintained on a dose of 2000 mg daily for 7 weeks further. Of the 20 patients enrolled in the study 13 (65%) completed the full maintenance dose phase of the study. The number of standard drinks per day consumed by the 16 evaluable subjects decreased from approximately 5.3 at baseline, to approximately 3.0 at 2 weeks, to approximately 2.0 at the end of the 10-week treatment period. Alcohol craving (OCDS scores) declined significantly from baseline. There were no significant changes in any measures of sleep quality (Medical Outcomes Sleep Scale). Two subjects reported irritability and one subject reported sedation.

Double-blind randomized studies are needed to better assess the efficacy of levetiracetam for the treatment of alcohol dependence. The metabolism of levetiracetam is less complicated than older antiseizure medications, which makes it easier to use and better tolerated, and it is not likely to interact with other medicines. Levetiracetam has also been shown to cause less cognitive function impairment than topiramate which could make it a more acceptable drug amongst patients.

Zonisamide

Zonisamide is a sulfonamide anticonvulsant. Its exact mechanism of action is not known but it is believed that while zonisamide may be a carbonic anhydrase inhibitor like acetazolamide, its primary mechanisms of action might be blocking repetitive firing of sodium ion channels and reduction of T-type calcium channel currents. Another theory is that zonisamide binds allosterically to GABA receptors like benzodiazepines or may be inhibiting the uptake of the inhibitory neurotransmitter GABA while enhancing the uptake of the excitatory neurotransmitter glutamate. Zonisamide may have an effect similar to that of topiramate and, therefore, has been tested for similar indications including the treatment of alcohol dependence.

In an open-label trial, the efficacy of zonisamide was examined in 22 outpatients with a diagnosis of alcohol dependence. Zonisamide was started at a dose of 50 mg day⁻¹ and was titrated to a maximum dose of 300 mg day⁻¹. Alcohol craving and alcohol consumption were assessed at weeks 2, 4, 6, 8, 10, and 12. The concentration of gamma-glutamyl transferase was used as an indirect measure of alcohol consumption. Significant improvement was observed in the visual analog scale for craving severity scores, weekly drink consumption, and gamma-glutamyl transferase. Zonisamide was well tolerated, with only a dropout due to adverse events. In a 12-week, double-blind, placebocontrolled, pilot trial conducted by Arias and colleagues in 2010, 40 alcohol-dependent subjects were randomly assigned to receive either placebo or zonisamide. Zonisamide was initiated at a dosage of 100 mg day⁻¹, which was increased by 100 mg day⁻¹ every 2 weeks for 8 weeks to a maximum dosage of 500 mg day⁻¹. The medication was continued for 4 weeks at the target dosage and then tapered and discontinued. The primary outcomes were drinks per week, HDDs per week, and abstinent days per week, which were measured using the Timeline Follow Back method. There was a significant medication by treatment week interaction effect favoring the zonisamide group for HDDs (P = 0.012), drinks per week (P = 0.004), and alcohol urge scores (P = 0.006). There was not a significant effect on the number or rate of increase in abstinent days. There were no serious adverse events reported and zonisamide treatment was well tolerated.

These findings provide preliminary support for the use of zonisamide to treat alcohol dependence. It appears to be safe and well tolerated in this sample and associated with improvement in both alcohol craving and alcohol consumption. Efforts to replicate and extend these findings are needed with bigger sampler sizes. It will be of interest to study whether zonisamide is associated with improvement in withdrawal symptoms, sleep, and dysphoria that alcoholics often report when they attempt to stop or reduce their drinking. The most common side effects commonly seen in patients taking zonisamide include drowsiness, loss of appetite, dizziness, headache, nausea, and agitation/irritability.

SUMMARY AND CONCLUSIONS

Anticonvulsant medications are a new vista in medications-development efforts, not only for treating

alcohol dependence but also for alleviating alcohol withdrawal symptoms. Indeed, anticonvulsants appear useful both for treating the acute withdrawal symptoms and, once abstinence has been achieved, for preventing relapse by modulating post-cessation craving and affective disturbance. Obviously, this is an attractive pharmacological prospect as the use of a single medication that is efficacious at the various stages of treatment reduces the need for polypharmacy, facilitates the buildup of dosing levels early in treatment, and minimizes the potential for unexpected adverse events. Research specifically designed to determine the utility and feasibility of such an approach is needed. Furthermore, because of the potential utility of certain anticonvulsants (e.g. valproate) in treating other psychiatric disorders such as bipolar disorder, it is possible that their utility might also be extended to treating comorbid psychiatric disorders.

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List of Abbreviations

CMDA cortico-mesolimbic dopamine GABA gamma-aminobutyric acid HDD heavy drinking day

OCDS Obsessive Compulsive Drinking Scale

VTA ventral tegmental area

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Medications for Treatment of Marijuana Dependence

Gillinder Bedi, Ziva D. Cooper, Margaret Haney

Division on Substance Abuse, New York State Psychiatric Institute, College of Physicians and Surgeons of Columbia University, New York, NY, USA

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Public awareness of the difficulties experienced by some heavy marijuana users has increased in recent years, as has scientific and clinical interest in marijuana-related problems. Despite the growth of research in this field, development of evidence-based treatments for marijuana dependence lags substantially behind research investigating treatments for dependence on other drugs. In this chapter, we focus on the status of evidence regarding pharmacological treatment for marijuana dependence. Although animal studies clearly provide important directions, we focus on providing a comprehensive overview of existing evidence about pharmacotherapy for marijuana dependence in humans. We begin with a short introduction to the use and neurobiological effects of marijuana, as well as a discussion of evidence demonstrating marijuana withdrawal and dependence and demand for treatment. After briefly considering different approaches to medication development for drug dependence in general, we provide an overview of research coming from the human

laboratory about possible medications for marijuana dependence. The small body of clinical research addressing pharmacotherapy for marijuana dependence is then presented, followed by an overview of likely future directions. Although there are currently no approved pharmacotherapies for marijuana dependence, we identify promising directions that will, we hope, yield efficacious treatment approaches in coming years.

MARIJUANA USE AND NEUROBIOLOGY: A BRIEF OVERVIEW

Marijuana, the dried flowering tops, buds, leaves, and stems of the hemp plant *Cannabis sativa*, is the most commonly used illegal drug worldwide. Recent estimates indicate that between 130 and 190 million people across the globe used marijuana at least once during 2008, representing 2.9–4.3% of the world population

from 15 to 64 years old. In the United States, 6.6% of people of 12 years old and over are estimated to have used marijuana at least monthly in 2009. This is an increase from the past 7 years, when estimates remained stable at around 6% of the adolescent and adult population. Rates of use are predictably higher in some segments of the population; for instance, just under 50% of 18-year olds in the United States report using marijuana at least once. Of people who ever try marijuana, a subset goes on to use daily, with progression to daily use thought to occur in 10-20% of those ever trying the drug. This rate of progression from initiation to daily marijuana use is lower than that for some other drugs, such as heroin. However, the large number of people who experiment with marijuana ensure that regular marijuana users constitute a larger group than regular users of any other illegal drug.

Marijuana contains at least 60 different cannabinoids; the effects and psychoactive characteristics of many remain poorly understood. However, the feeling of being "high" and other behavioral effects experienced after marijuana have been found to be primarily related to the actions of Δ^9 -tetrahydrocannabinol (THC), a cannabinoid that easily crosses the blood-brain barrier to enter the brain. The effects of THC appear to be mediated primarily by its action at cannabinoid receptors type 1 (CB1). CB1 receptors are found throughout the body, but occur at high densities in brain areas involved in bodily coordination, attention, memory and higher cognitive processes, sensory and time perception, and reinforcement of behavior by drugs as well as natural rewards such as sex. This pattern of brain CB1 receptor expression is consistent with the behavioral effects of marijuana, which in addition to feelings of relaxation, positive mood, and being "high", may include alterations to normal thought processes, reduced physical coordination, and changes to time perception.

MARIJUANA WITHDRAWAL

As noted, a substantial minority of people who try marijuana go on to use daily, a usage pattern conferring increased risk of marijuana-related problems. One problem experienced by heavy, regular marijuana users is withdrawal. The existence of a clinically significant withdrawal syndrome in regular marijuana users has long been a subject of debate. Indeed, the *Diagnostic and Statistical Manual of Mental Disorders* – Fourth edition (DSM-IV), the most commonly used psychiatric diagnostic system in the United States, does not recognize cannabis withdrawal. This situation, however, is likely to change in the next DSM edition, in recognition of substantial evidence that heavy marijuana use may result in significant negative symptoms on abstinence.

The first reports detailing symptoms of marijuana withdrawal were published over 30 years ago. Today, evidence of a marijuana withdrawal syndrome comes from a range of sources including animal studies, case reports, controlled laboratory studies of marijuana administration to humans, clinical studies in treatment-seeking marijuana users, and epidemiological investigations. Across studies, marijuana withdrawal comprises a relatively predictable, time-limited pattern of prominent negative affect, including irritability, anxiety and depressed mood, coupled with craving for marijuana, appetite loss, and insomnia. Increased aggression has also been reported. Symptoms of withdrawal commonly appear after around 24-h abstinence, reach their peak from 2 to 6 days, and largely abate within 2 weeks.

Although it has been debated whether such symptoms represent a 'true' withdrawal rather than an unmasking of previously existing psychiatric problems, there is now substantial evidence in favor of the former interpretation. In animals trained to self-administer THC, administration of a THC antagonist precipitates behavioral alterations indicative of withdrawal. In humans, marijuana withdrawal symptoms are reversed by double-blind administration of marijuana, but not by placebo marijuana. Double-blind administration of lowdose oral THC (dronabinol) improves withdrawal symptoms without detectable psychoactive effects. This pharmacological specificity of marijuana withdrawal is inconsistent with unmasking of pre-existing psychological distress. Remission of withdrawal symptoms, which commonly occurs within 2 weeks of ceasing use, also supports the existence of "true" marijuana withdrawal.

Thus, marijuana withdrawal appears due primarily to marijuana abstinence rather than unmasking of underlying psychopathology. A second question is the clinical significance of these symptoms in terms of both distress experienced and their role in precipitating relapse. Clearly, marijuana withdrawal is not medically dangerous, as can be withdrawal from alcohol or benzodiazepines. It is not as physically severe as withdrawal from some other drugs, such as opiates. Moreover, despite evidence that most daily marijuana smokers experience withdrawal symptoms, some do not. Thus, withdrawal from some other drugs produces symptoms of greater magnitude and severity than those experienced by heavy marijuana smokers. However, this does not indicate that marijuana withdrawal symptoms are not clinically significant; marijuana withdrawal appears similar in magnitude and severity to nicotine withdrawal, which is known to produce clinically significant distress and disrupt normal functioning. Moreover, the extent of nicotine withdrawal predicts relapse to cigarette smoking. Consistent with this evidence in cigarette smokers, many marijuana smokers in treatment report that withdrawal symptoms contribute to relapse. Thus, evidence suggests that marijuana abstinence produces withdrawal symptoms of clinically relevant severity, and that these symptoms likely contribute to relapse and ongoing use of marijuana in heavy marijuana users.

MARIJUANA DEPENDENCE AND DEMAND FOR TREATMENT

Relative to other abused drugs, marijuana has not typically been regarded as a drug of dependence. Moreover, targeted treatment for marijuana dependence has often been thought unnecessary. However, recent years have seen accumulating evidence that a percentage of regular marijuana users endorse criteria for dependence, most commonly uncontrolled use, unsuccessful efforts to stop or reduce use, and withdrawal symptoms. Of 18-year olds surveyed in the United States reporting use of marijuana, 16% met DSM-IV criteria for cannabis dependence. In Australia, one study found that 7% of young adults (of average age of 21) met cannabis dependence criteria. At a population level, 1.5% of Australians over 18 have been estimated to meet criteria for current cannabis dependence, endorsing on average four dependence symptoms. In the United States, lifetime cannabis dependence prevalence is estimated at around 4%. Thus, a subset of regular marijuana users endorse criteria indicative of problematic use and dependence on the drug.

Consistent with marijuana dependence, neurobiological and behavioral pharmacology data indicate that cannabinoids such as THC share mechanisms and characteristics with other drugs that produce dependence. In animals, THC induces dopamine release in the mesocorticolimbic circuitry, which is hypothesized to underpin reinforcement by drugs and other types of rewards. Consistent with this, rodents acquire self-administration of cannabinoids in a dose-dependent fashion. Moreover, in rodents, low doses of THC produce conditioned place preference, a behavioral measure used to test the conditioned positive effects of drugs.

Also consistent with evidence of dependence are data showing that a subset of marijuana smokers voluntarily present for treatment when such treatment is available. One study employed newspaper advertisements to recruit individuals seeking treatment for marijuana use, and reported that approximately 350 people presented over 3 months. In Western countries, treatment admissions for marijuana have increased in the past decade, with presentations doubling in the United States and tripling in Europe and Australia. Psychotherapeutic approaches including cognitive-behavioral therapy, motivational interviewing, and contingency management improve

outcomes for people with marijuana dependence, but rates of relapse are high at around 70%, consistent with relapse rates for other drugs. Thus, there is a clear rationale to develop treatments to improve the efficacy of currently available psychological interventions. Combination treatment with psychotherapy and pharmacotherapy provides the best outcome in other psychiatric disorders such as depression. Therefore, development of efficacious medications for marijuana dependence will likely complement existing options and improve treatment outcomes for this group.

PHARMACOTHERAPY: APPROACHES FOR SUBSTANCE DEPENDENCE

Recovery from substance dependence is best conceptualized as a dynamic process, with diverse pressures acting for abstinence and relapse at different stages. For instance, in the early days of abstinence, withdrawal symptoms are most prominent. Such symptoms may be strong motivators for relapse, and are known to predict relapse to a range of drugs. After withdrawal symptoms abate, however, other factors such as desire for the positive effects of the drug may be more relevant to the likelihood of relapse. In addition to these changing pressures over time, individuals vary in their experiences of withdrawal symptoms and cravings. Thus, there is a need for a range of medication approaches to assist different people, at different stages, to maintain abstinence.

Consistent with this need, there are a variety of approaches to pharmacotherapy for drug dependence. One approach is to use medications to alleviate the negative symptoms of withdrawal from the substance. Two kinds of medications can alleviate withdrawal. The first is substitute, or agonist, medications. These medications act in similar ways to the drug of dependence, but typically have slower onset and longer-lasting actions than the drug they replace, producing a less intense positive mood experience and having a lower liability to be abused. Examples of substitute medications include methadone for opiate addiction and nicotine patches for cigarette smokers. Substitute medications have the advantage of at least partially alleviating the range of withdrawal symptoms associated with the drug, because they work on the same neurobiological systems. However, although they have lower abuse liability than the drug they replace, agonist medications may be abused under certain circumstances (e.g. when the primary drug is not available).

A second approach is to employ medications to treat specific symptoms of withdrawal associated with the drug. For example, benzodiazepines are used to treat some symptoms of alcohol withdrawal, including anxiety and agitation, insomnia, and seizures. Cigarette smokers may be prescribed bupropion to treat anxiety, irritability, and cravings occurring during nicotine withdrawal. Advantages of this approach include the fact that the medications are less frequently liable to be abused (although benzodiazepines have a recognized abuse liability). Conversely, this treatment strategy only addresses specific withdrawal symptoms compared to substitute medications, which address a broader symptom range.

An alternative to treating withdrawal symptoms is to focus on blocking the positive subjective effects of a drug, or reducing the extent to which the drug is reinforcing. Medications falling into this category promote abstinence because the drug is no longer enjoyed or experienced as reinforcing. This approach commonly involves administration of an antagonist to block the receptors on which the drug exerts its influence. For example, naltrexone substantively attenuates the effects of opiates. Alternatively, a partial agonist can also block some of the positive subjective or reinforcing effects of the drug; for instance, buprenorphine is a partial opiate agonist used to treat opiate dependence.

There are also alternative approaches to medications for drug dependence, such as medications that, when combined with the drug of dependence, produce aversive effects, thus limiting use. Recent evidence also indicates that vaccines, which bind to the drug in plasma and prevent it from crossing the blood–brain barrier, may prove an effective addition to nicotine and cocaine treatment. However, these approaches have not been employed for the treatment of marijuana dependence, and so will not be discussed further here.

REDUCING MARIJUANA WITHDRAWAL SYMPTOMS IN THE LABORATORY

Most existing evidence about medications for marijuana dependence in humans comes from laboratory studies, which model the circumstances involved in drug use, withdrawal, and relapse in a controlled environment. Laboratory studies allow detailed, objective investigation of effects of medications on different aspects of drug-using behavior. For instance, whereas outpatient clinical trials measure treatment effects on drug use with urine screens and self-report, laboratory studies can monitor actual drug use as it happens. Laboratory testing also offers a small-scale, cost-effective way to assess likely medication benefits before starting more expensive randomized controlled clinical trials. In addition, initial laboratory studies can investigate potentially dangerous interactions between medications and the drug of abuse in a medically supervised environment. This is an important issue given that many drug users will, at least at some point, use their drug of choice while also taking the treatment medication.

One challenge of this type of research is that it involves controlled administration or self-administration of the drug of dependence, procedures requiring careful management of ethical issues. An important ethical constraint is that treatment-seeking drug users are not recruited. Instead, regular drug users who do not wish to stop drug use, and who use more drug than is offered in the laboratory, are enrolled. The methods of laboratory studies, then, endeavor to recreate (or "model") the pressures experienced by abstaining drug users.

A variety of potential treatment medications have been evaluated in laboratory research about marijuana withdrawal. Most promising to date are the results of studies incorporating an agonist approach, assessing effects of treatment with dronabinol on withdrawal in heavy marijuana smokers. In the first study using dronabinol, 10-mg capsules were administered five times daily while participants underwent monitored withdrawal. Dronabinol reduced negative feelings like anxiety and depression, as well as reports of sleeping difficulties, chills, and craving, without producing intoxication. Dronabinol also reversed the appetite loss common to marijuana withdrawal. Consistent with this laboratory investigation, an outpatient controlled study in non-treatment seekers also reported that dronabinol (30 mg and 90 mg daily) attenuated marijuana withdrawal in a dose-dependent way.

This initial evidence, then, suggested that an agonist approach could prove effective for marijuana withdrawal. However, although 50-mg daily dronabinol reduced a range of withdrawal symptoms in the laboratory, it did nothing to improve other symptoms, such as irritability. Moreover, in the initial laboratory study, participants took five capsules daily, a very difficult pattern to maintain in outpatients. To address these issues, a second laboratory study, assessing the effects of 20-mg dronabinol three times daily, followed. This follow-up study also built on the first by aiming to model not just withdrawal, but also relapse. Modeling relapse in a study of this kind is difficult, because participants are not treatment-seeking and so have no reason not to "relapse" (i.e. use the drug as soon as it becomes available). This is particularly the case if they have just experienced withdrawal. To model relapse, this second study therefore required participants to purchase marijuana using study earnings. After 3 days of withdrawal, subjects were offered active marijuana, but had to buy it by the puff. The first puff of the day was expensive (\$10), whereas after that, the price dropped. This approach aimed to mimic the pressures of "real world" relapse, where the first drug use is the most costly, representing a failed quit attempt. In contrast to the first study using the lower, more frequent dose of dronabinol, 20-mg dronabinol three times daily produced some intoxication. As in the initial study, dronabinol reversed the appetite loss associated with withdrawal and decreasing reports of having chills and feeling restless. Disappointingly, dronabinol did not decrease rates at which participants relapsed to marijuana use in the laboratory.

However, this study also assessed another medication, lofexidine, an anti-hypertensive now more commonly used to reduce opiate withdrawal symptoms. Lofexidine, which reduces noradrenaline neurotransmission, was investigated for marijuana withdrawal because animal studies have shown that noradrenergic signaling increases during cannabinoid withdrawal. It was reasoned that lofexidine might reverse this noradrenergic hyperactivity. Results of the study suggested that this reasoning was sound; lofexidine (2.4 mg day⁻¹) reduced symptoms such as chills, gastrointestinal complaints, and restlessness, while increasing sleep. Importantly, it also reduced relapse. However, lofexidine also decreased food intake and produced feelings of sedation.

Both dronabinol and lofexidine, then, showed some potential as medications for marijuana withdrawal, with some limitations. Importantly, however, the study included a combination condition, and the combination of dronabinol and lofexidine was the most effective approach to reduce both marijuana withdrawal symptoms and relapse. When treated with both medications, participants had better sleep and reported less restlessness and marijuana craving, as well as fewer gastrointestinal complaints and less chills. They also smoked less marijuana during the relapse phase. Thus, a combination medication approach employing both an agonist and another medication targeted to specific effects of withdrawal produced a reduction in a broad range of symptoms, as well as reducing relapse to marijuana use. These findings are the most promising laboratory evidence to date, showing medication effects on both marijuana withdrawal and relapse.

A range of other medications has also been studied for specific symptom alleviation in marijuana withdrawal, with varying degrees of success. Bupropion, an antidepressant acting on the noradrenaline and dopamine systems, is effective in reducing nicotine withdrawal symptoms. This medication was tested in marijuana smokers because some mood symptoms of nicotine withdrawal overlap with those of marijuana withdrawal. However, maintenance on bupropion (300 mg day⁻¹) actually increased negative mood (irritability, depression, and restlessness) and reports of sleeping difficulties in marijuana smokers in withdrawal in the laboratory. Thus, bupropion is unlikely to be effective for marijuana dependence.

One possible reason for these results is that bupropion produces mild stimulant effects, which may have exacerbated the agitation and insomnia many marijuana smokers experience during abstinence. To address this possibility, a subsequent laboratory study assessed the effects of nefazodone (450 mg day⁻¹), an antidepressant with a more sedating profile, on withdrawal symptoms in regular marijuana smokers. Nefazodone, which acts primarily through serotonergic and noradrenergic mechanisms, reduced anxiety and muscle pain during withdrawal. However, nefazodone did not reverse other negative mood symptoms or the decreased food intake associated with withdrawal. Thus, this study did not provide support for broad benefits of nefazodone in marijuana withdrawal.

Following a similar rationale, a recent study assessed effects of mirtazapine, also an antidepressant with sedative properties that acts on the noradrenaline and serotonin systems, on marijuana withdrawal and relapse in the laboratory. Despite reversing sleep disruptions and appetite loss, mirtazapine (30 mg day⁻¹) did not improve participants' mood during withdrawal, and did not decrease relapse. Overall, therefore, laboratory studies on antidepressants in marijuana withdrawal have yet to provide compelling evidence for their utility.

Another medication trialled in the laboratory is divalproex, a mood stabilizer that controls irritability, anger, and mood swings in bipolar disorder. Divalproex is also used to treat anxiety, irritability, and insomnia in alcohol withdrawal, suggesting that it might be useful in marijuana withdrawal. A laboratory study using divalproex, however, failed to support this, with divalproex (1500 mg day⁻¹) increasing reports of anxiety, irritability, and sleepiness during withdrawal. More broadly, divalproex also impaired cognitive performance and increased food intake regardless of whether marijuana was smoked or not, suggesting that this medication is unlikely to be well tolerated clinically.

Similarly, a recent laboratory study assessing the effects of baclofen, an antispasmodic agent that increases inhibitory gamma-aminobutyric acid signaling, failed to suggest likely clinical benefits for marijuana withdrawal. Baclofen (60, 90 mg day⁻¹) had few positive effects on mood or behavior during withdrawal, and did not reduce relapse. Moreover, baclofen also reduced cognitive performance across conditions.

In sum, a variety of different medications have been tested in the laboratory for their potential to alleviate withdrawal and relapse occurring during withdrawal. Most of these medications did not substantially reduce the broad range of marijuana withdrawal symptoms, and some actually made them worse. A combination of dronabinol and lofexidine, however, was the exception; this combination improved sleep and cognition, reduced craving and restlessness, and importantly,

reduced relapse. This combination approach, therefore, is a promising candidate for future testing in the clinic.

BLUNTING THE POSITIVE OR THE REINFORCING EFFECTS OF MARIJUANA IN THE LABORATORY

An alternative to medications for withdrawal is to develop medications that reduce the positive subjective effects of marijuana, or the capacity of marijuana to reinforce behavior. This approach, for example, has been used for treatment of opiate dependence. The CB1 receptor antagonist, rimonabant, used to treat obesity, was found to block many behavioral effects of cannabinoids in animals. In humans, an initial laboratory study found that acute doses of rimonabant blocked the effects of smoked marijuana in a dose-dependent way. Compared to placebo, the highest rimonabant dose tested (90 mg) reduced reports of feeling "high" and "stoned" after a marijuana cigarette by around 40%, while also reducing heart rate by about 60%. A followup study assessed the effects of 8 and 15 days of daily rimonabant (40 mg) on responses to marijuana. Compared to placebo, this dose significantly reduced heart rate effects of smoked marijuana on both days 8 and 15; it also reduced self-reported positive marijuana effects on day 8 but not 15. A single dose of 90-mg rimonabant was also tested in this study and reduced heart rate reactivity to marijuana, replicating findings of the earlier study. However, the blunting of positive subjective marijuana effects after single doses of 90-mg rimonabant in the first study was not replicated. Thus, these trials provided some evidence that rimonabant might be useful in partially blocking the positive effects of marijuana. However, clinical use of rimonabant for obesity in Europe demonstrated high rates of adverse psychiatric reactions, including severe depression and suicidality. Rimonabant was therefore not approved in the United States, and cannot be further investigated for marijuana dependence at this time.

Agonist treatments can also blunt the positive effects of drugs and their reinforcing potential, and there is some evidence that dronabinol may reduce the positive subjective effects of marijuana. The only laboratory study to have investigated this question to date used two doses of dronabinol (40 and 80 mg daily) with participants receiving each dose for 3 days. On each day, participants smoked a single marijuana cigarette, followed by four opportunities to choose between smoking a marijuana cigarette or collecting a \$2 voucher to be redeemed for cash at study completion. Both dronabinol doses reduced ratings of feeling high and experiencing positive effects from the morning marijuana

cigarette by day 3 of dronabinol dosing, and this effect persisted until day 4 even though no dronabinol was administered that day. Despite these changes to the effects of marijuana, however, dronabinol did not change the amount of marijuana participants chose to self-administer. Thus, while there is evidence that dronabinol reduces the positive effects of marijuana, this study did not indicate that it also blocks the reinforcing effects of the drug. It is possible, however, that the money offered as an alternative to marijuana (\$2) was not enough, and that dronabinol might reduce marijuana smoking under different circumstances.

An alternative approach to medications directly blocking the cannabinoid receptor is to target associated neurotransmitter systems that have been implicated in the effects of marijuana. The endogenous opiate system is one such system, with animal evidence indicating that opiate antagonists attenuate some behavioral effects of THC. Based on this evidence, a number of laboratory studies have assessed the effects of acute doses of naltrexone, an opiate antagonist used to treat alcohol and opiate dependence, on responses to dronabinol and marijuana in humans. Evidence is mixed. Early laboratory studies found that single naltrexone doses (50 or 200 mg) did not alter the effects of either dronabinol (either 7.5 or 15 mg) or marijuana in regular marijuana smokers, although naltrexone increased the positive subjective effects of higher doses of dronabinol (30 mg). Naltrexone also marginally increased the extent to which marijuana smokers chose to self-administer dronabinol (30 mg). Thus, this early evidence indicated a difference between the acute effects of opiate antagonists on cannabinoid responses in animals, where blunting of behavioral effects was observed, and in humans, where naltrexone appears to have no effect at lower THC doses and to produce an enhancement of both positive THC effects and cannabinoid reinforcement at higher THC doses. Although a lower, more opioid-selective dose of naltrexone (12 mg) has been shown to blunt the positive effects of 20 mg (but not 40 mg) of dronabinol in regular marijuana smokers, a laboratory study designed to test the effects of a range of single naltrexone doses (from 12 to 100 mg) on responses to marijuana cigarettes in marijuana smokers found that all naltrexone doses increased marijuana's positive subjective and cardiovascular effects. Thus, despite evidence in animals and one study in humans showing a blunting of cannabinoid effects after opiate antagonists, the balance of evidence in humans suggests that acute naltrexone doses actually enhance the positive effects of marijuana in regular marijuana smokers, indicating that naltrexone administration is unlikely to be effective in the treatment of marijuana dependence.

Other individual laboratory studies have assessed the effects of various medications on responses to marijuana. Clonidine, an anti-hypertensive that decreases noradrenergic release, is used to treat opiate, alcohol, and nicotine withdrawal. A laboratory study testing three regular marijuana smokers found that acute clonidine (0.1–0.4 mg) did not affect subjective responses to marijuana, but did blunt the cardiovascular increases after marijuana. Given the absence of any change in the mood effects of marijuana, the authors of this small study concluded that clonidine did not appear likely to be useful for marijuana dependence; no further research was undertaken.

The study testing effects of bupropion on marijuana withdrawal described above also assessed the effects of bupropion maintenance (300 mg day⁻¹) on response to smoked marijuana. Bupropion reduced some subjective effects of marijuana including feelings of sociability and feeling "high"; it also decreased social behavior after marijuana smoking. However, there were few other effects of bupropion on marijuana response. Similarly, maintenance on nefazodone (450 mg day⁻¹) and mirtazapine (30 mg day⁻¹) did little to alter the direct effects of marijuana. Existing data, therefore, do not support the likely utility of the antidepressants tested in terms of reducing the positive subjective effects of marijuana.

Individual studies, described above, have also assessed the effects of divalproex and baclofen on response to smoked marijuana. Divalproex (1500 mg) produced small but significant increases in ratings of feeling high after marijuana, with few other effects. Baclofen (60 mg) reduced feelings of being high after marijuana while the higher dose (90 mg) decreased ratings of both marijuana and cigarette craving during repeated marijuana administration. Again, there were few other effects of baclofen on response to smoked marijuana.

Thus, of medications assessed for their potential to blunt the positive effects of marijuana or its reinforcing capacity, the antagonist rimonabant and agonist treatment with dronabinol appear the most promising. However, rimonabant produces unacceptably high risks of adverse psychiatric reaction and is not available for clinical or research use in the United States or Europe. Whereas dronabinol appears to reduce the positive subjective effects of smoked marijuana, it did not reduce the reinforcing effects of the drug, as indicated by choice to self-administer marijuana. However, there are few studies addressing this possibility, and further research is required.

WHAT WORKS IN THE CLINIC?

Although laboratory studies provide important information and are cost and time effective, the utility of a medication ultimately depends on outcomes in clinical

settings. To date, there are only three published reports of randomized controlled trials (RCTs) assessing the effects of medications for marijuana dependence. The first report was a double-blind, placebo controlled pilot study of divalproex (250-2000 mg daily; adjusted to individual response) in combination with cognitivebehavioral relapse prevention therapy for adults with marijuana dependence. Twenty-five patients were randomized to either divalproex or placebo for an initial 6-week period after 2 weeks of placebo lead-in (a period in which participants receive placebo, used to stabilize baseline measurements, etc.). There was also a 6-week crossover phase; however, due to low retention during the final weeks of the study, data from the crossover were not analyzed. In the 19 patients who completed at least the initial 8 weeks (2-week placebo lead-in plus the initial 6-week double-blind period), selfreported irritability, marijuana craving, and marijuana use decreased over time. However, there was no difference between groups, indicating that divalproex did not offer any improvement over placebo. Similarly, divalproex did not affect rates of negative urine screens. Moreover, despite modest decreases in THC positive urine samples during treatment in the sample overall, few patients attained sustained abstinence. There was some evidence of poor medications compliance, possibly influencing results. Although the preliminary nature of this study prevents firm conclusions, these negative results are consistent with the laboratory study described above, which did not support the likely utility of divalproex.

A more recent, larger clinical trial assessed effects of the antidepressants bupropion (300 mg daily) and nefazodone (600 mg daily) versus placebo in participants with marijuana dependence seeking treatment for marijuana use. The trial lasted 13 weeks, with 1 week of placebo lead-in, 10 weeks of study medication, and 2 weeks of lead-out. All patients completed weekly sessions of a coping skills psychosocial intervention. One hundred and six participants were randomized to one of the study medications or placebo, and around half completed the 10-week medication phase. The findings of this trial, similar to those of the divalproex trial, were that marijuana use decreased with time, but was not affected by either bupropion or nefazodone. Moreover, these results were not altered after accounting for medication adherence. Similarly, although marijuana dependence and withdrawal symptoms decreased in the sample with time, there was no effect of bupropion or nefazodone. Results of this clinical trial are, therefore, consistent with the conclusions of earlier laboratory studies, suggesting that despite the rationale for investigating these medications, neither bupropion nor nefazodone are likely to be a useful adjunct to psychotherapy for marijuana dependence.

A final published randomized, controlled clinical trial was based on documented high levels of anxiety in chronic marijuana users, and the anxiety that marijuana smokers report during withdrawal. The authors reasoned that given that marijuana users report that marijuana reduces negative emotions like anxiety, reducing these emotions by use of the non-benzodiazepine anti-anxiety medication buspirone might assist marijuana smokers to maintain abstinence. This 12week trial recruited marijuana-dependent participants seeking treatment, and used buspirone in conjunction with a psychological intervention (two or three sessions of Motivational Interviewing during the first 4 weeks). Of 50 participants who were randomized, received the study medication, and provided at least one urine drug screen, 48% completed the trial. The buspirone condition had a target dose of 60 mg day⁻¹, depending on individual response. Although there was no significant effect of buspirone on marijuana abstinence as indicated by negative urine drug screens, there were trends toward patients in the buspirone condition having more frequent negative results, and providing a negative screen sooner after trial initiation. There was no direct effect of medication on self-reported anxiety, withdrawal symptoms, or craving. However, exploratory analyses indicated that decreased anxiety over the study predicted marijuana abstinence, suggesting that anxiety symptoms may prove a useful treatment target. Further research with buspirone or other anxiolytics therefore appears warranted.

In addition to these RCTs, a number of small openlabel trials and case studies have used a range of medications for marijuana dependence. There are two case reports of treatment of chronic, long-term marijuana smokers with dronabinol and other medications as necessary. In one case, the patient was medicated with dronabinol (40 mg daily) for 6 months and divalproex (250 mg) for irritability. In the second, the patient was maintained on dronabinol (10–15 mg daily) and also received modafinal (100 mg) to counter the energy decreases he experienced after dronabinol. In both cases, patients achieved and maintained abstinence, consistent with evidence from controlled studies suggesting that dronabinol may be an effective addition to marijuana dependence treatment.

Following a preclinical study showing that lithium carbonate inhibited the development of cannabinoid withdrawal in rodents, two open-label pilot studies investigated marijuana withdrawal after treatment with lithium. The first assessed withdrawal symptoms in treatment-seeking marijuana users on lithium (600–900 mg daily) for 6 days as outpatients. Of the nine patients enrolled, four reported that lithium improved withdrawal symptoms whereas five did not. However, patients were maintained in an uncontrolled environment without the

capacity to prevent continued marijuana use, a substantial limitation. A second open-label trial of lithium addressed this limitation by maintaining marijuana-dependent patients in an inpatient setting for 7 days while they were treated with lithium (1000 mg daily). Lithium was generally well tolerated in this short-term, inpatient protocol, supporting the safety of using lithium in this population. Although rates of reported withdrawal symptoms were lower and follow-up reports of abstinence higher than in some previous studies, whether this was an effect of lithium cannot be determined.

A case series assessed the effects of baclofen in six patients with both marijuana and nicotine dependence. Common side effects were sedation and lethargy, consistent with the cognitive impairment demonstrated in the earlier laboratory trial. The authors report that these effects were well tolerated, and that withdrawal symptoms decreased in patients, who maintained abstinence for between 1 and 13 months. However, the negative results of the earlier laboratory study of baclofen suggest that these case studies be interpreted cautiously.

The non-stimulant attention deficit hyperactivity disorder treatment atomoxetine, which acts on the noradrenergic system, has also been assessed in an 11-week open-label trial for treatment-seeking marijuana-dependent patients. The rationale for this trial was that cognitive enhancing effects of atomoxetine might be useful for marijuana smokers, given that some studies have identified lowered cognitive function in heavy marijuana users. Fourteen patients received atomoxetine (25-80 mg daily), with a 2-week titration period to the maximum tolerated dose followed by 7 weeks of treatment and a 2-week taper off the medication. Patients did not substantively reduce marijuana use; moreover they had high rates of negative gastrointestinal effects and other side effects such as anxiety. Further investigation of this medication for marijuana dependence does not appear warranted.

A recent open-label study in adolescents employed a novel approach to pharmacotherapy for marijuana dependence. This study employed the anti-oxidant N-acetylcysteine (NAC), a medication shown in animal studies to reverse alterations to the glutamate system associated with repeated self-administration of a range of addictive drugs. Thus, NAC is thought to normalize addiction-related neuropharmacological changes in the brain more generally, rather than targeting mechanisms associated specifically with marijuana dependence. Twenty-four participants took part in this study, in which they received NAC daily (2400 mg daily) over a 4-week period with no other intervention. The medication produced some mild to moderate side effects but was generally well tolerated. Selfreported, but not urine toxicology based, marijuana use decreased during treatment with NAC. Marijuana cravings also decreased. Thus, this medication may be a candidate for further, more controlled, investigation.

DIRECTIONS FOR THE FUTURE

Over the past decade, there has been a significant increase in laboratory-based and clinical research focusing on medications for marijuana dependence. A range of different treatments has been trialled, many with disappointing outcomes. However, there are some promising directions. Most promising to date is the combination of dronabinol and lofexidine, which was shown in a human laboratory study to reduce a broad range of withdrawal symptoms associated with marijuana abstinence in daily users. Importantly, this combination also reduced the amount of marijuana smoked during the 'relapse' phase of the study. A separate laboratory study also found that dronabinol reduced the positive subjective effects of smoked marijuana, however it did not affect the amount of marijuana participants self-administered. A recently completed clinical trial assessed the effect of dronabinol in treatment of marijuana dependence; the results of this trial are not yet available. Overall, existing evidence indicates that dronabinol in combination with lofexidine may be a useful approach to be tested in clinical settings. We are aware of an ongoing clinical study investigating this combination.

In addition to this combination, there are a number of possible directions that may yield effective treatments for marijuana dependence in the future. Despite overall disappointing results in clinical trials conducted to date, one trial found that improvement in anxiety symptoms over treatment predicted marijuana abstinence, suggesting that anxiety symptoms may prove a useful target. Thus, investigation of anxiety medications without abuse liability may present treatment opportunities. Two open-label studies have suggested that lithium is tolerated and may improve withdrawal symptoms, however, a study in animals showed that this effect of lithium was blocked by an antagonist of the neuropeptide oxytocin, suggesting that oxytocin release may mediate the effects of lithium on marijuana withdrawal. Thus, an intriguing possibility is whether administration of oxytocin would also attenuate withdrawal. An advantage of oxytocin over many other medications is that it does not appear to have effects such as sedation. A clinical study investigating the effect of intranasal oxytocin on marijuana withdrawal and dependence is currently in progress. Other possible directions for the future include new CB1 antagonists currently in development. In addition, fatty acid amide hydrolase inhibitors may have similar effects to agonists such as dronabinol by reducing the extent to which endogenous cannabinoids are metabolized.

Thus, a range of compounds may, in the future, yield treatments to improve outcomes for marijuana dependence. One other potential factor that may affect the outcomes of clinical trials is the extent to which individual participants, although recruited into abstinence-based programs, have abstinence versus moderation as their treatment goals. Taking these differences into account could contribute to a better understanding of the ways in which pharmacotherapy can assist those with marijuana dependence to achieve their goals with regard to marijuana use.

In summary, research into marijuana withdrawal, dependence, and treatment has expanded rapidly in the last decade. There remains much to understand about risk factors leading to chronic heavy marijuana use, and ways to assist users in treatment. However, existing evidence suggests that, in common with other drugs of dependence, combination treatment including an agonist component is likely to reduce aversive withdrawal symptoms, thus leading to better treatment outcomes for marijuana dependence.

SEE ALSO

Improving Medication Use in Addictions Treatment, Etiology and Prevention of Marijuana Use among College Students

List of Abbreviations

CB1 cannabinoid receptor type 1

DSM-IV Diagnostic and Statistical Manual of Mental Disorders -

Fourth edition

fMRI functional magnetic resonance imaging

NAC *N*-acetylcysteine

RCT randomized controlled trial THC Δ^9 -tetrahydrocannabinol

Glossary

Cannabinoids compounds that activate cannabinoid receptors. Includes compounds found in *Cannabis sativa* such as THC, compounds that occur naturally in the nervous system of animals and humans, and synthetic substances that bind to cannabinoid receptors.

Cannabis products containing THC, including marijuana and hashish.

Marijuana the dried flowering tops, buds, leaves, and stems of the hemp plant *Cannabis sativa*.

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Methadone Maintenance

Ayman Fareed Emory University, Decatur, GA, USA

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Opioid addiction is a chronic disease characterized by frequent relapses. Methadone maintenance has been an effective model for treatment of this chronic disease since the 1960s. Extensive research confirmed the safety and efficacy of this model for treatment of opioid dependence. Modern technology like brain imaging has been used recently to provide more information about methadone maintenance for treatment of opioid dependence. In this chapter, the reader will be updated about the basic and most recent information available about this model for treatment of opioid addiction.

MECHANISM OF ACTION OF OPIOIDS

Opioid drugs act by binding to certain receptors in the brain, which lead to specific actions based on the type of the receptor involved. There are four types of opioid receptors including mu, kappa, delta, and orphanin FQ nociceptin. The opioid receptors are also the binding sites for endogenous peptides (e.g. endorphins and enkephalins) which play an important role for modulating the response to pain, regulation of body temperature, respiration, endocrine and gastrointestinal activity, mood, motivation, and other functions. Exogenous opioids may act as agonists, partial agonists, or antagonists to these receptors. Most of the opioids with addictive potential are agonist at the mu receptor. These drugs activate the mesocorticolimbic dopaminergic system through their mu agonist property leading to euphoria, positive reinforcement, and drugseeking behavior. When opioid receptors are activated by an agonist (endogenous or exogenous), a chain of intracellular changes, involving second and third messenger systems, is usually activated. These changes not only produce immediate changes in the responsiveness of the opioid receptor-bearing neurons, but also lead to adaptive changes in other neuronal systems that interact with them. Tolerance (decreased responsiveness to the same concentration of the opioid at the receptor) usually occurs on continued activation of the receptor and altered excitability (withdrawal) develops, when the agonist is removed after a period of receptor occupancy.

PHARMACOLOGIC PROFILE OF OPIOIDS

Opioids are classified into natural and synthetic subclasses. Morphine is a natural opioid and can be detected in urine by immunoassay screening tests. Heroin (diacetylmorphine) is a synthetic opioid and is considered to be an illicit drug in many countries. It is rapidly hydrolyzed to 6-monoacetylmorphine (half-life 3-6 min) as a result of spontaneous hydrolysis and hydrolysis by cholinesterase, which in turn is hydrolyzed to inactive morphine-3-glucuronide and the active morphine-6-glucuronide following intravenous (IV) administration in humans. Duration of action of heroin is usually short, but elimination of its metabolite (morphine) depends on route of administration, drug dose, body weight, time elapsed since the last dose, and inter-individual pharmacokinetics. Heroin is mainly excreted in the urine as free and conjugated morphine.

Methadone is a long-acting synthetic opioid. It is a mu and delta receptor agonist, and N-methyl-D-aspartate antagonist. Methadone was originally developed by a German scientist in the late 1930s for treatment of pain. Methadone is a lipid-soluble medication. It can be detected in the blood within 15-45 min after oral administration. The peak plasma concentration occurs at 2.5–4 h after dosing with some dose-independent differences among patients (range 1-5 h). A second plasma peak may be detected probably due to enterohepatic recirculation. The oral bioavailability of methadone was found to be around 70-80% for doses between 10 and 60 mg with marked inter-subject variation (range 36–100%). The hepatic enzyme cytochrome P 450 (CYP) 3A4 plays a major role in the metabolism of methadone, with a predicted first-pass metabolism around 20%. CYP 2C19, CYP 2C9, and CYP2D6 are involved in the metabolism of methadone to a lesser extent. Methadone is highly bound to plasma protein including albumin, lipoprotein, and alpha-1 acid glycoprotein. Methadone has a low hepatic extraction and changes in the binding of methadone to plasma proteins can alter its total hepatic clearance but the free methadone concentration is expected to remain unchanged. Elimination of methadone is mediated by transformation, followed by renal and fecal excretion. Methadone is extensively metabolized in the body mainly in the liver but also by intestinal CYP 3A4. The main metabolite of methadone (2-ethylidene-1,5-dimethyl 1-3,3-diphenylpyrrolidine; EDDP) is inactive. In addition to methadone nine metabolites, including EDDP, have been identified in urine and three in feces.

OPIOID INTOXICATION AND OVERDOSE

Opioid intoxication and overdose may constitute a medical emergency. It usually happens in the context of illicit opioid use to achieve euphoria especially with IV heroin use. Prescribed opioid overdose has also been reported and the prevalence of mortality related to prescription opioid overdose increased drastically in the United States between 1999 and 2006. The number of emergency department visits related to nonmedical use of prescribed opioid significantly increased (111%) between 2004 and 2008. The highest numbers of visits were recorded for oxycodone, hydrocodone, and methadone. Cardinal signs of opioid intoxication and overdose include a reduced level of consciousness, which may range from drowsiness to a stuporous state to a coma. Other cardinal signs include pinpoint pupils and a depressed respiratory rate. Cyanosis, hypotension, bradycardia, and hypothermia may also be present. Death is usually from respiratory depression. Some case reports described nonfatal heroin overdose that was associated with significant morbidity. The most commonly reported signs and symptoms of overdose morbidity are pulmonary conditions such as edema and pneumonia and muscular complications such as rhabdomyolysis from prolonged pressure on muscles during coma and renal failure from lysis of muscle tissue. Cardiovascular and cognitive impairment have been reported. Warner Smith et al. also reported overdose-related morbidity including peripheral neuropathy, vomiting, temporal paralysis of limbs, chest infection, and seizures.

OPIOID WITHDRAWAL

Opioid withdrawal is a syndrome related to sudden discontinuation of opioids after prolonged period of use. Short-acting opioids such as heroin usually exhibit signs and symptoms of withdrawal within 8–12 h after the last dose. If untreated, it reaches a peak within 36–72 h and usually subsides substantially within 5 days. For long-acting opioids like methadone, withdrawal may reach a peak between 5 and 6 days, and the syndrome will not usually subside for 14–21 days. The signs and symptoms of opioid withdrawal may be classified as objective and subjective. Objective signs include vomiting, lacrimation, rhinorrhea, pupillary dilatation, piloerection, sweating, diarrhea, yawning, fever, and elevated pulse and blood pressure. Subjective symptoms may include dysphoric mood, insomnia, muscle aches and

cramps, abdominal pain, and colic. The clinical opiate withdrawal scale is usually used to classify the severity of opioid withdrawal based on the generated score.

OPIOID ABUSE AND DEPENDENCE

Opioids abuse and dependence reflect the behavior manifestations for the loss of control over opioid use. Abuse may reflect a milder degree of the deviated behavior associated with opioid use. The American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorders fourth edition text revision (DSM-IV-TR), defines opioid abuse as a maladaptive pattern of opioid use leading to clinically significant impairment or distress as manifested by one or more of the following occurring within a 12-month period: recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home; recurrent opioid use in situations in which it is physically hazardous; recurrent opioid-related legal problems; and continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids. It is important to note that opioid abuse does not include a pattern of use that could lead to physical impairment, that is, tolerance and withdrawal. Therefore, this pattern of the opioid use is mostly associated with loss of control, which may impair important areas of behavioral functioning. On the other hand, opioid dependence reflects severe forms of loss of control that could affect behavioral and physical functioning as well. DSM-IV-TR defines opioid dependence as a maladaptive pattern of opioid use leading to clinically significant impairment or distress as manifested by three or more of the following occurring at any time in the 12-month period: tolerance, as defined by a need for markedly increased amounts of opioids to achieve intoxication or desired effect, or markedly diminished effect with continued use of the same amount of opioids, opioid withdrawal signs and symptoms on discontinuation of opioid use, the opioid is often taken in larger amounts or over a longer period than was intended, there is a persistent desire or unsuccessful efforts to cut down or control use, a great deal of time is spent in activities necessary to obtain the opioid, use of opioid or recover from its effects, important social, occupational, or recreational activities are given up or reduced because of opioid use, opioid use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by opioid. It is also important to note that the signs and symptoms of physical dependence, that is, tolerance and withdrawal without other behavioral manifestations of the loss of control overuse would not be considered problematic use.

UTILIZATION OF METHADONE FOR TREATMENT OF OPIOID DEPENDENCE

Illicit opioid use produces euphoric effect which is usually the incentive for the drug-seeking behavior and addiction. Heroin has been the main source for illicitly used opioids for decades. Sniffing, smoking, and IV administration have been the most common routes for illicit heroin use. Recently, a new epidemic of nonmedical use of prescribed opioids emerged in the United States. New routes of administration of prescribed opioids have been reported in order to achieve euphoria by illicit users. These routes include chewing, crushing, and IV use of controlled release oxycodone (oxycontin), and licking of fentanyl patches. Inhalation of crushed opioids and oral ingestion of prescribed opioids for nonmedical use have also been reported. Over time the pattern of opioids' use by illicit users progresses from occasional to frequent or daily use due to the development of tolerance to its euphoric effect. These individuals may experience acute withdrawal syndrome on cutting down or discontinuation of the illicit opioid. Methadone has cross tolerance with other opioids and its long duration of action would make it an appropriate agent for treatment of opioid withdrawal syndrome and detoxification. Methadone 20-40 mg is usually sufficient to block the opioid withdrawal syndrome. Gradual taper of methadone by 5–10 mg every few days reduces the withdrawal syndrome and minimizes the patient's suffering. Opioid dependence is a chronic disease and frequent relapses have been reported following ambulatory or inpatient detoxification for that matter. Opioid craving is usually the trigger for relapse even after long periods of abstinence. Patients who fail abstinent-based models of treatment would be good candidates for methadone maintenance treatment (MMT).

METHADONE MAINTENANCE FOR MANAGEMENT OF OPIOID CRAVING

Craving is a subjective phenomenon that may be defined as an increased desire to use drugs or alcohol while being drug abstinent. It is associated with the use of substances that have reward reinforcing (euphoric) properties like alcohol, cocaine, and heroin. While craving is a subjective phenomenon, it can be triggered by environmental factors such as being exposed to drug-related cues. In the case of opioids, craving may occur due to the need to alleviate withdrawal symptoms (negative craving) or an increased desire to use opioids due to their euphoric effect (positive craving). A number of imaging studies have examined the neurobiologic correlates of heroin craving. Zijlstra et al. reported in their imaging study using single photon emission computed

tomography that opioid-dependent subjects had lower baseline dopamine type 2 receptors (D2Rs) in the left caudate nucleus compared to normal subjects. They also found that opioid-dependent subjects demonstrated higher dopamine (DA) release after cue exposure in the right putamen than that of controls. They added that chronic craving and anhedonia were positively correlated with DA release. They suggested that treatment strategies that increase D2Rs may, therefore, be an interesting approach to prevent relapse in opiate addiction. Sell et al. used positron emission tomography (PET) to study brain activity in opioid addicts being exposed to heroin related and neutral cues. They found that the self-reports of "urge to use" correlated strongly with increased regional blood flow in the inferior frontal and orbitofrontal cortex target regions of the mesolimbic dopaminergic system implicated in conditioning and reward. Xiao et al. studied brain activity in a group of thirsty heroin addicts being exposed to water and drugrelated cues using functional magnetic resonance imaging (fMRI). They found that drug-related cues activated bilateral inferior frontal cortex confirming the critical role of prefrontal cortex in opioid craving. Their results suggest that heroin craving may involve different neural circuits other than the desire from basic physiological derives, such as thirst. Shi et al. reported in two studies that MMT reduces cue-induced heroin craving. They assessed craving by a 10-point visual analog scale where participants were asked "How much do you feel the urge to use heroin?" In their most recent study, brain imaging PET was used to study the integrity of the striatum DA neurons in patients receiving MMT and patients with prolonged abstinence compared to nonopioid-dependent individuals. They found that there is a long-lasting impairment in the striatal DA neurons (DA transporter uptake in bilateral putamen but not in bilateral caudate), which is more prominent in methadone-maintained patients compared to patients with prolonged abstinence. However, heroin craving was significantly less in patients receiving MMT. So, in spite of the efficacy of MMT in reducing subjective heroin craving, it may prolong the recovery process of the striatum DA neurons in the brain of recovering addicts. Langleben et al. also studied heroin craving using fMRI in methadone-maintained patients. They postulated that the medial prefrontal cortex and the extended limbic system in methadone-maintained patients with a history of heroin dependence remain responsive to salient drug cues, which suggest a continued vulnerability to heroin craving and relapse (Fig. 43.1).

One may understand from these studies that heroindependent patients may have structural and functional brain abnormalities, which could increase their risk for heroin craving and relapse. This may also be the case for patients receiving MMT. Fareed et al. reported in a recent review study that methadone may help with heroin craving but patients in MMT may still be at risk of cue-induced heroin craving and relapse. Methadone has been the standard treatment of heroin dependence since 1960s. Despite the effectiveness of methadone in reducing heroin use, there have been reports about patients using heroin while receiving MMT. Opioid craving may play a factor for the continued use of heroin despite receiving MMT. There is evidence that methadone reduces heroin craving. Several studies supported that notion. Most of these studies reported an essential role for the methadone dose on heroin craving. They reported that being on higher doses of methadone may protect against craving in patients receiving MMT while being on lower doses or undergoing detoxification may increase the risk of craving. Therefore, it may be important to address heroin craving and risk of relapse for patients who are requesting detoxification. Also these data may provide a guideline for effective methadone dosing and prevention of relapse especially for patients who continue to experience heroin craving while being on lower doses of methadone. Methadone dose seems to be an important factor for blocking the euphoric effect and reduction of heroin craving for patients receiving MMT.

There is also evidence that patients in MMT are not immune from experiencing opioid craving. Some studies reported that patients in MMT may experience subjective craving for heroin while being on methadone. Childress et al. studied the risk of craving while being in MMT by examining the effect of the environment on the experience of craving. They found that a sizable proportion of the study Patients experienced subjective craving, subjective withdrawal, and withdrawal like physiological changes in response to drug-related stimuli, even in the artificial environment of a lab and despite maintenance on methadone. They also found that these patients are at more risk when they are in their home environment. Walter et al. demonstrated that methadone-maintained patients may be highly susceptible to drug cues even during time periods when peak methadone levels are expected. In their study, they reported discrepancy between saliva cortisol level as an objective measure of craving and selfreported heroin craving. As expected, they found a decrease in cortisol level after daily methadone dosing but unexpectedly, a greater increase in craving and negative affectivity after drug cues were detected post-methadone as compared to pre-methadone intake. Other studies reported a pattern of vulnerability to craving in response to being exposed to heroin cues or high level of stress. This pattern was significantly higher before methadone dose than after methodone dose (Fig. 43.1). The pharmacodynamic properties of methadone may play an important factor for this pattern of vulnerability to heroin craving before methadone dosing compared to after dosing.

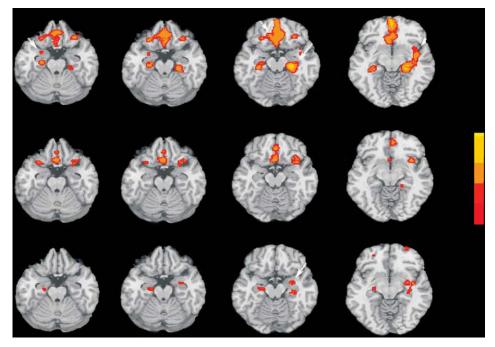


FIGURE 43.1 Activation maps of brain fMRI response to heroin-related stimuli in methadone maintenance patients before and after daily methadone dose. Top row: Heightened response to heroin-related stimuli compared with neutral stimuli, before the daily methadone dose, in the left and right orbitofrontal cortex, ventral anterior cingulate cortex, and hippocampal complex, the left insula, and the right amygdala. Middle row: After the daily methadone dose, heightened response to heroin-related stimuli in the left and right orbitofrontal cortex and hippocampal complex and the left insula. Bottom row: Significant differences between the response to heroin-related stimuli before the methadone dose compared with after the methadone dose, in the left amygdala, the left and right hippocampal complex, and the left insula. Images are displayed over a Talairach-normalized template in radiological convention (left hemisphere to the viewer's right) and thresholded at z>1.64, with spatial extent threshold of >20 voxels, uncorrected for multiple comparisons. Reprinted with permission from Langleben et al., Mar 2008. Acute effect of methadone maintenance dose on brain fMRI response to heroin-related cues. American Journal of Psychiatry 165, 390–394, (Copyright © 2008). American Psychiatric Association.

Methadone has a large inter-individual variability in response and some patients might be rapid metabolizers of methadone while others might be slow metabolizers. Genetic polymorphisms in genes coding for methadonemetabolizing enzymes, transporter proteins (p-glycoprotein; p-gp), and mu-opioid receptors may explain part of the observed inter-individual variation in the pharmacokinetics and pharmacodynamics of methadone. Genetic polymorphism could be the cause of high inter-individual variability of methadone blood concentration for a given dose. Therefore, the practice of obtaining methadone trough and peak levels for patients expressing craving while being on high dose is recommended. This practice may provide more objective data about the casual relationship between the methadone dose and opioid craving. Split dosing may also be recommended for patients with substantial difference between the trough and peak levels who may express craving at the end of the day.

DOSING GUIDELINES FOR MMT

Despite the common agreement that methadone is an effective treatment for opioid dependence, there has

been a wide variation for dosing among clinicians. Some clinicians have been conservative and leaning toward the low dose regimen. This practice may have a better safety profile for methadone side effects and overdose. However, patients who are treated with the lower dose range tend to do worse regarding illicit opioid use and retention in treatment. Several studies reported that methadone dose in the range of 60–100 mg daily is safe and effective for MMT compared to lower dosages. Based on these reports, the National Institute of Health (NIH) made a consensus to help clinicians with proper methadone dosing. They recommended a guideline for the proper methadone dose to be at least 60 mg daily. Despite the NIH consensus, many methadone programs are still using doses below the recommended guidelines. A survey was done to examine the extent to which US methadone clinics meet established standards for minimum dosage between 1988 and 2005. It was found that 40% of patients receive doses of at least 80 mg daily the threshold identified as recommended practice in recent work, 34% receive doses below 60 mg daily, and 17% receive doses below 40 mg daily. Some recent studies explored the efficacy and safety of methadone doses above 100 mg daily. Two naturalistic studies with a large number of patients reported that doses above 100 mg daily are safe and effective in long-term maintenance treatment. They indicated that response to MMT can be optimized when doses are individually titrated against signs and symptoms just like any chronic medical disease. Two recent clinical trials with a small number of patients reported that doses in the range of 120–150 mg daily are more effective in reducing heroin self-administration and suggest that the mechanism of this increased efficacy is by reduction of the positively reinforcing (euphoric) effect of heroin and not by reduction in opioid withdrawal discomfort.

It is noteworthy that the historic interest in methadone dosages. Most of the studies that were done in the 1980s and early 1990s used low doses below 60 mg daily. Then, this trend changed in the mid- and late 1990s where most of the studies looked at doses in the range of 60-100 mg daily. Since the early 2000s, a new interest in studying doses above 100 mg daily emerged. It seems that this historic interest in studying higher doses for MMT stems from the desire to reduce the illicit opioid use without jeopardizing safety. Methadone itself could impose some risk factors like cardiotoxicity and prolongation of QT interval (QT) on the electrocardiogram (EKG). This cardiotoxic side effect lead the Food and Drug Administration (FDA) to mandate a black box label to be added to the methadone brochure by the manufacturers. QT prolongation and Torsade de Pointes (TdP) have been reported in patients treated with methadone for opioid dependence or pain management. A dose-dependent effect on QT prolongation has been shown in some studies. Overall, prolonged QT or TdP has been observed at a wide range of methadone dose from 10 to 1200 mg daily.

The NIH did not yet provide recommendations for EKG screening for patients who are in MMT. However, an expert panel for EKG screening and monitoring for patients in methadone treatment recommended obtaining a pretreatment EKG for all patients to measure the QT interval and a follow-up EKG within 30 days and annually. Additional EKG is recommended if the methadone dosage exceeds 100 mg/day or if patients have unexplained syncope or seizures. If the QT interval is greater than 450 ms but less than 500 ms, the clinician needs to discuss the potential risks and benefits with patients and monitor them more frequently. If the QT interval exceeds 500 ms, the clinician needs to consider discontinuing or reducing the methadone dose; eliminating contributing factors, such as drugs that promote hypokalemia; or using an alternative therapy. Clinicians should be aware of interactions between methadone and other drugs that possess QT intervalprolonging properties or that slow the elimination of methadone.

At the present time, we have data to support the fact that the dose range of 60–100 mg daily is safe and effective for reducing illicit opioid use. However, this recommendation may change as there are some promising data about the safety and better efficacy of doses above 100 mg daily.

DRUG TO DRUG INTERACTION WITH METHADONE

Methadone is metabolized mainly through the hepatic CYP enzymes. Medications that induce the CYP 3A4 enzyme may increase the elimination of methadone and decrease its blood level. This effect may increase the possibility of opioid withdrawal. On the other hand, CYP 3A4 inhibitors may slow the metabolism of methadone and increase its blood concentration. The high blood concentration of methadone may increase the risk for side effects, for example, sedation and drowsiness.

Several medications such as rifampicin, phenobarbital, phenytoin, and carbamazepine increase methadone metabolism and the risk for opioid withdrawal. Other medications, for example, fluconazole, voriconazole, ciprofloxacin, and clarithromycin decrease methadone metabolism and increase its plasma concentration.

Anti human immunodeficiency virus (HIV) medications, for example, darunavir, nelfinavir, nevirapine, efavirenz, and lopinavir/ritonavir, may also increase methadone metabolism and result in opioid withdrawal. Methadone may decrease the blood level of didanosine and stavudine and increase the blood level of zidovudine. Drug to drug interactions between methadone and anti-HIV medications have the most clinically significant adverse effects. HIV is a common disease for patients receiving MMT. Therefore, clinicians need to be aware of this important drug to drug interaction to consider adjusting the methadone dose as needed.

Obtaining peak and trough level for methadone may help in the detection of this possible drug to drug interaction. Methadone dose may need to be adjusted based on the peak and trough levels to reduce the risk of side effects, overdose, or opioid withdrawal. The dose of methadone needs to be reduced for patients with liver diseases like hepatitis C due to impaired hepatic function.

RETENTION IN MMT

Retention in MMT is associated with better treatment outcome and dropping out is associated with poor outcome. Maddux et al. reported that time on methadone was inversely related to positive urine drug screens for morphine. Patients maintained on

methadone for 3 years or longer showed a marked decrease in urine drug screens positive for morphine. Another study reported that retention in MMT is associated with reduced risk for overdose mortality and dropping out increases that risk. Other studies reported that retention in MMT could improve other outcomes like spread of HIV and hepatitis, criminal activities, employment, and mortality. The goal of MMT should not be time limited. Some studies reported that the methadone dose range of 60–100 mg daily is associated with significantly improved retention in opioid maintenance treatment compared to lower doses. Other studies that compared doses in the range of 60–100 mg daily to lower doses did not find any statistically significant difference for retention. Therefore, the methadone dose by itself may not play an essential role for retaining patients in treatment. One study reported that receiving take home early in treatment enhanced treatment retention. Several factors might be associated with poor retention in MMT. Comorbid cocaine, alcohol, other illicit drugs, or psychiatric disorders may be associated with poor retention if they were not addressed early in treatment. Therefore, it is important to address the cocaine and other drug comorbidities early in treatment. Offering a referral to evidence-based psychotherapeutic intervention designed for treatment of drug addiction like cognitive behavior therapy or contingency management might be appropriate for this patient population. Also a higher level of care like intensive outpatient or residential treatment may be needed for some patients with comorbid drug addiction. Psychopharmacologic intervention for comorbid psychiatric disorders is also important to be addressed as part of the treatment plan. MMT programs may vary in offering ancillary services like case management, evidence-based psychotherapy, and resources to refer patients to a higher level of care if needed. Some programs may lack human and financial resources that contribute to their inability to meet care standards. Therefore, retention in treatment may vary across MMT programs.

METHADONE MAINTENANCE FOR PREVENTION OF ILLICIT OPIOID OVERDOSE

Some studies reported that nonfatal illicit drug overdose significantly predicted subsequent nonfatal drug overdose. Therefore, prevention of future opioid overdose in high-risk patients may reduce the mortality and morbidity in this population. Several studies reported that MMT could reduce the risk of overdose and mortality in this population. Brugal et al. recently reported that the life expectancy of their cohort of heroin users in MMT increased by 21 years during the period of

the study. They reported that the increased life expectancy was not just due to the decline in death due to acquired immune deficiency syndrome but also due to reduction of death related to illicit drug overdose. Caplehorn et al. performed a meta-analysis to study the relationship between being in MMT and the risk of drug-related mortality. They found that the MMT reduced the risk of overall mortality in this population by a quarter. They reported that the MMT reduced the risk of mortality primarily due to reduction of the risk of accidental overdose. They added that MMT primarily reduced the risk of mortality in these patients due to prevention of heroin overdose in particular. While being in MMT is protective against the risk of drug overdose and mortality, dropping out of MMT increases such risk. Langendam et al. reported in their cohort of drug users that attending a harm reduction MMT is associated with reduction of overdose death, while leaving treatment is associated with increasing the risk. On the other hand, several studies reported an increased risk of fatal drug overdose during the first few weeks of initiating MMT. Therefore, the induction period for MMT may constitute high risk for drug-related overdose. Illicit use of central nervous depressants like benzodiazepines or alcohol during this period may increase the risk of overdose and mortality. Increased patient monitoring and education about this risk during the induction phase of MMT may reduce mortality and morbidity related to drug overdose. Buprenorphine maintenance treatment (BMT) might be an alternative to MMT for certain high-risk patients. Buprenorphine may have a better safety profile than methadone due to its pharmacokinetic and pharmacodynamic properties. It is a partial agonist of the mu-opioid receptor and has a ceiling effect which may reduce the risk of drug overdose. It is also safer than methadone as regards its cardiotoxic effect. Bell et al. reported that the risk of overdose death during the 9-month period of their study was significantly lower for patients receiving BMT compared to patients on MMT. In another study, Bell et al. reported that BMT was associated with less mortality during the induction phase of treatment but shorter retention in treatment compared to MMT. Overall, one may understand from these data that opioid maintenance treatment with methadone or buprenorphine may reduce the risk of illicit opioid overdose and should be considered as a preventive measure for high-risk patients.

MANAGEMENT OF CO-OCCURRING MEDICAL CONDITIONS FOR METHADONE-MAINTAINED PATIENTS

Premature death is common in heroin-addicted patients. Some studies reported that the annual death

rate in this population is about 1–3%. Symth et al. reported that heroin addicts not receiving opioid agonist treatment die at an average age of 47 years. Several factors contribute to premature death in this population, including overdose, chronic liver disease, HIV infection, and accidents. Impulsivity, personality disorders, unemployment with lack of medical insurance, legal problems, high-risk behaviors such as IV drug use, and psychiatric comorbidity may also contribute to premature death in heroin addicts. Fortunately, MMT can prolong survival in this population because of the reduction in the aforementioned risk factors. MMT protected many patients from risks associated with illicit opioid use (e.g. drug overdose, accidents, homicide, suicide), so that these patients lived longer than heroin addicts who did not enter methadone treatment. However, patients maintained in long-term methadone treatment are still likely to have a higher incidence of chronic medical conditions and unhealthy life styles that may affect their quality of life and predispose them to premature death compared with the general population. Nevertheless, although patients on methadone may be protected from risk factors associated with active IV drug use, they are not immune from other diseases that increase the risk for premature mortality, for example, chronic obstructive pulmonary disease (COPD), hypertension (HTN), diabetes mellitus (DM), HIV, and/or hepatitis C. Indeed, the prevalence of chronic health conditions has been shown to be much greater in MMT patients than community populations. Howard et al. reported that men receiving methadone were more than six times more likely to have previously diagnosed DM compared with men who were not receiving methadone. Fareed et al. reported that 28% of MMT patients in their clinic also suffer from DM, a rate much higher than that seen in the general population (6.2%). They also found that an extraordinarily high percentage (86%) of the premature deaths in their MMT clinic occurred in patients with DM. Rosen et al. found that nearly 45% of MMT patients over the age of 50 suffer from HTN. In comparison, Fareed et al. describe the prevalence of HTN to be nearly 60% in patients receiving MMT in their clinic.

Although patients with history of heroin dependence and in MMT are at increased risk for chronic medical conditions, such as hepatitis C, HIV, HTN, and DM, there are minimal federal guidelines for medical care, specifically a physical examination on admission and annual screening for some infectious diseases, for example, HIV and hepatitis C. Medical care for patients in MMT varies across programs, and most programs provide minimal onsite medical services other than urine drug screening. Patients in MMT with medical comorbidities across the United States usually have limited access to laboratory testing, EKG screening,

and proper diagnosis and management of their medical comorbidities. This is not the case for MMT programs enrolled in the Veterans Healthcare Administration (VHA) system. The VHA system is unique among MMT programs in its capacity to provide comprehensive medical services, such as laboratory testing, access to routine EKG, medications for co-occurring conditions (e.g. for hepatitis C treatment and smoking cessation), and referral to subspecialty clinics if needed (e.g. hepatology and cardiology).

MMT has been available since 1960s. Because of the effectiveness of methadone maintenance in preventing drug use and its associated mortality, some patients, have been in MMT for decades. As this population becomes older, they are experiencing the emergence of medical problems associated with unhealthy life styles (i.e. cigarette smoking, obesity, lack of exercise) and with aging. Comorbid medical conditions may increase the risk of premature death in this population. The high rates of past IV drug use and, consequently, of hepatitis C and HIV in this patient population could be a risk factor for liver cancer, other types of malignant tumors, diabetes mellitus, and other chronic medical conditions. Smoking is a risk factor for different types of malignant cancer, including colorectal and lung cancer. Smoking is also a risk factor for COPD, coronary artery disease, cerebrovascular accidents, and other chronic medical conditions. Thus, the high rates of hepatitis C, HIV, and smoking in this patient population at entrance into methadone treatment may play a significant role in the later development of chronic medical diseases and increasing the odd of premature death. Thus, identifying risk factors for chronic medical conditions and potential targets for early intervention at entrance to MMT may reduce rates of morbidity and premature mortality in patients who are receiving methadone maintenance.

MANAGEMENT OF CO-OCCURRING ACUTE PAIN FOR METHADONE-MAINTAINED PATIENTS

Patients in MMT should not be denied adequate management of their acute pain conditions, for example, pain secondary to postsurgical conditions or bone fractures. These patients usually develop tolerance to the analgesic effect of their methadone dose. Methadone is usually prescribed once daily for treatment of opioid dependence. While the daily dosing may prevent withdrawal and block opioid craving, it may not provide analgesic effects for more than 4–6 h. Methadone duration of analgesia and potency are similar to morphine. Patients receiving MMT with co-occurring acute pain may need management with short-acting full opioid receptor agonists. Some clinicians may be reluctant to

prescribe short-acting opioids for this population due to the drug-seeking behavior of these patients. Therefore, ordering short-acting full agonists three four times per day as a standing order is preferable to as needed orders. Clinicians also need to be aware that ordering partial opioid receptor agonists like pentazocine or buprenorphine may precipitate opioid withdrawal and should be avoided for patients receiving MMT. Patients in MMT may need higher doses of the shortacting opioids than other patients due to their high tolerance. Over-sedation and respiratory rate should be monitored in these patients. The opioid dose may need to be adjusted if the patient experiences over-sedation, decreased respiratory rate, or other side effects.

METHADONE MAINTENANCE FOR TREATMENT OF OPIOID-DEPENDENT PREGNANT WOMEN

Illicit opioid use during pregnancy has been reported to be associated with adverse outcome to the mother and the fetus. Intrauterine growth retardation, premature delivery, low birth weight, small head circumference, still birth, and fetal death are common fetal complications among opioid pregnant women. Pregnant women with active illicit opioid use are at higher risk for poor nutrition, health status, and inadequate prenatal care. They usually have poor social support and may lose the custody of their infants due to their active opioid addiction. Offering treatment for opioid-dependent pregnant women may drastically improve the outcome for the mothers and their babies. MMT has been the standard treatment for opioid-dependent pregnant women. It reduces the high risk of relapse in this population which has been reported to be 41-96% after medication assisted detoxification. MMT can also reduce the adverse fetal outcome like premature delivery. Jones et al. compared the neonatal and maternal outcome for a group of opioid pregnant women receiving MMT versus another group who received methadone-assisted detoxification. They found that the group who received methadone-assisted withdrawal had a poorer maternal outcome compared to the methadone-maintained group. They concluded that MMT should be strongly considered as the primary treatment approach for opioid-dependent women. MMT has been reported to be associated with neonatal abstinence syndrome (NAS) characterized by nervous system hyperirritability and gastrointestinal, respiratory, and autonomic nervous system dysfunction. NAS may require pharmacologic treatment and prolonged hospitalization after delivery.

MMT has been recommended as the standard treatment for opioid-dependent pregnant women. This

recommendation may change due to a recently published multicenter, international, double-blind randomized clinical trial. In this study, Jones et al. compared the maternal and neonatal treatment outcome for a group of opioid-dependent pregnant women receiving MMT and another group receiving BMT. They found that the group who received BMT needed significantly less morphine for managing their NAS, had a significantly shorter hospital stay, and had a significantly shorter duration of treatment for the NAS. However, treatment was discontinued by 16 of the 89 women in the methadone group (18%) and 28 of the 86 women in the buprenorphine group (33%). Most of the women who left the buprenorphine group reported that they were not satisfied with treatment. The higher rate of satisfaction with methadone confirmed the important role it plays in treating pregnant women who are dependent on opioids. Moreover, given the partial agonistic activity of buprenorphine and its ceiling effect at maximal doses, it may not be the optimal treatment for all pregnant women with opioid dependence. They concluded that buprenorphine is an acceptable treatment for opioid dependence in pregnant women. Based on these new data, BMT might be recommended as an additional standard treatment for some opioiddependent pregnant women.

SEE ALSO

Antagonists for the Treatment of Opioid Dependence, Buprenorphine for Opioid Dependence, Pain and Addiction

List of Abbreviations

BMT buprenorphine maintenance treatment COPD chronic obstructive pulmonary disease

CYP cytochrome P 450
DA dopamine
DM diabetes mellitus

DSM-IV TR Diagnostic and Statistical Manual of Mental Disorders

Text Revision Fourth Edition Dopamine type 2 receptor

EDDP 2-Ethylidene-1,5-dimethyl 1-3,3-diphenylpyrrolidine

EKG Electrocardiogram

HIV Human immunodeficiency virus

HTN Hypertension

D2R

FDA Food and Drug Administration fMRI functional magnetic resonance imaging

IV Intravenous

MMT methadone maintenance treatment
NIH National Institute of Health
NAS neonatal abstinence syndrome

P-gp P-glycoprotein

PET positron emission tomography

QT QT interval TdP Torsade de Point

VHA Veteran Health Administration

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Buprenorphine for Opioid Dependence

Adam J. Gordon, Margaret M. Krumm University of Pittsburgh School of Medicine, Pittsburgh, PA, USA

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BUPRENORPHINE OPIOID AGONIST THERAPY

Opioid dependence is a chronic relapsing medical disorder afflicting millions worldwide, including as many as two million people in the United States. Untreated and ineffectively treated opioid dependence contributes to premature mortality and costly emergent use of health care and social services. A broad evidence base demonstrates the efficacy of opioid agonist therapy (e.g. methadone), and it is now considered the "gold standard" treatment for opioid dependence. In March 2005, the World Health Organization added buprenorphine as a complimentary medicine to the Model List of Essential Medicines thus encouraging access to buprenorphine treatment and legitimizing its role in opioid agonist treatment worldwide. Despite the strong evidence for the clinical effectiveness of opioid agonist therapy and the number afflicted with opioid dependence, medication-assisted recovery is offered to only a small proportion of those diagnosed. Lack of or suboptimum treatment contributes to incidence of other diseases, such as human immunodeficiency virus (HIV), viral hepatitis including hepatitis C, and a multitude of other mental and physical health disorders. People with opioid dependence also are disproportionately afflicted with social and environmental morbidities; illicit opioid use contributes to unemployment, homelessness, legal problems, and marital and family instability.

Opioid agonist therapy using buprenorphine or buprenorphine/naloxone (hereafter collectively termed "buprenorphine") is safe, effective, and cost-efficient treatment for opioid dependence. Since its introduction, buprenorphine has been an effective adjunct to other treatment. Buprenorphine opioid agonist therapy has the advantage of availability outside of specialized addiction treatment settings, thereby improving access to pharmacotherapy for opioid dependence. This is of particular importance

in resource-poor environments (e.g. under-developed countries, rural areas) where medication-assisted recovery may be the only option for opioid dependence treatment.

IMPROVING ACCESS TO OPIOID AGONIST THERAPY

In the 1980s, buprenorphine was first made available for prescription as an intravenous formulation for the treatment of pain. In the United States prior to October 2002, opioid agonist therapy - mainly through methadone opioid agonist treatment - was available only in licensed drug and alcohol programs. These programs continue to be regulated by state and federal entities that mandate clinical and programmatic procedures dictating whom can be admitted to the programs and how medication and non-pharmacotherapy (e.g. individual or group counseling) is provided over time. These requirements provide little flexibility in individualizing care. Meanwhile, several patient-, provider-, system-level barriers have been identified restricting quality methadone opioid agonist treatment in specialized programs. These barriers can include a finite capacity to treat patients, restrictive admission patient requirements (e.g. age, duration of physical opioid dependence), and physical distance from patients' homes. Several insurance barriers have also been identified.

Large health care systems generally provide opioid agonist treatment in formal programs, or they contract this type of care to out-of-network service providers. For instance, the Veterans Health Administration, a national health care insurance and provider network for United States military veterans, provides methadone in 42 programs and contracts out of network at an additional 10. Consequently, the treatment is effectively unavailable to patients who live prohibitively far from those facilities. Non-veteran populations in the United States are also limited in access to methadone treatment due to insurance, geographic, or ideological limitations. These barriers to methadone treatment (or any addiction treatment) may dissuade patients from entering treatment programs or providers from referring patients to this type of care.

In an effort to expand access to opioid agonist therapy beyond licensed addiction settings, the United States Congress made an amendment to the Drug Addiction Treatment Act (DATA-2000) in October 2002, allowing qualified physicians to prescribe and dispense approved medications in office-based practices for opioid dependence. In the United States, buprenorphine and buprenorphine/naloxone formulations continue to be the

only medications approved under this legislation for the treatment of opioid dependence.

In the United States, in order to begin prescribing buprenorphine in office-based practice, physicians must be appropriately qualified and have applied for a waiver from the United States Drug Enforcement Agency. Most practitioners become eligible to apply for a waiver by attending an 8 hour training through an approved training organization. Topics for these 8 hour trainings are uniform and include pharmacology of buprenorphine, guidance for its use, office policy, and common medical and psychiatric comorbidities of opioid dependence. As of 2006, over 10 000 physicians had completed the 8 hour courses, yet fewer than three-quarters actually requested and received a waiver to prescribe. Approved and waivered physicians may treat up to 30 patients with buprenorphine at any one time. After 1 year of being waivered, they may request an increase allowing a 100-patient census.

PHARMACOLOGY

Buprenorphine is a thebaine derivative significantly more potent than morphine. Buprenorphine has several actions physiologically. It is a mu-opioid receptor partial agonist, an epsilon-opioid receptor antagonist, a kappaopioid receptor antagonist, and a partial-to-full agonist at the ORL1 nociceptin receptor. Once absorbed, buprenorphine is metabolized primarily by the CYP3A4 isozymes of the hepatic cytochrome P450 system into the active metabolite norbuprenorphine via *N*-dealkylation. Buprenorphine and norbuprenorphine are metabolized through glucuronidation and eliminated in the bile.

There are several formulations of buprenorphine and buprenorphine/naloxone that allow for several routes of administration. Currently, there are two sublingual formulations of buprenorphine: buprenorphine hydrochloride and a combination of buprenorphine hydrochloride and naloxone hydrochloride in a ratio of 4:1. Other formulations include a parenteral injection (buprenorphine), sublingual film (buprenorphine/naloxone), subdermal implants (buprenorphine), and transdermal patch (buprenorphine). Other formulations are also under investigation. While buprenorphine can be administered orally in an ethanolic solution, it undergoes extensive first-pass metabolism, limiting its oral bioavailability. Both the sublingual tablet and liquid formulation (used in early studies on buprenorphine) are effective when administered sublingually.

Buprenorphine has several pharmacologic properties that makes it a compelling treatment for opioid dependence. These properties include: (1) partial agonist characteristics, (2) high affinity to the opioid receptor, (3) long half-life and slow elimination, and (4) high safety PHARMACOLOGY 419

profile. These properties render buprenorphine efficacious and potentially safer in the treatment of opioid dependence as compared to other pharmacologic therapies such as methadone.

Buprenorphine is a partial opioid agonist at the muopioid receptor. Like full opioid agonists (e.g. morphine, heroin), it interacts with nerve cells to produce analgesia, respiratory depression, and euphoria; however, it stimulates the receptor only partially. As the dose of buprenorphine increases, a ceiling effect much lower than that of full agonists is reached. Clinically, the partial agonist properties of buprenorphine provide the patient with the same effects as full agonists, such as heroin, morphine, and methadone, but with less intensity. The medication reduces craving associated with chronic opioid use, minimizes any euphoria associated with its administration, and eliminates or greatly reduces the opioid withdrawal syndrome.

In addition to the partial agonist effect, buprenorphine has a high affinity to opioid receptors making it useful in reducing illicit use in a buprenorphine-maintained patient. If a pure opioid is taken concurrently, the patient will not experience the full effect of the pure opioid because it will be essentially blocked from the mu-opioid receptor. Likewise, if a patient under the influence of an opioid takes buprenorphine, the patient may experience precipitated opioid withdrawal syndrome as the full opioid agonist is suddenly displaced from the receptor. This necessitates monitoring and thorough patient education during the induction phase of buprenorphine treatment. Buprenorphine's long half-life – approximately 36 h – is advantageous because it allows longer dosing intervals. Some clinicians note success with dosing every other day or even three times weekly.

Research into the safety of buprenorphine has been encouraging. Buprenorphine does not appear to affect the QT interval, a problem often associated with other opioids, including methadone. Because of the partial agonist and ceiling effects of buprenorphine, the risk of overdose is reduced. However, concurrent use of alcohol and other respiratory depressants such as benzodiazepines has been implicated in some morbidity and mortality, particularly in countries where high doses of benzodiazepines and buprenorphine (though not buprenorphine/naloxone injection) are more common. As with other opioid medications, buprenorphine can cause such findings as miosis (constricted pupils), somnolence/drowsiness, and generalized pruritus (itchy skin), but since buprenorphine is a partial agonist, patients experience these side effects to a lesser extent than with full agonists.

Diversion is the act of using a medication inappropriately or distributing it to others. Several pharmacologic and formulation characteristics discourage patients from diverting buprenorphine. As discussed above, buprenorphine is a partial agonist. As such, its effects are less intense (e.g. less euphoria) than those of full agonists; therefore, patients who abuse illicit opioids may not seek buprenorphine to "get high." Rather, if supplies of illicit pure opioids (e.g. heroin, prescription opioid medications) are unavailable, buprenorphine may be used as a form of self-medication to simply stave off withdrawal until a pure opioid is available. Second, because buprenorphine has a long half-life and slowly dissociates from the opioid receptor, one who uses it illicitly will be under its effects for some time, thereby reducing the effect of pure agonists (e.g. heroin). In sum, buprenorphine's ceiling effect and long half-life opioid misusers may deter from abusing buprenorphine.

The third property of buprenorphine that discourages diversion is present only in the combination formulations of tabs and films, which contain both buprenorphine and naloxone; the latter is an opioid antagonist, and its presence reduces the attractiveness of injecting the medication. While buprenorphine is absorbed sublingually (55% bioavailability), sublingual bioavailability of naloxone is negligible. Both have 100% intravenous bioavailability. If a patient takes buprenorphine/naloxone appropriately (i.e. sublingually), the buprenorphine is absorbed while the naloxone is not, and the patient will experience a buprenorphine effect. If a patient takes buprenorphine/naloxone intravenously after mechanical or chemical reconstitution, naloxone inhibits buprenorphine; in the opioid dependent, the withdrawal syndrome will be acutely precipitated. The naloxone in the combination tablet serves to temper desire to inject the medication. This reduces diversion and indirectly reduces spread of communicable comorbid conditions associated with opioid dependence (e.g. HIV, hepatitis).

The general consensus is that the only patients who should receive the buprenorphine mono-product are pregnant women. As of this writing, at least two pharmaceutical companies are making generic buprenorphine mono-product tablets that are cheaper than the yet still trade-only buprenorphine/naloxone tablet and films, raising fears that when physicians opt to prescribe the less expensive formulation, risks associated with diversion will increase.

Of the formulations, only the sublingual tablets and films are approved for use in the treatment of opioid dependence. Other formulations have been increasingly examined for the treatment of pain, particularly perioperative pain (primarily through the parental formulation), articular/spinal analgesia, chronic pain (primarily transdermal formulations), and noncancer pain. These other formulations may eventually be approved and used for the treatment of opioid dependence. There is some interest in buprenorphine being used for

hyperalgesic syndromes; however, there is no methodologically rigorous literature to support the use of sublingual buprenorphine in treating pain. Nonetheless, a growing number of clinicians are using buprenorphine for pain and pain syndromes. Some practitioners believe that the strong safety profile of buprenorphine may make the medication a preferred agent for pain. Additionally, some believe that buprenorphine may reduce the incidence of opioid addiction in the pain patient. Further studies of buprenorphine for pain are certainly called for.

CLINICAL CONSIDERATIONS

Several clinical guidelines, protocols, and other guidance have been published and disseminated by various organizations, governmental agencies, and expert panels to assist practitioners in buprenorphine care for the treatment of opioid dependence. Currently, there are but a handful of studies that suggest buprenorphine therapy over other evidence-based treatments, including methadone opioid agonist therapy. Furthermore, there is little evidence available to guide clinipatient characteristics cians about which environments may predict a better response with buprenorphine opioid agonist therapy over other treatments. There appear to be some patient and provider selection biases regarding entry into buprenorphine care. In some samples of patients, younger patients and patients with fewer medical and mental health disorders may preferentially seek buprenorphine over other agonist treatments. The ability to consolidate regular medical care with treatment of opioid dependence may be attractive to patients. Patients may preferentially choose not to go to licensed specialty addiction treatment programs to avoid requirements in treatment and for fear of the stigma associated with such programs.

Several patient and environmental factors should be assessed in any patient seeking office-based treatment using buprenorphine. At a minimum, patients should be or have been diagnosed with opioid dependence. Clinicians should assess and document history of and current opioid use, other substance use, and comorbid medical and psychiatric conditions. Attention should be paid to communicable diseases associated with illicit opioid use, such as HIV and viral hepatitis. Prior to initiating any opioid agonist therapy, the clinician should assess for the presence of social supports, family, friends, employment, housing, finances, legal problems, and patients' readiness to participate in treatment. Essentially, a comprehensive history and physical exam is necessary for any patient who is being

considered for opioid agonist treatment, including buprenorphine treatment.

TREATING OPIOID WITHDRAWAL SYNDROME

Buprenorphine can be used to treat acute opioid withdrawal syndrome or provide maintenance therapy over weeks, months, and years. Opioid withdrawal syndrome - also called opioid abstinence syndrome can be thought of as a two-phase process: an acute initial phase where patients experience physical and psychological consequences of reduction or elimination of opioids, and a longer phase - the protracted abstinence syndrome – which is predominately a long-term urge to use opioids. Physical symptoms of opioid withdrawal syndrome can last as long as 6 months, and psychological aspects of withdrawal can last much longer. There may be some advantage in using buprenorphine to manage opioid withdrawal. Buprenorphine's slow dissociation from the opioid receptors imparts a long duration of action and less severe withdrawal symptoms compared to other pure opioid agonists that are often used to "detoxify" patients using medically assisted withdrawal protocols.

In several research studies, buprenorphine has been shown to be an effective agent in pharmacological tapered management to reduce acute opioid withdrawal severity, morbidity, and frequency of opioid withdrawal symptoms. In a large study of heroin-dependent patients in a primary care setting, buprenorphine was superior to clonidine and combined clonidine and naltrexone in reducing opioid withdrawal symptoms. Furthermore, patients were more likely to more deeply engage in treatment of their opioid dependence when treated with buprenorphine. In a large study in clinical practices in the National Institute of Drug Abuse's Clinical Trial Network, buprenorphine was found to be superior to clonidine in 13-day medically supervised withdrawal. In several large reviews of the literature, good summative evidence exists that medically supervised withdrawal using buprenorphine is superior to other medications, including methadone and other opioids.

The goal of any medically supervised withdrawal using pharmaceutical agents is continued engagement in treatment of opioid dependence and potentially further opioid agonist maintenance therapy. While buprenorphine is effective for the treatment of opioid withdrawal and opioid withdrawal syndrome, the benefits of maintenance therapy with buprenorphine are superior to those of medically supervised treatment of withdrawal. In one study, investigators compared subjects who were maintained on buprenorphine over a year versus those who were "detoxified" in

standardized treatment of opioid withdrawal syndrome over a few weeks. Intense, comprehensive psychosocial treatments were available to each subject, and subjects were encouraged to continue the addiction treatments. All of the subjects who were detoxified were lost to follow-up and accrued a 20% mortality rate; there was no mortality in the buprenorphine-maintained subjects. This study was the first to conclude that opioid agonist maintenance therapy using buprenorphine achieves better patient outcomes than detoxification using buprenorphine.

INDUCTION, STABILIZATION, MAINTENANCE, AND DISCONTINUATION

Long-term treatment with buprenorphine occurs through a series of phases known as (1) induction, (2) stabilization, (3) maintenance, and (4) discontinuation. The length and intensity of these phases are often patient-specific, but some general consensus practices have been described.

Induction is the phase in which the clinician guides the patient in transitioning from pure opioids to buprenorphine, both physiologically and psychologically. As discussed above, buprenorphine may cause acute withdrawal if taken concurrently with pure opioids; the first dose of buprenorphine must be timed correctly to avoid this. When the induction appointment is scheduled, the clinician advises the patient to end opioid use at a certain time based on the length of action of the patient's drug of choice. The importance of establishing rapport and garnering the trust of the patient cannot be overstated because the patient needs to present to the induction visit in mild-to-moderate withdrawal. An objective measure of opioid withdrawal should be used, such as the clinical opiate withdrawal scale (COWS), to assist clinicians in accurately assessing the severity of opioid withdrawal. Once in moderate withdrawal (e.g. a score of 13 on the COWS), the first dose of buprenorphine – usually between 2 and 16 mg - is administered, and the patient is monitored. Earlier guidelines recommended that the buprenorphine mono-product be used for induction, but clinical experience has proven that the buprenorphine/naloxone combination formulation is just as efficacious and discourages surreptitious diversion. The majority of clinicians induct patients as described above in an office environment. It should be noted, however, that several investigators have found some patients to be candidates for induction in nonoffice settings, including home-induction, and this strategy appears to be more cost-effective.

Stabilization is the phase in which the clinician seeks to find the optimal dose of buprenorphine for each patient; that is, the dose that eliminates withdrawal symptoms and cravings for illicit opioids. While this varies by country, region, and population treated, patients are generally stable on 8–24 mg of buprenorphine daily. Dosing adjustments may be necessary due to disease processes, relapse, drug cravings, liver disease, medications that interact with the cytochrome P450 system, and other factors. However, an adequate dose is essential. In a study of patients taking up to 16 mg of buprenorphine, increasing doses of buprenorphine incurred an improved outcome - opioid-free urine drug screens – but a dose response effect did not occur for the clinical outcome of opioid craving. A recent consensus panel indicated that many patients do not require doses above 16 mg and that maintenance doses above this level may encourage buprenorphine diversion.

Maintenance is considered a period when patients' other medical and psychosocial needs can be addressed. Patients often work on vocational, family, and housing stability. During this phase, patients are encouraged to engage in other treatment modalities, such as formal individual or group counseling, self-help programs or groups, and provider-initiated therapy such as motivational interviewing, contingency management, or cognitive behavioral therapy. The role of non-pharmacologic treatment is important and should be considered essential for all patients treated with buprenorphine for opioid dependence. Current regulations in the United States are such that access to additional, specialty addiction treatment is required prior to initiating buprenorphine office-based care, and emerging evidence suggests that patients do better on buprenorphine when non-pharmacologic treatment is part of their treatment.

There is a paucity of evidence to guide clinicians regarding the length of buprenorphine maintenance for the best outcomes; patients have been maintained on opioid agonist therapy (i.e. methadone) for a lifetime. In addition, because of the short history of buprenorphine care for the treatment of opioid dependence, little clinical or anecdotal evidence exists. Several studies suggest that longer buprenorphine agonist therapy is better than shorter duration of care, that premature discontinuation is associated with worse outcomes, and that a flexible medically supervised taper of buprenorphine should occur when the goal is discontinuation of the medicine. In a review of more than 30 methadone discharge studies, investigators found that most patients who left methadone treatment were not assessed by their clinicians as being ready for discharge; among patients who began a therapeutic methadone discharge, most did not complete the detoxification; and among patients who completed a planned methadone discharge, most relapsed to heroin use. Thus far, there

is little reason to expect a different outcome when discontinuing buprenorphine treatment.

CLINICAL OUTCOMES

Buprenorphine has been shown to be safe and effective in the treatment of opioid dependence both in clinical trials and in real-world practice. Physicians who have been prescribing buprenorphine in office-based settings have found that the medication is effective and results in high levels of overall patient and provider satisfaction. There has been extensive research on the use of buprenorphine in reducing the use of illicit opioids and the harm associated with opioid dependence, and office-based care with buprenorphine improves behavior- and disease-specific metrics associated with illicit opioid use, best exemplified by reduction in HIV risk behaviors and improvement of HIV disease indices such as viral load. Further investigations have demonstrated positive system-level outcomes, such as reduced inappropriate utilization of health services and improved cost-effectiveness compared to traditional treatments, including methadone. These findings have been replicated in large health care and health system environments. Several studies are highlighted below.

Buprenorphine opioid agonist therapy combined with non-pharmacologic addiction treatment seems to be better than non-pharmacologic treatment alone. In one study, investigators examined patients in outpatient treatment settings and found that buprenorphine mono- and combination tablets were superior to placebo with the outcomes of drug-free urine samples and diminished craving for opioids. In another study, investigators assessed the rate and predictors of treatment retention for patients induced and maintained on buprenorphine in a primary care setting in a 6-month period. At 24 weeks, 59% of patients on buprenorphine opioid agonist therapy remained engaged in treatment. The investigators concluded that abstinence during the first week of treatment and engagement in addiction counseling were critical for patient retention. Employment was also a predictor of retention.

Buprenorphine opioid agonist therapy seems to be equivalent to opioid agonist treatment using methadone in several controlled research studies. In a 17-week randomized study of 220 subjects, investigators compared levomethadyl acetate (LAAM, 75–115 mg (taken off the United States market in 2003 due to cardiac arrhythmias)) administered three times a week, buprenorphine (16–32 mg) administered three times a week, and high-dose (60–100 mg) and low-dose (20 mg) methadone administered daily as

treatments for opioid dependence. Clinical outcomes investigated were treatment retention, 12 or more consecutive opioid-negative urine specimens, and subject report of drug use severity. Treatment retention and subject report of severity was worst in the low-dose methadone group. The percentage of subjects with 12 or more consecutive opioid-negative urine specimens was 36% in the LAAM group, 26% in the buprenorphine group, 28% in the high-dose methadone group, and 8% in the low-dose methadone group, which was a highly significant finding. In sum, buprenorphine was found to be as efficacious as high-dose methadone in promoting drug-free urine and treatment retention. Other investigators demonstrated that in subjects provided 8 mg buprenorphine or 50 mg of methadone with flexible dosing regimens, treatment retention in both groups over 16 weeks was similar. In another study, investigators found that methadone- and buprenorphine-maintained subjects experienced similarly reduced craving and illicit opioid use; however, the buprenorphine-maintained individuals were more likely to continue abstinence from illicit opioid abstinence over time.

Emerging results indicate that buprenorphine results in lasting positive outcomes in primary care settings. In one study, investigators examined officebased outcomes of subjects with both low and high socioeconomic status on buprenorphine opioid agonist therapy. They found that 77% of patients in buprenorphine therapy remained in buprenorphine therapy for 42 months and that retention in treatment was associated with participation in a self-help group, employabstaining from illicit substances, and improved functional status. Interestingly, there was no difference in outcomes based on socioeconomic factors. The investigators concluded that buprenorphine office-based treatment in primary care practices was a viable option that conferred improvement in outcomes when coupled with abstinence-oriented counseling programs.

Other investigators examined long-term outcomes of primary care office-based treatment using buprenorphine. They followed 53 patients who had already been stabilized for 6 months on buprenorphine and evaluated retention, illicit drug use, dose, satisfaction, and any adverse events. Of those in care, 91% had opioid-negative urine specimens with a mean dose of buprenorphine at 17 mg. The investigators concluded that selective opioid-dependent patients exhibit moderate levels of retention in primary care office-based treatment, no adverse events were related to buprenorphine, and 40% of patients who had been stabilized on buprenorphine for 6 months maintained abstinence for an additional 2 years, which is typical of patients on methadone maintenance.

The site of care, whether within an addiction or general medical clinic, may not predict success of buprenorphine opioid agonist therapy. In one investigation, investigators compared outcomes, costs, and incremental cost-effectiveness of detoxification and subsequent maintenance therapy between a drug treatment center and six outpatient general medical practices in Australia. They found that buprenorphine care was similar in terms of efficacy and cost-effectiveness in the two different settings.

USE IN SPECIAL POPULATIONS

Studies indicate that buprenorphine treatment reduces incidence of disease associated with illicit opioid use and improves disease-specific metrics of other diseases. A preponderance of the evidence suggests that opioid agonist therapy reduces drugrelated behaviors that carry a high risk of HIV transmission. For instance, in one study, investigators found that primary care-based buprenorphine treatment reduced drug-related HIV risks. Buprenorphine may be an ideal treatment for opioid dependence in HIV patients and has been successfully integrated with ongoing HIV care. While buprenorphine does appear to interact with some HIV medications, this interaction does not appear to be clinically important. Buprenorphine has been used in several countries with significant HIV populations and is specifically advocated for because of its association with reduction of risk of HIV infection. A recent study found that among eight countries -Australia, as well as select developing countries in Asia, Eastern Europe, and the Middle East - opioid agonist therapy substantially reduced in HIV-exposure risk associated with intravenous drug use.

Several investigators examining buprenorphine for subjects with HIV have found positive outcomes that are of particular clinical relevance to this population: decreased HIV RNA levels, increased CD4 counts, and improved compliance to HIV treatment. In addition, other investigators have found improvement in drugrelated outcomes of integrated HIV and buprenorphine care. In a large prospective study of opioid-dependent subjects with HIV, investigators found that for a clinical outcome of any previous 30-day illicit drug use, buprenorphine was associated with a decrease in illicit use among patients; 84% at baseline reported any illicit use in the past 30 days whereas 42% of those remaining in care after 1 year reported illicit use. In addition, quality of life and quality of care indicators may be improved for HIV patients taking buprenorphine. Integrated buprenorphine and HIV care may address transmission risk behaviors – an important secondary HIV prevention strategy among adults and youth.

HIV-infected patients seem to prefer buprenorphine care over other opioid dependence treatment modalities. Despite these preferences and buprenorphine's efficacy in HIV populations, there are physician and systemic barriers to implementing office-based opioid agonist treatment. Some cite concern about lack of access to addiction experts. Financing issues, workforce and training issues, lack of experience, operational consequences of conceptual differences between HIV care and addiction treatment, and other policies are barriers to the integration of buprenorphine into HIV care as well.

Emerging evidence indicates that buprenorphine may be a useful adjunctive treatment for patients infected with hepatitis or with coinfection of hepatitis and HIV. In addition, there is some evidence of successful use of buprenorphine in prison and re-entry populations, and further emerging evidence suggests that buprenorphine may be safe and effective for adolescents and youth who use illicit opioids. In an interesting study comparing homeless and non-homeless patients in office-based buprenorphine care, investigators examined rate of treatment failure, time to treatment failure, and any illicit drug use. They found that while homeless patients had more comorbid conditions than nonhomeless patients, outcomes were similar; only 21% of homeless patients and 22% of housed patients failed office-based treatment. Both housed and nonhoused samples had median retention of treatment at 9 months, only 4% of both groups who remained in care at one year had used illicit opioids, employment rates increased in both groups, and one-third of the homeless sample obtained stable housing.

Illicit opioid use among pregnant women is a growing problem, and it has deleterious consequences for mother and infant. There is burgeoning clinical and investigative evidence that buprenorphine use in pregnancy results in positive outcomes for both the mother and infant when compared to no treatment or traditional therapies such as methadone. One group recently summarized the literature regarding buprenorphine versus methadone in the treatment of pregnant opioiddependent patients and concluded that buprenorphine is safe and effective in pregnant adults. In another recent double-blind, double dummy, flexible dosing, randomized controlled study in which buprenorphine and methadone were compared in pregnant opioid-dependent patients, investigators found that buprenorphine was an acceptable treatment for opioid dependence in pregnant women. Neonates needed less morphine for neonatal abstinence syndrome and had shorter hospital days when buprenorphine was used in pregnancy compared to methadone. Several prior studies did not find a dose relationship between buprenorphine dose and neonatal abstinence syndrome.

ACCESS AND COST-EFFECTIVENESS OF BUPRENORPHINE CARE

Access to buprenorphine care is increasing worldwide. In 2008, an estimated 16232 physicians in the United States had been certified to prescribe buprenorphine (i.e. completed the 8-h training). Approximately 585000 patients have been treated with buprenorphine in the United States; as many as 70% are receiving maintenance treatment, and there have been approximately 4.1 million total prescriptions written.

The adoption of office-based buprenorphine opioid agonist therapy in the United States over the last decade represents a dramatic paradigm shift regarding how patients seek and receive care, as well as how providers care for opioid-dependent individuals. The shift from specialty addiction treatment in designated, tightly regulated addiction programs to more integrated outpatient primary care, psychiatric care, addiction care, and specialty (e.g. HIV, pain clinics) environments continues to challenge health care providers. Implementing buprenorphine care within large health networks may be particularly challenging, and it tends to be slow. For example, 3 years after the introduction of buprenorphine in the United States Veteran Health Administration, only 719 Veterans had been treated with it. In addition, implementation of buprenorphine has not been uniform across the country; provider-, administrative-, and facility-factors impede buprenorphine use. These numbers are especially disappointing when contrasted with the rate of buprenorphine adoption in the United Kingdom; prescribing rapidly increased in England upon introduction in 1999 such that by the end of 2003, buprenorphine represented 23% of all opioid prescriptions.

Despite the help buprenorphine offers to patients with opioid dependence, there appears to be concern over continued access to this medication for vulnerable populations. For example, among United States Medicaid populations, investigators found that patients with heart failure, diabetes, hepatitis C, major depression, and anxiety were less likely to receive buprenorphine treatment. This may suggest variability in patient access, treatment preferences, and level of care. High co-payments for medications, even through government assistance programs such as Medicare in the United States, may limit patient access to opioid agonist therapy.

In research abroad, buprenorphine was found to be cost-efficient compared to other forms of pharmacotherapy. Several studies have demonstrated a cost equivalency and cost-benefit of using buprenorphine over other treatment modalities. The costs associated with buprenorphine use within the confines of

outpatient care are generally limited to the physician costs and the medication. In contrast, in the United States, methadone maintenance therapy incurs significant infrastructure, labor, and dispensing costs because it is dispensed in tightly regulated settings. In essence, when compared to methadone treatment, despite the higher medication cost, buprenorphine treatment in outpatient offices may be less costly. Other investigators found that buprenorphine maintenance therapy (up to 12 months) was cost-effective compared to brief buprenorphine detoxification in a clinical trial of opioid-dependent youth.

When buprenorphine was first introduced in the United States, a study found that only at a price of \$5 or less per dose would buprenorphine opioid agonist therapy be more cost-effective than methadone. The same authors later found that in the United States Veterans Health Administration, treatment with buprenorphine was no more expensive than with methadone. Another group of investigators evaluated the cost of treatment for opioid dependence; they compared methadone provided in specialty clinics, office-based methadone, and office-based buprenorphine. While clinic-based methadone was found to be least expensive, the cost of buprenorphine tablets accounted for the majority in the difference in costs; thus, depending on benefits and co-payments, office-based treatment using buprenorphine may be less expensive for patients.

Investigators recently found that flexible-dose methadone and buprenorphine maintenance opioid agonist therapy are more clinically effective and more costeffective than no drug therapy in opioid-dependent patients. A flexible dosing strategy with methadone was found be somewhat more effective in maintaining individuals in treatment than flexible-dose buprenorphine and was therefore associated with slightly higher health gain and lower costs. In a randomized controlled trial using flexible-dose regimens in drug treatment specialty clinics in two Australian cities, other investigators concluded that buprenorphine treatment was not as effective as methadone treatment, but neither was more cost-effective. Similarly, in a randomized, open-label, 12-month study of heroin-dependent subjects receiving individualized treatment of buprenorphine or methadone opioid agonist therapy in a community setting, investigators did not find any significant differences in costs or outcomes between either treatment.

Buprenorphine care may reduce overall costs of health care. In one study, for patients with documented use of prescription opioids prior to initiation, treatment with buprenorphine was associated with a reduction in opioid utilization and cost in the first year of follow-up.

There may be attitudinal and logistical barriers that inhibit implementation of buprenorphine therapy. Providers may perceive a lack of resources to handle FURTHER READING 425

office-based opioid dependence therapy, they may believe such treatment is inappropriate outside of licensed, opioid agonist treatment programs, or they may simply choose not to treat it. Several studies have found provider reluctance in prescribing buprenorphine, but several reveal a positive attitude of physicians and pharmacists toward buprenorphine. Physician certification trainings and retraining may help. A major focus in the United States is mentoring and training physicians in appropriate care of patients with opioid dependence using office-based treatment modalities.

MISUSE AND DIVERSION

As access to buprenorphine has increased, so has concern about misuse and diversion of the medication. The addition of naloxone to buprenorphine reduces its overdose, abuse, and diversion potential. While there has been minimal diversion of buprenorphine in the United States compared to methadone and oxycodone – both widely prescribed by physicians - buprenorphine misuse does occur. Several population-based investigations in a variety of countries indicate that buprenorphine can be counted as a widely abused illicit substance. Some investigators found that over 30% of patients beginning treatment with buprenorphine in office-based practice subsequently injected it, although clinical experience in the United States indicates that it is not a typical practice. Most diversion occurs due to sublingual route. Other investigators have confirmed this; while diversion of buprenorphine is common, it is done more often to alleviate opioid withdrawal symptoms through a sublingual route and reduce use of other illicit opioids rather than to seek a high through sublingual or injection routes of administration. Major predictors of misuse included perceptions of inadequate dose and psychiatric comorbidity, including suicidality or prior suicide attempt. In Australia, investigators found that compared to methadone diversion in methadone care, buprenorphine diversion in buprenorphine care was threefold.

In general, providers are finding that while diversion of buprenorphine is occurring, the misuse tends to be limited to use in lieu of other opioids when they are not available or for self-medicating opioid withdrawal symptoms. Anecdotally, this diversion has led more patients to seek treatment for their opioid dependence. Many patients try buprenorphine illicitly, find it effective in reducing craving, and then seek out practitioners who provide the medication in office-based care. It is rare that a patient first entering treatment claims to have not heard about or tried buprenorphine.

SUMMARY

Opioid dependence is a disease that is best treated with a comprehensive treatment paradigm. Medication-assisted treatment using opioid agonist therapy has a vast evidence-based documenting reduction of illicit opioid use, improvement of comorbid conditions and functioning, and improvement of retention in a longitudinal, comprehensive treatment program. Recently, office-based treatment using the partial opioid agonist buprenorphine has improved patient access to opioid agonist treatment. In the United States, office-based buprenorphine care has provided addiction treatment outside of licensed opioid agonist treatment programs.

Buprenorphine has unique properties that make it attractive in the treatment of opioid dependence including low ceiling effect compared to full agonist opioids, high affinity for opioid receptors, and long half-life. A multitude of studies have demonstrated the efficacy, clinical effectiveness, safety, and cost-effectiveness of buprenorphine opioid agonist therapy. In certain populations, buprenorphine has been shown to be superior to other medications for treatment of opioid withdrawal syndrome and maintenance opioid agonist therapy. In concert with non-pharmacologic treatments for opioid dependence, buprenorphine therapy may be an essential adjunct treatment, especially in resource-poor locations or for patients who do not have access to other modalities of opioid dependence care.

SEE ALSO

Health Care Reforms and Treatment for Substance Use Disorders, Improving Medication Use in Addictions Treatment, Methadone Maintenance, Antagonists for the Treatment of Opioid Dependence

List of Abbreviations

COWS clinical opiate withdrawal scale HIV human immunodeficiency virus

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Antagonists for the Treatment of Opioid Dependence

Colin Brewer*, Evgeny Krupitsky\$

*The Stapleford Centre, London, UK ^{\$}St. Petersburg Bekheterv Research Psychoneurological Institute, St. Petersburg, Russia

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INTRODUCTION

Unlike many therapeutic agents, naltrexone (NTX) was not discovered by chance. It was a result of the US government program to produce opiate antagonists, specifically because it was thought that they might be useful in the treatment of opiate dependence. Some early creations of this program turned out to be unsuitable because of toxic effects. Cyclazocine, for example, could produce hallucinations. On the other hand, the program also led to the development of naloxone, which has been very widely used and, like naltrexone, has very low organ toxicity. Indeed, given that product information sheets for NTX still routinely contain warnings about hepatotoxicity, it

is appropriate at this stage to note that for nearly two decades, NTX has been routinely, safely, and effectively used – often at relatively high and prolonged dosage – to treat the distressing pruritus that frequently accompanies severe jaundice caused by a variety of serious and life-threatening liver diseases (see below).

RATIONALE AND THEORETICAL BACKGROUND

The rationale for using opiate antagonists to treat opiate dependence is to some extent self-evident: a drug that effectively blocks the attractive effects of heroin and other agonists is likely, on commonsense grounds, to reduce or abolish the intake of opiates while effective antagonist blood levels exist because using opiates would be pharmacologically pointless. On that basis, one might predict the rapid resumption of opiates when NTX use ceased, which was exactly what happened in many (but not all) earlier studies of oral NTX. However, Wickler theorized two decades before NTX was synthesized that an effective antagonist might help to achieve a more lasting abstinence from opiates by the cognitive-behavioral processes of extinction and negative reinforcement. To this end, some heroin addicts were encouraged to inject or smoke heroin while their opiate receptors were blocked with NTX, albeit for rather short periods. Unfortunately, no significant lasting reduction in craving was observed. While there is now good evidence from randomized controlled trials (RCTs) for the effectiveness of NTX in treating opiate dependence, it may be that the use of NTX in the real world of opiate dependence as opposed to the clinical or animal laboratory setting needs alternative or additional theoretical arguments. We address this issue later in the chapter.

CLINICAL BACKGROUND AND THE COMPLIANCE PROBLEM

When NTX became available for clinical use in the early 1970s, it soon became apparent that although it effectively blocked opiate agonist effects in humans as it had done in laboratory animals, humans had an annoying (if unsurprising) tendency to discontinue NTX if they were simply given a supply and advised to take it daily to protect themselves against temptation. Within a couple of years of its first clinical use, the need for a long-acting preparation was becoming apparent and the first studies of potential matrices and vehicles for such preparations appeared. As was said in the context of disulfiram (DSF) - another addiction treatment medication that has important conceptual similarities with NTX, which we will discuss later - "For any drug which has to be taken daily on a chronic basis and for which compliance is a problem, administration in depot form as an implant is an obvious solution." Here, we merely note that ambivalence about taking medication – "poor compliance" or, in the current politically correct locution, "poor adherence" – is a common problem with most treatments, especially when treatment must be prolonged. However, it is important to note that in some oral NTX studies, compliance was considerably improved by therapeutic contracts that involved third parties (ranging from family members and colleagues to probation officers) in supervising oral consumption. Not surprisingly, outcomes also improved.

It might seem obvious that compliance with a particular treatment is crucial to the outcome of that treatment but that is too simplistic in approach. It is now clear from several studies that patients who comply with treatment not only have better outcomes but also differ in several other important respects from patients who do not comply. Compliance, in essence, means following medical instructions. People who do not follow medical instructions may have several reasons for their lack of cooperation, ranging from failure or inability to understand the instructions, to various beliefs and attitudes that make them actively hostile to the proffered advice. They may also be generally inefficient and disorganized in their lives, or affected by short-term stress or distress that distracts them from their usual efficiency. People who comply are thus more likely to have social and personality characteristics, which lead to more favorable outcomes (compared with noncompliers) regardless of the treatment.

However, at a strictly therapeutic level, compliance with a particular pharmacological or psychological treatment only matters if the treatment in question actually has specific positive effects over and above any placebo or nonspecific effects that it may have. To comply perfectly with an objectively ineffective treatment confers, by definition, no benefit over equally perfect compliance with an appropriate and equivalent placebo treatment. For example, RCTs of DSF implants often show quite impressive levels of abstinence but no difference between active and placebo implants, because no commercially available DSF implant has provided effective or even measurable blood levels of DSF or its active metabolites; or any response to unanticipated alcohol challenges given intravenously. Conversely, even partial compliance with a significantly effective treatment may give better outcomes than good compliance with an ineffective one. Since NTX blocks opiates very effectively, it follows that maximizing compliance is more than usually important, and the most recent systematic review confirms that without supervised administration, the effectiveness of oral NTX in opiate abuse is modest at best.

The compliance problem is surely even greater in patients who request treatment for addictions because such patients are, we suggest, usually ambivalent by definition about having treatment. If they were consistently 100% in favor of discontinuing their addiction, they would hardly need treatment, except perhaps for transient help in managing unpleasant physical withdrawal symptoms. Conversely, if they were consistently 100% opposed to discontinuing their addiction, they would not be willingly present for the treatment in the first place. Thus, the large majority of patients seeking

or accepting treatment can be assumed to have mixed feelings about taking medication designed to discourage them from doing what a part of them very much wants to carry on doing. This is not likely to be a prominent factor in poor compliance with antihypertensive or antidiabetic medication, since few, if any, patients want to be hypertensive or suffer from poorly controlled diabetes. Poor compliance with this sort of medication probably stems more from forgetfulness, ordinary (as opposed to pathological) human failings, confusion (especially with multiple medications), inadequacies in the doctor–patient relationship, and side effects rather than from any fundamental ambivalence about treatment.

Indeed, the more effective the anti-addiction medication, the greater the ambivalence, for there is less potential for conflict about complying with a medication (or with a nonpharmacological treatment) that actually has little or no specific effect on consumption of the target drug of abuse. It is not difficult (to put it mildly) for patients to relapse while consistently taking NTX or acamprosate for alcohol abuse, or while regularly attending Alcoholics Anonymous meetings. In contrast, it really is impossible to relapse to true opiate dependence while maintaining adequate NTX blood levels, though this statement needs a few qualifications, as we discuss later.

THE DEVELOPMENT OF NALTREXONE IMPLANTS (NTXI) AND DEPOT INJECTIONS OF NALTREXONE (DINTX)

The first animal studies of possible depot preparations appeared in the mid-1970s. Human studies, under the aegis of NIDA, with a range of implant formulations, such as esterification and NTX microspheres covered with biodegradable plastics, were published in the 1980s. The implants were small enough to be inserted subcutaneously with a trocar and cannula and gave NTX levels lasting up to several weeks. Attempts to make a commercially viable depot preparation began in the early 1990s but despite the obvious and pressing need, nothing was clinically available by the mid-1990s even for "named patient" use.

In 1996, George Malmberg of Wedgwood Pharmacy, Sewell, NJ, produced some experimental implants based on standard implant technology as applied to a number of other drugs, using NTX powder compacted with a small amount of magnesium stearate. The first developed implants contained only 100 mg of NTX and were inserted subcutaneously with a trocar and cannula. Early studies with volunteers, including a physician, indicated that tissue tolerance was acceptable and that clinically effective blood levels were reached, as judged

by the ability of the implants to block challenge doses of opiates. To increase the duration of action, larger implants containing 1 g of NTX were manufactured. They were cylindrical in shape but at approximately 9 mm diameter (and about 20 mm long) needed to be inserted through a.c.1 cm incision under local analgesia. They appeared to provide blockade for 5–7 weeks on average and completely prevented relapse during the first four weeks after detoxification in a consecutive series of the first 54 patients treated in Britain. All patients were made aware that these implants had not passed through any of the usual testing and licensing procedures (or indeed, any animal studies) but both patients and physicians could be reassured by previous NTX implant studies and by the very low organ toxicity of NTX (see below) as demonstrated in over a decade of oral use.

In Germany in the late 1990s, Partecke and her hospital pharmacist produced implants made of compressed pure NTX base, rather than the hydrochloride salt of NTX used in previous implants and without any stearate component. They contained 800 mg of NTX. Clinical studies indicated the expected improvement in outcomes compared with oral NTX and pharmacokinetic studies confirmed that effective blood NTX levels were maintained for several weeks.

Despite their immediately obvious value in preventing early relapse, it was also soon apparent, as with oral NTX, that most patients needed the protection of NTX for much longer than the 6–8 weeks, which was the typical maximum duration of these "first-generation" implants. If patients did not have further implants early in treatment, relapse quite often (but by no means always) tended to follow, sometimes quite soon after the blockade had worn off. This problem would also have occurred with the injectable, microsphere depot preparations that were being developed, had they been available for treating opiate abusers, since they only provided adequate blockade for 4–5 weeks. It is true that clinicians using these preparations had more time before opiate antagonism disappeared to persuade reluctant patients of the need for a further NTX treatment than is the case with oral NTX. However, given the typical ambivalence about treatment discussed above, it was to be expected that the uptake of repeated implants would decline over time, unless treatments were tied to, for example, a probation order, as discussed above.

Accordingly, alternative implant technologies were exploited to extend the duration of blockade not just by a few weeks but also by several months. By 2001, unlicensed but pharmacologically active "second generation" NTX implants became available, produced by Dr George O'Neil of Go Medical in Australia, referred to henceforth as the Go Medical Implant (GMI). They used some of the technology studied in the early 1980s

in that the NTX was contained in biodegradable (polylactate or poly-glycolate) plastic-covered microspheres. However, instead of being suspended in an inert liquid vehicle, as with depot injections, the microspheres were compressed with additional biodegradable plastic into pellets about 8 mm in diameter for subcutaneous insertion through a small incision, so that diffusion – and hence duration of action – could be prolonged almost at will, depending on microsphere size, rate of biodegradation, the proportion of NTX to matrix, and the number of pellets that were inserted. From the earliest publications, it appeared that this implant could maintain effective blockade for as much as six months in some cases.

In 2007, Vivitrol, became the first of several depot injections of NTX under development to receive a license, initially for alcohol abuse treatment only. It is still (at the time of writing) the only licensed injection but in 2010 its license was extended to include opiate-abuse treatment, though it had already been used "off label" for this purpose.

PHARMACOKINETICS OF NTXI AND DINTX

Hulse et al. (2004) compared blood NTX and 6-βnaltrexol (6BNTX) with single (n = 10) or double (n = 24) GMIs in patients having treatment for heroin abuse. In most patients, free NTX levels remained above 2 ng ml⁻¹ and 1 ng ml⁻¹ for approximately 90 and 136 days, respectively, with the single GMI containing 1.1 g of NTX. For the double implant, the figures were 188 and 293 days. In a later study by Ngo et al. (2008), the additive effect of a triple implant was compared with the data already obtained by Hulse et al. (2004). As expected, the triple implant maintained levels above 2 ng ml⁻¹ (standardized for a 70 kg body weight) for longer periods (145 days versus 136 days for the double and 95 days for the single implant). However, the difference was not statistically significant. In a study by Kunoe et al. (2009) described in more detail below, blood samples were taken from 14 of the 26 patients with the GMI. NTX levels remained above 1 ng ml⁻¹ throughout the 6 months of the study and above 2 ng ml⁻¹ for about 5 months.

In several implant studies (and as is true of many other drugs) NTX levels showed marked variation between subjects. Since this has also been observed during constant dosing with oral NTX, it is unlikely to be due entirely, or even largely, to the release characteristics of the implant. However, some variation in release rates seems to bound arise from variations in such local and general factors as vascularity, age, sex, and liver function. There were also 16 cases in which, rather than showing a steady fall, a later blood sample gave a higher level than the previous one. This, too, probably

reflects variation in the rate at which local tissue fluids reach and penetrate the implant matrix.

Comer et al. (2002) studied NTX blood levels and the response to various test doses of diamorphine (up to 25 mg) in 12 heroin-dependent patients. Half of them received a low dose (194 mg NTX base) and the other half received a higher (double) dose of 384 mg of a DINTX under development. Plasma NTX levels remained above 1 ng ml⁻¹ for 3 and 4 weeks after the lower and higher doses, respectively. Subjective effects of heroin were antagonized for 3 and 5 weeks respectively.

Using first generation Wedgewood implants, Waal et al. (2002) showed that blood NTX at or above the widely accepted minimum effective level of 1–2 ng ml⁻¹ were maintained for periods ranging from 5 to 10 weeks. However, in both the first-generation implants and DINTX preparations and unlike GMIs, once NTX blood levels decline to this minimum figure, NTX usually disappears entirely from the blood within a week or two. This means that – as with any conventional medication-free abstinence-based treatment program – patients who use heroin, especially by injection, are at risk of potentially lethal opiate overdose (OOD). In contrast, the long pharmacological "tail" of the GMI means that even when NTX blood levels drop below the conventional minimum at around 6 months, they may still prevent lethal respiratory depression for a further 3–6 months.

OPIOID OVERDOSE PREVENTION

During the period when an implant provides serum NTX levels at or above the conventional minimal effective range of 1–2 ng ml⁻¹, it will generally block all agonist effects of even large doses of heroin and most other opiates including both the desired euphoriant effects and the dangerous (and usually undesired) respiratory depressant effects. The highest reported medically observed challenge dose, described in more detail below, involved the administration of 500 mg of pure diamorphine intranasally with no sign of any agonist effects. This is much more than the diamorphine contained in typical individual doses of street heroin used by all but the most severe and well-supplied addicts. As NTX levels fall, heroin users may eventually obtain a euphoriant effect, but it seems that the level needs to fall further still before respiratory depressant effects are seen. This is a very fortunate feature of NTX pharmacology because patients whose opiate receptors have been blocked (or who have simply abstained without NTX) for several months lose their tolerance and risk death or anoxic/apneic brain damage if they abuse opiates again. In one case, an implanted patient, abstinent for several months, was employed as a heroin courier in Russia precisely because he was assumed to be immune to temptation. However, he injected an unknown but evidently enormous amount of the heroin he was supposed to be selling. He experienced brief unconsciousness and apnea but recovered spontaneously and completely in a minute or two. Clearly, the NTX blocked all but the transient highest peak of the agonist effects. Without NTX, he would almost certainly have died.

It was thus reassuring but unsurprising when two GMI studies found large reductions in the expected incidence of OOD for as much as a year after implantation. This was true both for a group of adolescents at high risk for OOD and for implanted patients in general. Interestingly, in the latter study, there was an increase in nonopiate sedative overdoses from eight cases of preimplantation to 16 afterward. However, 9 of the 16 occurred in the first week or two after implantation and were probably caused by attempts to deal with the unpleasant withdrawal symptoms (including intractable insomnia) that normally make the period immediately following detoxification (by any method) such a difficult and relapse-prone stage in treatment.

EFFECTIVENESS STUDIES OF NTXI AND DINTX

Having described the theoretical and historical background and pharmacokinetics of depot and implanted NTX and the marked OOD-preventing qualities of longer-acting implants, we now summarize the RCTs that have been published in the last few years. They have largely confirmed the positive results that were consistently reported in earlier uncontrolled studies. The first three studies below used the GMI.

Hulse et al. randomized 70 patients to active GMI (2.3 g of NTX) and placebo NTX capsules, or to placebo implant and oral NTX 50 mg day $^{-1}$. In both the cases, family members were encouraged to supervise consumption of oral medication. At 6-months follow-up, more implant than oral patients had NTX levels above 2 ng ml $^{-1}$ (p < 0.001); 17 versus 62% of patients reported regular heroin use; 63 versus 26% reported being abstinent (p < 0.003), 49 and 21% respectively being confirmed by urinalysis. Patients on oral NTX started using heroin at an earlier stage (median (SE) 115 (12) versus 158 (9.4) days); NTX levels in implant patients were above 1 and 2 ng ml $^{-1}$ for 101 (95% CI 83–119) and 56 (39–73) days respectively for men and 124 (88–175) and 43 (16–79) days for women.

It is important to note that all patients who presented for withdrawal and NTX induction were successfully started on oral or implanted NTX with no dropouts, using an outpatient procedure lasting only a few hours. The study, therefore, did not exclude those heroin addicts with unusually severe withdrawal symptoms (or ambivalence) who often discharge themselves prematurely from conventional inpatient or, even more often, outpatient withdrawal programs. The typical true completion rate even in many "centers of excellence" is less than 30%. In contrast, on an "intention-to-treat" (ITT) basis, 100% of the patients in this study reached this vital stage of treatment.

Kunoe et al. conducted a multicenter, open-label study of 56 patients (approximately 85% heroin injectors) aged ≥18 years from various inpatient detoxification programs in SE Norway and willing to be randomized. If detoxification was completed, they received either normal post-detox care (control) or normal care plus a GMI. Participants were fairly typical of the total population of the 15 clinics. ITT analysis showed significantly less opioid use than controls on all opioid use measures. For example, implant patients used heroin for a mean of 17.9 days (versus 63.6 days for controls) in the 180-day follow-up. Differences were even more significant in the 49 patients who completed treatment. A follow-up study found that 51% requested and received a second implant.

Lobmaier et al. studied imprisoned heroin-related offenders, who are at especially high risk of relapse (and fatal overdose) after release. They compared the effects of GMI or methadone maintenance treatment (MMT) on the use of heroin (and other illicit drugs) and criminality among heroin-dependent inmates after they left prison. Forty-six volunteers were randomly allocated to GMI or MMT before release, though they found it unexpectedly difficult to recruit the planned number of inmates willing to be randomized. However, ITT analyses showed reductions in both groups in the use of heroin and benzodiazepines, as well as criminality, 6 months after prison release. They concluded that NTX implants "may be a valuable treatment option in prison settings."

In Russia, RCTs have recently been completed and published involving both Prodetoxon, a "first generation" type of implant, and Vivitrol. The first long-acting, sustained-release NTX formulation available in Russia was an implant (Prodetoxon; Fidelity Capital, Moscow, Russia). It contains 1000 mg of NTX that is slowly released after being inserted subcutaneously in the abdominal wall via a small incision. It was registered in Russia in 2005 and shown to block opioids for 2 months, but this time frame was extended to 3 months during the past year, based on clinical experience. As of this writing, it is the only officially registered NTX implant in the world. In this large scale double-blind, double dummy placebo-controlled RCT comparing NTX implant to both oral NTX and placebo implant, 306 recently detoxified opioid addicts were randomized to a 6-month course of biweekly drug counseling and one of three medication groups, each having 102 patients: NTX implant (1000 mg, 3 times - every other month) + Oral placebo daily (NI + OP), Placebo implant + Oral NTX (PI + ON) (50 mg day $^{-1}$), and double placebo (implant and oral) (PI + OP). Medications were administered under double-dummy/ double-blind conditions. Urine drug testing and brief psychiatric evaluations were done at each biweekly visit. Oral medication compliance was evaluated using a urine riboflavin marker. According to the study results, the number of heroin negative urines revealed a clear advantage of the NTX implant group over the two others: The cumulative proportion of heroin negative urines in NI+OP group was 63.6% compared to 42.7% in PI + ON group and 34.1% in PI + OP group (p < 0.0001, Fisher Exact test). Survival analysis also revealed a significantly greater retention in NI+OP group compared to two other groups: 53% of the patients in NI+OP group completed treatment compared to 16% in PI + ON and 11% in PI + OP groups (p < 0.001). The number of nonsurgical adverse events was limited with no difference between groups. However, surgical adverse events (wound infections, local site reactions) were higher in the NI + OP group (5% of all implantations) compared to the two other groups (1%). Thus, this long-acting NTX implant was generally well-tolerated and more effective than oral NTX and placebo for preventing relapse to opioid dependence. No significant differences were detected between groups in physical and social anhedonia, thus implying that the long-acting NTX did not interfere with normal pleasurable stimuli. As with our previous studies oral NTX, psychiatric symptoms (anxiety, depression, opioid craving) were markedly reduced in patients who remained in treatment and did not relapse, and no differences were noted between groups for those who remained in treatment and did not relapse.

Implantable NTX formulations have several limitations. First, they require a minor surgical procedure that carries with it the risk of wound infections and cosmetic defects. Second, it is possible for the patient to remove the implant within the first few weeks, as Prodetoxon slowly dissolves and can be removed reasonably intact in that period. Third, in some patients (<10%), the implant appeared to block opioids for less than 2 months. Therefore, a long-acting, slow-release formulation that is injectable and simple to use and does not require surgery might have some advantages over an implant formulation.

Three sustained-release, DINTX formulations have been developed in the past 10–15 years: Vivitrol (Alkermes, Waltham, MA), Depotrex (Biotech, Bethesda, MD), and Naltrel (DrugAbuse Sciences, Hayward, CA). Only Vivitrol has US Food and Drug Administration

approval. It is administered via a monthly intramuscular injection and approved for prevention of relapse to alcohol dependence. It is available in the United States, Europe, and Russia, and recent studies have found that a monthly intramuscular injection also blocks the subjective effects of opioids. A multicenter study of Vivitrol has recently been completed in Russia and led to FDA approval of Vivitrol for opiate dependence. A double-blind, placebo-controlled, randomized 24-week trial recruited adults with opioid dependence disorder, <30 days of inpatient detoxification and >7 days off all opioids. Participants received monthly intramuscular Vivitrol 380 mg (n = 126) or an identical looking placebo (n = 124) with 12 biweekly counseling sessions. The primary outcome was confirmed abstinence, based on opioid-negative urine drug tests as well as self-report of nonuse during weeks 5–24.

Group differences on the primary outcome of confirmed abstinence were significant (p = 0.0002) with Vivitrol yielding a median of 90% confirmed abstinent weeks versus 35% for placebo. Vivitrol-treated patients self-reported a median of 99.2% opioid-free days versus 60.4% for placebo (p = 0.0004). An anticraving effect was observed, with an average reduction of -10.1 for Vivitrol versus +0.7 for placebo (p < 0.0001). Median retention was >168 days with Vivitrol versus 96 days with placebo (p = 0.0042). Naloxone challenge confirmed relapse to physiological opioid dependence in 17 placebo patients versus one Vivitrol patient, a 94% difference (p < 0.0001). Reduced HIV risk behavior, improved mental health function, and higher global clinical index ratings were observed with Vivitrol versus placebo. Vivitrol was well-tolerated and no Vivitrol-treated patients died, overdosed, or discontinued due to severe adverse events. Vivitrol, in conjunction with psychosocial treatment, demonstrated efficacy versus placebo across multiple recovery goals, including prevention of relapse, in patients with a history of opioid dependence. Thus, Vivitrol represents a new medical approach, quite distinct from opioid maintenance treatment, through once-monthly, injectable, opioid blockade.

LOCAL SIDE EFFECTS

Histological changes in tissues adjacent to GMIs have been studied at 1–38 months post-insertion. Initial and expected inflammatory and foreign body reactions steadily reduced until they disappeared by the end of the period. In a later GMI study, ultrasound was used to monitor the in vivo changes at 139 implant sites in 71 subjects at periods ranging from 2 to 1808 days after implantation. Patients were recruited by being approached, in sequential order, within four time blocks

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postimplant (1-142 days, 216-399 days, 439-756 days and 896+ days). The ultrasound appearance of the separate tablets of the implant changed from being welldemarcated to less demarcation, followed by gradual coalescence into a single mass. A second radiologist, together with the first, independently assessed the amount of the remaining implant material. This had completely disappeared by an average of 1201 days postimplant. The radiologist who assessed the appearances was blind to the length of time since implantation. Additional assessment was provided by a nurse (also blinded to the time period) who examined the implant area visually and by palpation and also by patient selfreports. Both studies showed that in general, the implants were well-tolerated. As the authors note, the polymer used in the implants has been safely used for many years, not only in the comparatively small volumes required for absorbable sutures but also, since at least the mid-1980s, for the much larger volumes needed, for example, in absorbable screws for the fixation of bone fractures.

With first-generation implants containing magnesium stearate, both giant cells and stearate crystals may be seen. Some formulations incorporate a slowrelease corticosteroid trying to reduce tissue reactions.

SYSTEMIC SIDE EFFECTS

Liver

One potential disadvantage of any implanted drug is that if significant side effects of the active constituent occur, the implant may have to be removed. This is of particular concern where DINTX is concerned, since it is almost impossible to remove the intramuscular drug deposit but it is also an important consideration for any still-unlicensed preparation. Fortunately, in some 40 years of clinical use, NTX has not been associated with any serious organ toxicity that might limit its prescription. The only one regularly mentioned as important is hepatotoxicity, and a special warning about it still appears in the prescribing literature of most countries where NTX is marketed. These warnings are misleading but the reason for their existence (and persistence) is little known. H. Kleber was involved in some early 1970s clinical studies and reports (personal communication) that there was pressure to change NTX's status from "experimental" to a drug that could be used without too much bureaucratic obstruction in clinical trials. The pressure originated in many US servicemen who started abusing heroin in Vietnam in that period and were expected to need treatment when they returned home. Full toxicity trials had not been concluded but the evidence was reassuring. The authorities agreed in 1972 to ease restrictions on its use, provided that "black box" warnings about possible hepatotoxicity were displayed, since some studies had raised concerns. Having entered the official literature, the warning has remained there, though its justification is now very questionable.

As noted by and Brewer and Wong, the best evidence for this statement is not the numerous toxicity studies published since 1972 but the fact that for nearly two decades, oral NTX has been safely used, often for many months and at high daily doses, to relieve the intense pruritus of severe jaundice. The high bilirubin levels are usually due to serious liver disease, sometimes life-threatening. Even if jaundice is secondary to obstruction, severe biliary stasis itself often causes significant disturbance of liver function tests (LFTs). While NTX use may occasionally be associated with moderately abnormal LFTs, they did not cause any obvious abnormal deterioration in health or lead to any clinical alarm in any of the reported cases. All abnormalities disappeared rapidly when NTX was discontinued and sometimes even when it was not. Consequently, where strong indications exist for NTX treatment in either opiate or alcohol abuse, even serious liver disease should not be an automatic contraindication, and the appearance of LFT abnormalities after starting NTX treatment should lead to observation and frequent review rather than to instant termination of treatment. Brewer and Wong described a patient who became jaundiced from Hepatitis B 1 week after NTX implantation, having apparently become infected some 6 weeks earlier. The implant was not removed but the acute illness followed its normal course and the jaundice resolved in the normal way without specific treatment. In real clinical life, NTX appears to have no significant hepatotoxicity. Rashes due to specific hypersensitivity to NTX have been reported but are very rare.

NTX in Pregnancy

O'Neil, Pereira, and Brewer described their experiences of treating 25 pregnant heroin addicts with oral NTX in three different countries (Australia, Portugal, and Britain, respectively). Interestingly, all the women were started on NTX – mostly in the second or third trimester – using relatively rapid NTX induction under oral or intravenous sedation. In four cases contributed by O'Neil (who is an obstetrician and gynecologist as well as an addiction physician) NTX induction was done with ultrasound fetal monitoring. In none of the 25 cases was any fetal distress observed during NTX induction and precipitated withdrawal. Obstetric

outcomes were "reasonably unremarkable." All had good APGAR scores and all, except two with marginally low birthweights, had normal head circumference. Delivery was vaginal and spontaneous in all except two cases. In the single case among this group contributed by Brewer and treated in the late 1980s, it proved possible to follow-up the child involved at the age of 10. Her milestones and development were normal and she was making satisfactory progress at an ordinary school. After starting NTX, only 3 of the 25 women resumed heroin use before delivery and two of those requested and received further treatment with NTX before giving birth.

Hulse and O'Neil reported a series of eight pregnancies involving women with long histories of refractory heroin abuse. Six of them became pregnant not long after NTX implantation, underlining the rapidity with which normal fertility and menstruation may return when heroin abuse ceases. All eight were free of opiate dependence throughout pregnancy, following implantation, and delivered infants who showed no withdrawal symptoms and had high APGAR scores. Four had normal, full-term deliveries, one was induced, and three had elective Caesarians.

In a nonrandomized study, pregnancy outcomes in a group of 17 women treated with GMIs (16 of whom conceived after implantation) were compared with a group of 90 pregnant women treated with MMT. The results were also compared with national Australian averages. There were significantly more low-birthweight infants in the MMT group (24 versus 5.6% national average and 5.9% in the NTX group); significantly more deliveries ≤37 weeks in MMT group (23 versus 4.6% national average and 11.7% in the NTX group); and significantly higher APGAR scores in the NTX versus the MMT group. Again, all infants in the NTX group were free of opiate withdrawal symptoms on delivery. Even without confirmation from randomized studies, these findings may already have important implications for the choice of management offered to opioid-dependent women who are either pregnant or have a high likelihood of childbearing in the shortterm. The advantages of avoiding the problems of neonatal withdrawal, distress to mother, baby, and nursing staff alike and often involving prolonged and costly intensive care, hardly need to be pointed out. These reports suggest that for pregnant opiate addicts (a group of women who typically have less than ideal obstetric and fetal outcomes), treatment with NTX merits urgent studies comparing it with MMT - the current gold standard. Furthermore, it is a common experience that at least for the duration of the pregnancy, pregnant women are much more highly motivated than the average heroin addict to give up drugs of dependence, not excluding tobacco.

MENTAL HEALTH AFTER IMPLANTATION

Lowered mood and energy levels are common in the weeks and months following opiate withdrawal. The theory that at least some heroin addicts use opiates to self-medicate for underlying mood disorders created understandable concern that prolonged and inescapable blockade of opiate receptors might lead to an increase in depression and/or other psychiatric conditions. Fortunately, a study by Ngo et al found that in 359 patients followed for an average of 1.78 years postimplantation, hospital admission rates for all psychiatric diagnoses declined significantly, except for mood disorders (predominantly depressive rather than manic) which, however, did not show any increase.

NEW TREATMENTS, NEW PROBLEMS: SOME NOVEL PHENOMENA OCCASIONALLY APPEARING DURING NTXI AND DINTX TREATMENT

Can the Antagonist Effects of NTX Implants Be Overridden?

As early as 1998, it was reported that a "first-generation" implant produced blood levels 2 weeks after insertion that were clearly sufficient to block the effects of 1000 µg of fentanil administered in 50 µg doses intravenously every minute over the course of 20 min. This total dose is equivalent to about 1000 mg of pethidine (ten times the usual maximum analgesic dose in opiate-naïve patients) or between 0.3 and 0.5 g of British street heroin. However, the NTX blood level at the time of challenge could not be measured. In 2002, Brewer described two patients who received relatively large doses of pure diamorphine to test the blocking power of implanted NTX. (It should be mentioned that in Britain, diamorphine may be – and quite commonly is – prescribed for analgesia by any physician, though to prescribe it for the treatment of heroin addiction itself, a special license is required. Since NTX-implanted patients are, almost by definition, not addicted to heroin, this means that diamorphine, like any other opiate or opioid, can be legitimately prescribed for diagnostic purposes in such patients.)

In one case, the patient claimed a heroin-sniffing habit of up to 10 g day⁻¹. Following a supervised test dose that confirmed his very high tolerance, he was maintained for a week on 200 mg of oral morphine four times daily until, during rapid antagonist induction (RAI) under general anesthesia, a GMI containing 2.2 g NTX was inserted subcutaneously. Six days later, blood was taken for NTX levels. The next day, he sniffed 500 mg

of pharmaceutical diamorphine under medical supervision over a period of 40 min. No changes in pupil size or respiratory rate were seen during this period or subsequently. Serum NTX was 2.8 ng ml⁻¹ (i.e. not much higher than the usual minimum effective range) and $6-\beta$ NTX was 9.0 ng ml^{-1} . Serum levels of morphine and 6-monoacetyl morphine were 525 ng ml⁻¹ and 164 ng ml⁻¹ respectively (These opiate levels were so high that the laboratory asked whether the sample was taken for postmortem).

In the same paper, Brewer described another patient who normally smoked 1 g day⁻¹ of heroin and had a 24-h RAI under oral sedation in hospital, during which a "first generation" 1 g NTXI was inserted. When he tried using heroin again out of curiosity about 3 weeks later, he claimed that he could feel typical effects and he used several times subsequently. It seemed important to discover whether or not this was a true opiate effect. Blood was taken and immediately afterward 100 mg of diamorphine was injected intravenously over 3 min (=c.250 mg of typical British street heroin). No objective opiate effects were observed but he reported feeling "slightly relaxed" after 70 mg of dosage. A challenge with intravenous infusion of 800 µg of naloxone produced no reaction. Had he been experiencing true agonist effects, this relatively large dose of antagonist would surely have produced significant withdrawal symptoms. After these opiate and antagonist challenges, he swallowed 50 mg of NTX. Another blood sample was taken 4 h later, and the challenge repeated with 100 mg of intravenous infusion of diamorphine. There were similar mild subjective sensations but again, no objective changes occurred. It is unlikely that he experienced partial breakthrough of the blockade since the sensations were similar even when antagonist levels were considerably increased after oral NTX. Serum NTX levels before and 4 h after oral NTX were 5 and 15 ng ml^{-1} , respectively. 6-βNTX levels were 12 and 56 ng ml⁻¹, respectively. This is an example of "pseudo-breakthrough" (see below).

NTX is a competitive antagonist and can therefore, in principle, be overridden by sufficiently high serum levels of agonists. Buprenorphine, with its high receptor-affinity, is the opioid most capable of overriding the blockade but its intrinsic antagonist effects mean that overriding carries little risk of respiratory arrest. Clearly, even modest NTX levels can block very large amounts of heroin but as with all drugs, some patients will need higher (or lower) doses than usual to achieve the desired effects. Brewer and Streel reported a case in which an NTX level of only 1.5 ng ml⁻¹ blocked a test dose of 500 µg of intravenously infused fentanil but also another patient who showed euphoria and sedation (but no respiratory depression) after smoking only about 100 mg of pure diamorphine equivalent despite a blood NTX level above 4 ng ml⁻¹. However, they stressed that such cases of overriding are rare. As with all drugs, if the effect is inadequate, increasing the NTX dose and blood level is an obvious therapeutic response.

As was described by Krupitsky et al., the blockade provided by prodetoxon is very difficult to override. However, it is possible to accomplish it with a very high dose of heroin (~10-fold compared with the usual daily dose). Attempts to overcome the naltrexone implant blockade are not common and are usually unsuccessful because naltrexone has high affinity for the μ-opioid receptor. If a patient can obtain a large dose of heroin or other opiate, he or she may be able to feel the opioid effects, but they are usually attenuated. Patients on naltrexone have survived even a very high dose of heroin. Of course, a patient who stops naltrexone and then returns to his or her pre-NTX dose of heroin will have diminished tolerance and could suffer a serious or fatal overdose.

Breakthrough and Pseudo-Breakthrough

Overriding NTXs opiate blockade is clearly possible if blood NTX levels are below the conventional minimum and sometimes even if they are not. Overriding is also possible if agonist levels are high enough, though the dose may need to be extremely high. However, the matter is more complex than it appears, because not everything that sounds like breakthrough, from the patient's description, represents true breakthrough, for there is much more to opiate dependence than the pharmacological effects of the drug in question. There are large psychosocial components of most forms of drug dependence and some addictions – e.g. to food or sex – involve no external pharmacology at all. The ritual of drug-taking can be even more important than the pharmacology as is shown by case reports of addiction to placebos including an apparent withdrawal syndrome. This is especially the case when heroin is injected, partly because a separate "needle addiction" has been convincingly documented and partly because the "rush" or "pharmacological orgasm" that follows intravenous injection is probably more rapid and more intense than is obtainable by slower means of putting relatively large doses of intoxicants into the cerebral blood supply.

Another factor may be that when heroin is injected intravenously, it causes – like other opiates to a greater or lesser extent - histamine release. This presumably accounts for the local or generalized flushing that is often seen after intravenous heroin or morphine infusion and since histamine release is not mediated through opiate receptors, it is not blocked by opiate antagonists. We speculate that it may contribute to the problem posed by a small but particularly interesting group of patients who continue to inject heroin despite experiencing no true opiate effects following appropriate test doses of morphine or diamorphine.

Brewer and Streel's chapter also describes a young woman with a history of anxiety preceding intravenous heroin abuse and of much failed treatment, who received a first-generation Malmberg implant. She injected heroin occasionally during the first month after implantation but following a third consecutive implant, started to inject almost daily. Though she insisted that she was getting typical heroin effects, there was no objective opiate response to appropriate test doses of intravenous diamorphine. There was no reaction to high doses of intravenous naloxone either. On two occasions, serum NTX and 6-βNTX were well above conventional minimally effective antagonist levels. Fortunately, with appropriate counseling and support, she was able to abandon this behavior. Eight years later (at the time of writing) she remains opiate-free and leads a full and fairly conventional life.

COGNITIVE-BEHAVIORAL ASPECTS OF DEPOT AND IMPLANTED NTX TREATMENT

The rationale of depot injections or implants of NTX is that once the patient's ambivalence about starting treatment has been overcome at least for long enough to accept the first implant or injection, that ambivalence cannot easily (or at all, in the case of depot injections) lead to withdrawal from antagonist treatment within a few days or even hours. This may be more important in treating opiate dependence than the use of depot NTX in alcohol abuse (which we mention only in passing) because while alcohol withdrawal symptoms are relatively short-lived and often mild or absent even in daily drinkers, some purely physiological opiate withdrawal symptoms typically persist for weeks or months and may, for an unfortunate minority, be both persistent and seriously distressing. Addicts know from experience that these symptoms can be instantly relieved by taking opiates and this knowledge is a factor in the typically high rates of relapse in the first month or two after withdrawal, even in programs that report "unusually high rates of abstinence." As well as exposure to opiate- and addiction-related cues, which we will discuss shortly, patients commonly cite poor sleep as a reason for early relapse. Post-withdrawal insomnia is often persistent.

The earliest studies of the first, unlicensed and relatively short-acting NTX implants that became available in the mid-1990s showed that, as theoretically predicted, they could virtually abolish relapse to dependent use

during the crucial first month. As mentioned above, those "first generation" implants typically gave adequate NTX blood levels (i.e. $\geq 1-2 \text{ ng ml}^{-1}$) for at least 6–7 weeks. This meant that whether or not patients consistently wanted to remain physiologically opiatefree throughout that period, they had little alternative in practice. Not surprisingly, when NTX levels eventually fell below blocking levels, some patients returned to regular opiate use, either because they succumbed to the temptations to resume their old habits or because they were so distressed by persistent withdrawal symptoms that they chose, often with regret, to start or resume agonist maintenance. As we have noted, helping patients to resist temptation, of various kinds, is a central goal of all addiction treatment. It seemed likely that for a useful proportion of patients who might otherwise have had an early relapse, this implant-mediated 1–2 months abstinence helped them to get through the worst of withdrawal and get used to opiate-free habits of thought and behavior for long enough to have a better chance of persisting in those habits during the next few months. However, the optimal duration of treatment with depot or implanted NTX is a crucially important issue. So is the duration (and relative importance) of the psychosocial interventions that are usually advised in addition to NTX treatment.

HOW LONG SHOULD NTX DEPOT/ IMPLANT TREATMENT LAST?

In their 2003 paper, Brewer and Streel suggested a controlled trial of single short-acting versus single long-acting implant (i.e. 1–2 months versus 5–6 months). They predicted that, other things being equal – including access to psychosocial interventions - the long-acting implant would prove more effective at 12 months, because recovery from opiate dependence requires not only the acquisition of new, more adaptive habits but also the abandonment or weakening of old, maladaptive ones. This is an educational process and in all such processes, outcome is proportional to the length of exposure to the learning intervention. As yet, no such trial has been carried out. Their testable hypothesis was that patients who had their opiate receptors consistently blocked for longer rather than shorter periods would have a correspondingly higher chance of both learning and consolidating these vital new cognitive-behavioral responses and of extinguishing the old, undesired ones, with fewer possibilities of interrupting the educational process by even brief relapses. In that respect, Wickler's original theory may still have some validity. But whereas he seemed to be expecting the behavioral process to be a relatively rapid one involving simple Pavlovian extinction, we suggest that the main psychological process that CONCLUSION 437

reinforces the pharmacological effects of NTX is *exposure* and response-prevention (ERP), the standard, evidence-based cognitive-behavioral treatment for compulsive behavior. For while attempts to equate addictions with obsessive-compulsive disorder have not proved very persuasive, there is clearly an element of compulsivity about addictive behaviors and they are also clearly cuerelated, even at a fundamental neurophysiological level, as shown by several fMRI studies involving exposure to appropriate cues.

That ERP in addiction usually needs to last not just for a few weeks or months but for more than a year emerges from a study which found that alcoholics usually needed to abstain for 18 months before they had made and consolidated "a pronounced (cognitive) shift from 'deprived users' to 'determined abstainers'." They were "able to say,' well, that's how I used to handle these problems, but no longer'." Similarly, in a 7-year follow-up of alcoholic patients treated with supervised DSF and regular psychosocial input, it was found that relapse was less likely if DSF was taken for more than 20 months.

A 2.5-year follow-up study found that: "Achieving abstinence from illicit opioids was associated with concurrent improvement in other aspects of functioning including reduction of criminal activity, improved medical status, improved social functioning, and reduced abuse of other psychoactive substances. However, many of these improvements were reversed immediately if relapse to opioid use occurred." During this time, it hardly needs to be said, attention may be needed to aspects of the patient's life other than the temptation to relapse to opiate use. Alcohol abuse quite often accompanies opiate dependence and may become more prominent after opiate withdrawal. In this context it is significant that even good compliance with oral NTX at this stage does not prevent the emergence or recurrence of alcohol abuse and supervised DSF may be indicated. If the patient was a poly-drug abuser, NTX should not be expected to prevent the continuing abuse of nonopiate drugs. However, if opiate abuse was the major problem, then removing opiates from the patient's drug menu and assistance with social integration may lead to reductions in the use of other drugs. One must also distinguish between the short-lived increase in nonopiate drug use - especially sedatives that often seems to represent the self-medication of opiate withdrawal symptoms, and more persistent patterns of abuse, which may obviously be more therapeutically challenging.

All this is entirely consistent with the theory and practice of relapse-prevention, which emphasizes relearning, self-efficacy, self-control and an altered self-image and sees alcoholism (and in principle, the abuse of other substances) as inappropriate, learned behavior in general and as inappropriate coping behavior in

particular. Control is regained by successfully and repeatedly confronting, without alcohol, the situations and attitudes, which formerly resulted in excessive drinking. Other studies stress the importance of substance-related cues in relapse and note that patients rated them as the most important precipitant. Negative emotional states and social pressure are also important factors. Another Wicklerian relapse-prevention paper argues that: "To obtain maximum protection against relapse, extinction should 'recreate' all the original learning contexts (i.e. all possible drug cues)." Brewer and Streel's paper makes an analogy between ERP for addictions and "immersion" methods of teaching foreign languages. One language-teaching authority states that the most effective and efficient methods of foreign language learning involve intensive exposure to the new language and pressure to use it, even imperfectly, combined with not allowing the student to use his or her habitual language. An even more intensive learning technique is "submersion," in which during the hours outside school, students are urged to avoid speaking their first language and to live and associate only with people who speak the new language. "The real language laboratory" according to this authority, "is the foreign country....One obvious explanation for failure to achieve fluency ... is lack of exposure....Progress can only be achieved through extending the length of contact time between learner and language."

"In short" Brewer and Streel stated, "our hypothesis is that abstinence becomes easier with practice; that the longer and more uninterrupted the practice, the better; and that [NTX implants] can facilitate this process. The idea is not a new one. As Hamlet says to Gertrude, (Act 3, Sc. 4.): 'Refrain tonight, and that shall lend a kind of easiness to the next abstinence; the next more easy. For use almost can change the stamp of nature, and either curb the devil, or throw him out, with wondrous potency.' Or as Aristotle (in his Nichomachean Ethics) put it even earlier: 'We become temperate by abstaining from indulgence and we are the better able to abstain from indulgence after we have become temperate.'"

CONCLUSION

Treatment with depot-injections and implants of NTX has the ability to transform the management of opiate/ opioid dependence or abuse by making relapse to opiates difficult or impossible provided the patient attends as planned for treatment. This is not the case with any other intervention in this field. Long-acting implants also increase the chance that patients will avoid dying from accidental or intentional OOD in the difficult first few months after withdrawal, before new

opiate-free cognitive-behavioral habits have become ingrained. NTX preparations of this kind are emphatically not a substitute for the therapeutic relationship and psychosocial interventions but they can greatly reinforce these important components of treatment. Even in countries or organizations where depot or implanted preparations are not available, much can be done – especially with parole- or probation-linkage but also by using Community Reinforcement and Network techniques – to improve compliance with oral NTX and thus improve outcomes.

SEE ALSO

Antagonists for the Treatment of Opioid Dependence, Naltrexone and Opioid Antagonists for Alcohol Dependence, Disulfiram for Alcohol and Other Drug Use

List of Abbreviations

DINTX depot injection(s) of naltrexone

DSF disulfiram

ERP exposure and response-prevention

GMI GoMedical implant ITT intention-to-treat LFT liver function test

MMT methadone maintenance treatment

NTX naltrexone

NTXI naltrexone implant OOD opioid overdose

RAI rapid antagonist induction RCT randomized controlled trial

Glossary

Naltrexone an opioid receptor antagonist, blocks all the effects of opioid receptor agonists like heroin and other opiates.

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Pharmacotherapy of Cocaine Dependence

Matthew Brensilver, Steven Shoptaw David Geffen School of Medicine, UCLA, Los Angeles, CA, USA

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INTRODUCTION

The United Nations Office on Drugs and Crime reported that in the past decade encouraging trends in cocaine use have emerged in the United States. Annual prevalence among adults is estimated at 2.6%, and 4% among high school seniors – striking declines from the late 1980s when rates exceeded 10%. Positive tests for cocaine in the US workforce have declined substantially and the size of the cocaine market has stabilized. Nevertheless, cocaine abuse and dependence continues to represent a formidable worldwide public health burden. Escalating patterns of use have been observed in other parts of the world, notably, Europe, and the United States remains the largest single consumer of the drug. Each year, 15.9 million people use cocaine worldwide and it is estimated that 18% are cocaine dependent a dependence ratio higher than any drug other than heroin. The drug causes tens of thousands of deaths annually and accounts for a significant proportion of emergency room visits.

Psychosocial interventions such as contingency management and cognitive behavioral therapy reduce cocaine use. Indeed, one meta-analysis published in 2008 reported an effect size of d = 0.62 for psychosocial

treatments for cocaine dependence, which is in the moderate-to-large range. However, treatment response is highly variable and almost 70% of participants in clinical trials, where treatment quality is likely to be high, fail to achieve abstinence. This highlights the urgent need for efficacious treatment strategies, notably, pharmacotherapy. This chapter describes the rationale and targets for cocaine pharmacotherapies, reviews the evidence for select agents, discusses emerging pharmacogenetic data, and proposes directions for future work.

RATIONALE OF MEDICATION TARGETS FOR COCAINE PHARMACOTHERAPY

Addiction is a complex disorder with multiple biological systems that interact to produce symptoms of uncontrolled drug-seeking behavior. Pharmacotherapies target different mechanisms of addiction, including the positive reinforcement of the intoxicating effects, the negative reinforcing effects of withdrawal and craving, and the pathologic neuroadaptations within related neurotransmitter systems. Cocaine is a psychostimulant but its neurobiological effects differ

from other stimulants, such as methamphetamine. While methamphetamine increases extracellular levels of monoamines, in part, through the disruption of vesicular storage, cocaine acts primarily to inhibit dopamine reuptake through blocking the dopamine transporter system. This action of cocaine quickly and dramatically increases the amount of dopamine in the synapse, which corresponds with the rewarding effects experienced acutely with use.

The positive intoxicating effects of cocaine are mediated by neurotransmitter systems including dopamine and norepinephrine, although dopaminergic effects appear primary in the acute euphoric effects making this a clear target for pharmacotherapy. Using preclinical models, Koob's work has shown that after repeated administration, a series of neuroadaptations occur, which described as an opponent process model whereby within-system and between-system neuroadaptations occur as a response to the acute reinforcing effects of repeated drug administration. This process is characterized by the increasing recruitment of anti-reward processes, including hypoactivity in the dopaminergic system and alterations in hypothalamic-pituitaryadrenal (HPA) axis functioning. It is during this period of neuroadaptation that motivation to obtain nondrug rewards is attenuated and behavioral symptoms of abuse and dependence are observed as correlates. Changes in these circuits are also associated with chronic irritability and dysphoria that are commonly experienced during early periods of abstinence from cocaine, lending more support for identifying these mechanisms as potential targets to develop pharmacotherapies.

The vast majority of clinical trials of cocaine pharmacotherapies have evaluated medications that target one or more of these neurobiological systems that support cocaine dependence and have mechanisms of action that can be broadly classified as either agonists or antagonists. Antagonist approaches are medications that bind to receptors and block activity of the cell, altering neurotransmission and attenuating or eliminating reinforcing effects of acute cocaine administration. Antagonists compete with agonists but have minimal or no intrinsic activity at the receptor site. Notable examples of antagonist approaches in addiction medicine include the opioid antagonist naltrexone for opioid dependence – a well-studied compound also showing efficacy for alcohol and perhaps amphetamine dependence. In contrast, agonist therapies seek to promote cocaine abstinence by reducing withdrawal symptoms and negative affective consequences in the early abstinence. Agonists act pharmacologically similar to the targeted drug and typically feature high receptor affinity but lower intrinsic activity, thereby mitigating withdrawal. Agonist therapies are preferred treatments for opioid dependence (e.g. methadone,

buprenorphine) and for nicotine dependence (nicotine replacement therapies).

Meta-analyses on cocaine pharmacotherapy have been conducted for agonist strategies, antipsychotics, anticonvulsants, disulfiram, and for different classes of medications including antidepressants. The next section summarizes those findings and focuses on subsequent pharmacotherapy developments.

CLINICAL STUDIES OF PHARMACOTHERAPIES FOR COCAINE DEPENDENCE

GABAergic Therapies

In response to emerging clinical and preclinical data, the gamma aminobutyric acid (GABA) system has gained increasing attention as a pharmacotherapy target for cocaine dependence. GABA is the major inhibitory neurotransmitter system and modulation of GABA has indirect effects on dopaminergic neurotransmission. GABA neurons participate actively in the mesolimbic dopamine system - the neurological system that mediates the reinforcing effects of cocaine. Medication approaches that potentiate GABA-mediated inhibitory neurotransmission may work to block reinforcing effects of elevated drug-induced extracellular dopamine concentrations following cocaine use, ultimately leading to reduction or elimination of drug use. GABAergic medications that have been evaluated include marketed drugs with anticonvulsant and antispastic indications. These medications act on the GABA system through a range of pharmacologic mechanisms, including functioning as agonists, inhibiting reuptake of GABA by disrupting GABA transporters, or inhibiting the enzymatic degradation of extracellular GABA.

Two recent meta-analyses examined the efficacy of anticonvulsants for cocaine dependence. Minozzi and colleagues reviewed 15 randomized controlled trials of medications including carbamazepine, tiagabine, gabapentin, phenytoin, lamotrigine, and topiramate. The methodological rigor of the studies was good, although sample sizes were generally small. Overall, 1066 cocaine-dependent participants were randomized to this set of studies. Meta-analytic findings showed no evidence of efficacy for these medications in terms of the two primary outcomes: use of cocaine (assessed via self-report or urinalysis) or study retention. Similarly, secondary outcome measures including craving, dependence severity, depression, and anxiety all evidenced equivalence between active and placebo conditions. In head-to-head comparisons between specific medications and placebo, no additional evidence for efficacy emerged. While no effects were observed, one notable pilot trial from Kampman's group showed statistically significant reductions in cocaine use during the last 4 weeks of a 13-week trial for 20 cocainedependent subjects assigned to 200 mg day⁻¹ topiramate compared to 20 subjects assigned to placebo. There is continued interest in evaluating topiramate as a potential mono- or combination pharmacotherapy for cocaine dependence. A more recent meta-analysis by Alvarez and colleagues largely confirmed an overall lack of efficacy for cocaine pharmacotherapies with some kind of GABAergic activity. Using a slightly different pool of studies, one report of carbamazepine showed weak evidence over placebo for increased retention among cocaine-dependent users with comorbid affective disorders, though no differences were observed for cocaine use.

Subsequent to the publication of these two meta-analyses, a great deal of excitement was generated by a randomized placebo-controlled, double-blind trial of γ -vinyl- γ -aminobutyric acid (vigabatrin), which inhibits the catabolism of synaptic GABA, thereby elevating GABA concentrations. One hundred and three cocainedependent, treatment-seeking parolees, not mandated by the judicial system to seek treatment, participated in 9 weeks of active treatment and 4 weeks of followup. Subjects in the treatment group (28%) featured significantly greater end-of-trial abstinence as compared with the placebo group (8%). This finding is especially important as the US Food and Drug Administration requires that an experimental medication must significantly improve abstinence rates during the last weeks of a trial over placebo as a condition for approval for marketing as a cocaine pharmacotherapy. More recent evidence has dampened enthusiasm for studying vigabatrin with stimulant abusers, including concerns regarding visual field defects. Some data show vigabatrin raises blood pressure and heart rate in the presence of relevant doses of methamphetamine and one episode of medication-induced hypertension was noted in the cocaine trial, although symptoms resolved and did not require additional treatment. While results of a replication study have not been published, concerns regarding side effects of vigabatrin dampen enthusiasm for the compound. The potential risk-to-benefit ratio for vigabatrin in the absence of clear efficacy may slow its future development. The pharmaceutical company that developed vigabatrin has manufactured a similar and new compound that has shown promise as a cocaine pharmacotherapy in preclinical studies.

A great deal of energy has been expended evaluating the antispastic medication, baclofen, a GABA-B agonist as a cocaine pharmacotherapy. In Shoptaw's initial clinical trial, no main effect of baclofen over placebo was observed in reducing cocaine use or in increasing retention in a 16-week double-blind, randomized trial. Secondary analyses, however, showed that baclofen appeared to have differential efficacy for subjects with more severe levels of cocaine dependence at baseline. Additional evidence for baclofen includes reliable effects observed in reducing cocaine self-administration in primates and in human laboratory settings. Selfadministration of stimulants in experimental settings with laboratory animals and humans is thought to provide the best evidence that a medication will show efficacy as a treatment in outpatient settings. Yet, in an adequately powered (n = 160), multisite, randomized, placebo-controlled replication trial, baclofen produced no significant effect over placebo along cocaine use retention or subjective effect measures. The only rational conclusion regarding the clinical utility of baclofen at this point is that while it is possible that the medication has effects on reducing cocaine use in some subgroups, such effects are not observed in general samples of cocaine-dependent individuals.

As a class of medications, the preponderance of the evidence provides little support for anticonvulsants as treatment for cocaine dependence. Some relatively small effects were observed for topiramate and vigabatrin over placebo, although confirmatory evidence has been elusive. The failure to find an effect in clinical trials is frustrating, given some of the strong preclinical findings, but the negative findings in clinical trials highlight the complexity of identifying an effective cocaine pharmacotherapy.

Dopamine Antagonists and Partial Agonists

Due to the prominent role of dopamine in the acute rewarding effects of cocaine use and abuse, the rationale for evaluating medications that dampen or block dopamine transmission (i.e. antipsychotics) has strong theoretical attraction. In addition, the availability of atypical antipsychotics, with their reduced likelihood of extrapyramidal side effects, made this class of medications attractive candidates as cocaine pharmacotherapies. However, antagonist medications consistently fail as a cocaine pharmacotherapy. In a large, early trial of the D₂/5-HT₂ antagonist risperidone, cocaine-dependent individuals were randomized to placebo – 2 mg, 4 mg, or 8 mg of active medication. Findings showed no statistically significant effects of risperidone at any dosage over placebo along retention or proportion of benzoylecgonine-positive urine screens (benzoylecgonine is the primary metabolite of cocaine in urine), leading to the conclusion that dopamine antagonists, as a class, likely would not have a place in treatment of nonpsychotic cocainedependent individuals.

Several trials of antipsychotics for cocaine dependence, mostly at low to moderate doses, were

summarized in a Cochrane meta-analysis that reviewed outcomes for three risperidone studies, three olanzapine studies, and two trials with haloperidol. The manner in which cocaine use outcomes were reported precluded easy summarization, but the preponderance of evidence suggested no benefits to treatment using these antipsychotics as measured by benzoylecgonine in urine, treatment retention, levels of craving, or psychiatric symptoms. A few reports not included in the Cochrane review showed similarly disappointing outcomes. A subsequent trial of olanzapine found no effect on any outcome measure. Longacting injectable risperidone was assessed in a small randomized placebo-controlled trial with cocainedependent men. Although underpowered to detect treatment differences, no advantage for active medication over placebo was observed. Among cocainedependent individuals with schizophrenia, haloperidol decreased cocaine craving but increased cocaine use compared to placebo.

Although antipsychotics with purely antagonist properties have effectively been ruled out as a medication for cocaine dependence, there has been intensive interest in considering partial dopamine agonists as a strategy for treating stimulant dependence, likely due to the wildly successful use of the partial agonist medication buprenorphine in treating opioid dependence. Aripiprazole is a new generation antipsychotic medication that features partial dopamine agonist properties at D₂ which may reflect functional selectivity and has diverse effects at both serotonin and other dopamine receptors. Outside one open label trial of aripiprazole with 10 cocaine-dependent men with comorbid schizophrenia, we are aware of only one trial with a targeted enrollment of 275 subjects that is presently being conducted as part of the National Institute on Drug Abuse's (NIDA) Intramural Research Program. In amphetaminedependent individuals, aripiprazole had an iatrogenic effect on drug use in one trial, leading many trialists to have skepticism for the treatment of stimulant dependence using this approach. More, aripiprazole caused a dose-dependent enhancement of the reinforcing effects of cocaine in one human laboratory study. So while some antipsychotics have shown some promise for other addictive disorders (a recent review highlighted some efficacy for clozapine in the treatment of alcoholism and cannabis dependence), the available evidence does not support further evaluation of dopamine antagonists or partial agonists as cocaine pharmacotherapy.

Dopaminergic Neurotransmission Enhancing Therapies

Research evaluating medications that enhance dopamine transmission shows some elements of efficacy.

One early review of nonpsychostimulant dopaminergic agonists (i.e. direct agonists) that included amantadine, bromocriptine, and pergolide reported that although there were glimmers of medication effects in some of the findings, the preponderance of the evidence showed no robust efficacy as measured by benzoylecgoninenegative urine screens or by treatment retention. One small, early screening trial of the long-acting dopamine agonist cabergoline suggested the medication produced significantly more benzoylecgonine-negative urine screens than placebo. In a secondary analysis of all dopamine agonists in the NIDA-sponsored effort to identify candidate medications, the cocaine rapid evaluation screening trial (which included the cabergoline trial), no significant effect was observed as a class along any main outcome measure.

Mixed evidence of efficacy is observed for the dopamine precursor, levodopa. In two randomized trials, using two doses of levodopa, no evidence for efficacy was seen for benzoylecgonine-free urine screens, retention, craving, or mood. In a third trial of levodopa that incorporated behavioral treatments of clinical management, cognitive behavioral therapy or cognitive behavioral therapy, and voucher-based incentives for cocaine urine screens, however, a main effect was found for medication – 62% benzoylecgonine-positive screens for the active conditions and 79% for placebo. Specific behavioral intervention by medication effects was observed to suggest that levodopa enhanced the reinforcing salience of contingencies in behavioral therapy. This finding illustrates the complex interplay between medications and behavioral treatments, but also provides an indication that agonist strategies may help subgroups of individuals access behavioral treatments to reduce their cocaine use.

Agonist medications with similar pharmacological profiles to stimulants but with low abuse liability have been proposed as replacement therapies for cocaine dependence. There is a strong conceptual argument for "indirect" agonist replacement treatment for stimulant dependence, particularly dexamphetamine, methylphenidate, modafinil, and bupropion as treatment candidates. While substantial preclinical and human laboratory evidence suggests that efficacy should be strong with these medications, the review of clinical trials provides more tentative evidence. In a metaanalysis of trials of dexamphetamine, methylphenidate, modafinil, bupropion, selegiline, and mazindol for cocaine dependence, no effects of these medications on cocaine use were observed as measured by urine screen or self-report nor were there medication effects on treatment retention. There was, however, a statistical trend favoring medication for sustained abstinence. Subgroups of cocaine-dependent individuals who have comorbid opioid dependence benefitted substantially from dexamphetamine and bupropion in terms of heroin use and as a rule appeared to benefit more from psychostimulants in terms of cocaine abuse than did cocaine-dependent individuals who were not opioid dependent.

Indeed, findings for primary cocaine-dependent versus cocaine-dependent individuals with other comorbidities, including opioid dependence, can be divergent. In a randomized controlled trial with cocaine-dependent adults comorbid for attention deficit hyperactivity disorder (ADHD), methylphenidate did not improve ADHD symptoms, yet did show a significant and independent effect on reducing the probability of a benzoylecgonine-positive urine sample. These trials and their meta-analysis are consistent in articulating that agonist medications have a significant and consistent effect on at least some aspects of cocaine use when evaluated in randomized controlled trials.

Subsequently, two high-quality randomized trials were conducted with oral methamphetamine and modafinil as therapies. In one, cocaine-dependent individuals were randomized to immediate release methamphetamine (30 mg day⁻¹), sustained release methamphetamine (30 mg day⁻¹), or placebo. The 30 participants in the sustained release arm exhibited lower rates of benzoylecgonine-positive urine samples (29%), compared with the two other arms, which were not distinguished from each other. Medication adherence was good as several measures were taken in order to minimize the threat of misuse or diversion.

Dackis' original positive finding of modafinil over placebo for reducing cocaine use injected a great deal of enthusiasm to the field and to the approach of agonist treatment for cocaine dependence. Yet in the context of the meta-analytic methods, weaker medication effects of the medication were noted. Specifically, when outcomes from the original trial were examined in the meta-analysis, the proportion of benzoylecgonine-free urine screens was not different for medication and placebo groups, though there was an interaction between medication by time favoring modafinil. In a replication trial, the protocol was extended to 12 weeks of treatment and 4 weeks of follow-up visits, with two doses of modafinil: placebo, 200 mg day⁻¹, or 400 mg day⁻¹. Results showed no differences in the proportion of cocaine nonuse days and treatment retention between any active and placebo conditions. In post hoc analysis, however, participants without current or past alcohol dependence showed significant effects of modafinil over placebo – those with the comorbid dependence did not. There are other factors that can diminish enthusiasm for the utility of modafinil as a treatment agent, including a lack of preclinical and human laboratory support. Still, two recent reviews highlighted promise for modafinil as an abstinence initiation medication and an anti-relapse agent and it is possible that effects may be observed for the medication to have significant effects in specific subgroups.

Antidepressant and Serotonergic Therapies

During the 1990s, the tricyclic antidepressant, desipramine, was extensively examined as was fluoxetine as cocaine pharmacotherapy. An early meta-analysis reviewed outcomes of 18 studies of antidepressants for cocaine dependence, with the majority of studies included evaluating desipramine or fluoxetine. Only three studies showed a medication effect on reduction of cocaine use; the remaining 15 were null. No medication effects were observed for retention. In cocaine-dependent patients with comorbid depression, participants assigned to a desipramine condition showed antidepressant effects of the medication and showed improved mood that correlated negatively with cocaine use. Yet there was no evidence of a direct medication effect on cocaine use. Consistent with levodopa, contingency management seemed to boost desipramine efficacy in buprenorphine-maintained individuals with comorbid cocaine dependence. As with other putative cocaine pharmacotherapies, desipramine produces an interesting pattern of outcomes, although no consistent effects in the broad population of cocainedependent individuals are observed for the medication.

No consistent effects are observed for the broad category of serotonergic medications. In a placebo-controlled trial of fluoxetine in the presence or absence of contingent vouchers for sustained abstinence with methadone-maintained comorbid cocaine-dependent individuals, no medication effects were observed. The group receiving placebo and the vouchers, however, evidenced the lowest probability of cocaine usage and the highest retention in treatment. In a similar placebo-controlled randomized trial of the serotonin precursor tryptophan, participants completed a 5-day residential stabilization period, which insured initial cocaine abstinence, and were randomized to a 2 (tryptophan, placebo) by 2 (attendance-based contingency, cocaine abstinence contingency) design. While no significant medication effect was observed along any marker of drug use or retention, there was an effect for the vouchers, with abstinence-based vouchers outperforming attendance-based vouchers in producing superior outcomes in cocaine abstinence. Nefazodone, a weak serotonin-norepinephrine-dopamine reuptake inhibitor, similarly showed no effects on cocaine use or retention in a large sample (n = 210) of cocainedependent adults, though attrition was high in both conditions (79% total) complicating conclusions on efficacy. Interestingly, Moeller's group studied the selective serotonin reuptake inhibitor citalogram and reported initial efficacy of citalopram over placebo in reducing cocaine-positive urine samples in a randomized trial of 67 participants. All subjects received contingency management and cognitive behavioral therapy. In light of the persistently negative findings with selective serotonin reuptake inhibitors, the authors theorize the observed citalopram effect could be due to the selectivity of the medication – particularly its low affinity for 5-HT_{2C} receptors.

Three doses of the anti-emetic 5-HT₃ receptor antagonist ondansetron (0.5, 2, and 8 mg day⁻¹) were compared to placebo for 8 weeks in the context of weekly cognitive behavioral therapy. Cocaine-dependent participants randomized to the 2 mg condition performed worse in terms of percentage of weekly mean nonuse days compared to placebo. In contrast, the 8 mg group outperformed all others in terms of reductions in cocaine use and increases in retention. Explanations for results using ondansetron as a cocaine pharmacotherapy become more difficult to explain in the context of the same group's observation of a pharmacogenetic effect in a similarly designed trial of ondansetron for alcohol dependence. In this trial, alcohol-dependent participants who had homozygous long form (LL) of the 5'-regulatory region of the 5-HT transporter (5-HTTPLR) showed significant reductions in drinking days and drinks per drinking day compared to participants with other variants (heterozygous long short (LS) or homozygous short (SS)). Importantly, this genetic analysis was prospectively planned and genotype was used as a factor in the randomization. Analyses of the full sample without genotype data showed no effects of ondansetron on drinking outcomes. Together, these findings imply that the negative trial of ondansetron for cocaine may have been due to unmeasured variation related to genotypes. A well-sized, randomized, placebo-controlled trial of ondansetron for methamphetamine dependence at the three active doses that also failed to include a prospective genotype hypothesis showed no differences between conditions. As with other medication strategies as cocaine pharmacotherapy, subgroups may exist for which serotonergic medications improve treatment outcome. On balance, however, there is little compelling support for further evaluation of serotonergic medications.

Disulfiram

Disulfiram has been utilized as a treatment for alcoholism for over 60 years. It functions as an aldehyde dehydrogenase inhibitor. The impaired metabolism of alcohol and increased concentration of acetaldehyde creates unpleasant subjective effects that deter alcohol consumption. As cocaine and alcohol are co-abused, one plausible mechanism by which disulfiram might exert effects is through a reduction of alcohol and its cueing effect for cocaine usage. Yet a more likely mechanism to explain disulfiram efficacy in cocaine-dependent populations involves inhibition of dopamine beta-hydroxylase. Recent work that disentangled

disulfiram effects on cocaine abstinence initiation from its ability to support relapse prevention has demonstrated that disulfiram blocks cocaine-induced reinstatement in laboratory animals through disruption of the conversion of dopamine and the resultant altered ratio of dopamine to norepinephrine. This strong evidence points to inhibition of the enzyme dopamine betahydroxylase as the mechanism of action for disulfiram action in reducing cocaine use.

Several randomized, placebo-controlled trials support disulfiram as a cocaine pharmacotherapy. The interpretation of data on the clinical utility of disulfiram for cocaine dependence, however, is complicated by much of the human work being completed using subjects who are comorbid opioid dependent or comorbid alcohol dependent in the clinical trials. No major clinical trial of disulfiram has been conducted for patients with primary cocaine dependence as their sole diagnosis. The presence of a second chemical dependency may index a higher level addictive process and thus complicates interpretation of these data.

In a recent Cochrane review, seven trials of disulfiram that involved 492 subjects each included individuals with two substance dependencies - five included patients with cocaine dependence and alcohol abuse or dependence; two enrolled individuals with cocaine dependence with concurrent opioid dependence who were maintained on methadone or buprenorphine. Four direct comparisons between disulfiram and placebo were made, while other arms tested disulfiram against naltrexone or a nonpharmacologic treatment. In the comparisons with placebo, there was no significant effect of the medication on treatment retention. Though variability across the studies in the measurement of cocaine use precluded meta-analytic comparisons, the available evidence failed to identify a strong general effect of disulfiram over placebo. Disulfiram, however, demonstrated superior effects over naltrexone.

Subgroup analyses of disulfiram effects in the review showed interesting findings. In two randomized clinical trials, secondary analyses showed gender to moderate treatment responsiveness, whereby men benefitted from disulfiram and women did not. In one trial, the benefits of disulfiram accrued only to those who were abstinent from alcohol during the course of the treatment. Specifically, for those who abstained, disulfiram, cognitive behavioral therapy, and their combination were effective in reducing cocaine use and these outcomes improved over the course of the 12-week treatment period. In contrast, for those reporting a single drink or more during treatment, medication or therapy showed no benefits in terms of cocaine usage. This finding suggests two conclusions: insofar as disulfiram positively affects cocaine usage, this effect is not fully mediated by a reduction in alcohol consumption; second, it is possible that individuals with comorbid alcohol abuse may be medication nonadherent or that comorbid alcoholism dampens the therapeutic utility of the medication (as observed in the large modafinil trial).

A recent report by Oliveto's group found a nonlinear dose-response relationship for disulfiram as a cocaine treatment. After a period of stabilization on methadone, cocaine and opioid-dependent participants were randomized to placebo or 62.5 mg, 125 mg, or 250 mg of disulfiram for 12 weeks. Participants were included in the analyses only if they completed the first 2 weeks of treatment. Over the full course of treatment, disulfiram did not impact opioid use, compliance with methadone treatment, nor did it exert an effect on drinking, although this may have been due to a very low level of drinking in the sample. In terms of the percentage of urine samples negative for benzoylecgonine, generalized linear mixed effects models showed that both the 250 mg and the placebo condition significantly reduced cocaine use. By contrast, the midrange dosage conditions for disulfiram increased cocaine consumption. The "inverted U" effects on cocaine use observed in this trial are difficult to explain and may be best understood as a function of the complex pharmacology and behavioral effects of disulfiram. The authors conclude that disulfiram in doses lower than 250 mg may be contraindicated for cocaine and opioid-dependent individuals. The viability of 250 mg compared to a higher dose (e.g. 500 mg) remains unclear.

New Directions

The variable and overall weak effects of medications evaluated for cocaine dependence contribute to an intense interest in identifying novel compounds that may help patients reach their cocaine use goals. The cannabinoid system is of relevance in addiction based, in part, on its selective increase of dopaminergic transmission in the nucleus accumbens - a brain region critically involved in addictive disease. CB₁ receptor modulation inhibits glutamate release broadly across the striatum and its inhibition has been shown to attenuate cocaine primeinduced reinstatement in a rodent model. There is substantial preclinical evidence for the utility of CB₁ receptor antagonists, highlighting the potential of this mechanism as a cocaine pharmacotherapy. One such agent, rimonabant, was being evaluated as an anti-obesity treatment and as a candidate for treating nicotine, cannabis, and alcohol dependence. Emerging concerns, however, over suicidal behaviors led to the termination of numerous clinical trials. Still, the evidence for medications that modulate the cannabinoid system is strong and other CB₁ receptor modulators are under development.

Koob's model highlights the importance of the stress systems in perpetuating addictive processes. According to his model, three stages are distinguished within the addictive cycle that starts with drug preoccupation, proceeds to drug intoxication, and follows with withdrawal and prominent negative affect. Several neuropharmacological mechanisms are involved in this cycle, including norepinephrine, orexin, vasopressin, dynorphin, and corticotrophin-releasing factor. Dysregulation of biological stress response systems are implicated in a range of physical and psychological disorders with the HPA axis receiving considerable attention as the biological intermediary linking stress and disease. When appropriately regulated, the HPA axis describes an integrated system linking brain structures and a cascade of hormonal effects that provides an adaptive basis for responding to threats to homeostasis. In response to acute stress, corticotropin-releasing hormone (CRH) is released, which in turn activates the synthesis of adrenocorticotropic hormone (ACTH). ACTH enters general circulation and triggers the release of adrenal cortical glucocorticoids.

Koob's group provided initial preclinical evidence supporting his model showing alterations of CRH functioning partially mediated increases in drug taking, in anxiety-like symptoms of withdrawal, and in stressinduced reinstatement. Additional support for the model is found in humans. Among cocaine-dependent adults who completed a social stress test, attenuated ACTH and cortisol responses associated with shorter latency to first cocaine use and with cocaine use in the 30 days after discharge from inpatient detoxification. More, CRH administered (1 μg kg⁻¹) intravenously to cocaine-dependent men and women produced a craving response and caused a stress response that was higher than that observed in control participants. Together, these findings highlight potential pharmacologic approaches modulating HPA function as cocaine pharmacotherapy. The approach is also being evaluated in alcohol dependence. An investigative selective CRH antagonist is currently being evaluated by researchers within the National Institute on Alcohol Abuse and Alcoholism for its ability to reduce alcohol craving in detoxified alcohol-dependent women.

A different and very innovative approach to cocaine pharmacotherapy involves immunotherapy and has been dubbed the "cocaine vaccine," though its mechanism is different from vaccines for infectious diseases. The cocaine vaccine is theorized to minimize the amount of cocaine that acts on the central nervous system using antibodies. This mechanism of the vaccine couples a cocaine derivative with a carrier protein, which elicits an immune response, that is, production of cocaine antibodies. Once antibodies are developed, future administrations of cocaine are bound to the antibodies, thereby preventing uptake of cocaine across the blood–brain barrier. This effect also reduces or eliminates the

rewarding effects caused by acute use of cocaine. Two clinical trials provided initial evidence of the robustness of the antibody response, as well as initial safety and early efficacy among cocaine users. A subsequent trial demonstrated that more robust immune responses to the vaccine blunted the subjective effects of smoked cocaine, with a statistical trend for decreased cocaine usage. Tachycardia was associated with antibody levels, perhaps as a function of increased levels of cocaine peripherally. A randomized placebo-controlled trial of 115 methadone-maintained cocaine-dependent participants was recently conducted and reported that while no main effects were observed in terms of probability of cocaine-free urine across a 24-week study period, antibody response was highly variable and was not expected to exert a therapeutic response for all individuals in the treatment condition. The data were reanalyzed with individuals stratified by immune responsiveness (38% of treatment group achieved adequate immune responses). Those with robust responses outperformed the low immune response and placebo group in terms of likelihood of total abstinence for the last 8 weeks of the trial. Although these findings are promising, there is value in development of a formulation that extends the period of adequate antibody levels to confer blockade of subjective effects and to expand the proportion of individuals who achieve these levels. Additionally, the approach would likely require substantial motivation and behavioral support to adhere to the repeated booster injections and to avoid trying to overwhelm the capacities of the antibodies by using high doses of cocaine. A multicenter trial with a targeted enrollment of 300 is currently underway.

EXPLAINING VARIABILITY OF TREATMENT OUTCOMES

Moderating Variables and Pharmacogenetics

Across most of the literature on cocaine pharmacotherapies, it is a common clinical observation that some patients respond favorably to a pharmacotherapy, while others with the same disease show no response. It appears that across many studies of "cocaine dependence" medications, substantial heterogeneity exists within this particular class of patients. Demographic psychiatric variables, comorbidity, co-abused substances, social support levels, neurobiological characteristics, and genetic factors, among others, have been demonstrated as moderators of treatment responsiveness. While frustrating, the identification of key factors that define subgroups of patients is a key issue, as moderating variables have interfered with identification of broadly effective cocaine medications. Across trials, the most consistent factor that corresponds with treatment outcome is level of baseline cocaine use at baseline - generally, those patients with lower levels of baseline use of cocaine respond better to treatment (measured by urine benzoylecgonine and by retention) than those with higher levels of use at baseline. As well, severity of pretreatment dependence and of withdrawal symptoms has been a generally consistent predictor of treatment failure. Concurrent heroin abuse presents an additional challenge to treatment compliance and alcohol use is generally associated with poorer outcomes, although there are inconsistencies in the literature. Given the complex pharmacological and common interactions of stimulants with cigarette smoking, it is perhaps not surprising that nicotine dependence and cocaine may have synergistic effects and compromise treatment outcomes.

In addition to the variables highlighted above, genetic characteristics function as moderators of therapeutic responsiveness. The substantial between-individual variability in medication response, paired with generally small intrapatient variability, suggests the role of heritable factors in medication response. Such observations have generated considerable interest among addiction researchers in pharmacogenetics – the study of genetic factors that account for the variability in treatment responsiveness. Through a variety of biological mechanisms - drug metabolism, absorption, distribution, and excretion – genetic factors interact with pharmacotherapies to impact treatment outcomes. Pharmacotherapies tailored for specific genetic profiles may promote positive therapeutic responses, mitigate problems associated with toxicity, and improve compliance. Single nucleotide polymorphisms (SNPs) – that represent stable and identifiable biomarkers - account for the vast majority of genetic diversity. Etiological studies linking particular genetic factors with specific psychiatric disorders have identified candidate genes but these genes confer weak and nonspecific risk that interacts in complex ways with other pathogenic factors. However, preliminary suggestions from studies of psychotropic medications suggest that certain pharmacogenetic effect sizes may be larger than those for etiological candidate genes. Candidate gene polymorphisms might be related to dopaminergic function, metabolism of a medication or drug of abuse, or etiologically significant genetic markers. Promising discoveries have been made regarding the role of pharmacogenetic responses to putative medications for opiate and alcohol dependence. Less work exists for cocaine and the psychostimulants as genetic modulators of dopaminergic function may contribute to inconsistent responses to medications across drug classes. While in an early stage of development, these polymorphisms have been identified that may affect dopamine beta-hydroxylase (C-1021T), dopamine transporter function (SLC6A3), and genes regulating the dopamine receptor (D2) availability, which may encourage more targeted medication development approaches.

CONCLUSIONS AND FUTURE DIRECTIONS

Before highlighting the positive developments, it is worth acknowledging that the number of trials with negative results is striking. Several possibilities may account for this fact. First, medication adherence is lower than would be expected in trials for nonaddictive disorders. Extensive efforts are undertaken to mitigate this problem, including pill counts and fluorescing urine specimen to detect riboflavin, which is commonly included with the medications. These methods are imperfect and the development of technologies to support adherence may be useful. Second, attrition is quite high – often substantially more than 50%. Generally, assumptions are made that a participant who has dropped out of the study is using cocaine and positive urine screens are imputed. While attrition likely signals treatment failure, the absence of confirmatory data makes estimates of therapeutic effects more conservative. Statistical methods to minimize the bias created by missing data are available but popular models used to analyze trial data, such as generalized estimating equations, require assumptions about attrition that are often untenable. Third, powerful moderating variables – often unmeasured – dilute medication effects for subgroups. The promise of pharmacogenetics is great although sample size limitations often preclude detailed investigations within a single trial. The need for researchers to make the collection of genetic material routine for all study participants is great. Finally, the complexity of neuroadaptations consequent to chronic drug administration is humbling: The brain's attempt to maintain homeostasis amidst an unprecedented capacity to alter neurochemistry using cocaine broadly disturbs the balance between and within brain regulatory systems. As well, the vulnerability to drug dependence is positively associated with liabilities for other psychopathological conditions which further complicate outcomes. Given these factors, it is unsurprising that development of pharmacotherapies for addiction has been difficult.

Despite these challenges, there are some promising developments in the pharmacotherapy of cocaine dependence. There have been some signals for vigabatrin, ondansetron, disulfiram, and modafinil, although the evidence is mixed. While meta-analytic approaches analyzing an entire class of medications have been

negative, this may not always be the optimal way of interpreting the findings from diverse trials. The immunotherapy approach is novel and preliminary data have been encouraging. New directions include cannabinoid receptor antagonists and medications that modulate HPA functioning. The importance of distinguishing between abstinence initiation and relapse prevention has been emphasized and medications may be useful for one outcome while ineffective for the other. The prognostic significance of baseline cocaine use is clear. It may thus be useful to establish baseline abstinence through a brief inpatient period as treatment is initiated. While as a field, trial procedures are far better defined than when significant effort to identifying a medication for cocaine dependence 25 years ago, there are substantial efforts needed to reduce heterogeneity and to increase precision in assessing potential medication efficacy.

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SEE ALSO

Dissemination of Evidence-Based Treatment into Practice, Brief Feedback-Focused Interventions, Multisystemic Therapy for Adolescent Substance Use, Individual and Group Counseling for Substance Use Disorders, Faith-Based Substance Abuse Programs, Evaluating Treatment Efficacy, Improving Medication Use in Addictions Treatment, Disparities in Health Services for the Treatment of Substance Use Disorders, Cognitive Behavioral Therapies, HIV/AIDS and Substance Abuse, Driving While Impaired (Treatments), Psychological Treatments for Pathological Gambling, Diagnostic Dilemmas in Comorbidity, Behavioral Treatments for Smoking, PTSD and Substance Abuse Treatment, Methadone Maintenance, Agonist-Like (Substitution) Treatment for Cocaine and Other Stimulant Dependence, Medication Development for Amphetamine Dependence, Vaccines for Addictive Disorders, Comorbid Addictions and Schizophrenia, Medication for Cravings in Substance Use Disorders, Dissemination of Evidence-**Based Treatment into Practice**

List of Abbreviations

ACTH adrenocorticotropic hormone
CRH corticotropin-releasing hormone
GABA gamma amino butyric acid

Glossary

Agonist a chemical that binds to and triggers a response from a receptor, often mimicking the action of a naturally occurring substance.

Antagonist a chemical that blocks the action of an agonist.

Benzoylecgonine the primary metabolite of cocaine in urine.

Meta-analysis a statistical technique that combines the outcomes from several trials to evaluate the effect size for a particular type of treatment compared to a placebo condition.

Partial agonist a chemical that binds at a receptor, but produces a response submaximal to a full agonist.

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Agonist-Like (Substitution) Treatment for Cocaine and Other Stimulant Dependence

John Grabowski, Marc Mooney, David Herin University of Minnesota, Minneapolis, MN, USA

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STIMULANT USE, ABUSE, AND DEPENDENCE

Stimulant medications, for example amphetamine analogs, have been extensively used to treat specific medical and psychiatric problems including narcolepsy and attention deficit and activity disorders. They were used in the past with some benefit to treat overweight conditions. Amphetamine analogs have also been used in the past to treat depression and are now sometimes used as adjuncts, or additional medications when standard antidepressant effects must be bolstered. These medications can also be used to enhance performance that has deteriorated due to boredom or fatigue. This has been true of the amphetamine analogs, and a novel stimulant, modafinil, has been approved by the US Food and Drug Administration (FDA) to modulate sleepwake disturbances and performance impairment in shift

workers who must change from night, to day, or afternoon schedules frequently. These drugs can have psychological effects that are perceived as 'positive'. A large illicit trade in cocaine, as well as methamphetamine supports excessive use of these agents for these non-therapeutic effects. In turn, as the problem for the individual becomes more and more severe, treatment is essential. This section considers the treatment strategy of administering controlled regimens of a drug very much like the drug that has caused problems. This strategy has been called 'substitution', 'replacement', 'agonist treatment', or 'agonist-like' treatment. As discussed, it is effective in the treatment of heroin, as well as nicotine dependence. Extensive research and clinical experience suggest that stimulant medications may be effective for treatment of stimulant dependence. Certainly the controlled clinical trials and some community treatment programs to date have demonstrated 'proof of concept'. However, while research and discussion of the strategy continue, it is not an approach currently supported by the FDA. More research and further demonstrations of safety and effectiveness will be necessary to move the approach to the forefront of treatment of severe stimulant dependence, but there is growing support for the strategy.

HISTORICAL PERSPECTIVE

Low to moderate dose stimulants, with the capacity to sustain wakefulness, enhance mood and performance, have been used safely throughout human history. Yet, when ingested at high doses they can cause behavioral and psychological aberrations and biological damage. Caffeine, and its surrogates across cultures, are and have been the mostly widely used and generally socially acceptable drugs. Yet these relatively benign agents can be packaged in formulations that lead to untoward consequences. For example, some 'energy drinks' have high caffeine levels ("Cocaine" – 288 mg, "Spike Shooter" – 300 mg) in small volumes; repeated ingestion in short periods, particularly in the face of drug interactions, can have serious consequences. The US Food and Drug Administration in November of 2010 specifically issued warnings to companies producing beverages combining high caffeine doses with up to 10% alcohol. Oral coca leaf use as practiced in the South American Andes for centuries was relatively benign, while extracted and refined cocaine (salt or base) repeatedly injected or smoked can have enduring social, psychiatric, and medical consequences (including death).

There have been successive epidemics of hazardous stimulant use in United States and world history, the first 130 years ago in the 1880s. David Musto, psychiatrist and historian, has noted that societal and public health response to a dramatic increase in cocaine use that began in the 1970s, and more recently the surge of methamphetamine use, reflect clear failure to learn from past episodes. Stimulants effects (some therapeutic and beneficial with others being exceptionally hazardous) combined with characteristics of the productivity and pharmaceutically oriented culture, require that thoughtful consideration be given to efficacious use, prevention of misuse, and treatment of stimulant use disorders when they emerge. Here the focus is on development of one component of effective treatment when disease prevention efforts fail and dangerous use and societal consequences result.

PREVALENCE

A long standing project (Monitoring The Future) to track drug use among high school students

conducted by Lloyd Johnson and colleagues indicates that cocaine use among high school seniors peaked in the 1978–1988 period in the range of 7–10%. Since then use has fluctuated in the 3–7% range. Use has generally been more common among young people with fewer educational and other resources, in large metropolitan areas, among Hispanics and Whites compared to African Americans, and more common among males than females. Many surveys, including this one segregated 'crack' from cocaine (hydrochloride), for which use was in the 1–4% range with the same peak periods. Methamphetamine use (which has been tracked by MTF since 1991) has generally persisted in the 1–5% range in this population.

A complementary survey conducted by SAMHSA titled "National Survey on Drug Use & Health" generates data on use in individuals 12 years and older from a national sample. The ever-used sample in 1998 (versus past year or past month) indicated an average of 10% of those surveyed had some experience with cocaine (hydrochloride) compared to 2% for "crack". In 2009, the SAMHSA survey reported 1.6 million current cocaine users and about half that number of methamphetamine users. Again, while the prevalence of use of cocaine and other non-prescription stimulants varies, the general patterns of use persist. While declines in use have occurred since the most recent peaks there is some evidence that use is again increasing.

Obviously, potentially harmful stimulant use occurs broadly in the world. The European Monitoring Centre for Drugs and Drug Addiction has reported that lifetime cocaine use across the European Union countries ranges from less than 1% to over 8% (mean approximately 4%) and lifetime use of amphetamine analogs ranges from less than 1% to approximately 11% (mean approximately 3%). Amphetamine analog use in several Asian countries is reportedly substantially higher than those in Australia, the EU or US according to the United Nations Office on Drug Abuse and Crime (UNODC). However, as noted by the 2010 report of the International Harm Reduction Association, the data sources are highly variable in quality and many caveats apply to their interpretation; for example, the UNODC report indicated a range from 16 to 51 million users worldwide. Still, it is clear that the problems are substantial and broad in scope.

These oscillating patterns of amphetamine analog and cocaine use, with periods of accelerated use and peaks every so many decades, indicate that use of these or alternative robust stimulants will emerge in the future. It is thus essential that there be a clearly prescribed suite of interventions that can be applied as needed when recurrences of these disorders emerge.

DETERMINANTS OF COCAINE AND OTHER STIMULANT USE DISORDERS

Substance use disorders, here cocaine and other stimulant abuse, as with some other medical conditions, reflect a complex interplay of biological, behavioral, and social factors. Thus, a wide range of factors ranging from the social environment to molecular genetics contributes to the observed effects of stimulant drugs. Cardiovascular disease or obesity, sometimes intertwined, are consequences of genetics, other biology, behavioral factors (e.g. eating or inactivity), along with social and environmental circumstances. Similarly, stimulant use is established in a social-environmental context (e.g. peers). Stimulants have pronounced and significant effects on neurochemistry (inherent to the rewarding or reinforcing effects) of the brain that might promote or diminish use. Moderate use at intermediate doses produces effects that are perceived as positive, while protracted use or binges of high dose use have distinctly adverse psychological/psychiatric consequences. As dose increases and binges or chronic use emerge, risk of adverse medical consequences including cardiovascular collapse, heart attacks, and stroke greatly increase. Further, higher doses and chronic use can produce a shift from a sense of well being to severe psychiatric and behavioral disturbances. Biological and psychiatric effects may be influenced by genetic factors predisposing some individuals to positive responses to stimulants. The relative contribution of any of these determinants to use, progression to persistent use, or for that matter avoiding use varies across individuals. Yet the behavioral end point, for example, among those engaging in use to the point of detrimental consequences, appear the same. Conversely, those not using, are non-users whether due to genes, unpleasant psychic responses, or discomforting cardiovascular response.

One set of determinants is related to the drug and the manner in which it is used. While 'cocaine is cocaine', the route of administration and preparation form and, of course, dose, can greatly influence response. In the 1970s as cocaine availability and use in the population escalated, Ronald Siegel of UCLA followed a large group of users who self-administered by the intranasal route. Among those who shifted to smoking cocaine, consequences and severity of resultant disorders increased while somewhat stable use existed among those who continued to use intranasally. It is suggested that higher doses and higher peak blood, and brain, levels can be achieved via inhalation (here smoking) than nasal administration and ultimately more severe dependence and disease burden for the individual. Conversely, use of coca tea preparations as practiced in the Andes areas of South America reportedly is analogous to coffee drinking.

With multiple factors influencing use, the optimal intervention required in the face of compulsively persistent hazardous use becomes complex. Development of effective treatments has proven difficult and much research has found patients to be refractory to even intensive psychosocial interventions.

TREATMENT OPTIONS FOR STIMULANT ABUSE AND DEPENDENCE

In the two decades from 1990 to the present, substantial research efforts have been undertaken to identify effective treatments for stimulant dependence. Much of this research has been funded by the US National Institutes of Health through its National Institute on Drug Abuse. The two main foci were behaviorally based interventions and medications, with the addition over the last decade of efforts to develop a vaccine. The premise of the vaccine strategy is that cocaine antibodies would develop, binding with the molecule, thus preventing drug action. Behavioral therapy development efforts were of several types; some focusing on motivational features, but the bulk focusing on cognitive therapy or clear contingency management based behavioral interventions. Scientific studies of these interventions point directly to the substantial efficacy and effectiveness of contingency management approach, under a variety of names, with effectiveness of 'cognitive behavioral' also evident. Concurrent with funding therapy studies, NIDA devoted substantial funding to supporting investigators conducting studies with medications for cocaine dependence, and later methamphetamine dependence. It is assumed that the optimal treatment for stimulant dependence might come from joint action of behavior therapy combined with medication. Thus, virtually all medication clinical trials had some form of behavioral intervention. Still, given the diversity of the stimulant using population, it is likely that there will be individual differences in need and responsiveness to behavioral therapy, medication, or combinations.

Conceptually, the approaches to developing a pharmacologically based intervention for cocaine dependence, or other drug dependence, are an antagonist-like treatment, an agonist-like treatment, and symptomatic treatment. An antagonist treatment would be the analog of naltrexone for heroin/opioid use, that is a medication that 'blocks' the effects when an opioid is taken, whether by mouth, intravenously, or by smoking. Examples of medications with some 'antagonist' like properties for cocaine include the antipsychotic drugs haloperidol, risperidone, and olanzapine. While some preclinical research has suggested such medications might block self-administration or attenuate effects of

stimulants, results of clinical research have been unfavorable. Further, these antagonists have substantial untoward side effects. An agonist treatment would be equivalent to methadone for opioid dependence; that is, limited 'replacement' or 'substitution' of the abused drugs effects with another agent. Examples of agonistlike medications for cocaine and other stimulants include cocaine itself, amphetamine analogs, methylphenidate, novel agents like modafinil, as well as ldopa. As with any medication, these two have varying levels of side effects, some potentially serious. Generally, as efficacy increases for the specific purpose of stimulant dependence treatment, magnitude of potential side effects increases. Thus, the critical issue is establishing a well-controlled treatment regimen. Symptomatic treatment would be equivalent to using medications that alleviate one or another of the symptoms during the period after cessation of use. An array of other medications has been examined including gabapentin, carbamazepine, selegiline, fluoxetine, and other SSRIs. Logical theoretical rationale has underpinned investigation of each but little support has emerged from clinical evaluations.

GOALS OF AGONIST TREATMENT

At the neurochemical level, agonist-like treatment, that is 'replacing' some though not all of the effects of the problem drug, can take several forms. For example, one major effect of stimulants is on the dopamine system. Dopamine levels can be affected by blocking its reuptake into neurons or enhancing its release from neurons by modulating various elements of the dopaminergic system. Scientists in preclinical animal laboratories, human laboratory settings and clinical environments have argued for and conducted research to determine optimal medications to modulate or regulate dopamine. Others have focused on the role of the serotonin and other systems. Of course, the systems of the brain work in concert. Perturbations in one system or one brain area necessarily alter relative effects of other systems. Cocaine and other stimulants have broad actions on multiple systems and thus broader consideration of the neurochemistry and plausible treatments is considered important. Richard Rothman and Michael Baumann, two scientists at the National Institute on Drug Abuse intramural research program, as well as others, have argued that the most efficacious medications will broadly effect or replace, some of the actions on dopamine and serotonin.

Ultimately there are at least three clear goals in the agonist-like strategy for treatment of stimulant dependence. One is related to stabilizing cognitive function in the individual who might have experience permanent or temporary damage or dysfunction as a consequence of stimulant abuse. Stimulant drugs do have substantial efficacy in enhancing 'performance' that has been impaired, for example by sleep deprivation, or in this case drug abuse. Long-term excessive use of stimulants can also affect other functions; thus biological stabilization can be another goal. The primary goal is to eliminate or at least drastically reduce drug abuse itself, that is diminish the individuals desire/craving and most important, the behaviors directed at seeking and taking the stimulant drug.

FACTORS PRESUMED NECESSARY FOR EFFECTIVE TREATMENT AND DIMINISHED RISK

Just as any medical treatment has risks, agonist treatment of stimulant dependence could have associated problems. Some voice the concern that the treatment medication itself will be misused by patients or "diverted" and be misused by others. These concerns exist in opioid substitution treatment, were one of great concern regarding nicotine replacement, but might also be problematic for other treatments involving psychoactive drugs. This problem can be substantially obviated by an effective well-designed treatment regimen. When prescribed by clinicians in the United Kingdom and Australia, this has been accomplished by requiring daily pharmacy/dispensing visits, much like the methadone treatment system in the United States. While problems emerge in opioid replacement treatment, substantial controls on distribution, use of daily monitored dosing early in treatment, and so on are in place to reduce risk. On the other hand, unduly arduous requirements will likely diminish participation in treatment.

Stimulant drugs also have risks associated with their direct effects, for example, increases in blood pressure and heart rate and other cardiovascular consequences. These risks can be diminished by implementing a controlled regimen but also by careful pre-treatment evaluation. Clinical studies in which stimulant drugs have been administered in stable therapeutic regimens have found only modest changes in blood pressure and heart rate that are not clinically significant. Similarly, concerns that the psychic effects of stable dosing might lead to reinitiation of excessive illicit drug use have not been substantiated.

What steps can be taken to diminish risk while providing therapeutic benefit? The answers come from converging findings of preclinical research with animals, research with drug users and normal volunteers in human laboratory settings, well-controlled clinical trials, experience with other agonist therapies such

as methadone, LAAM, or buprenorphine and observing patterns of excessive drug us. First, as mentioned, a stable daily regimen with well-controlled dosing is essential. (Consistent medication taking as prescribed is essential to any effective therapeutic effort.) Second, the regimen must be as simple as possible. (The more doses required per day, the less likely there will be consistent adherence to the regimen.) The characteristics of action, or effect of the medication when taken are important. Recall that the most hazardous problematic drug use occurs when there are high peak effects that occur nearly immediately after dosing, for example when drugs are smoked or administered intravenously. Common patterns of excessive and hazardous stimulant use involve frequent drug taking, high doses with high peak effects, and a route of administration with rapid onset, followed by offset and renewed dosing. A stimulant 'binge' may involve repeated dosing over days. Conversely, the data and observations indicate that the ideal therapeutic regimen involves a drug preparation form that has slow, gradual onset, prolonged stable action, and slow offset using the minimum dose necessary to diminish illicit drug use while stabilizing function.

CLINICAL EVALUATIONS OF AGONIST-LIKE MEDICATIONS FOR STIMULANT DEPENDENCE

A number of early reports, many from England, in the 1980s and 1990s described clinicians prescribing d-amphetamine for the treatment of amphetamine dependence, particularly in patients who were using the drug intravenously. These reports characteristically described patients engaging in severely problematic drug use. Not uncommonly, the individuals had additional medical or psychiatric problems (e.g. HIV, psychosis) not directly related to the drug abuse but greatly complicating treatment. The clinicians prescribed moderate to high doses of d-amphetamine (e.g. 60–120 mg) that were ingested daily. Unfortunately, the available preparations were often 'immediate' release rather than 'sustained' or 'extended' release. While use of the extended release forms would be preferred based on current data, the clinicians found substantial amelioration of the drug dependence problems in many patients.

From here forward, the premise of this presentation is first, that a number of 'agonist-like' medications are available and could be approved and applied to treatment. These agents differ substantially in robustness as stimulants and typically in the scope of action, some being very specific, others modulating multiple aspects of brain neurochemistry and behavior. Second, it is clear

that there are differing levels of disorder severity among individuals who appear for treatment. There are some users who engage in controlled intermittent use. Some individuals are intermittent, infrequent users who nonetheless at intervals engage in persistent compulsive use to use. Others engage in chronic use, using substantial quantities of stimulant drugs many times a month. In some cases, these more severe users have multiple related or unrelated medical or psychiatric problems. Combining the two observations; first that there is a suite of agonist-like agents with different action spectra and robustness as stimulants and, second that there is a spectrum of severity of use in individuals seeking treatment, one arrives at the logical conclusion that the optimal approach may reside in matching the medication characteristics with severity of the presentation. This parallels practice in other areas of psychiatry specifically, and medicine generally. Based on this we make a hierarchical presentation combining the two features, agonist robustness and disorder severity. The bulk of the clinical research described here has been conducted by researchers at the University of Texas, University of Minnesota, and the University of Pennsylvania in the United States, at the University of Adelaide, as well as community clinics in Melbourne and Sydney, in Australia. Providing additional background and support for the agonist approach, the preclinical and human laboratory research was conducted primarily by scientists at the University of Kentucky, Columbia University, Harvard University, and the Medical College of Virginia. Virtually all of the work conducted in the United States was funded by the National Institute on Drug Abuse, one institute of the National Institutes on Health.

1-Dopa/Carbidopa

An approved medication combination, l-dopa/carbidopa, is approved for use in Parkinson's disease and as a precursor is presumed to directly increase brain dopamine levels. It is highly specific in its action (altering only dopamine levels directly but presumably indirectly modulating other systems) and has essentially no abuse liability. That is, the stimulant users who might receive the medication in treatment could not achieve substantive 'positive' psychic effects/highs. Based on its action, its primary function would be to produce relatively stable dopamine levels and modulate behaviors directly related to this effect. While the medication does have side effects they are nominal at the doses that have been examined for cocaine dependence. Only a few clinical studies have been conducted and they have involved administering l-dopa/carbidopa to cocaine using subjects. Mooney and his colleagues found that while the medication was well tolerated and safe in a population that had moderate disorder severity, there was no reduction in cocaine use over the 12-week study. However, other colleagues headed by Schmitz conducted and reported the results of a complex study combining l-dopa/carbidopa with several behavioral therapies. One therapy, contingency management, combined with behavior therapy did produce significant improvement, that is, reductions in cocaine use. Still, it is clear that l-dopa/carbidopa treatment of stimulant dependence would likely only be effective in the least severe patients, and then only when combined with a relatively powerful behavior therapy approach.

Modafinil

The mechanism of action, or means by which modafinil produces an effect, is not well understood but appears to differ from that of other 'stimulant' like agents such as methylphenidate or amphetamine analogs. Still, it appears to interact in some way with the dopaminergic system as well as others. Behaviorally, it can enhance mood and produce wakefulness. It is approved for use in treatment of narcolepsy and for wake-sleep cycle disturbances produced, for example, by shift work. In standard models to determine abuse liability, that is the extent to which the medication might have positive and sought-after psychic or behavioral effects, it has some effect and thus might be misused. It is plausible that the "misuse" will be for purposes of perceived benefits to "productivity" rather than achieving euphoria or highs. The side effects are relatively modest. In studies initiated by Dackis, Kampman, O'Brien, and colleagues there appeared to be a positive effect of modafinil in reducing cocaine use. Later clinical research suggested that the efficacy of modafinil in reducing cocaine or amphetamine use was modest, though more evident in certain less severe patient groups. It does appear that modafinil produces some essential effects such as mood enhancement, increased activity, and wakefulness that may contribute to utility it might have in treatment of stimulant dependence. Still, the composite data suggest that it may be most effective as the agonist-like, or substitution treatment for individuals with less severe dependence and generally less complicated medical and psychiatric presentations.

Methylphenidate

As an FDA approved medication, methylphenidate is widely used for the treatment of attention deficit and hyperactivity disorders and narcolepsy. There are a number of preparation forms including oral immediate and extended release as well as transdermal

(patch) versions. Methylphenidate has distinct stimulant-like actions and acts on various central nervous system arousal mechanisms. It is similar to amphetamine analogs and cocaine in its actions and increases availability of dopamine, inhibiting reuptake, and to a much lesser extent norepinephrine. Methylphenidate has clear positive psychic effects and abuse liability in all preclinical and clinical models used to evaluate this characteristic of drugs. It can produce serious psychiatric disturbance as well as other serious side effects, notably cardiovascular when used at high doses, particularly when used in continuous binges. In the 1980s, scientists at Yale University suggested potential benefit for treatment of cocaine dependence, but in particular in individuals who were 'self-medicating' to self-treat, for example, attention related problems; the results were negative. Subsequently other researchers administering low to moderate doses reported negative results in relatively severe cocaineusing patients, though preclinical research suggested that might reduce stimulant intake. Recently, a group in Denmark headed by Tiihonen reported that high doses of methylphenidate reduced amphetamine abuse but that the effect emerged slowly (e.g. over an 18-week period, and that this persisted over the year long observation period). It seems likely that methylphenidate could serve as an agonist-like or replacement agent, though the conditions for successful treatment may be somewhat limited.

d-Amphetamine

As an FDA approved medication, the primary indications of d-amphetamine, are narcolepsy as well as attendeficit and activity related disorders. d-Amphetamine neurochemical effects include direct release of dopamine and norepinephrine and decreased reuptake. As with other medications in this class, whether used in therapeutics or misuse, effects on the dopaminergic systems are pronounced. It should also be noted that, d-amphetamine can also affect serotonin systems. Thus, it has multiple effects and is distinctly a robust stimulant. It also has relatively high abuse liability by most measures. As mentioned, some UK clinicians administered immediate release d-amphetamine with the hope that they could stabilize and treat patients using illicit amphetamines. Grabowski and his colleagues developed and completed a series of studies examining amphetamine analogs for the treatment of cocaine dependence. Notably, they emphasized use of a preparation form of d-amphetamine that had slower onset and longer duration of action than the immediate release preparations. The successive studies provided critical support for the agonist strategy for treatment of stimulant dependence. This work also indicated that a well-controlled regimen was safe and well tolerated by the subject/patients in the studies. In particular, the effects on cardiovascular function were nominal and not clinically significance. It is assumed that this was due in part to the subjects existing tolerance to stimulant type medications. However, the stabilized and apparently normalized cardiovascular function may also have been related to the elimination or substantial reductions in stimulant use by many patients. This research also included redundant strategies to measure compliance using mechanical means (e.g. specialized dispensing bottles, pill blister packs) and a biochemical marker (riboflavin). The composite data indicated high rates of compliance with the medication regimen by the subjects and there was no evidence of diversion. Other investigators including Longo, White, and colleagues, and earlier Shearer and Wodak, in Australia have provided further support for proof of concept in treatment of individuals misusing amphetamines. Most recently, in a study initiated by Herin, a new d-amphetamine preparation, lisdexamfetamine, with presumed benefit in longer duration, limited peak effects and some reduction in abuse potential is being examined for treatment of cocaine users. Concurrent and subsequent research by other scientists (e.g. Negus, Rush, Hart) provided corroboration from preclinical animal studies and human laboratory research for some of the assumptions underlying the agonist strategy.

Methamphetamine

This medication is used for the treatment of narcolepsy, attention deficit, and activity related disorders. It has effects on dopamine, serotonin, and norepinephrine systems in the brain, acting to release these neurotransmitters and block reuptake. As with other amphetamine analogs, cardiovascular effects are of concern but are dose dependent and modest within the therapeutic dosing range. As with other robust stimulants, methamphetamine can have profound psychological and behavioral effects when consumed chronically at high doses. As noted regarding prevalence of illicit use, methamphetamine can be abused and has high abuse liability in preclinical animal and human laboratory models designed to test this characteristic. As with other stimulants, it can enhance mood and performance and transiently diminish fatigue within the normal dosing range. A sustained/ extended release form of methamphetamine was evaluated for the treatment of cocaine dependence in a controlled clinical trial reported by Mooney and Grabowski and colleagues. This work strongly supported

the agonist conceptualization for treatment of stimulant dependence. Generally, the function of the subjects was stabilized or normalized. Highly significant reductions, nearly suppression, of cocaine use were observed in the group receiving methamphetamine versus placebo. Further, there were no significant changes in food intake or cardiovascular parameters. And again, compliance with the medication regimen was excellent and diversion was absent in this treatment seeking population. This single, but well-controlled clinical trial using a robust stimulant with broad neurochemical action provides extremely strong support for pursuing development of the agonist strategy for the treatment of stimulant dependence. Most notable is that this study supports the hypothesis proposed by Rothman and Baumann and discussed by the authors of the research described in the foregoing sections. That is, a robust stimulant with multiple actions paralleling the drugs of abuse, but with slower onset and longer duration of action administered under a well-controlled regimen can be implemented to safely treat stimulant dependence with minimal risk.

IMPEDIMENTS TO DEVELOPMENT AND APPROVAL OF AGONIST MEDICATION FOR STIMULANT DEPENDENCE

Stimulant use disorders are prevalent and documented epidemics have been cyclic over the last 120 years. Yet stimulant drugs have been used effectively in therapeutics and social commerce for millennia. Clearly identifiable determinants separate the two cases. Therapeutic (e.g. methylphenidate, amphetamine analogs) and social (e.g. caffeine, khat) use typically involves the oral route of administration, dosing within a narrow range and a host of either regulatory or social controls guiding use. Hazardous or toxic use typically involves chronicity, high doses, and routes of administration with relatively instantaneous onset (e.g. intravenous, inhalation).

Recognizing these distinctions was requisite to establishing methadone for treatment of heroin dependence. While the regulations governing methadone treatment are onerous for the patient, many thousands have benefitted from maintenance on this robust opioid, which is also used for cancer or other diseases involving chronic pain. Further, problems such as criminal activity, medical consequences, and the like associated with effective treatment are diminished. Cigarette smoking and other tobacco use have been effectively treated with a variety of nicotine preparations. Contrasted with opioid and stimulant dependence, the concern over nicotine replacement was not illicit immediately disabling drug use or criminal activity, but instead it

revolved around the long-term consequences of morbidity and mortality associated with a publicly promoted and legally available product. Again, there was resistance to use of an agonist, nicotine, for treatment. Here too, as with methadone, the primal objections were twofold, "there will be deaths and diversion" (one fear was that children would become dependent on the gum). Particularly important in each case is that the initial treatment strategy involved a medication that raised legitimate concerns due to side effects, misuse and the like, but that now, in each case, safer medications were developed, are now available and are extremely effective; varenicline and bupropion for nicotine dependence and buprenorphine for opioid dependence. In the case of stimulants, development of new, effective, and safer medications (e.g. lisdexamfetamine) can be expected.

The foregoing points prompt consideration of the risks and benefits as well as the objections to development and approval of stimulants for treatment of stimulant dependence. Objections are primarily those related to the possibility that an individual treated with the medication might sell, or otherwise convey it to others. While such risks can exist, they have not been found to be present in treatment seeking patients in clinical studies and can be addressed by a well-controlled treatment regimen. Risks to the patient, who is seeking treatment because she or he has used illicit stimulants, will also be determined by the regimen and composite treatment provided; and it must be recalled that these will be individuals who have made the initial step by seeking help. Establishing the opportunity for access to treatment that may facilitate long-term abstinence from the hazards of the world of illicit drug use certainly seems adequately justified.

As proposed above, one aspect of the conceptualization that has been considered is a graded approach to treatment based on the available medications and severity of the disorder. There is a spectrum of medications from specific with low abuse liability and limited efficacy to robust agents with broad action, high efficacy, but also high abuse liability. Patients come to treatment with differing severity. In clinical trials and clinic practice alike, low severity patients are commonly found to be reasonably successful in treatment whether receiving active medication or placebo and simply receiving effective behavior therapy. Thus, a strategy of matching severity to medication, as is done in many areas of medicine is reasonable.

Ultimately, accepting the existing data as well as new data as they emerge supporting the agonist approach to treatment, the impediments to development are both more substantial and more concrete. There must be support among professional and governmental entities devoted to the science and treatment of substance use disorders. There must be a commercial entity willing to take on the responsibility of conducting final pivotal research that will support an FDA approval of use. The commercial entity would likely require assurances of economic incentives for development since the population requiring treatment is small and profits will be limited. This reality does not negate the severity of the condition but recognizes the circumstances of medication development and use, at least in the United States. Beyond this, it can be expected that substantial resistance to the approach will come from both governmental agencies (e.g. the Drug Enforcement Administration) and private groups who are not necessarily supportive of the analogous treatments (e.g. methadone or buprenorphine for opioid dependence). The case is made more difficult by treatment framework proposed; using a graded approach of medication administration associated with severity. This dictates that the target population is limited and profit is lessened, though in general more severe is the standard for the disorder. Conceivably, special legislation could be developed that would permit bypassing some regulatory hurdles.

CONCLUSION

Accumulating scientific data indicate that use of stimulants is a safe, tolerable, and efficacious approach to treatment of stimulant dependence. In many domains of medicine, the data would be adequate to proceed along the standard drug approval mechanisms. Some clinicians are currently prescribing stimulants for stimulant dependence in a number of countries. Some jurisdictions (metropolitan areas) in several countries are developing pilot projects and establishing treatment availability based on the premise of harm reduction. These are important efforts to demonstrating effectiveness and practicality yet are impractical solutions to wide spread availability. In the domain of substance use disorders many social factors, stigmatization, and criminalization of those with the disorder, and far ranging concerns do impede progress toward making treatment available. Thus, political and social factors as well as scientific data will converge to determine the course of approval of efficacious medications for stimulant dependence.

SEE ALSO

Evidence-Based Treatment, Harm Reduction Approaches, Etiology and Prevention of Stimulants (Including Cocaine, Amphetamines and Misuse of Prescription Stimulants), Pharmacotherapy of Cocaine FURTHER READING 457

Dependence, Medication Development for Amphetamine Dependence

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Medication Development for Amphetamine Dependence

Keith Heinzerling

UCLA Substance Abuse Pharmacotherapy Unit, Los Angeles, CA, USA

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INTRODUCTION

Amphetamine (AMP) and its *N*-methyl derivative methamphetamine (MA) are potent psychostimulants. Oral formulations of AMP and MA are used therapeutically for the treatment of attention deficit hyperactivity disorder (ADHD) and narcolepsy and occasionally to treat obesity. AMP and MA are also commonly abused, with AMP being the form most often abused in Europe and MA more commonly abused in North America, Asia, and Australia. Abuse of AMP/MA usually involves much higher doses than those used therapeutically and may be via oral, intranasal, smoked, or intravenous route. Acute administration at therapeutic doses results in moderate stimulation of the central nervous

and cardiovascular systems producing increased alertness, decreased sleep, improved cognition, and increased heart rate and blood pressure. High doses typical of chronic abuse result in an intense euphoria and may cause agitation, hallucinations, and frank psychosis.

AMP/MA dependence is characterized by tolerance, compulsive use, cravings, and inability to control use. Following chronic abuse, a characteristic withdrawal syndrome occurs on cessation with symptoms of fatigue, increased sleep (called a "crash"), depressed mood, anhedonia, and impaired cognition. Similar to cocaine, AMP/MA increases central nervous system monoamines (dopamine, norepinephrine, and to a lesser degree serotonin), although the mechanism of action

differs. While cocaine increases synaptic monoamines by blocking neuronal reuptake, AMP/MA triggers release of monoamines from neurons via reverse transport via the dopamine transporter. The half-life of AMP/MA is 12-16 h and as a result intense binge use episodes seen with cocaine are not as common with AMP/MA with as many as half of patients seeking treatment in clinical trials for AMP/MA using the drug daily. Personal and public health consequences of AMP/MA abuse include the social sequelae of addiction including family problems and criminal activity; psychiatric symptoms including depressed mood, psychosis, and suicidality; cardiovascular complications including increased risk of heart attack, stroke, and arrhythmias; and increased HIV transmission especially among men who have sex with men and use MA.

Currently, no medications have been proven effective for AMP/MA dependence. Behavioral therapies including cognitive behavioral therapy (CBT) and contingency management are variably effective with high rates of treatment failure especially in patients using AMP/MA daily at treatment entry. As a result, development of an effective medication to augment existing behavioral therapies is an important public health imperative. Medication development for AMP/ MA usually begins with assessment of a potential pharmacotherapy in animal models with medications that reduce AMP/MA self-administration in animals being of particular interest. Initial clinical testing occurs in a phase I safety/interaction study usually in an inpatient human laboratory setting where the objective is to determine the safety of the medication in combination with AMP/MA and to insure that the medication does not augment the cardiovascular adverse effects of AMP/ MA. Initial efficacy testing is usually in an outpatient phase II clinical trial that compares active medication to placebo, with a behavioral platform such as CBT, in a treatment-seeking population of AMP/MA users.

The following is a summary of medications that have completed initial testing in randomized, double-blind, placebo-controlled clinical trials (phase I and in some cases phase II). Owing to the importance of monamines and the mesolimbic dopamine system in AMP/MA dependence, several medications targeting dopaminergic systems have been tested. But medications targeting other neurotransmitter systems have also been evaluated including GABA, acetylcholine, opioids, glutamate, serotonin, and angiotensin-converting enzyme. AMP/MA abuse is associated with cognitive deficits particularly in the domains of attention, memory, and executive functions and targeting of these cognitive deficits with pharamcotherapies to treat AMP/MA dependence is a promising area of research. To date, no medication has been approved for AMP/ MA dependence, although bupropion has shown preliminary efficacy in several small clinical trials. Detailed results of phase I/phase II clinical trials completed to date are discussed below followed by a summary of implications for future research aimed at the development of safe and effective medications for AMP/MA dependence.

BUPROPION

The medication with the greatest support for safety and efficacy in clinical trials for AMP/MA dependence is bupropion, a dopamine/norepineprine reuptake inhibitor and noncompetitive nicotinic acetylcholine receptor antagonist, which is an approved treatment for depression and cigarette smoking cessation. Bupropion's clinical effect in AMP/MA dependence (and cigarette smoking cessation) was originally thought to be due to dopamine transporter (DAT) blockade and subsequent increases in dopaminergic tone resulting in reduced cravings and withdrawal symptoms, particularly anhedonia. But studies documenting only weak DAT blockade (approximately 25%) by clinical doses of bupropion in humans suggest that additional mechanisms are likely involved. Bupropion also blocks the norepinephrine transporter (NET) and reduced firing of noradrenergic neurons following AMP/MA administration due to NET blockade, and auto-inhibition via presynaptic norepinephrine receptors has also been hypothesized as a mechanism for bupropion in AMP/ MA dependence.

In addition to blockade of catecholamine transporters, bupropion has effects on neuronal cellular dopamine processing that may contribute to its effect in AMP/ MA dependence. AMP/MA disrupts functioning of neuronal vesicular monoamine transporter-2 (VMAT-2) resulting in impaired ability to sequester cytosolic dopamine in synaptic vesicles, generation of toxic reactive oxygenation species, and increased release of dopamine into the synapse via DAT reverse transport. Bupropion increases VMAT-2 function and triggers trafficking of vesicles into the cytoplasm of presynaptic neurons in vitro via an unknown mechanism involving DAT and presynaptic D2 dopamine receptors. As a result, bupropion may counteract AMP/MA-induced cellular disruptions in dopaminergic functioning by restoring the normal cellular processes responsible for neuronal dopamine disposition and processing.

Recent research has also identified a potential role for cholinergic modulation of the mesolimbic dopamine system via the habenulo-interpeduncular pathway in the actions of a variety of drugs of abuse including AMP/MA. In preclinical studies, MA causes the release of acetylcholine in the interpeduncular nucleus and blockade of $\alpha 3\beta 4$ nicotinic acetylcholine receptors in

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the medial habenula, interpeduncular nucleus, and the basolateral amygdala reduced MA self-administration in rats. Bupropion is a noncompetitive antagonist at multiple nicotinic acetylcholine receptors including $\alpha 3\beta 4$, and antagonism of nicotinic receptors may underlie bupropion's effect in AMP/MA dependence, although human studies to support this mechanism of action are lacking.

Clinical studies support bupropion as a safe and efficacious medication for the treatment of AMP/MA dependence in specific patient subgroups. In a human lab study with nontreatment-seeking MA-dependent participants, bupropion reduced the subjective (quality of drug high and any drug effect) and cardiovascular (heart rate and blood pressure) effects of MA more than placebo. Bupropion also significantly reduced MA metabolism, as expected due to bupropion's known inhibition of the 2D6 cytochrome P450 isoenzyme which metabolizes MA into AMP, yet the altered MA pharmacokinetics with bupropion did not result in enhanced cardiovascular or adverse effects. Whether altered MA metabolism is involved in the altered MA subjective effects with bupropion is not known but warrants further investigation.

Several clinical trials have evaluated the safety and efficacy of bupropion versus placebo, provided in conjunction with outpatient behavioral therapy, in treatment-seeking MA-dependent participants. Two independent trials (N = 151 and N = 73) found no significant effect for bupropion on MA use in the total sample, but both found a statistically significant effect for bupropion in reducing MA use in the subgroup of participants with lowerfrequency of baseline MA use (self-reported MA use on 18 or fewer of the past 30 days in one study and 0–2 of 6 baseline urine screens positive for MA in the other). Re-analysis of data from the larger study found a statistically significant effect for bupropion on rates of MA abstinence in the final 2 weeks of treatment for all but daily MA users (24% of bupropion participants MA abstinent during the final 2 weeks versus 6% of placebo participants, p = 0.01, effect size 0.4 for bupropion). An additional small trial of bupropion versus placebo in high-risk MA using men who have sex with men found bupropion to be acceptable and well tolerated, but the trial was not powered to detect potential treatment effects on MA use. Additional studies in this important clinical population are warranted. Bupropion has been safe and well tolerated in human MA studies to date, and in particular there have been no major cardiovascular toxicities detected. Rare but important side effects of bupropion are seizures and suicidality, and it is important to note that clinical trials have excluded patients at high risk for these conditions.

Additional clinical trials attempting to replicate the efficacy of bupropion for treating MA dependence in

MA users with less than daily use are currently underway (results expected in 2012) and if positive may lead to the eventual approval of bupropion for this indication. Yet despite these encouraging results, many important research questions and clinical problems remain unanswered. Although better than placebo, only approximately one quarter of participants with less than daily MA use achieve MA abstinence by the end of treatment with bupropion, and bupropion has no demonstrated efficacy in the most severely affected subgroup, daily MA users. The mechanism of action responsible for bupropion's effect in AMP/MA dependence has also not been established. As a result, research to optimize outcomes with bupropion and/or identify medications with superior efficacy is needed. For example, human lab studies show a blunting of MA subjective effects following 30 mg of intravenous MA (a low dose relative to those typical for daily MA users) and bupropion failed to benefit heavy/daily MA users in clinical trials, but whether bupropion may benefit heavy/daily MA users following a reduction in MA use frequency/dose, either via existing behavioral therapies or a future pharmacotherapy, is not known. Furthermore, clarification of bupropion's mechanism of action in AMP/MA dependence would provide a molecular target for future medications that may be effective in patients who do not respond to bupropion.

NALTREXONE

Naltrexone is a mu-opioid receptor antagonist that is approved for the treatment of opioid dependence and alcohol dependence. Preclinical and clinical studies support a role for the endogenous opioid system in AMP/MA dependence via interactions with mesolimbic dopaminergic neurons. Naltrexone reduces AMP/MA-induced behavioral and locomotor sensitization, conditioned place preference, and reinstatement of drug-seeking in rodent models and decreases AMP selfadministration in rhesus monkeys. Intra-nucleus accumbens naloxone (another mu-opioid receptor antagonist) reduced AMP-induced impulsive behavior in rats while the development of MA-induced behavioral sensitization was attenuated in mu-opioid receptor knockout mice. Naltrexone significantly reduced AMP subjective effects in human lab studies with non-AMP-dependent as well as AMP-dependent volunteers. In a randomized clinical trial among AMP-dependent participants who had achieved initial AMP abstinence during a 2-week lead-in period (N = 80), AMP use and cravings were significantly lower and time to AMP relapse longer with naltrexone relative to placebo. A small clinical trial among nontreatment-seeking MA-dependent participants comparing the combination of naltrexone and N-acetyl cysteine to placebo, without a behavioral therapy platform (as participants were not treatment seeking), found no difference in cravings or self-reported MA use with naltrexone/ N-acetyl cysteine relative to placebo. If confirmed in subsequent studies, these results may suggest that naltrexone has efficacy in preventing relapse following initial AMP/ MA abstinence, but may not be effective in inducing abstinence during active AMP/MA use. An additional consideration for future studies of naltrexone for AMP/MA dependence is pharmacogenetic studies showing that response to naltrexone for alcohol dependence is influenced by a polymorphism in the mu-opioid receptor gene (OPRM1 A118G). Results of preclinical and early clinical studies with naltrexone, as well as the availability of a long-acting depot formulation of naltrexone for oncemonthly injection, make naltrexone either alone or possibly in combination with other medications an attractive candidate medication for preventing AMP/MA relapse.

DEXTROAMPHETAMINE

A substitution approach to treating AMP/MA dependence has been tested using D-amphetamine. Substitution approaches are effective in treating cigarette smoking cessation (nicotine replacement) and opioid dependence (methadone and buprenorphine), but are limited by concerns related to potential adverse effects as well as the need for strict precautions to limit misuse, abuse, and diversion. A randomized trial of high dose D-amphetamine (20 mg day^{-1} then increased 10 mg daily over the initial 14 days until stabilized or at a maximum dose of 110 mg day⁻¹; average stabilization dose of 80 mg day⁻¹) for MA dependence (N = 49) found significantly longer treatment retention and lower withdrawal symptoms with D-amphetamine relative to placebo. There was no statistically significant difference in MA use for D-amphetamine versus placebo, but severity of MA dependence symptoms were less with D-amphetamine at the end of treatment. There were no serious cardiovascular or psychiatric adverse events. D-Amphetamine was provided via daily supervised dosing at pharmacies with no take-home doses and 86% of participants used MA via the intravenous route. Another randomized trial examined sustained release of D-amphetamine 60 mg daily (60 mg once on day 1 followed by 30 mg BID thereafter) versus placebo for MA dependence (N = 60). MA withdrawal symptoms and cravings, but not MA use, were significantly lower with D-amphetamine relative to placebo and there were no serious cardiovascular or psychiatric adverse events with D-amphetamine. Based on these results, high dose D-amphetamine may have a role as a harm reduction approach for AMP/MA dependence when other treatments have failed but concerns about abuse and diversion of high dose amphetamine in AMP/MA-dependent patients are a serious barrier to wide spread adoption of substitution treatment for AMP/MA dependence.

MODAFINIL

Modafinil is a non-amphetamine stimulant that is approved for narcolepsy and excessive daytime sleepiness associated with obstructive sleep apnea. While a variety of potential mechanisms have been proposed for modafinil, human imaging studies suggest that modafinil increases dopamine via DAT blockade. Chronic AMP/MA abuse is associated with cognitive dysfunction, particularly in learning, memory, attention, and executive functions, which may result in poor treatment outcomes especially with existing cognitive behavioral therapies. Modafinil improves cognition and may be effective for AMP/MA dependence via amelioration of cognitive dysfunction. Modafinil reduced cue- and MA-induced reinstatement of MA self-administration in rats. In human lab studies with MA-dependent volunteers, modafinil improves learning and memory, with the largest effect among participants with baseline deficits in cognitive function. Two randomized clinical trials of modafinil versus placebo (modafinil 200 mg daily, N = 80; modafinil 400 mg daily, N = 71) for MA dependence found no significant effect for modafinil on MA use in a general sample of MA users. Whether modafinil may be effective for AMP/MA dependence in subgroups of MA users with greater baseline cognitive dysfunction, similar to results of human lab studies, has not been assessed in clinical trials.

METHYLPHENIDATE

Methylphenidate is a dopamine-reuptake inhibitor approved for the treatment of ADHD. Similar to bupropion, methylphenidate counteracts MA-induced disruptions of VMAT-2 functioning and prevents the subsequent accumulation of cytoplasmic dopamine and toxic reactive oxygenation species that are thought to contribute to MA-induced neurotoxicity. But pretreatment with methylphenidate did not reduce MA selfadministration in rhesus monkeys, while pretreatment with MA or bupropion did reduce MA self-administration in the same set of experiments. One randomized clinical trial comparing controlled-release methylphenidate (N = 17) or aripiprazole (N = 19) to placebo (N = 17) in intravenous AMP/MA users found significantly lower rates of AMP/MA use with methylpheidate compared to placebo, but evaluation of the results is hampered by the fact that the trial was discontinued early after an interim analysis found increased

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AMP/MA use in the aripiprazole group. Another small trial compared methylphenidate to placebo in AMP-dependent participants with ADHD and found no difference in ADHD symptoms or AMP use for methylphenidate versus placebo. A phase II clinical trial of sustained-release methylphenidate for MA dependence is underway in the United States and conclusions concerning the efficacy of methylphenidate for AMP/MA dependence await completion of adequately powered clinical trials.

ARIPIPRAZOLE

Aripiprazole is an atypical antipsychotic that is a partial agonist at D2 dopamine and 5HT_{1A} serotonin receptors. A dopamine partial agonist may be useful in treating AMP/MA dependence by providing some agonist effect (similar to substitution approaches but potentially safer) while antagonizing AMP/MA effects. Aripiprazole reduces the discriminative-stimulus and subjective effects of AMP in healthy non-AMPdependent volunteers. But among MA-dependent participants in a human lab study, aripiprazole increased MAinduced craving and subjective effects and the one clinical trial to date of aripiprazole for AMP dependence was terminated prematurely due to significantly higher AMP use with aripiprazole relative to placebo in an interim analysis. As a result, aripiprazole is not considered a viable candidate medication for AMP/MA dependence.

BACLOFEN

Baclofen is a selective GABA_B agonist that may be effective for AMP/MA dependence via increasing GABA-ergic modulation of the mesolimbic dopamine system. Baclofen reduces the expression of MA-induced conditioned place preference and MA self-administration in rats. But in a randomized trial for MA dependence, baclofen did not reduce MA use more than placebo in preplanned analyses, although there was an effect in post hoc analyses for baclofen in reducing MA use among participants with the highest medication adherence. Thrice daily dosing and drowsiness, the most common side effect, may limit adherence, and thereby efficacy, with baclofen in MA dependence. Still, these preliminary results suggest targeting GABA may be effective for AMP/MA dependence. Future formulations/ analogues of baclofen or other GABA-ergic medications may yet prove effective. For example, a GABA_B positive allosteric modulator reduced AMP-conditioned place preference in rats and may be available for clinical testing in the future.

GAMMA-VINYL-GABA

Gamma-vinyl-GABA (GVG) is an antiepileptic that irreversibly inhibits GABA transaminsase, the enzyme that metabolizes the inhibitory neurotransmitter GABA, thereby increasing CNS GABA and inhibitory tone. Increased GABA may be an effective strategy for treating AMP/MA dependence as GABA-ergic neurons modulate mesolimbic dopamine functioning and may thereby dampen the rewarding effects of AMP/MA. In rats, GVG inhibits MA-induced increases in dopamine in the nucleus accumbens and prevents reinstatement of MAconditioned place preference following MA administration. GVG was well tolerated in a small open-label clinical trial (N = 30) for MA dependence in Mexico. In a phase I safety-interaction trial in the United States, GVG did not significantly alter MA subjective effects relative to placebo and there was a trend toward enhanced cardiovascular response to MA with GVG. Subsequent development of GVG for MA dependence in the United States was halted due to potential cardiovascular safety concerns, although the mechanism whereby GVG would enhance cardiovascular response to MA is unknown. The best-known adverse effect of GVG is ocular toxicity resulting in peripheral visual field defects, but this has not been observed with short-term use in trials for AMP/MA dependence.

TOPIRAMATE

Topiramate is an anticonvulsant that increases GABA transmission and inhibits glutamatergic transmission and has shown preliminary efficacy for alcohol dependence. In a human lab study in MA-dependent volunteers (N=10), topiramate increased MA subjective effects ("stimulate" and "euphoria") following experimental MA infusions. There was a trend toward increased MA plasma levels with topiramate, suggesting that enhanced MA effects with topiramate may be the result of a pharmacokinetic interaction, and further clinical development is unlikely to be safe or effective.

GABAPENTIN

Gabapentin is an antiepileptic that binds to voltage-gated calcium channels (VGCC). In mice, MA treatment increases levels of the $\alpha 2/\delta -1$ subunit of VGCCs in the nucleus accumbens and frontal cortex. Gabapentin reduces MA-induced increases in the $\alpha 2/\delta -1$ subunit and blocks expression of MA-conditioned place preference in mice. Gabapentin did not reduce MA use more than placebo in the one randomized clinical trial for MA dependence in humans.

VARENICLINE

Varenicline is an $\alpha 4/\beta 2$ nicotinic acetylcholine receptor partial agonist that is approved for cigarette smoking cessation. Similar to bupropion, which has shown preliminary efficacy for MA dependence in early clinical trials, varenicline may be effective for AMP/MA dependence by modulating mesolimbic dopamine transmission via binding to $\alpha 4/\beta 2$ nicotinic receptors on neurons in the ventral tegmental area and/or antagonizing of nicotinic acetylcholine receptors. Clinically, varenicline improves cognition, especially attention and memory, during smoking cessation treatment and may be useful in ameliorating the cognitive dysfunction that has been observed in chronic AMP/MA abusers. In a human safety-interaction study among MA-dependent cigarette smokers (N = 12), cardiovascular response and psychiatric adverse events following MA infusions were similar for varenicline and placebo. In a small pilot randomized clinical trial among treatment-seeking outpatients with MA dependence (N = 20), varenicline improved retention and reduced MA use and cravings more than placebo. Rare but serious psychiatric adverse events, including suicide, have been reported with varenicline in cigarette smoking cessation treatment but have not been observed in the limited clinical studies of varenicline for MA dependence to date. A phase II trial of varencline for MA dependence (N=90) is currently scheduled to begin enrollment in mid-2011.

LOBELINE

Lobeline, an alkaloid of *Lobelia inflata* (Indian Tobacco), is a nicotinic receptor antagonist, inhibitor of VMAT-2 function and has low affinity for the dopamine and serotonin transporters. MA disrupts VMAT-2 functioning resulting in increased cytosolic dopamine and release of dopamine into the synapse. Lobeline inhibits MA-induced dopamine release in vitro and reduces MA self-administration in rats presumably due to its effects at VMAT-2 and the dopamine transporter, but it has not been tested for AMP/MA dependence in human clinical trials. Gastrointestinal side effects (nausea and vomiting due to nicotinic effects) may limit the clinical utility of lobeline although related molecules more selective for VMAT-2 are in early stages of development and may be tested for AMP/MA dependence in the future.

RIVASTIGMINE

Rivastigmine is an acetylcholinesterase inhibitor with cognitive enhancing effects that is used to treat

dementia. In addition to increasing dopamine release, MA also triggers release of acetylcholine in the ventral tegmental area and donepezil, another acetylcholinesterase inhibitor, reduced MA-seeking behavior in rats. In a human lab study among nontreatment-seeking MA-dependent volunteers (N = 23), rivastigmine significantly reduced the subjective "desire" for MA relative to placebo, but did not reduce MA-self administration in a laboratory choice paradigm relative to placebo. Additional studies of cholinergic medications for AMP/MA dependence are warranted.

SELECTIVE SEROTONIN REUPTAKE INHIBITORS

Selective serotonin reuptake inhibitors (SSRIs) are antidepressants that increase serotonin via blockade of reuptake via the serotonin transporter. AMP/MA causes release of serotonin, in addition to dopamine and norepinephrine, and depressive symptoms are typical and often severe during AMP/MA withdrawal and as a result SSRIs were some of the first medications tested for AMP/MA dependence. Randomized clinical trials found no benefit for fluoxetine or paroxetine in reducing MA use relative to placebo. In a randomized trial of sertraline for MA dependence, treatment dropout and adverse events (particularly gastrointestinal symptoms and sexual dysfunction) were significantly higher with sertraline than placebo. As a result, SSRIs are not indicated for the primary treatment of AMP/MA dependence, but may have a role in treating AMP/MA users with depression that does not remit following abstinence from AMP/MA use, although bupropion may be preferred to SSRIs given the efficacy of bupropion in early MA dependence clinical trials.

ONDANSETRON

Ondansetron is an antiemetic that modulates mesolimbic dopamine function via blocking serotonin (5HT₃) receptors. Ondansetron blunted AMP subjective effects in a lab study in healthy non-AMP-dependent volunteers. A large randomized, double-blind trial (N=150) of ondansetron for MA dependence failed to find an effect for ondansetron (0.25, 1, and 4 mg twice daily) on MA use relative to placebo.

PERINDOPRIL

Perindopril is an angiotensin-converting enzyme (ACE) inhibitor and antihypertensive. Preclinical

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studies showing an effect of brain ACE systems on mesolimbic dopamine provide the rationale for testing ACE inhibitors for treating AMP/MA dependence. There was no significant effect of perindopril on MA cardiovascular or subjective effects overall in a human lab study, although MA subjective effects were lower relative to placebo among participants receiving 2 and 4 mg of perindopril, but not those receiving 8 mg perindopril, leaving open the possibility that future studies with intermediate doses may show an effect for perindopril in MA dependence.

SUMMARY AND FUTURE IMPLICATIONS

While no medications have been proven effective for AMP/MA dependence, bupropion has shown preliminary efficacy among MA users with less than daily MA use at treatment baseline. Two confirmatory clinical trials with bupropion in less than daily MA users are currently underway, and results of these studies will determine if bupropion is likely to be approved as a treatment for AMP/MA dependence. Regardless of the outcome of these trials, many important research and clinical questions regarding AMP/MA dependence pharamcotherapy remain unanswered. First, no medications have shown efficacy in achieving AMP/MA abstinence in the most severely addicted patients, including daily AMP/MA users, although substitution approaches may increase treatment retention and reduce severity of AMP/MA dependence. Research to better quantify potential health and societal benefits of treatments that reduce AMP/MA use but do not achieve total abstinence is warranted. Also, whether bupropion (or another medication) is effective in sustaining abstinence in daily users following a brief inpatient stabilization to achieve initial abstinence warrants investigation. Furthermore, clinical trial designs that account for the clinical and potentially biological heterogeneity among AMP/MA-dependent patients and are capable of isolating medication effects in specific subgroups are needed. It seems likely that like other areas of medicine, personalized approaches to pharmacotherapy for AMP/ MA dependence will be needed in order to achieve optimal treatment outcomes for all patient subgroups. With this in mind, testing of medications with a variety of different mechanisms in multiple subgroups of AMP/ MA users, especially those with varying frequency of AMP/MA use at treatment baseline, will likely be necessary in order to identify several effective medications such that clinicians can tailor pharmacotherapy to each patient's individual needs.

List of Abbreviations

ACE angiotensin-converting enzyme
ADHD attention deficit hyperactivity disorder

AMP amphetamine

CBT cognitive behavioral therapy
DAT dopamine transporter
GVG Gamma-vinyl-GABA
MA methamphetamine
NET norepinephrine transporter

SSRI selective serotonin reuptake inhibitor VGCC voltage-gated calcium channels VMAT-2 vesicular monoamine transporter-2

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http://www.nida.nih.gov - National Institute on Drug Abuse (NIDA).

http://learn.genetics.utah.edu/content/addiction/ – The New Science of Addiction: Genetics and the Brain.

http://www.uclasarx.org/ – UCLA Substance Abuse Pharmaco-therapy Unit (UCLA SARx).

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Medications for Sedative Dependence

Annemarie Heberlein, Thomas Hillemacher

Medical School Hannover, Clinic of Psychiatry, Socialpsychiatry and Psychotherapy, Center of Addiction Research (CARe), Hannover, Germany

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SEDATIVE DEPENDENCE

The term "Sedative dependence" describes the psychic and physical dependence from medications that are classified as "sedatives" because of their relaxing, sleep-inducing properties. Although various drugs can be classified as "sedatives," i.e. barbiturates and antipsychotics with sedative properties, benzodiazepines and the "non-benzodiazepine" sedative hypnotics, in particular zaleplon and zolpidem, are those sedatives that are most clinically relevant.

Benzodiazepines are most commonly prescribed because of their quick sedative and hypnotic effects, which make benzodiazepines effective as co-medication in the treatment of various psychiatric diseases such as agitated depression, anxiety, and sleep disturbances. Besides these common indications, benzodiazepines are often (mis-)used because of their relaxing and mood improving properties.

The addictive potential of benzodiazepines ranks from medium to high depending on the individual benzodiazepine medication. In particular, the onset and the duration of action have been identified as pharmacological variables that contribute to the risk of addiction (see Subgroups of Benzodiazepine-Dependent Patients).

Substance dependence as defined by the criteria of the DSM-IV is defined by at least three of the following symptoms occurring in a 12-month period leading to the necessity of treatment:

- 1. Tolerance: Tolerance means the partial or complete loss of the effects desired caused by adaptive processes, although the drug is taken continuously. Tolerance typically results in self-directed, nonprescribed increase of the dosage taken.
- **2.** Withdrawal: Tapering of dosage or stopping of intake is associated with a typical withdrawal

- syndrome, that is substance specific and a manifestation of the substance-specific neuroadaptive process within central neurotransmission (e.g. symptoms of increased glutamatergic neurotransmission in patients suffering from benzodiazepine dependence).
- **3.** Ongoing drug use over longer time periods than intended or prescribed.
- **4.** Spending most of the days with activities that are associated with drug use as obtainment, intake, and recovering from side effects.
- 5. Disregard of any further activities due to drug use.
- **6.** Ongoing drug use although the existing knowledge about potential harmfulness of ongoing drug intake or manifestation of permanent side effects.

BENZODIAZEPINES

Benzodiazepines are sedative drugs that are prescribed because of their anxiolytic, relaxing, and hypnotic (sleep-inducing) properties. Moreover, a positive mood effect is known. Besides those desired effects, benzodiazepines show side effects such as decrease of muscular tone, anticonvulsive, and amnesic effects (in particular anterograde amnesic effects that can contribute to the dementia like symptoms often seen in long-term benzodiazepine users). Because of their anxiolytic, relaxing qualities, benzodiazepines are widely used not only to treat insomnia and anxiety but also because of their muscle relaxing properties. The main effects and clinical uses of benzodiazepines include the following:

- Effects on mood and agitation: co-treatment in the case of agitated psychosis, catatonia, severe depression
- Anxiolytic properties: treatment of anxiety disorders
- Hypnotic properties: treatment of insomnia
- Muscle relaxing properties: co-treatment of spine diseases, dystonia, and muscle spams
- Treatment of movement disorders, like akathisia and tardive dyskinesia following long-term treatment with typical antipsychotics
- Anticonvulsant properties: treatment of epilepsy and withdrawal syndromes (as alcohol withdrawal)
- Amnesic properties, in particular antegrade amnesia

The intake of benzodiazepines over longer time periods (e.g. continuous intake over a period of 2–4 weeks) has been proven to be associated with the risk of dependence and the occurrence of a typical benzodiazepine withdrawal syndrome (see Subgroups of Benzodiazepine-Dependent Patients) when treatment is stopped without tapering of dosage. Several risk factors that contribute to the development of benzodiazepine dependence have

been investigated by clinical observational studies: For example, certain personality traits like dependent and emotional unstable personality traits have been shown to increase the risk of benzodiazepine dependence. Also, the pharmacology of the benzodiazepine used, its bioavailability, the speed of absorption, diffusion, and invasion, has been shown to contribute to the risk of dependence. In particular, benzodiazepines that quickly reach high plasma peeks are known to increase the risk of dependence. Consistently, those benzodiazepines have been shown to be commonly misused in polydrug users via intravenous application in order to further increase the onset of drug action (e.g. flunitrazepam). Factors that increase the risk of dependence include the following:

- Duration of treatment (in particular treatment periods longer than 2 weeks)
- Dosage taken
- Chronic psychiatric diseases such as depression, dysthymia, anxiety
- Anamnesis or ongoing drug dependence
- Emotional unstable and dependent personality traits
- Properties of the benzodiazepine taken (bioavailability, half-life, plasma peek, oral versus i.v. use (e.g. flunitrazepam))

Table 49.1 gives an overview about various benzodiazepine derivates and the pharmacological half-lives.

TABLE 49.1 Overview of Different Benzodiazepine Derivates

Benzodiazepine derivate	Pharmacological half-life	Diazepam equivalent dosage
Diazepam	20-100	10 mg
Alprazolam	6–12 h	1 mg
Bromazepam	10-20 h	4.5 mg
Chlordiazepoxid	5–30 h	20 mg
Clobazam	12-60 h	20 mg
Clorazepat	36-200	15 mg
Flunitrazepam	18-26	1 mg
Flurazepam	40-250	30 mg
Lorazepam	10-20	1–2 mg
Lormetazepam	10-12	1 mg
Medazepam	36-200	20 mg
Nitrazepam	15-38	5 mg
Oxazepam	4-15	30 mg
Prazepam	36-200	20 mg
Temazepam	8-22	20 mg
Triazolam	2	0.25 mg

Note: These estimates are based on the results from Heberlein A et al: Fortschr Neurol Psychiatr. 2009 Jan; 77(1): 7–15. Epub 2008 Dec 19.

SUBGROUPS OF BENZODIAZEPINE-DEPENDENT PATIENTS

Benzodiazepine dependence is a common disease: About 2% of general population have been reported to suffer from benzodiazepine dependence. In general, two groups suffering from benzodiazepine dependence can be distinguished: On the one hand, there is a large group of persons, who get a medical prescription aiming the treatment of anxiety or muscle spasm. Typically those patients use benzodiazepines as prescribed without increasing their dosages. Those who have trouble controlling their use of benzodiazepines often do so to avoid potential negative effects of treatment cessation. They fear the recurrence of those symptoms for which the benzodiazepines have been prescribed. Those persons, suffering from the so-called "low dosage" benzodiazepine dependence," are usually elderly women (aging 60 years and above) suffering from depression, anxiety, or insomnia. The second, equally prevalent, group of benzodiazepine-dependent patients are patients with multidrug dependence, who suffer from "high dosage benzodiazepine dependence." Contrasting to the "low dosage benzodiazepine-dependent patients" this group shows typical addictive behaviors such as increase of dosage without medical prescription, increase of tolerance of intended drug effects, intravenous application or application with further addictive substances (as heroin, cocaine, amphetamines, antidepressants) in order to increase the drug effects as well as illegal drug-selling.

BENZODIAZEPINE WITHDRAWAL SYNDROME

Since the first discovery of the benzodiazepine chlordiazepoxide more than 40 years ago, benzodiazepine tolerance and withdrawal have been documented. Tolerance first develops to the sedative effects, followed by tolerance to benzodiazepines' anticonvulsant actions and its anxiolytic effects. Even low dose treatment with benzodiazepines over a distinct time period can provoke tolerance as well as withdrawal, supporting the relevance of "low dosage dependence." Signs and symptoms of benzodiazepine withdrawal include the following:

- Agitation
- Insomnia, inability to sleep, and disturbed sleeping
- Loss of appetite and weight loss
- Nausea, vomiting, and diarrhea
- Seizure
- Tremor
- Muscle spasms

- Increase of blood pressure, pulse, and body temperature
- Headache
- Hallucinations, in particular perceptual hallucinations
- Psychiatric symptoms such as anxiety, depression, and irritation

Besides the common physiological withdrawal syndrome also psychological withdrawal symptoms are known, caused by those "psychological" effects of the sedative independent from its pharmacological actions. In contrast to the typical physiological withdrawal syndrome noted above, the psychological withdrawal syndrome is mainly characterized by psychiatric symptoms such as depression, anxiety, and agitation and rather mild bodily symptoms that can be explained as a consequence of psychic agitation or anxiety.

NEUROBIOLOGICAL ACTIONS OF BENZODIAZEPINES

In the central nervous system, benzodiazepines are ligands at the GABA_A receptor. They bind to the benzodiazepine binding site, which enhances the affinity of the gamma-aminobutyric acid (GABA) to its (GABA_A)-receptor. Through this process, benzodiazepines reinforce the inhibitory effects of GABAergic neurotransmission in general.

The GABA_A receptor is known to be a ligand-gated ion channel like glycine or nicotinic acetylcholine receptors. It consists out of five different subunits that are circled around a central ion channel, which is selectively permeable to chloride ions. Benzodiazepines' binding to the receptor results in increasing the GABA mediated amount of Cl⁻ currents and the frequency of the chloride channel opening in response to GABA, without altering the mean duration of the channel opening time. The composition of the five subunits, which form the central chloride channel, differs: until now 19 differential subunits are known, containing the subunits α_{1-6} , β_{1-3} , γ_{1-3} , δ , ε , θ , π , ρ_{1-3} . Further evidence supports the existence of further subunits that have not been investigated yet. Though, GABA_A receptors consisting out of two α, two β subunits and an additional subunit, mostly γ are known to be most clinical relevant. Consistently, the most abundant combination – constituting a percentage degree of 43% in rat brains – is α_1 , β_2 , and γ_2 .

The benzodiazepine binding site is located between the γ_2 and the nearby α -subunit of the GABA_A receptor, whereby the existence of the γ_2 -subunit is exigent for benzodiazepine binding. Also, a homologous GABA binding site exists at the GABA_A receptor, that is

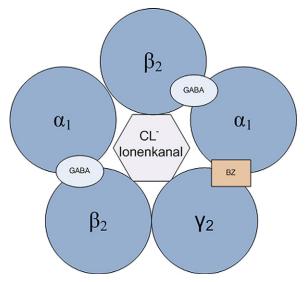


FIGURE 49.1 Composition of the GABA_A receptor and the GABA and benzodiazepine binding site (BZ, benzodiazepines). *Adapted from Heberlein A et al: Fortschr Neurol Psychiatr.* 2009 *Jan;* 77(1): 7–15. *Epub* 2008 *Dec* 19.

comprised out of the $\alpha_{1,2,3,5}$ and the β_2 subunit. Except the benzodiazepine and the GABA binding site, five other binding sites have been described that bind the sedative barbiturates, neurosteroids, picrotoxin, Cl⁻, and Zn²⁺ (see Fig. 49.1 for detail).

Because of the great diversity of the GABA_A receptor conformation and the distinct localization of the several GABA subunit compositions in the rat brain, it has been hypothesized that the composition of the subunits forming the GABA_A receptor could be responsible for the particular functions of the receptor and could even be involved in the constitution of tolerance and withdrawal during benzodiazepine therapy. Until now, this coherency is not completely proven, but evidence increases that the subunits of GABA_A receptors deliver different aspects of the effects of benzodiazepines:

- The α₁ subunit has been associated with sedative, anterograde amnesic, and anticonvulsive effects of benzodiazepine therapy
- **2.** The α_2 or α_3 subunit seems to deliver the anxiolytic effects of benzodiazepine treatment
- 3. The α_5 subunit seems to be involved in memory impairment due to benzodiazepine therapy.

Consistent with a subunit-specific delivery of the several effects of benzodiazepine therapy, in genetic modulated "knock-in" mice, that exhibit inoperable α_1 subunits because of a α_1 (H101R) point mutation, diazepam lacks sedative and amnesic effects. Moreover, in α_2 "knock out" mice that exhibit α_2 subunits, which are insensitive to diazepam because of an artificially engendered α_2 (H101R) point mutation, diazepam fails to show anxiolytic effects.

THE NEUROBIOLOGY OF BENZODIAZEPINE DEPENDENCE

Although intensive efforts have been made to investigate the underlying molecular mechanisms of tolerance and dependence associated with benzodiazepine therapy, the neurobiological basis of sedative dependence has not been fully elucidated yet.

Regarding the neurobiological processes underlying benzodiazepine dependence, alterations in the GABA_A receptor structure have been proven to exist, but these results remain inconsistent and are therefore not sufficient in elucidating the complex processes explaining the occurrence of benzodiazepine dependence. Also, alterations in the glutamatergic neurotransmission have been investigated due to benzodiazepine therapy. It is likely that regulatory mechanisms that oppose the pharmacological enhanced GABAergic neurotransmission result in the increases in glutamatergic neurotransmission observed. Furthermore, alterations in the activity of the hypothalamic pituitary axis (HPA) have been reported, which are directly or subsequently involved in the occurrence of the clinical benzodiazepine withdrawal syndrome. For example, the release of corticotropin releasing hormone (CRH), adrenocorticotropin, and cortisol is decreased during benzodiazepine therapy, whereas withdrawal from benzodiazepines results in an increase of these parameters. New psychopharmacological strategies utilize these newly investigated coherencies and try to modulate the activity of the HPA in order to treat patients suffering from sedative dependence.

Alterations in the GABA_A Receptor

In order to further scrutinize the involvement of special subunits in the development of benzodiazepine dependence, the expression of subunit-specific mRNA during therapy and withdrawal from benzodiazepines was investigated: Thus, greater alterations should be observable in those subunits that are mainly involved in benzodiazepine binding than in those that are not involved. Because of the assumption that α_4 and α_6 render the GABA_A receptor insensitive to benzodiazepine treatment, a possible higher expression of GABAA receptors which contain the α_4 or α_6 and a lower expression of $\alpha_{1,2,3,4,5}$ was assumed to be a result of long-time benzodiazepine treatment. Though, the results obtained until today do not fully confirm the hypothesis of a subunitspecific adaption mechanism of the GABAA receptor underlying the development of benzodiazepine dependence. Furthermore, the hypothesis that benzodiazepine treatment may result in downregulation of the total number of the GABA_A receptor has not yet been proven.

Alterations in the Glutamatergic Neurotransmission

Because of the hypothesis that prolonged therapy with benzodiazepines could provoke compensatory changes in those neuronal systems that normally oppose the GABAergic neurotransmission, the effects of benzodiazepine treatment on glutamatergic neurotransmission have been a main focus of research. According to this hypothesis, withdrawal symptoms could be explained as an enhanced excitatory glutamatergic neurotransmission that is no longer antagonized by the inhibitory GABAergic neurotransmission after cessation of benzodiazepine therapy. Indeed, a significant increase of in vitro glutamate release in the hippocampus of rats that were chronically treated with lorazepam was reported as well as neuroadaptive alterations in the receptors of the glutamate system due to benzodiazepine dependence. Thus, adaption of the glutamatergic neurotransmission seems to be involved, not only in the typical benzodiazepine withdrawal symptoms but also in long-term potentiation. Long-term potentiation is the basis of neuroplasticity – in the development of the so-called addictive memory, the consolidation of substance-related memories that increase the substance craving dependent on certain locations and situations (so-called cue reactivity).

Alterations in the Regulation of the HPA

Besides its modulation of GABAergic and glutamtergic neurotransmission, benzodiazepine treatment is known to affect further central regulatory circuits such as the HPA. In particular, alterations in the regulation of the HPA have been found to contribute to the development of benzodiazepine dependence as well as to the development of typical benzodiazepine withdrawal signs. For example, various studies showed time-dependent suppression of HPA-activity during treatment with benzodiazepines and an increase in HPA activity during benzodiazepine withdrawal, similar to withdrawal syndromes provoked by ethanol, opioids, and even cocaine. Regarding benzodiazepines, there is evidence that individual benzodiazepines can decrease the exercise-induced activation of the HPA, which fits well with the relaxing and anxiolytic properties of benzodiazepines in general. Moreover, preclinical study results suggest that benzodiazepines may even directly interfere with the regulation of the HPA by affecting the stress-induced transcription of the hypothalamic corticotropin releasing factor and thereby the downstream activity of the HPA and the cortisol release from the adrenal gland. See Fig. 49.2 for details.

MODEL OF THE DEVELOPMENT OF BENZODIAZEPINE DEPENDENCE

Clinical research indicates that both psychic and neurobiological causes contribute to the development of benzodiazepine dependence.

Similar to hypotheses regarding affective disorders, the development of benzodiazepine dependence has been explained by a multicausal model that consists of a combination of psychic factors, like stressful life events, and neurobiological factors, like genetic prevalence. Certain genetic risk profiles, like dependent, anxious personality traits, predispose the intake of sedative drugs. The drug profile of the benzodiazepine taken increases the risk of dependence by the presence of the desired effects and by the relief from unwanted symptoms. In this way, the relief gained by benzodiazepine treatment serves as positive reinforcement that supports the development of dependence. Figure 49.3 shows this hypothetical cascade of the factors contributing to benzodiazepine dependence.

TREATMENT OF BENZODIAZEPINE DEPENDENCE

Established Therapeutic Methods

Tapering of dosage after switching from a short-term benzodiazepine like lorazepam to a longer acting benzodiazepine like diazepam (see Table 49.1 for detail) is the most proven and most common strategy of benzodiazepine withdrawal. Dosage tapering without switching to medium-long half-life benzodiazepines has been associated with increased relapse during withdrawal because of the increase of intensity of withdrawal symptoms dependent on the half-life and the metabolism of the drug. Although some authors also recommend rapid dosage reduction strategies – for example halving the dosage in the beginning of the benzodiazepine withdrawal – clinical evidence suggests that slow tapering of the dosage is associated with lower relapse rates.

Various established drug strategies have been tested in terms of decreasing withdrawal symptoms and substituting for benzodiazepine's effects after successful withdrawal. However, therapeutic strategies such as the use of β -receptor antagonist Propranolol, the anxiolytic Buspirone, and the steroid hormone progesterone did not prove to be efficacious in randomized clinical studies. There are study results that suggest that the antihistamine hydroxycin may prove efficacious in terms of reducing clinical anxiety and alleviation of benzodiazepine withdrawal symptoms. Though, study results that have replicated this

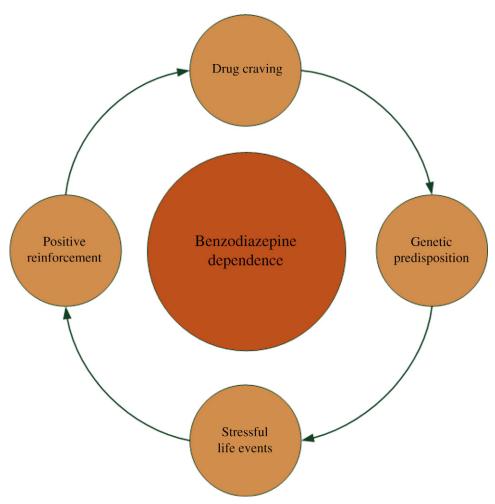


FIGURE 49.2 Cascade of the cortisol release from the adrenal gland. Although study results are not consistent, there is evidence that benzodiazepines decrease the transcription of corticotropin releasing factor and thereby decrease the activity of the HPA axis resulting in decreased release of cortisol from the adrenal glands.

finding are lacking. Tricyclic antidepressants may reduce withdrawal symptoms, most likely by their own sedative qualities, but a significant impact on relapse rate was not shown in clinical studies. Likewise, the anticonvulsant carbamazepine has been reported to alleviate the symptoms of benzodiazepine

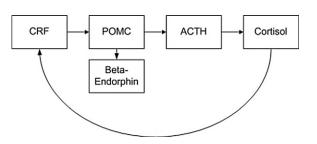


FIGURE 49.3 Psychological and neurobiological reasons contributing together to the development of benzodiazepine dependence.

withdrawal. Actual study reports show that the anxiolytic gabapentin is also effective in reducing the intensity of withdrawal and may reduce the relapse rates after successful benzodiazepine withdrawal. Below is an overview of substances that are known because to be effective in alleviation of benzodiazepine withdrawal symptoms.

- Tricyclic antidepressants intensity of withdrawal symptoms.
- Carbamazepine intensity of withdrawal symptoms, anticonvulsion. Some study reports point toward a decrease of relapse rates by carbamazepine therapy throughout and following benzodiazepine withdrawal.
- Gabapentin intensity of withdrawal symptoms and decrease of relapse.
- Hydroxycin intensity of withdrawal symptoms (contrary findings).

Substances That Are Currently Being Investigated

GABA_A Receptor

Recently developed substances, showing subunit selectivity at the GABAA receptor, were used in order to further investigate the coherences between GABAA subunit composition and related benzodiazepine effects: SL 65 14 98, for example, is a pyridole derivate that shows selectivity for non-α₁ containing GABA_A receptors and potentates GABA effects fully at GABA_A α₂ receptors and with lower efficacy at GABA_A α₃ receptors. At α_1 and α_5 receptors, SL 65 14 98 shows only partial agonism as determined by measuring the modulation of GABA-mediated CL-flux in vitro. Studies in nonhuman primates revealed that SL 65 14 98 could engender anxiolytic effects similar to diazepam, whereas muscle weakness, sedation, and ataxia, regularly seen during diazepam treatment, appeared only at doses that were much higher than those that evoked the anxiolytic effects. In drug discrimination tests, SL 65 14 98 motivated the primates as well as triazolam to work for an intravenous injection, an effect, which could be blocked by the α_1 subunit antagonist beta-carboline-3-carboxylate-t-butyl ester (beta-CCT), because of a connectivity between reinforcing effects of benzodiazepines and their bindings properties to the α_1 subunit of the GABA_A receptor.

Similar to SL 65 14 98, L-838,417 shows no affinity difference in binding to GABAA receptors containing $\alpha_{1,2,3,5}$ subunits. However, it shows only potentiation of GABAergic effects at GABAA receptors that contain the $\alpha_{2,3,5}$ subunit. At α_1 containing GABA_A receptors, it acts as an antagonist. Like SL 65 14 98, L-838,417 shows anxiolytic and anticonvulsant properties without motor impairments or sedative effects. In suppressive tasks like the Vogel conflict test, L-838,417 engendered anticonflict effects in mice without increasing unpunished drinking behavior in comparison to chlordiazepoxide or bretazanil. Moreover, SL 65 14 98 did not invoke tolerance to its anticonvulsant effects nor shows physical dependence after repeated administration. After intermittent treatment, even a tendency to increase of effects was observed, which was denoted by a lower minimal dose required (3 instead of 10 mg kg⁻¹ bodyweight) in order to gain anxiolytic effects in suppressive tasks. In mice treated with L-838,417, or as well with SL 65 14 98, the inverse benzodiazepine agonist FG 7142 did not provoke clonic seizures, whereas in the same study, mice that were treated with either triazolam, clonazepam, diazepam, or alprazolam - substances that exhibit unselective affinity to GABAA receptor subunits showed seizures regularly after a single dose of FG 7142. Altogether a higher rate of clonic seizures under sudden withdrawal, provoked by treatment with FG-7142,

was encountered in mice that had been treated with nonselective benzodiazepines, in which the possibility of seizures was descending gradually: triazolam = clonazepam = diazepam > alprazolam = midazolam = lorazepam.

Also, benzodiazepines that exhibit a subunit-specific affinity to the GABAA receptor like zolpidem - a substance which has a tenfold greater affinity to GABA_A receptors that contain an α_1 subunit – have been reported to show less tolerance and decreased sensitivity to seizures and likewise a reduced propensity to induce physical dependence in rodents, baboons, and humans. Likewise abecarnil, another GABA_A ligand, that binds with the highest affinity to the α_1 subunit and acts as a full agonist only at α_3 subunits, does not produce diazepam like tolerance and withdrawal symptoms. Although subunit selectivity is promising regarding the development of dependence, clinical evidence suggests that the non-benzodiazepine sedative hypnotics are associated with the risk of dependence, which is mostly explained by a dosage dependent loss of binding selectivity. Below is a list of substances with specificity for certain subunits of the GABAA – receptors that have been associated with decreased risk for dependence:

- SL 65 14 98
- L-838,417
- the non-benzodiazepines zaleplone, zolpidem, and abecarnil

Glutamatergic Neurotransmission

Preclinical study results indicate that modulation of glutamatergic neurotransmission that is typically increased during benzodiazepine withdrawal may as well reduce benzodiazepine withdrawal signs. The NMDA receptor antagonists MK-801, dizocilpine, and infenprodil were efficient in suppression of benzodiazepine withdrawal symptoms in animal models of diazepam dependence. Also, the AMPA-receptor antagonist GYKI 52466 reduced significantly diazepam withdrawal signs.

HPA

CRH1-receptor antagonists such as DMP-904 and R121919 showed efficiency in reducing anxiety and depression in preclinical studies. Therefore, CRH1 receptor antagonists may be as well useful in partly substituting the effects obtained by benzodiazepine therapy without any addictive potential (so far as known). Moreover, the CRH1-receptor antagonist R121919 was efficient in reducing benzodiazepine withdrawal symptoms in an animal model of benzodiazepine dependence. Therefore, CRH1 antagonists may be a valuable treatment option as well in respect of the effects currently obtained by benzodiazepines as in respect with the treatment of

benzodiazepine withdrawal, if further studies support the results obtained until now. Below is a list of substances that are currently investigated in order to treat benzodiazepine withdrawal symptoms:

- Modulation of glutamatergic neurotransmission: NMDA antagonists: MK-801, dizocilpine, infenprodil, AMPA-receptor antagonists: GYKI 52466
- Modulation of the HPA: CRH1-antagonists: DMP-904, R121919
- Gabapentin (promising results from clinical studies)

CONCLUSION

Benzodiazepine dependence is a prevalent chronically relapsing disorder. The gold standard of treatment of benzodiazepine dependence is a gradual dosage tapering that may be assisted by tricyclic antidepressants, carbamazepine, or gabapentin. Preclinical study results suggest that there may be further treatment options by modulation of the HPA or by development of substances showing specificity at the GABA_A receptor. Thus, further research is necessary in order to improve the treatment possibilities of benzodiazepine dependence.

List of Abbreviations

Cl chloride channel of the GABA_A receptor CRH corticotropin releasing hormone

GABA gamma-aminobutyric acid HPA hypothalamic pituitary axis

Glossary

Anxiolytic reducing anxiety.

Hypothalamic pituitary axis regulatory circle that regulates the release of the stress hormone cortisol from the adrenal gland.

Sedatives drugs having hypnotic (sleep-inducing), relaxing and anxiolytic properties.

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The Treatment of Depressed Alcoholics

Jack R. Cornelius*,\$

*Western Psychiatric Institute and Clinic, University of Pittsburgh Medical Center, Pittsburgh, PA, USA

\$Pittsburgh VA Healthcare System, Pittsburgh, PA, USA

Definition of Co-Occurring Major Depression and and Mood stabilizers) for Treating Co-Occurring 475 479 of Alcohol Dependence MDD/AD Epidemiology of Co-Occurring Major Depression Pharmacotherapy for Adolescents and Young Adults and Alcohol Dependence 476 with Co-Occurring MDD/AD 479 Onset and Course of Co-Occurring MDD/AD 476 Twelve-Step Programs and Psychosocial Therapies for Co-Occurring MDD/AD 479 477 Treatment Utilization of Co-Occurring MDD/AD Conclusions and Future Directions for Research Antidepressant Pharmacotherapy for Adults with involving Co-Occurring MDD/AD 480 Co-Occurring MDD/AD 477 **Acknowledgments** 481 Other Forms of Pharmacotherapy (Disulfiram, Conflicts of Interest 481 Lithium, Naltrexone, Acamprosate, Ondansetron,

DEFINITION OF CO-OCCURRING MAJOR DEPRESSION AND OF ALCOHOL DEPENDENCE

In this chapter, the term co-occurring major depression and alcohol dependence will be used to indicate the simultaneous presence of those two disorders, without necessarily implying any particular relationship between the two disorders. A discussion of the mechanisms underlying the associations between alcohol use disorders (AUDs) and depression is beyond the scope of this chapter. A discussion of other possible co-occurring conditions is also beyond the scope of this chapter, though patients with co-occurring major depression and alcohol dependence often demonstrate other substance use disorders and other psychiatric disorders as well.

The nosologic system that is currently used for diagnosis of psychiatric disorders is the *Diagnostic and Statistical Manual*, 4th Edition (DSM-IV) diagnostic system,

which was first published in 2000. A relatively minor revision of that diagnostic system was subsequently written, called the DSM-IV Text Revision, which focused on minor revisions of the DSM-IV text. According to the DSM-IV, there are two alcohol use disorders: alcohol alcohol dependence. In the diagnostic criteria for those two alcohol-related disorders are the same as those for other substance use disorders. AUDs are characterized by maladaptive patterns of alcohol consumption manifested by symptoms leading to clinically significant impairment or distress. The diagnosis of alcohol abuse focuses on alcohol-related negative consequences of alcohol use, while alcohol dependence focuses on a pathological pattern of compulsive alcohol seeking and use that indicates addiction. Alcohol abuse is manifested by the presence of one or more specific alcohol-related symptoms from a list of four symptoms occurring within 12-month period. Those four alcohol-related symptoms of alcohol abuse include (1) recurrent alcohol use resulting in a failure to fulfill major role obligations at work, school, or home; (2) recurrent alcohol use in situations in which it is physically hazardous (such as driving while intoxicated); (3) recurrent alcohol-related legal problems; and (4) continued alcohol use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of alcohol (such as arguments with spouse about consequences of intoxication). DSM-IV alcohol dependence is manifested by the presence of three or more specific symptoms from a list of seven alcohol-related symptoms occurring at any time in the same 12-month period. Those alcohol dependence criteria include the following: (1) tolerance for alcohol, as defined by a need for markedly increased amounts of alcohol to achieve intoxication or markedly diminished effect with continued use of alcohol; (2) alcohol withdrawal; (3) the substance (alcohol) is often taken in larger amounts or over a longer period of time that was intended; (4) a persistent desire or unsuccessful efforts to cut down or control alcohol use; (5) a great deal of time is spent in activities necessary to obtain alcohol; (6) important social, occupational, or recreational activities are given up or reduced because of alcohol use; (7) alcohol use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by alcohol. Substantial changes in the diagnostic criteria for AUDs and for other diagnoses are being considered for the upcoming DSM-V diagnostic system, which is currently scheduled to be published in 2013.

According to DSM-IV, major depressive disorder is a clinical disorder characterized by one or more major depressive episodes without a history of manic, mixed, or hypomanic episodes. The essential feature of a major depressive episode is a period of at least 2 weeks during which there is either depressed mood or the loss of interest or pleasure in nearly all activities. Criteria for the diagnosis of a major depressive episode include the presence of five or more depressive symptoms from a list of nine possible symptoms that are present during the same 2-week period. At least one of the symptoms must be either (1) depressed mood or (2) loss of interest or pleasure. The other criteria include the following: (3) weight loss; (4) insomnia or hypersomnia; (5) psychomotor agitation or retardation; (6) fatigue; (7) feelings of worthlessness or guilt; (8) decreased concentration; (9) recurrent thoughts of death. In addition, the presence of this disorder must represent a change from previous functioning, and must not include symptoms that are clearly due to a general medical condition. Other depressive disorders can also be present among persons with major depressive disorder, such as the chronic depressive disorder of dysthymia.

EPIDEMIOLOGY OF CO-OCCURRING MAJOR DEPRESSION AND ALCOHOL DEPENDENCE

Major depressive disorder (MDD) and alcohol dependence (AD) are among the most prevalent psychiatric disorders in the United States, and both are associated with substantial society and personal costs. MDD is the most prevalent mood disorder in the United States. Alcohol dependence is the most common (non-tobacco) substance use disorder, and alcohol is the most commonly used psychoactive (mind-altering) substance in the United States. Those disorders co-occur more commonly than would be expected by chance alone. The co-occurrence of alcohol dependence and major depressive disorder (AD/MDD) is particularly common in treatment settings. Acute increases in depressive symptoms among persons with co-occurring MDD/AD are primarily related to drinking larger quantities per drinking occasion, are less related to overall drinking volume and relatively unrelated to drinking frequency.

In 2001–03, AUDs afflicted 17.6 million adult Americans, according to the National Epidemiologic Survey on Alcohol and Related Conditions (NESARC) study, including about 8 million adult Americans with alcohol dependence. The NESARC study was the largest and most ambitious comorbidity study ever conducted. The NESARC study was conducted in 2001-03, addressing a representative US sample involving the unprecedented sample size of 43 093 respondents, using a diagnostic instrument based on the DSM-IV. The 12-month prevalence of alcohol abuse and dependence were 4.7 and 3.8% in the NESARC sample; the total lifetime prevalence of any AUD was 30.3%. Alcohol dependence was more prevalent among men, whites, Native Americans, younger and unmarried adults, and those with lower incomes. In an analysis by Hasin et al. (2005) involving persons in the NESARC study with MDD in the prior 12 months, 14% had an AUD, whereas, among those with lifetime MDD, 40% had an AUD. Conversely, data from the NESARC study demonstrated that the lifetime rate of alcohol dependence among those with MDD is 21%. Thus, the co-occurrence of major depression and alcohol dependence is very common in the United States.

ONSET AND COURSE OF CO-OCCURRING MDD/AD

Most AUDs have their onset between the ages of 15 and 30, according to the NESARC study. The mean age of onset is 22 years of age, and the highest rate for onset of abuse and dependence occurs at age 19, decreasing thereafter. Comorbidity is the rule rather

than the exception among young people, though it continues to be very common in later life as well. The risk factor profile for co-occurring disorders is different from those for "pure" disorders. For example, co-occurring disorders tend to be more prevalent among younger person, while alcohol dependence and major depression alone are not more prevalent among middle age or older adults. Also, reports suggest that co-occurring major depression is more prevalent among women with alcohol dependence than among men with alcohol dependence. In addition, reports suggest that depressed males tend to have a more severe clinical profile with respect to their alcoholism than do depressed alcoholic females. Thus, demographic factors such as age and gender appear to affect the clinical presentation of co-occurring alcohol dependence/major depression, which could conceivably mean that treatment outcomes could vary across those demographic characteristics.

The presence of alcohol dependence has an adverse effect on the course of co-occurring major depression, and vice versa. For example, current depression predicts poorer treatment response and higher rates of alcohol relapse. Conversely, remission in alcohol dependence increases the chances of remission in depression. In some setting, such as chemical dependency treatment facilities, mood symptoms often resolve soon after abstinence is achieved, while in other settings, such as dual diagnosis units of psychiatric hospitals, depressive symptoms often persist after any alcohol withdrawal symptoms have abated. The level of alcohol intake among persons with AUDs typically decreases as individuals enter middle age and later life. Chronic mild to moderate depression (dysthymia) is common among persons with co-occurring disorders. Data from the NESARC study demonstrate that there is a substantial level of natural recovery from alcohol dependence, though participation in alcohol treatment is associated with improved outcomes. However, since alcohol dependence and major depression are typically chronic disorders, short-term alterations of alcohol intake or depressive symptoms are of limited importance in predicting long-term outcome, and long-term studies of course and treatment outcome are of crucial importance. Unfortunately, long-term treatment outcome studies are rarely performed among those with co-occurring major depression and alcohol dependence.

TREATMENT UTILIZATION OF CO-OCCURRING MDD/AD

Most persons with comorbid MDD/AD or with alcohol dependence alone do not seek treatment. The prevalence of treatment seeking in the past year noted in the NESARC study was only 6% among those with

an AUD alone, though that percentage increased to 22% among those with a comorbid disorder. Some estimates suggest that only 4% of full-time college students with an AUD received any alcohol service in the past year, and only 2% reported a perceived need for alcohol treatment, despite the widespread prevalence of AUDs among college students. In the NESARC study population, only one-quarter of the persons with alcohol dependence ever received treatment. The majority of individuals with an AUD never receive formal alcohol treatment, nor do they participate in self-help groups. Among persons with alcohol dependence, the presence of depression is associated with higher levels of treatment participation. Many communities lack integrated treatment systems that could provide for comprehensive diagnosis and appropriate integrated treatment of both the depressive disorder and the alcoholism. Persons with co-occurring disorders are frequently under diagnosed and are often undertreated when they present for evaluation. Several studies have concluded that some physicians have negative attitudes toward persons with alcohol dependence, and vary widely in their willingness to treat that disorder. In recent years, increasing stringent service utilization review criteria have often been imposed on treatment providers by third-party payers for alcoholism and mental health treatment services. Those more stringent review criteria have limited the availability of services and shortened the period of time those services can be provided to persons with co-occurring disorders. The selective serotonin reuptake inhibitor (SSRI) antidepressants are the most commonly prescribed antidepressant medications for treating depressed alcoholics, probably more because of their superior tolerability and safety following overdose rather than because of any advantage in efficacy versus other antidepressant medications.

ANTIDEPRESSANT PHARMACOTHERAPY FOR ADULTS WITH CO-OCCURRING MDD/AD

For decades, few data were gathered regarding the effectiveness of various possible treatments for co-occurring conditions because persons with co-occurring conditions were systematically excluded from treatment trials. Most of the controlled clinical trials of various antidepressant medications and other medications for the treatment of co-occurring major depression/AUD have been conducted in the last two decades, funded mostly by the National Institute on Alcohol Abuse and Alcoholism (NIAAA). Co-occurring major depression in combination with alcohol dependence is the most studied form of comorbidity during that time period, presumably because those disorders are particularly

prevalent. In the past, many clinicians were reluctant to treat depression in a patient with active alcohol dependence until a sustained period of sobriety had been demonstrated. However, over the past few decades, the treatment of co-occurring disorders has undergone a broad shift in approach, from treating alcohol abuse before providing mental health care to providing simultaneous treatment for each disorder, regardless of the status of the comorbid disorder.

The most common paradigm employed in the pharmacotherapy trials to date is the examination of the efficacy of a single antidepressant medication to influence both the depressive symptom and the alcohol use of the treatment population. A meta-analysis was conducted involving the treatment of co-occurring depression and alcohol or other drug dependence, which was published by Nunes and Levin in 2004. That meta-analysis involved 14 placebo-controlled clinical trials, with a total of 848 patients. Those studies included five involving tricyclic antidepressants, seven with selective serotonin reuptake inhibitors, and two from other classes of antidepressant medications. Slightly over half (8) of those 14 studies were reported as demonstrating significant or treating significant antidepressant effects, while the other 6 studies demonstrated no significant effect for decreasing depressive symptoms. The outcome findings were generally similar across the different classes of antidepressant medications. The pooled effect size of antidepressant treatment outcome was modest (i.e. 0.38). The rates of depression response were 52% for those taking antidepressant medication and 38% among those taking placebo. Placebo response, defined as the percentage reduction in the Hamilton Depression rating scale in the placebo group, was a powerful predictor of antidepressant effect, explaining 71% of the variance. Thus, most of the decrease in depressive symptoms was not attributable to the antidepressant medication, but instead resulted from other factors such as therapy or spontaneous improvement. The pooled effect size for antidepressant medication for alcohol and other substance reduction was low (i.e. 0.25). Thus, antidepressant medications had a larger effect on depressive symptoms than on alcohol consumption. The level of improvement in drinking and other substance use was related to the level of improvement in depressive symptoms. In studies demonstrating a strong effect on depressive symptoms, a significant decrease in alcohol use was often observed, but in studies with a small medication effect on depressive symptoms, very little improvement in level of drinking was noted. That meta-analysis concluded that antidepressant medication was effective in treating depressive symptoms among patient with alcohol dependence, but found a more modest therapeutic effect of antidepressant medications for treating the pathological alcohol use of person with co-occurring disorders.

Another recent meta-analysis (Hesse, 2004) involving subjects with depression in combination with alcohol or other substance use disorders found that studies using cognitive-behavioral therapy (CBT) found no medication effect, whereas with no therapy intervention, medication was superior to placebo. That meta-analysis concluded that there is no evidence that antidepressant medication is more efficacious in reducing alcohol or drug use when used in combination with conjunctive psychosocial treat. The author of that paper further concluded that in the presence of an appropriate psychosocial intervention, medication may not be necessary for the majority of alcohol or other substance abusers with depressive disorders. Another meta-analysis (Johnson, 2008) concluded that SSRI medication may demonstrate efficacy only in certain subtypes of alcoholic.

Only one study to date (Cornelius et al., 1997) has evaluated the efficacy of an SSRI medication (or any other antidepressant medication) versus placebo among the most severely depressed subjects who commonly demonstrated suicidal ideations in addition to their other very prominent depressive and alcohol-related symptoms. That study recruited participants with cooccurring alcohol dependence and major depression from an inpatient dual diagnosis unit of a psychiatric hospital rather from a chemical dependency treatment facility or from an outpatient setting. The results of that study demonstrated superiority for the SSRI medication compared to placebo for treating both the depressive symptoms and the alcohol use of those persons.

To date, there is a limited experience with combinations of medications to treat major depression and alcohol dependence. Two placebo-controlled studies assessing naltrexone or disulfiram augmentation of sertraline concluded that the combination of medications was no more effective than the antidepressant medication alone for treating depressive symptoms or alcoholrelated symptoms. Two other open-label studies suggested efficacy in depressive symptoms and alcohol-related symptoms with the combination of medications, though the open-label design of those studies and the lack of placebo-controlled groups limit the interpretation of their findings. In the last year, study results from the University of Pennsylvania were published comparing the combination of an SSRI medication (sertraline) and naltrexone versus either drug alone or placebo. The results of that study demonstrated superiority for the combination of antidepressant medication and naltrexone for achieving abstinence from alcohol. The authors of that study concluded that persons with both disorders would benefit from combination treatment with

antidepressant medication and medication such as naltrexone for alcohol dependence. The results of that study have not yet been replicated nor refuted.

OTHER FORMS OF PHARMACOTHERAPY (DISULFIRAM, LITHIUM, NALTREXONE, ACAMPROSATE, ONDANSETRON, AND MOOD STABILIZERS) FOR TREATING CO-OCCURRING MDD/AD

Three medications have been approved by the Food and Drug Administration (FDA) for the treatment of alcohol dependence, including disulfiram, naltrexone, and acamprosate. Disulfiram (Antabuse) is an aversive agent that does not decrease craving for alcohol. Disulfiram has been used for decades to treat chronic alcohol dependence by producing an acute sensitivity to alcohol in which unpleasant effects occur when even a small amount of alcohol is consumed. Disulfiram is most effective when given to those who are highly compliant or who are receiving their medication under supervision. Trials involving lithium have not demonstrated superiority for that medication versus placebo for treating either the level of alcohol ingestion or the level of depressive symptoms of depressed alcoholics. In 1995, the US FDA approved the use of the medication naltrexone (ReVia) as an aid in preventing relapse among recovering alcoholics. At the time of its approval, naltrexone was the first medication approved by the FDA for alcoholism treatment in almost 50 years. However, naltrexone has a limited effect size, and it demonstrates significant side effects, so its level of use across the country has been relatively low. More recently, the medication acamprosate (Campral) has shown a small but statistically significant effect in European trials involving alcohol dependence, and it is relatively well tolerated. However, the results from the COMBINE Study, a large well-designed American Study, found no evidence of efficacy, which raises questions about its efficacy. Other newer medications have also shown promise for treatment of alcohol dependence, such as ondansetron and various mood stabililzers such as topiramate (which are often anticonvulsant medications), though those medications have not been fully tested, and have not received approval by the FDA for use in treating alcohol dependence. To date, adequately powered double-blind placebocontrolled trials of disulfiram, naltrexone, or acamprosate, ondansetron, or mood stabilizers have been conducted among persons with co-occurring major depressive disorder and alcohol dependence, so the effectiveness of those medications in that population remains unclear.

PHARMACOTHERAPY FOR ADOLESCENTS AND YOUNG ADULTS WITH CO-OCCURRING MDD/AD

Adolescent-onset depression is associated with a higher level of co-occurring disorders than adult-onset depression. Nonetheless, progress in adolescent and young adult psychopharmacological research of psychiatric disorders and of substance use disorders has suffered notable delay, especially compared with the achievements in middle-age adult psychopharmacology. Adolescents with comorbid disorders have unique treatment needs both because of their stage of development and because of their comorbid disorders. Because data about medication safety and efficacy in middle-age adults can rarely be extrapolated to adolescents and children, there is no substitute for psychopharmacological research in that young population of persons with AUDs. The few studies involving antidepressant medications or other medications among comorbid adolescent populations which have been conducted to date have generally shown at most limited efficacy for those medications for treating depressive symptoms and have shown no clear efficacy for treating alcohol dependence or other substance use disorders. Consequently, to date no medication has clearly demonstrated efficacy for treating youthful populations with co-occurring major depression and alcohol dependence. Therefore, most youth with those co-occurring disorders are currently treated with counseling rather than with medications.

TWELVE-STEP PROGRAMS AND PSYCHOSOCIAL THERAPIES FOR CO-OCCURRING MDD/AD

A variety of psychosocial therapies have demonstrated some level of efficacy for treatment of non-cooccurring and co-occurring alcohol dependence. For example, 12-step self-help programs such as Alcoholics Anonymous (AA) and related self-help groups are a very commonly used form of therapy. AA focuses on 12 consecutive activities, or steps, that persons with alcohol dependence should achieve during the recovery process, in an attempt to attain lasting sobriety. AA appears to result in positive outcomes for many of its members, though its efficacy has rarely been assessed in randomized clinical trials. The beneficial effects of AA may in part result from the development of coping skills and from the replacement of the participant's social network of drinking friends with a group of AA members who can provide support for maintaining abstinence from alcohol. Twelve-step treatment programs are often used in combination with other forms of treatment such as professional counseling or medication therapy. Few controlled studies to date have evaluated the effectiveness of AA or similar therapies among persons with alcohol dependence in combination with major depression or other psychiatric disorders, so the efficacy of AA among comorbid populations is unclear.

A variety of psychosocial therapies have been used in recent decades for treatment of alcohol dependence, such as CBT, motivational enhancement therapy, couples therapy, and a variety of brief interventions. To date, the largest study of psychosocial therapy for treatment of alcoholism was Project MATCH. Project MATCH was a large multisite clinical trial to assess whether persons with alcohol dependence could be matched to the most effective psychosocial treatment for their alcohol dependence, based on their clinical characteristics. That study focused on CBT, Motivational Enhancement Therapy, and Twelve-Step Facilitation. All three therapies appeared to demonstrate efficacy in that study, and produced similar outcomes. Essentially no consistent patient-treatment matches were found in that study (Cutler and Fishbain, 2005). The authors of that paper concluded that available data suggest that current psychosocial treatments for alcoholism are not particularly effective. Project MATCH did not evaluate whether co-occurring psychiatric disorders serve as a potential factor that might be used to more effectively match persons with alcohol dependence to optimal therapy. Thus, the optimal psychosocial therapy for cooccurring disorders remains unclear.

Recently, brief interventions have been designed for treatment of alcohol dependence and related disorders. Brief interventions have often focused on treatment of persons receiving counseling from primary care physicians. Brief interventions generally consist of information on negative consequences of alcohol consumption and advice on strategies to achieve moderation or abstinence. However, to date, no large-scale controlled studies have been conducted involving brief interventions for treatment of major depression and alcohol dependence. Therefore, it is unclear whether brief interventions are effective for treating that population.

CONCLUSIONS AND FUTURE DIRECTIONS FOR RESEARCH INVOLVING CO-OCCURRING MDD/AD

Co-occurring major depressive disorder in combination with alcohol dependence is a very prevalent condition. Despite the increased number of clinical trials among treatment populations with major depression and alcohol dependence in the last two decades, treatment needs for this population are still largely unmet, and the efficacy of currently available treatments for this population continue to be suboptimal. Various medications and therapies have demonstrated partial efficacy for treatment of comorbid disorders, though the magnitude and scope of that improvement is often limited. To date, no medication or therapy or any combination of treatments has been found to be consistently effective in the treatment of this co-occurring population. No controlled trials have been conducted for many of the potential treatment modalities among populations with co-occurring disorders. Therefore, controversy persists regarding how to best treat patients with co-occurring major depression in combination with alcohol dependence. The number of studies that have been conducted involving various forms of treatment for co-occurring disorders remains small, and only a few such studies are currently ongoing.

Future studies are warranted to evaluate the efficacy of the full range of medications and therapies for treatment of persons with major depression in combination with alcohol dependence. Future studies are warranted to develop new medications and therapies for treating this co-occurring condition. For example, studies are warranted to assess the utility of cannabinoid CB1 receptor antagonism, modulators of glutamate or GABA transmission, opioid antagonists, or stress-related neuropeptides as possible treatments of "pure" or co-occurring alcohol dependence (Heilig et al., 2006). Future studies are needed to assess the efficacy of newer antidepressants with new mechanisms of action such as mirtazapine for treating depressed alcoholics. Future studies are warranted to evaluate predictors of treatment response, and to assess the efficacy of various combinations of medications and other treatments. Studies are warranted to clarify the optimal dose, duration, and sequence of treatment. Studies are needed to clarify the optimal behavioral therapy platforms to utilize in conjunction with treatment medications when conducting pharmacotherapy studies, since such behavioral therapies can results in ceiling effects which reduce the likelihood of being able to demonstrate medication effects. Studies are needed to assess which behavioral therapy platforms are best for use in combination with the various pharmacotherapies in clinical practice. Future studies are warranted to assess the efficacy of various treatments in special populations such as in adolescents, geriatric patients, jails, psychiatric hospitals, and inpatient and outpatient substance treatment facilities. Future studies are warranted to clarify how treatment of either the alcoholism or the depressive disorder affects the outcome of the other disorder. Longterm studies are needed to determine whether treatments which demonstrate efficacy in acute phase trials continue to demonstrate efficacy over longer periods of time, since alcohol dependence and major depression are often chronic illnesses. Studies are warranted to clarify the barriers to the translation of research findings into clinical FURTHER READING 481

practice among persons with co-occurring disorders, and to clarify how to engage the practitioner community to incorporate medications and other therapies into the treatment process. Finally, treatment studies are warranted in conjunction with basic sciences studies to clarify the biological mechanisms underlying the co-occurrence of depressive disorders and AUDs, and to elucidate the pathways underlying their treatment response.

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CONFLICTS OF INTEREST

"The contents of this chapter do not represent the views of the Department of Veterans Affairs or the United States Government."

SEE ALSO

Treatment for Co-occurring Substance Abuse and Mental Health Disorders

List of Abbreviations

AA alcoholics anonymous
AD alcohol dependence
AUD alcohol use disorder

CBT cognitive-behavioral therapy

DSM-IV Diagnostic and Statistical Manual, 4th Edition

MDD major depressive disorder

NESARC National Epidemiologic Survey on Alcohol and Related

Conditions

SSRI selective serotonin reuptake inhibitor

Glossary

Alcohol abuse one of two DSM-IV alcohol use disorders, which involves meeting one of four criteria related to certain negative consequences of alcohol use (i.e. impairment in role functioning due to alcohol use, hazardous alcohol use, alcohol-related legal problems, alcohol-related interpersonal problems).

Alcohol dependence one of two DSM-IV alcohol use disorders, which requires that three or more of seven criteria (i.e. tolerance,

withdrawal, using more or longer than intended, strong desire or failed attempts to limit use, much time spent using, reduce activities in order to use, substance-related psychological or physical problems) co-occur within a 1-year period.

Diagnostic and Statistical Manual (DSM) of Mental Disorders the DSM is published by the American Psychiatric Association, and provides operational definitions for common mental disorders. DSM is currently in its fourth edition (DSM-IV; 2000); a fifth edition will be published in 2013. DSM-IV recognizes two alcohol use disorders: abuse and dependence.

Major depressive disorder a clinical disorder characterized by one or more major depressive episodes without a history of manic, mixed, or hypomanic episodes. The essential feature of a major depressive episode is a period of at least 2 weeks during which there is either depressed mood or the loss of interest or pleasure in nearly all activities. Criteria for the diagnosis of a major depressive episode include the presence of five or more depressive symptoms from a list of nine possible symptoms that are present during the same 2-week period.

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Medications for Comorbid Bipolar Disorder and Addiction

Edson Sherwood Brown

The University of Texas Southwestern Medical Center at Dallas, Dallas, TX, USA

OUTLINE

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PREVALENCE OF SUBSTANCE USE DISORDERS IN PEOPLE WITH BIPOLAR DISORDER

Bipolar disorder (BPD) is a severe and persistent psychiatric illness characterized by periods of depression and mania/hypomania, and/or mixed states. In the Epidemiologic Catchment Area (ECA) study (n = 20,291), the US lifetime prevalence of bipolar I and II disorders was 1.3%. In the National Comorbidity Survey (NCS), the lifetime prevalence of mania (consistent with bipolar I disorder) was 1.6%. The lifetime rates of bipolar spectrum disorder, using a broader definition of mood symptoms, are between 3 and 6.5%. Thus, BPDs are more common than other psychiatric disorders, such as schizophrenia, or other brain diseases, including seizures.

Abuse and dependence of alcohol and other substances are also common. Kraepelin recognized the frequent occurrence of alcoholism in manic-depression a century ago. The US lifetime prevalence of any substance use disorder (SUD) is between 9 and 27%. The prevalence rates of SUD in people with BPD are much higher than in the general population. In the United States, three large population-based studies have examined the prevalence rates of comorbid substance abuse and BPD. All three studies reported rates of SUD that were considerably higher in bipolar patients than in the general population. In the ECA study, 61% of patients with bipolar I disorder and 48% of patients with bipolar II disorder had lifetime substance abuse or dependence. The reported lifetime prevalence of any alcohol diagnosis in patients with a bipolar diagnosis (bipolar I and II) was 44%, and the lifetime prevalence of drug abuse and/or dependence was 34%. BPD had a higher lifetime prevalence of comorbid SUD than other psychiatric disorders, such as schizophrenia (47%), unipolar major depression (27%), and anxiety disorders (24%). In the NCS, the odds ratios in patients with a history of mania were 9.7 for alcohol dependence and 8.4 for drug dependence. The National Epidemiologic Survey on Alcohol and Related Conditions (NESARC) reported the 12-month prevalence of SUD was 27.9% in persons with a history of mania, and 26.6% in those with a history of hypomania. By comparison, the rate of SUD was 9.4% in persons without a mood disorder. Thus, SUDs are clearly much more common in persons with BPD than in the general population.

IMPACT OF SUD ON BPD TREATMENT AND OF BPD ON SUD TREATMENT

The negative impact of SUD on BPD has been reported in numerous studies. Treatment nonadherence in bipolar patients with comorbid SUD compared to bipolar patients without SUD is well documented. Aggression and violence appear to be significantly greater in BPD patients with an SUD. These behaviors can be associated with interaction with the legal system. McDermott and colleagues reported that female inmates with BPD had over 38 times the risk and male inmates five times the risk of an SUD than patients with BPD in community treatment. Patients with BPD and comorbid SUD have significantly increased rates of suicidal ideation, attempted suicides, and recurrent suicidal behavior.

Comorbid alcohol and drug use disorders negatively affect the course and treatment outcomes of BPD. Weiss and colleagues observed that recovery from BPD is less likely in patients with past or current comorbid SUD than in patients without SUD, and recovery is less likely in patients with current than with past SUD. Furthermore, patients with current or past SUD report lower quality of life than those with BPD and no SUD. Increased rates of hospitalization and lower rates of recovery during hospitalization are also reported in BPD with SUD. Salloum and colleagues reported that persons with bipolar disorder and concurrent alcohol use disorders present with more severe, and a higher number of mood-related and manic symptoms, including mood lability, impulsivity, and violent behavior. Female bipolar patients with alcohol abuse/dependence report more depressive symptoms as compared to either male bipolar alcoholics or both male and female nonalcoholic bipolar patients. Ostacher and colleagues noted that SUD is associated with greater risk of switching from a depressed phase to a manic, hypomanic, or mixed phase, but not longer time to recover from depression, while Gao and colleagues reported that a factor that may complicate recovery is less than optimal treatment adherence.

TREATMENT CONSIDERATIONS IN PERSONS WITH COMORBID BPD AND SUDs

Pharmacotherapy of Co-Occurring BPD and SUD

Despite the frequency of SUDs in people with BPD, relatively few clinical trials have been conducted in this population. One reason that few trials have been conducted in patients with BPD and SUD may be that many large clinical trials (e.g. registration trials by pharmaceutical companies) specifically exclude participants with current, active substance use. Thus, the vast majority of research is conducted in BPD patients who are not using drugs or alcohol.

The first two randomized, controlled trials in this population did not specifically target patients with BPD, although some were included. Brady and colleagues examined carbamazepine in cocaine-dependent persons with (n = 57) and without (n = 82) affective disorders (including major depressive disorder or BPD) who were randomly assigned to 12 weeks of treatment. In patients with affective disorders, a trend was observed toward fewer cocaine-positive urine drug screens (p = 0.08) and a reduction in depressive symptom severity with carbamazepine as compared to placebo. In those without affective disorders, carbamazepine treatment did not have a greater impact on cocaine use than placebo. These results suggest that some medications may be relatively ineffective in "pure" cocaine-dependent populations, but potentially more effective in dual-diagnosis patients. Geller and colleagues gave 6-week, randomized, double-blind, parallel-group, placebo-controlled treatment with lithium into adolescents with bipolar I or II disorder, or recurrent major depressive disorder with predictors of future bipolar diagnosis (e.g. delusions, switching during antidepressant treatment, psychomotor retardation, and family history of BPD) and comorbid substance abuse (primarily alcohol or cannabis). The mean age of onset of BPD in the study was 9.4 years for bipolar I, 11.1 years for bipolar II, and 15.3 years for substance use. Those taking lithium had significantly fewer positive urine drug screens and greater improvement on a global measure than those receiving placebo.

The first randomized, placebo-controlled trial specifically targeting BPD and SUD evaluated the efficacy of valproate in 59 alcohol-dependent bipolar I patients in a 24-week, double-blind, placebo-controlled study by Salloum and colleagues. Participants were randomized to receive either valproate or placebo added to lithium and psychosocial treatment. Those assigned to valproate had significantly fewer heavy drinking days and a trend of fewer drinks per drinking day than those assigned to

placebo. Perhaps due to the add-on design, valproate was not associated with improvement in mood symptoms. However, changes in manic and depressive symptoms correlated with alcohol use outcomes. These findings suggest that valproate may have a positive effect on alcohol consumption in bipolar patients independent of improvements in mood.

Few controlled clinical trials have investigated the efficacy of atypical antipsychotics in dual-diagnosis patients. A randomized but open-label study evaluated discontinuing typical antipsychotics (neuroleptics) and, if needed, using the atypical antipsychotic quetiapine as a rescue medication, or continuing on the typical antipsychotics for 12 weeks in patients with cocaine or amphetamine abuse or dependence, and neuroleptic use was conducted by Brown and colleagues. Twentynine patients, 13 of whom were bipolar, were enrolled. The group discontinued from the neuroleptics had a significant reduction in drug craving as compared to those continuing the neuroleptics. The overall improvement in this group was largely due to a subgroup that was switched to quetiapine, in which significant improvement in craving as well as psychiatric symptoms was observed. Quetiapine was well tolerated, and patients randomized to quetiapine stayed in the study longer than the treatment-as-usual group. In a small pilot study, Brown and colleagues randomized 12 outpatients with BPD and cocaine dependence to 12 weeks of quetiapine or placebo as add-on therapy. Significant between-group differences were observed on measures of cocaine use or craving. However, the quetiapine group had significantly fewer heavy drinking days than the placebo group and showed a trend toward longer treatment retention. Differences in depression scores also favored quetiapine with a large effect size. Nejtek and colleagues randomized 124 patients with BPD and cocaine or amphetamine dependence to 20 weeks of quetiapine or risperidone. Improvement in mood and reduction in drug craving was observed in both groups but no between-group differences were found. Two studies have investigated quetiapine for alcohol dependence and BPD. In a single site study, a total of 115 patients with BPD and alcohol dependence were randomized to quetiapine or placebo for 12 weeks by Brown and colleagues. In the sample as a whole no significant differences in alcohol-related outcomes were observed. However, those with heavier baseline alcohol use showed larger effect sizes on some measures. The group receiving quetiapine had a greater reduction in depressive symptom severity during the trial. This finding suggests that quetiapine may be effective for bipolar depression even in persons with active alcohol use. In a multisite study by Stedman and colleagues, 362 outpatients with bipolar I disorder and taking lithium or divalproex were randomized to quetiapine (up to 800 mg day⁻¹) for 12 weeks. A trend toward greater improvement on the Clinical Global Impression with quetiapine versus placebo was observed. However, mood and alcohol-related outcomes did not differ significantly between groups.

Two trials of nutritional supplements have been reported. Citicoline is a naturally occurring medication sold as an over-the-counter nutritional supplement in the United States and a prescription drug in much of the rest of the world. It is involved in phospholipid metabolism and alters neurotransmitter (e.g. dopamine, serotonin, acetyl choline) levels in the brain. Citicoline is neuroprotective in animal models of hypoxia and large, controlled trials suggest that it improves cognition in patients with vascular dementia. A 12-week, randomized, placebo-controlled trial of citicoline in 44 patients with BPD or schizoaffective disorder and cocaine dependence by Brown and colleagues reported improvement in certain aspects of declarative memory, fewer cocaine-positive urines, and with no reported differences in mood with citicoline versus placebo. In this trial, citicoline was well tolerated with significantly fewer side effects than placebo. Pregnenolone is another naturally occurring nutritional supplement. It is a precursor to cortisol and gonadal steroids, and may decrease negative symptoms of schizophrenia. Pregnenolone was examined in a randomized, double-blind, placebo-controlled trial in 70 outpatients with major depressive disorder or bipolar depression and a history of substance use by Osuji and colleagues. No differences in substance use, craving, or cognition were observed. However, a significant reduction in manic and depressive symptoms was observed with pregnenolone as compared to placebo. Pregnenolone was well tolerated in this population.

The best-studied medication for alcohol dependence may be naltrexone, an antagonist at opiate receptors. Clinical trials support the efficacy of naltrexone in decreasing alcohol use and craving. Two controlled trials have examined naltrexone in patients with BPD. A reduction in alcohol consumption was reported by Petrakis and colleagues in a group of 254 dual-diagnosis patients with a variety of psychiatric disorders, including 49 with BPD, treated with naltrexone, disulfaram, or the combination. Recently, Brown and colleagues conducted a randomized, placebo-controlled trial of naltrexone in 50 outpatients with BPD. A reduction was reported in some alcohol use measures, alcohol craving, depressive symptoms, as well as some liver enzymes with naltrexone as compared to placebo. To date, no randomized clinical trials have been reported on the use of acamprosate, disulfiram, or topiramate in patients with BPD and alcohol dependence.

Psychotherapy can be used as monotherapy for substance use and depression and potentially

adjunctively with pharmacotherapy for BPD. Cognitivebehavioral therapy (CBT) approaches have been examined in controlled trials for BPD and SUDs by both Schmitz and colleagues and Weiss and colleagues. Integrated group therapy (IGT) is a treatment paradigm consisting of 20 weekly group sessions specifically developed for patients with BPD and SUDs. In a 6-month pilot study, patients receiving IGT remained abstinent longer than patients not receiving the treatment and were more likely to stay abstinent during the observation period. Individual CBT was examined in a 12-week randomized trial compared to medication monitoring in patients with BPD and an SUD. While patients receiving CBT during their medication treatment did not improve significantly more than those receiving medication monitoring on substance use measures, there were significant improvements in medication compliance and depressive symptoms in the CBT group. Thus, this intervention could be a useful adjunct to other treatments.

CONCLUSIONS

The treatment of patients with BPD and SUD has been the topic of relatively little investigation. This paucity of data has clinical implications because SUDs are more common in patients with BPD than any other Axis I illness, and are associated with greater rates of hospitalization, violence toward self and others, and treatment nonadherence. Based on the controlled studies that included at least some patients with BPD, the data suggest that lithium, valproate, citicoline, naltrexone, and possibly quetiapine and carbamazepine may be associated with a reduction in substance use. Carbamazepine, pregnenolone, and quetiapine may be associated with improvement in mood, and citicoline with improvement in memory, in this population. More research is needed in dual-diagnosis samples on both standard treatments for BPD and standard treatments for SUDs and combinations of these medications. An additional area in need of research is the combination of pharmacotherapy with psychotherapy. Given the limited available data, it is not possible to make specific treatment recommendations for the treatment of patients with BPD and SUD at this time. A general recommendation, not yet confirmed by controlled data, would be to effectively treat mood symptoms with medications for BPD and consider pharmacotherapy or psychotherapy targeting the substance of abuse.

SEE ALSO

Screening and Assessment of Comorbidity, Diagnostic Dilemmas in Comorbidity, Treatment for

Co-occurring Substance Abuse and Mental Health Disorders, The Treatment of Depressed Alcoholics, Medication for Cravings in Substance Use Disorders, Improving Medication Use in Addictions Treatment

List of Abbreviations

BPD bipolar disorder

CBT cognitive-behavioral therapy

ECA Epidemiologic Catchment Area

IGT integrated group therapy

NCS National Comorbidity SurveySUD substance use disorder

Glossary

Atypical antipsychotics an imprecise term generally describing newer antipsychotics, which may be approved for both schizophrenia and mood disorder, and that frequently have fewer extrapyramidal side effects than older antipsychotics.

Dual-diagnosis the presence of a severe psychiatric illness, such as bipolar disorder or schizophrenia, along with a drug or alcohol use disorder.

Epidemiology a branch of medicine that studies diseases in populations.

Mood lability a state characterized by frequent or abrupt changes in mood.

Receptor antagonist a substance that prevents, rather than facilitates biological responses when binding to a receptor.

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52

Treatment of Anxiety in Substance-Using Patients

Michael Soyka*,\$

*Ludwig Maximilian University Munich, Munich, Germany \$Private Hospital Meiringen, Meiringen, Switzerland

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DEFINITION OF ANXIETY DISORDERS

A number of different anxiety disorders are known and defined, such as generalized anxiety disorder, panic disorder with and without agoraphobia, social phobia, and specific phobias. Obsessive-compulsive disorder and posttraumatic stress disorder will not be addressed in this chapter. According to DSM-IV, generalized anxiety disorder (GAD) is characterized by an array of mental and somatic symptoms, including excessive worry – persisting for 6 months or longer – combined with autonomic, musculoskeletal, gastrointestinal, and respiratory symptoms. Current diagnostic criteria require prolonged feelings of anxiety and worry accompanied by at least three of the following six key symptoms: restlessness, fatigue, impaired concentration, irritability, muscle tension, and disruptions in patterns of sleep. Panic disorder (PD) is characterized by recurrent panic attacks with intense fear or discomfort, accompanied by at least 4 of 13 somatic and mental symptoms (14 in ICD-10). A panic attack usually reaches a peak within 10 min and lasts 30-45 min on average. Typically, the patient is afraid of suffering from a serious medical condition such as myocardial infarction. About two-thirds of patients with PD also suffer from agoraphobia, which is characterized by fear of places or situations from which escape might be difficult or in which help may not be available in the event of having an unexpected panic attack. Typical risk situations include standing in a crowd or in line, being outside the home alone, or traveling in a bus, aircraft, train, or car. These situations are avoided or endured with marked distress.

Specific phobias are characterized by excessive or unreasonable fear of single objects or situations (e.g. heights, animals, flying, seeing blood, etc.). Social phobia (or social anxiety disorder, SAD) is characterized by marked, persistent, unreasonable fear of being observed or evaluated negatively by others in social performance or interaction situations and is associated with somatic and cognitive symptoms. The feared situations are avoided or endured with anxiety or distress. These situations include fear of speaking in public or to unfamiliar people or being exposed to possible scrutiny by others. Affected individuals may blush or show more severe symptoms.

The pathophysiology of GAD and other anxiety disorders is somewhat unclear. There is some evidence

for a modest genetic risk. Impaired serotonergic and GABAergic neurotransmission have been discussed as key factors in GAD; both neurotransmitters are also strongly modified by alcohol intake. Other relevant neurotransmitters involved are norepinephrine, cholecystokinin, and corticotrophin-releasing factors; impairments of the benzodiazepine receptor are also probably involved.

EPIDEMIOLOGY

Anxiety disorders are very frequent. In the US National Comorbidity Survey, the lifetime prevalence for any anxiety disorder was 28.8%, and for the 12-month prevalence 18.1%. GAD has a 12-month prevalence of 3.1% in the United States and a lifetime prevalence of 5.7–6.4% in the United States and Europe. Women have a two- to threefold increased risk for GAD. Lifetime and 12-month prevalence rates for agoraphobia without panic are 1.4 and 0.8%, respectively; for panic disorder, 4.7% and 2.7%; for specific phobia, 12% and 6.8%; and for the somewhat controversial diagnosis of SAD, 12.1% and 6.8%.

Table 52.1 gives an overview of the prevalence of dual diagnoses of various psychiatric disorders and substance use disorders (SUDs). Generally, epidemiologic studies indicate a two- to threefold increased risk for alcohol use disorders in patients with anxiety disorders. Grant et al. (2005) reported data on GAD from the National Epidemiologic Survey on Alcohol and Related Conditions, which studied a large (N = 43~093) representative sample of the adult US population; prevalence rates for 12-month and lifetime GAD were 2.1 and 4.1%, respectively. Higher rates were found for males. GAD was highly comorbid with substance use in general and other anxiety, mood, and personality disorders. Specifically, the odds ratios for any alcohol use disorder were 2.0 for 12-month prevalence and 2.2 for lifetime prevalence. While the comorbidity with alcohol abuse was not increased (respective odds ratios 1.0 and 1.1), the odds ratios for alcohol dependence were significant (3.1 and 2.8). Similar results – i.e. an association with dependence but not abuse – were found for nicotine and drug dependence, which had the strongest relationship (odds ratios 9.9 and 5.2, respectively) In addition, as shown in previous studies, there was also a strong association of GAD with other mood and anxiety disorders. Further analysis of this database showed that men with GAD

TABLE 52.1 Frequency of Dual Diagnoses (Moggi and Donati, 2004)

Substance use disorder A		ol abuse	Alcohol	dependence	Drug	abuse	Drug dependence		Any substance use disor	
Psychiatric disorder	%	OR	%	OR	%	OR	%	OR	%	OR
Schizophrenia										
ECA	9.7	1.9	24.0	3.8*	14.6	6.9*	12.9	4.2*	47.0	4.6*
Affective disorder										
Major Depression										
ECA	5.0	0.9	11.6	1.6	7.3	3.3*	10.7	3.7*	27.2	1.9*
NCS	9.1	1.0	26.4	2.7*	6.6	1.7*	15.4	2.8*	41.4	2.3*
Dysthymia										
ECA	4.8	0.8	18.9	3.9*	8.1	3.6	10.8	3.6*	31.4	2.4*
NCS	8.6	0.9	28.7	1.0	5.8	1.3	16.7	2.5	40.0	1.9
Anxiety disorders										
ECA	5.8	1.0	12.2	1.8*	5.0	2.3*	6.9	2.4*	23.7	1.7*
NCS	40.9	2.1*	44.9	2.2*	47.6	2.5*	55.4	3.3*	_	_
Antisocial personality disorder										
ECA	22.1	5.4*	51.5	14.7*	11.2	5.2*	30.8	15.6*	83.6	29.6*
NCS	25.7	8.8*	37.1	9.9*	33.8	8.3*	43.9	9.8*	_	_

^{*}p < .05

ECA: Epidemiologic Catchment Area Study

NCS: National Comorbidity Study

Note: These estimates are based on the results from Moggi F, Dual diagnosis. Comorbidity of psychiatric disorders and addiction (in German). Bern: Huber publishers, 2nd edition 2007.

had significantly higher rates of comorbid alcohol and drug use disorders and reported greater use of alcohol and drugs to help relieve GAD symptoms.

An association of alcohol dependence, but not abuse, with anxiety disorders (and depression) was also shown in a recent Dutch Study. This study included 2329 people with lifetime DSM-IV anxiety disorders or depressive disorders or both and 652 controls. Prevalence rates for alcohol dependence in persons with combined anxiety/depression were 20.3% and in controls, 5.5%. Prevalence of alcohol abuse was similar in all groups (about 12%). Independent risk factors for alcohol dependence included male gender, vulnerability factors such as a family history of alcohol dependence or anxiety/depression, childhood trauma, smoking, drug dependence, and early onset of anxiety/depression.

More recent data come from a cross-sectional population-based study conducted in 2004–2005 in a nationally representative sample of 34 653 US adults. Mood, anxiety, and SUDs were addressed using the Alcohol Use Disorder and Associated Disabilities Interview Schedule-DSM-IV version. The authors defined five cluster alcoholic subtypes, some with heightened risk for GAD or social phobia, among numerous other factors (Clusters 3, 4, and especially 5). Follow-up data suggest that these empirical typologies predict differential clinical outcomes 3 years later.

For drug abuse, a large national epidemiologic survey in the United States indicated a 12-month and lifetime prevalence of 1.4 and 7.7%, respectively, which clearly exceeds the rates of drug dependence (0.6 and 2.6%, respectively). Drug use and dependence were associated with male sex, low socioeconomic status and other social variables, other SUDs, and antisocial personality. Drug dependence was associated with mood disorders and GAD. Twelve-month prevalence for drug use disorders was associated with any anxiety disorder with an odds ratio of 2.7. Among those, any panic disorder was associated with an odds ratio of 3.9 (with agoraphobia: 5.6, without: 3.1); social phobia, 2.6; specific phobia, 2.3; and GAD, 4.5. When adjusted for demographic characteristics and other psychiatric disorders, any anxiety disorder was associated with drug use disorders with an odds ratio of 2.1; drug abuse, 1.5; and drug dependence, 2.8. For drug dependence, GAD had an odds ratio of 2.5. In conclusion, these data correspond in part to studies in alcohol use disorders showing that drug dependence rather than abuse is associated with anxiety disorders, specifically GAD.

Comorbid mental and SUDs may occur concurrently and successively. The chronological relationship between the onset of the two disorders does not necessarily reflect the etiology or cause of the comorbidity. There are far fewer longitudinal studies on this issue. The temporal interrelationship between the onset of anxiety disorders and alcohol use disorders is complex. Long-term longitudinal

studies in studies of patients with anxiety disorders did not indicate an association of phobias with the onset of alcohol use disorders but rather a modest association between adult subclinical specific phobias and later-onset alcohol use disorders (odds ratio 3.2), which was stronger in women than men. Other studies also suggest that specific phobias occur prior to alcohol use disorders.

Flensborg-Madsen et al. (2010) studied the potential effects of alcohol intake (not alcohol use disorders) upon the risk of psychiatric disorders. This prospective cohort study included participants of the Copenhagen City Heart Study (N = 18 146), who were followed up for up to 26 years. Alcohol intake was measured by self-report, while psychiatric diagnoses were measured through registers. For women, drinking above sensible limits increased the risk for psychiatric disorders in general and especially for anxiety disorders (risk: 2.00). For men, a weekly low to moderate alcohol intake seemed to have a protective effect against developing a psychiatric disorder. Risk for anxiety disorders was lower in men drinking more than 14 drinks per week (0.79). The authors discussed the "apparent protective effect" of alcohol among men as a sign of mental and social well-being and normal functioning.

The database for drug use is more limited. Liang et al. (2011) performed a retrospective cohort study using data from the 2007 National Survey of Mental Health and Well-being (MHW) in 8841 adult Australians. Previously, Teeson et al. (2009) had reported data from this study indicating that 19% of males and 8% of females with an anxiety disorder had a co-existing SUD and 26% of males and 11% of females with an affective disorder had a coexisting SUD. Overall prevalence for drug dependence was 2.56%. Individuals with an affective disorder or anxiety disorder were at higher risk of harmful use and drug dependence (males: 9.3%; females: 3.9%). Again, the self-medication theory or common genetic factors were discussed to explain these findings.

REASONS FOR COMORBIDITY OF ANXIETY DISORDERS AND SUBSTANCE USE

Self-Medication Theory

Community-based epidemiologic studies show a 2.2-fold increased risk for anxiety disorders among individuals with alcohol dependence compared to the general population. There is a lifetime prevalence of 6–20% for anxiety disorders among alcoholics. Social and specific phobias have the highest risk. Differential diagnosis can be difficult because of overlapping symptoms.

As is the case in other psychiatric disorders comorbid with SUDs, some form of self-medication has been

discussed as a possible explanation. The relaxing, tension- and stress-reducing and sedating effects of alcohol in particular are well established and clear. Short-term consumption of alcohol or benzodiazepines diminishes anxiety in patients with panic disorder. This has been explained by means of cognitive processes and the expectancy of the drug's effect. In contrast, long-term use of alcohol and possibly other drugs may induce anxiety disorders. Anxiety is a frequent symptom in alcohol and drug withdrawal, but there is no clear experimental evidence for the induction of anxiety disorders by alcoholism. In SAD, clinical findings on the interrelationship with alcohol use are inconsistent.

Anxious patients may start to use alcohol or drugs to reduce anxiety and medicate their distress. Anxiety disorders frequently precede the onset of alcohol use disorders. Among individuals drawn from a nationally representative survey of US citizens ($N=25\,342$), only 20% of anxious patients endorsed drinking to control anxiety symptoms. This small group of patients drank more alcohol, had a higher cross-sectional rate of alcohol dependence, and were at a higher risk for developing new alcohol dependence over 4 years compared to anxious non-self-medicators. It is not fully understood why some individuals with anxiety disorder use alcohol to relieve symptoms, while apparently many others do not. Cognitive factors such as the expected effect of alcohol may be relevant.

Another explanation is that alcohol or drug use disorders may cause anxiety. Anxiety and inner restlessness are frequent symptoms in alcohol or drug withdrawal and repeated withdrawals may trigger or kindle anxiety Disorder A → Disorder B
Unidirectional direct causal relationship

Disorder A ← Disorder B
Bidirectional direct causal relationship

Disorder A → Disorder C → Disorder B
Unidirectional indirect causal relationship

Common factors Disorder B
Common factors - model

FIGURE 52.1 Model of the etiology of comorbidity of psychiatric disorders and substance use disorders. (from Moggi, 2007, with permission)

disorders. This theory has not been studied in great detail.

Finally, there may be common causes for anxiety and SUDs.

Animal studies indicate a genetic linkage between anxiety disorders and alcohol use disorders. A family history of alcoholism seems to be associated with alcohol and anxiety disorders in offspring. In addition, research in humans has tried to identify specific genes that are associated with both disorders. An integrated model to understand the relationship between SUDs and anxiety disorders has been proposed (see Figs. 52.1 and 52.2).

Sexual abuse and childhood trauma can also influence the risk of anxiety disorders and substance use. There is a plethora of studies on the association between sexual abuse and the risk for SUDs. A very recent study further evaluated the interrelationship by studying

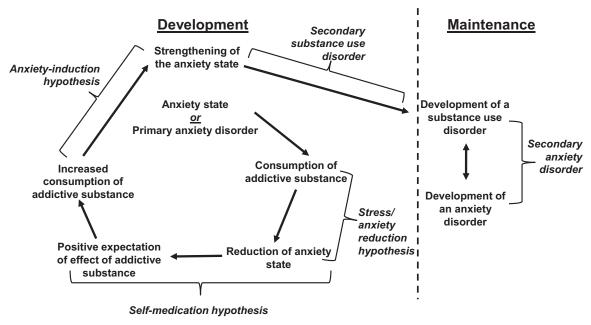


FIGURE 52.2 Vicious circle model of the comorbidity of anxiety and substance use disorders. Adapted from Moggi f Dual diagnosis. Comorbidity of psychiatric disorders and addiction (in German). Bern: Huber publishers, 2. edition 2007.

psychiatric mediators in 192 alcohol-dependent, treatment-seeking women and healthy controls. The association of sexual abuse with alcohol dependence was limited to the most severe category of sexual abuse (vaginal or anal penetration). Of the five psychiatric disorders tested, anxiety, anorexia nervosa, and bulimia (but not posttraumatic stress disorder) were identified as potential mediators of the abuse-alcohol dependence association. In fact, the statistical association was strongest for anxiety disorders.

PREVENTION AND THERAPY

Anxiety and SUDs usually start in adolescence or early adulthood, although onset is not restricted to this age. Prevention strategies that include early diagnosis and intervention should be aimed at younger individuals. Although successful interventions for anxiety or SUDs are available, none has been studied in comorbid disorders. From a prevention point of view, identifying individuals at risk for later substance use is a key goal because it offers opportunities for early intervention.

Treatment seeking in dual-diagnosis patients is rather low, increases with the severity of personal problems related to substance use, and is highest in those with anxiety and depression. Individuals with a coexisting psychiatric disorder such as anxiety and SUDs usually have a poorer treatment response and outcome and more personal and social problems, suffer from more impairment, and generate larger costs. Anxiety disorders were found to predict negative outcome in some alcohol treatment studies but not in others. Only a few well-designed clinical studies exist for comorbid anxiety or depression and SUDs.

A number of pharmacologic agents are available for treatment of anxiety disorders without comorbid SUDs. Available compounds include selective serotonin inhibitors (SSRIs), selective serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), calcium channel modulator pregabalin, reversible inhibitor of monoamine oxidase A moclobemide, irreversible monoamine oxidase inhibitors, benzodiazepine, the 5-HT_{1A}-agnoist buspirone, antihistamines, atypical antipsychotics, anticonvulsants, beta-adrenergic blockers, and other homeopathic and herbal preparations.

In general, in the treatment of comorbid patients the same guidelines must be considered for treatment of nonsubstance-using patients. Pharmacologic interactions with alcohol or other drugs of abuse must be taken into account. All named drugs apart from benzodiazepines have no abuse potential. Benzodiazepines have a more rapid onset of action than other drugs.

Multiple studies have been performed on the pharmacologic treatment of anxiety disorders. In panic

disorder and agoraphobia, the clearest evidence is available for various SSRIs, the SNRI venlafaxin, the TCAs clomipramine and imipramine, and some benzodiazepines. For GAD, the most evidence has been obtained again for SSRIs, for the SNRIs venlafaxine and duloxetine, the TCA imipramine, pregabalin, the atypical antipsychotic quetiapine, and benzodiazepines. For SAD, several SSRIs are recommended, as well as venlafaxine and the MAOI phenelzine.

These recommendations deserve some clinical comments from the substance use perspective. The risk of interactions of TCAs with alcohol is significant (e.g. blackouts or cardiac dysfunction), therefore these drugs are not first choice, at least in nonabstinent patients.

For short-term use, treatment with benzodiazepines has been established, although these substances hold the risk for abuse and dependence, especially in patients with SUDs. However, longer treatment of up to 12 months is generally recommended. The TCA imipramine, buspirone, SSRIs, and SNRIs are established medications for longer use. Other antidepressants such as venlafaxine or more recently pregabalin have also been studied, with promising results.

Only a few pharmacotherapeutic trials have been conducted in patients with alcohol dependence and anxiety disorder. One study found that paroxetine reduces anxiety symptoms in patients with comorbidity, and another found that it reduces social anxiety in patients with alcohol use disorders. A meta-analysis of five published studies showed a positive effect of buspirone on treatment retention and anxiety, but the effect on alcohol consumption was less clear. Buspirone is no longer available in many markets.

Acamprosate is an anti-craving drug with proven efficacy in reducing relapse rates in alcohol-dependent patients. Some open-label studies suggest that the drug is effective as an augmentation for anxiety disorders, but no studies are available in comorbid patients.

Usually, both pharmacologic and psychotherapeutic approaches are combined for the treatment of anxiety disorders. A number of psychological interventions have been studied and have shown efficacy in anxiety disorders. The first step is usually some form of psychoeducation and information about the diagnosis, etiology, and treatment options.

Substance-induced anxiety symptoms frequently occur during detoxification from alcohol, benzodiazepines, or intoxication with cannabis or psychostimulants (cocaine, amphetamine) but usually improve or vanish within a few weeks. Anxiety disorders independent from substance use should be addressed in psychotherapy. Exposure therapy (usually in the form of gradual exposure in vivo, but also performed as "flooding") and response prevention are very effective in specific phobia, SAD, and agoraphobia. In this treatment

setting, patients are usually confronted with a feared situation, for example using an underground train in agoraphobia or imagining and nearing a feared animal. Various cognitive strategies have been proposed for panic attacks and other symptoms that cannot be treated with exposure. The efficacy of cognitive-behavior therapy (CBT) was shown in a meta-analysis of 108 studies. CBT is based on cognitive models emphasizing the role of worrying, metacognitions, and avoidance behavior. A more recent review of meta-analytic findings also confirmed the efficacy of CBT in anxiety disorders, although few of these studies included a placebo condition. For anxiety disorders, studies comparing CBT with a wait-list control group found significantly larger effect sizes than those comparing CBT with an attention placebo. The evidence for psychodynamic therapies in anxiety disorders, although frequently used, is very limited. Treatment strategies are adapted to be used in different settings, ranging from one brief session to longer intervention over weeks and months. Both individual and group therapies are used in anxiety disorders.

Psychological interventions in comorbid anxiety and SUDs have not been studied in great detail. The fundamental question is whether it is best to address one disorder or the other or offer integrated treatment. Schade et al. (2005) reported results of a randomized controlled trial, 96 abstinent alcohol-dependent patients with comorbid social phobia or agoraphobia who were treated with an intensive 32-week psychosocial relapse-prevention program alone or in combination with CBT for anxiety and an optional SSRI. Additional anxiety therapy improved anxiety symptoms but not alcohol relapse rates. Avants et al. (1998) studied patients in an outpatient methadone program who were receiving either case management plus CBT (MA–) or case management plus an intensive manualized program (MAplus) and subdivided patients into social severe anxious (SAplus) and light anxious (SA-). SAplus patients were more abstinent from heroin, showed a stronger decrease in anxiety symptoms, and had less risk behavior when participating in the MA-group while there were no differences between MA-patients. The authors concluded that social anxiety patients in a methadone program may benefit more from less intensive programs.

Baillie et al. (2007) reviewed six randomized controlled trials of treatment for comorbid anxiety and SUD and concluded that for patients with more than moderate substance dependence there is clear and consistent evidence that standard treatment for SUDs leads to the best outcomes. The view is shared by other reviews. Treating anxiety first and "removing self-medication rationalizations" for drinking may be a rational approach in many dual-diagnosis patients

and may lead to a greater treatment compliance when focusing on alcohol. Special CBT approaches to reduce the expectancies for tension reduction from alcohol may help to reduce anxiety symptoms. Interpersonal group psychotherapy has not been studied in great detail in patients with comorbid psychiatric disorders and anxiety.

FUTURE PROSPECTS

While the epidemiologic evidence for a significant comorbidity between SUDs and anxiety disorders is robust, more longitudinal studies are necessary to fully understand the relationship. Only a few therapeutic and intervention studies have been published to date. For psychotherapy, more integrated treatment approaches should be developed and studied.

SEE ALSO

Screening and Assessment of Comorbidity, Implications of Comorbidity for Clinical Practice, Treatment for Co-occurring Substance Abuse and Mental Health Disorders

List of Abbreviations

CBT cognitive-behavioral therapy

ECA Epidemiologic Catchment Area Study

GAD generalized anxiety disorder

NCS National Comorbidity Study

PD panic disorder

SAD social anxiety disorder

SSRIs selective serotonin reuptake inhibitors

SNRIs serotonin norepinephrine reuptake inhibitors

SUD substance use disordersTCAs tricyclic antidepressants

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53

Comorbid Addictions and Schizophrenia

E. Cabrina Campbell*, \$\\$, Irene M. Hurford*, \$\\$, Alex Z. Esposito*, \$\\$, Janice Lybrand\$, Stephan C. Mann**, Stanley N. Caroff*, \$\\$

*University of Pennsylvania School of Medicine, Philadelphia, PA, USA *Philadelphia Veterans Medical Center, Philadelphia, PA, USA **Central Montgomery MH/MR Center, Norristown, PA, USA

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INTRODUCTION

Addiction and schizophrenia are both chronic disorders with serious complications, consequences, and costs for the individual and society at large. Schizophrenia most often has a chronic deteriorating course. The main component of schizophrenia is psychosis, defined as difficulty in distinguishing what is real from what is not real or impaired reality testing. This is manifested by positive symptoms such as hallucinations and delusions. Auditory hallucinations are common alone or in combination with hallucinations of the other four senses.

Other positive symptoms are delusions, which are fixed false beliefs. Persecutory (paranoid) delusions are quite frightening. Additional clinical manifestations are disorganized thoughts and behavior. Negative symptoms of profound deficits are often experienced during the residual phases of schizophrenia. Negative symptoms include alogia, avolition, and flattened affect. All of the negative symptoms disrupt interpersonal relationships and impair ability to function. Cognitive

deficits of schizophrenia are likely to contribute to the difficulty in treatment of addiction. Schizophrenia is one of the most expensive disorders in all of medicine. Even though it occurs in only 1% of the population it totals 2.5% of all the health care cost. It is estimated to cost \$26 000 per year per schizophrenia patient.

Although pharmacotherapy of schizophrenia with antipsychotic agents has achieved significant gains in positive symptom control, patients are often only partially treated and remain disabled by negative and cognitive deficits, poor treatment adherence, and lack of social and economic support. Management of this disorder is made much more difficult by the common association with comorbid substance abuse, which interferes with effective pharmacotherapy and efforts at rehabilitation, while adding the additional health-related and social burdens of the consequences of addiction. Thus, detection and treatment of addiction must accompany efforts to help patients with schizophrenia.

In addition to managing the two disorders simultaneously, careful diagnostic consideration is necessary in distinguishing first-episode schizophrenia from

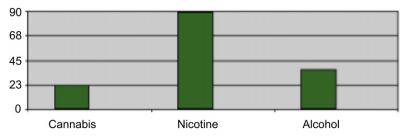


FIGURE 53.1 Percentage of comorbid substance abuse in schizophrenia patients.

psychosis induced by substances of abuse since the two disorders often co-occur. The usual age of onset is late adolescence to young adulthood in both conditions. Two out of three patients diagnosed with first-episode schizophrenia, in retrospect, use drugs in the premorbid stages prior to the onset of psychotic symptoms.

If patients do not have substantial periods of sobriety, it is difficult to differentiate the clinical diagnosis of schizophrenia with certainty from substance-induced psychosis. Though drug use may trigger the clinical manifestation of schizophrenia, it is clearly not the cause. Likewise schizophrenia is not the cause of substance abuse.

EPIDEMIOLOGY

One percent of the population has schizophrenia and this percentage remains constant. However, substance abuse has significantly increased. Prior to the 1960s, concurrent schizophrenia and substance abuse were observed or at least described infrequently. Since then, the situation has changed dramatically. Deinstitutionalization is a factor since schizophrenia patients now have more access to drugs in their communities.

The lifetime prevalence of addiction in the general population is 16%. In contrast, the lifetime prevalence rate in patients with schizophrenia is about 47%. The only other Axis I Disorder that has a higher rate of comorbid addiction is bipolar disorder (61%). This issue exists in the United States and internationally (Australia, Switzerland, Italy, Germany, England). When nicotine is included, the rates are staggeringly high. Studies have shown that 75–90% of patients with schizophrenia smoke tobacco compared with 20% of the general population.

In special populations, such as among prisoners and the homeless, the rates of co-occurring schizophrenia and addictions are highest. Among prisoners, 90% of the patients who have schizophrenia abuse substances. In fact, schizophrenia patients with comorbid addiction are more likely to become violent and intertwined in the criminal justice system. Younger males are more likely to be afflicted with both disorders. In the homeless population, 70% of schizophrenia patients abuse substances.

There are geographic differences: cocaine is used more often in urban areas than rural areas.

In order of frequency, substances abused by schizophrenia patients include nicotine, alcohol, cannabis, and cocaine. Alcohol is three times more likely and other substances of abuse are five times more likely in schizophrenia than the general population. Two or more substances are often abused. There has been no reduction in tobacco use among schizophrenia patients in the last 40 years. Conversely, there has been a significant decline in the number of smokers in the general population. Patients with schizophrenia are less likely to abuse amphetamines, opioids, and sedative hypnotics than the aforementioned drugs (Fig. 53.1).

Abuse of substances in schizophrenia may go undiagnosed and undetected. Roughly half of patients with schizophrenia have a comorbid addiction problem. Evaluation of substance abuse needs to be assessed in every patient, and assessments need to be done throughout their lifetime. Table 53.1 shows the time period in which cannabis, cocaine, and opioids can be detected in urine.

NEUROBIOLOGY OF ADDICTION AND SCHIZOPHRENIA

Self-medication of schizophrenia with substances of abuse has been hypothesized. The idea is that substances are used to reduce symptoms. This hypothesis presupposes that substances selected would match the symptoms experienced. For example, schizophrenics would choose stimulants for negative symptoms. But this is not the case and most studies do not support this hypothesis.

Schizophrenics use what is more readily available and affordable. Reasons for use are similar to the general population, e.g. "to get high," to decrease depression, to

TABLE 53.1 Time for Detection of Substances

Alcohol	$<24\;h$
Cocaine	3–7 days
Cannabis	4–7 weeks

relax, to increase pleasure, and to increase energy. The psychiatric symptom most associated with addiction among patients with schizophrenia is depression.

A more nuanced explanation of the neurobiology of addiction and schizophrenia involves mesocorticolimbic brain reward circuits. In schizophrenia, there is a postulated deficiency in dopamine-mediated mesocorticolimbic brain reward circuits. Substances of abuse ameliorate this deficit. Drugs such as alcohol, nicotine, cocaine may reinforce the reward system in the brain by increasing the level of dopamine in the nucleus accumbens of the limbic system.

In the mesolimbic regions and anterior striatum, deficiencies of dopaminergic neurons result in cravings. Therefore, schizophrenia patients are exquisitely vulnerable to addiction. When substances of abuse are introduced to schizophrenic patients, signal detection is modified. Then, negative effects of schizophrenia improve overall both with and without antipsychotic medications.

For example, nicotine affects the dopamine reward pathway. The dopaminergic and glutamatergic systems are involved in the etiology of schizophrenia. Nicotine binds nicotinic acetylcholine receptors in the midbrain during smoking. These neurons project from the ventral tegmental area to the prefrontal cortex and dopamine is released. Dopamine release in the nucleus acumbens leads to experiences of reward. This promotes impulsive, addictive behavior.

Hypofunction of dopamine in the prefrontal cortex mediates both cognitive deficits and negative symptoms. So by nicotine activating dopamine release in the prefrontal cortex, smoking is thought to decrease negative symptoms and cognitive deficits. This is correlated with the high rate of nicotine addiction in the schizophrenia patients.

Among the cognitive deficits in schizophrenia is visual–spatial memory. Hypofunction of cortical dopamine in the hippocampus of schizophrenics results in impaired performance in visual–spatial working memory. Smoking leads to improvement in tasks at least temporarily. Similarly in the prefrontal cortex of schizophrenia patients, attention, another cognitive dysfunction, is improved with smoking.

Abnormalities in emotion and motivation of schizophrenia patients are also attributed to dopamine system. Abusing cannabis doubles the risk of psychosis in schizophrenia patients. Also there is an earlier age of onset (17 versus 25) of schizophrenia patients who already have a history of cannabis abuse. Cannabinoid and dopamine receptor interactions in the prefrontal cortex, ventral tegmental area, and amygdala are thought to be vital in understanding the emotional associative learning difficulties in both addiction and schizophrenia.

There is an increase in risk of schizophrenia to 10% in first degree relatives and a 50% increased risk in monozygotic twins. But in terms of familial contributions in dual diagnosed patients, family history of schizophrenia does not correspond to substance use disorders in patients with schizophrenia. And substance use disorders are not associated with family members with schizophrenia.

COURSE AND CONSEQUENCES OF DUAL DISORDERS

Addiction is not the cause of schizophrenia and schizophrenia is not the cause of addiction. Rather, the effect of schizophrenia and addiction are bidirectional and each worsens the course of the other. Patients with addiction problems have an earlier age of onset of schizophrenia than patients without addiction. In addition, schizophrenia patients with comorbid substance abuse at the time of their first episode of psychosis are more likely to be men, with a longer duration of untreated psychosis, more severely ill, and be poor responders to antipsychotic medications. In short, substance abuse triggers and exacerbates psychosis that worsens the course of schizophrenia.

Moreover, schizophrenic patients who abuse drugs have an increased risk of suicide, are less compliant with treatment, often homeless, unemployed, violent, and frequently hospitalized (see Table 53.2). Substance abuse and violence are powerful predictors of acute psychotic episodes in patients with schizophrenia. In fact, schizophrenia patients who have a substance use disorder have twice the rate of hospitalization than those without substance disorders. Thus, these comorbid diagnoses occur more frequently among inpatients than outpatients. Up to 50% of readmissions for schizophrenia have been attributed to addiction.

Furthermore, addicted schizophrenia patients have significant medical complications. Rates of HIV, tuberculosis, hepatitis, and traumatic injury are higher in this population. They also have more smoking-related illnesses such as chronic obstructive pulmonary disease (COPD) and cardiovascular diseases. The rate of COPD in this comorbid patient population is 22.6% compared to 7.6% of the population at large. These illnesses

TABLE 53.2 Effects on Schizophrenia Patients Who Abuse Drugs

Stable living situation	\downarrow	Homelessness	1
Compliance with treatment	\downarrow	Hospitalization	1
Employment	\downarrow	Suicide/Violence	↑

exacerbate costs and creates additional treatment burden. Both morbidity and mortality are increased in patients with comorbid schizophrenia and addiction.

However, smokers have reduction in antipsychotic drug-induced parkinsonism from the alteration in cholinergic and dopaminergic systems. Despite the negative impact substances have on course of illness, substances improve signal detection capability of the dopamine pathway, which leads to improvement in how patients feel subjectively which is powerful given the many negative consequences of drug use. Yet, patients abuse substances anyway.

INTEGRATED TREATMENT

As we do with all substance-abuse patients, we recommend addiction-specific psychotherapeutic techniques such as motivational interviewing and 12-step programs. Alcoholics Anonymous is the foundation of substance-abuse treatment. However, patients with schizophrenia report particular difficulties with these approaches that need to be addressed during treatment (see Table 53.3).

Since avolition is a core negative symptom of schizophrenia, it can be especially difficult to motivate them to set recovery-oriented goals. Patients with schizophrenia may never have attained particular goals such as obtaining a driver's license, job, property, or getting married. However, when schizophrenia patients are in group together with other dual diagnosis patients, who also discuss severe mental illness, they are better able to identify, engage, and benefit.

The best approach to treatment is to treat both disorders simultaneously. Sequential treatment of addiction first is no longer recommended. Antipsychotic medications enable patients to participate in psychosocial treatment which is the foundation of addiction treatment. Due to the chronic nature of schizophrenia, an integrated approach must be long-term and appropriately embedded within the context of psychiatric services. In this setting, there is less alcohol and drug use, better retention in treatment, and enhanced participation.

Since homelessness is prevalent in this patient population, support through residential treatment setting is

TABLE 53.3 Barriers to Psychotherapy Treatment of Addiction among Patients with Schizophrenia

Feel different, uncomfortable in large groups, and watched, embarrassed

Difficulty sitting still and restless in long meetings

No identification with social loss

Resent confrontation

important. Vocational rehabilitation is effective when available. For patients who have difficulty managing their funds or who typically spend much of their money on drugs or alcohol during the first few days of the month, a fiduciary can make a difference. Fiduciary arrangements could curtail the unnecessary admissions that occur when a patient is out of funds and has no place to sleep or eat. A fiduciary can assist in securing a living situation and paying expenses before releasing small amounts of money to the patient for discretionary spending (Table 53.4).

Typical antipsychotic medications have been observed to increase rate of smoking in patients who have schizophrenia. Nicotine is thought to counteract the extrapyramidal side effects of these first generation antipsychotic agents. Atypical antipsychotics are much less likely to generate extrapyramidal side effects and may have a particular role in treatment of schizophrenia patients with comorbid addictions.

Due to its alpha adrenergic blockade activity and weak blockade of dopamine receptors, clozapine is unique and superior for treatment of co-occurring addiction. Clozapine reportedly increases dopamine release in the prefrontal cortex and improves signal-detection capacity of the mesocorticolimbic dopamine-mediated circuitry.

Therefore, clozapine is thought to ameliorate or correct the mesorticolimbic brain reward circuit deficiency that contributes to substance abuse in this patient population. But, quetiapine and olanzapine, and risperidone do not show these robust findings.

Nicotine

Schizophrenia patients are both more frequent and efficient smokers (taking more and deeper puffs). More frequent is defined as more than 25 cigarettes a day. Heavy smokers have an increase in hallucinations and delusions (positive symptoms) and fewer difficulties with flat affect, alogia, avolition (negative symptoms).

In addition tobacco, not nicotine, induces the cytochrome P450 isoenzyme CYP1A2 and this system also metabolizes some antipsychotic medications resulting in less available level of these medications. Therefore,

TABLE 53.4 Essential Components of Integrated Therapy

Supervised residential living

Case management

On-site treatment of addiction

Respect and empathy to foster strong therapeutic alliance, less confrontational

Collaborative goal setting

Psychopharmacology

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smokers require higher dosages of antipsychotics exposing them to more cost and increase side effects. If smokers are able to quit, this may necessitate a decreased dose of medications. Likewise heavy caffeine use may also result in the induction of CYP1A2 and decrease the level of medications as well.

The combination of typical antipsychotics and nicotine replacement therapy (NRT) is safe and effective. Clozapine decreases negative symptoms and smoking. Therefore, treatment with clozapine is superior to the combination treatment of nicotine addiction.

Similar to the general population, buproprion can be helpful with smoking cessation in schizophrenia patients. Since buproprion has dopaminergic and noradrenergic effects, it has the potential to worsen psychosis. It also inhibits the CYP 450 2D6 system resulting in elevated levels of some antipsychotics. One must be mindful of this drug–drug interaction when prescribing these agents together.

Furthermore, cigarettes are a gateway to alcohol abuse and use of illicit substances. Smoking is present before alcohol dependence in virtually every patient. Tobacco dependence is basically a precursor to alcohol addiction among patients with schizophrenia

Alcohol

Thirty-seven percent of patients with schizophrenia abuse alcohol. Once diagnosed with schizophrenia, being a violent offender was the strongest predictor of alcohol use disorder. Alcohol worsens the course of schizophrenia.

Naltrexone is effective for alcohol addiction particularly in patients with family history of addiction. Naltrexone in addition to antipsychotic medications results in less alcohol cravings, less drinking days, and less heavy drinking days among the schizophrenia patients. Moreover naltrexone does not worsen psychosis.

Cannabis

There continues to be controversy regarding the therapeutic effects of cannabis in certain disease states. However, in schizophrenia use of cannabis has deleterious effects. Currently, there is no approved pharmacologic treatment of cannabis dependence for schizophrenia patients or for patients in general.

Cocaine

Schizophrenia patients are observed to use cocaine less often than nicotine, alcohol, and cannabis. Perhaps this is because cocaine is more difficult to obtain than the above three. Though reports show a role for clozapine in the reduction of cocaine use, risperidone does

not show reduction in cocaine use and olanzapine has equivocal effects.

Opioids

Schizophrenia patients are much less likely to abuse opioids compared with other drugs mentioned above. The treatment of schizophrenia patients, who abuse opiods, is the same as nonpsychotic patients. Treatment with methadone or buprenorphine has been found to be useful and safe.

CONCLUSION

There is an unusually high rate of addiction among patients with schizophrenia. Comorbid addiction and schizophrenia are highly associated in terms of neurobiology and worsening course of both individual disorders. Though substances of abuse have the immediate effect of increase in pleasure; they ultimately worsen the course of schizophrenia resulting in more frequent acute psychotic episodes.

The negative consequences affect society as a whole. The cost of cigarettes is approximately 27% of the monthly income of many patients with schizophrenia. Costs are elevated also because of increased health care expenses including additional medical burden, rehospitalization, and homelessness.

In patients who use chronically and are psychotic, it is beneficial to treat psychosis even in the face of addiction. Treatment of psychosis increases patient's engagement in addiction treatment, thereby helping to decrease substance abuse. This results in patients staying in treatment and reduction in psychotic symptoms. Treatment by the same clinician or clinical team is critical.

Substances of abuse are known to decrease compliance with treatment contributing to the number one reason of acute psychotic relapse. Both addiction and schizophrenia are chronic disorders that necessitate open-ended and continuous treatment. Likely recurrent interventions are required lifelong, since problems with addiction can occur during any phase of illness.

SEE ALSO

Comorbid Addictions and Schizophrenia, Improving the Quality of Addiction Treatment, Diagnostic Dilemmas in Comorbidity, Screening and Assessment of Comorbidity, Implications of Comorbidity for Clinical Practice, Motivational Enhancement Approaches, Twelve-Step Facilitation Therapy, Methadone Maintenance, Medications to Treat Addictions: Nicotine Replacement, Naltrexone and Opioid Antagonists for Alcohol Dependence

List of Abbreviations

COPD chronic obstructive pulmonary disease **CYP** cytochrome P 450 enzymes

Glossary

Atypical antipsychotics second generation, serotonin and dopamine receptors antagonist.

Dual diagnosis having both mental illness and addiction problems. **Negative symptoms** deficits in attention, motivation, affect, speech, pleasure.

Positive symptoms hallucinations and delusions.

Typical antipsychotics first generation, dopamine receptor antagonist.

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Relevant Websites

http://www.psych.org - American Psychiatric Association.

http://www.nami.org - National Alliance on Mental Illness.

http://www.dsgonline.com/rtp/resources.html-Recovery to Practice.

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Pain and Addiction

Martin D. Cheatle

Center for Studies of Addiction, University of Pennsylvania, Philadelphia, PA, USA

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INTRODUCTION

In 1914, the Harrison Narcotic Act was created as opium and cocaine were previously unregulated, used liberally in the treatment of a variety of ailments, and became associated with criminal activity. In 1919, the Supreme Court ratified the Harrison Anti-Narcotic Act with the intention to regulate the importation, exportation, manufacturing, and distributing of opium and cocaine. Under this act addiction was not deemed disease and physicians were restricted from prescribing maintenance opiate therapy to addicted patients. Those who prescribed opiates to addicts were censored, lost their medical license, and were incarcerated in some cases. Addiction was criminalized leading to resultant undertreatment of legitimate pain disorders causing undue suffering of pain patients. Over time through advocacy from the public and scientific communities and published articles on the safety and efficacy of opioids in the treatment of pain, the intractable pain statutes reviewed by Joranson and Gilson in 1997 supporting opioid therapy for chronic pain including non-cancer pain were adopted.

Despite this evolution in philosophy regarding the therapeutic use of opioids, chronic pain remains a serious healthcare problem with associated economic burden. The person afflicted with pain can experience an array of problems including sleep disturbance, mood disorders, loss of work and family roles, sexual dysfunction, and diminished self-esteem all of which compromises quality of life. Delays in healing, changes in the central nervous system (neuroplasticity), depression, suicide, and opioid addiction (OA) can occur if pain is mismanaged or undertreated. Regardless of the enormity of the problem of chronic pain, growing concerns about addiction and diversion of opioids have contributed to the

inadequate treatment of pain, including acute episodes, end of life, and cancer pain, and especially in patients with chronic non-cancer pain (CNCP).

The individual struggling with both pain and cooccurring addiction is a particularly challenging case. Clinically, there are additional impediments in managing pain in this patient population as certain treatments such as opioid therapy are contraindicated or must be utilized judiciously and these patients carry added disease burden. Economically, patients with pain and addiction consume more healthcare resources. For example, White and colleagues in 2005 examined the database of medical and pharmacy claims from 16 health plans between 1998 and 2002 and classified opioid abusers by ICD-9-CM codes. A matched sample of non-abusers was also extracted for comparison. Results indicated that the prevalence of opioid abuse was low (eight in 10 000 persons), but the associated medical and pharmacy costs for abusers as compared to non-abusers were significantly higher. Abusers had a higher prevalence of nonopioid poisoning, psychiatric disorders, hepatitis (A, B, or C), and pancreatitis in contrast to non-abusers. Average annual direct healthcare costs for abusers were eight times greater than for non-abusers (\$15 884 versus \$1830) and mean annual drug costs were more than five times higher for abusers as compared to non-abusers (\$2034 versus \$386).

Prescription Opioid Abuse

Clinicians managing chronic pain patients (CPPs) are typically faced with the responsibility of providing the appropriate standard of care to alleviate suffering, which includes chronic opioid therapy (COT) while not complicating recovery by exposing the vulnerable patient to the potential of opioid abuse and OA. It has been the position of many experienced pain clinicians and of organized pain societies such as the American Pain Society (APS) and the American Academy of Pain Medicine (AAPM) that the majority of individuals afflicted with chronic pain can be managed safely with opioids. However, there is ongoing debate regarding COT (3 months or longer) in the CPP population due to fear of diversion, addiction, and respiratory depression, as well as loss of efficacy due to tolerance. There is continuing discussion regarding the policy of moderate opioid prescribing in CPPs given the rising prevalence of prescription opioid abuse and OA in the country. For example, Substance Abuse and Mental Health Services Administration (SAMHSA) from the 2010 National Survey on Drug Use and Health (NSDUH) report the incidence of past month nonmedical use of pain relievers is substantially higher than that of stimulants, tranquilizers, or sedatives. In 2009, nonmedical use of pain relievers (2.2 million) was only slightly less common than the use of marijuana (2.4 million) for past year initiates among persons aged 12 or older (Fig. 54.1). Monitoring the future 2011 national results on adolescent drug use from Johnston and colleagues revealed that the use of narcotics other than heroin by 12th graders almost tripled from 3.3% in 1992 to 9.5% in 2004. From 2005 to 2010 the rate leveled between 8.7 and 9.2% (Fig. 54.2). Results from the 2010 SAMHSA Treatment Episode Data Set and the Drug Abuse Warning Network were also telling. Admission

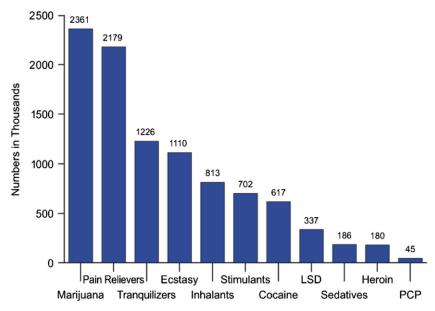


FIGURE 54.1 Past year initiates of specific illicit drugs among persons aged 12 or older: 2009. Substance Abuse and Mental Health Services Administration., 2010. Results from the 2009 National Survey on Drug Use and Health, vol. I. Summary of National Findings (Office of Applied Studies, NSDUH Series H-38A, HHS Publication No. SMA 10-4856 Findings). Rockville, MD.

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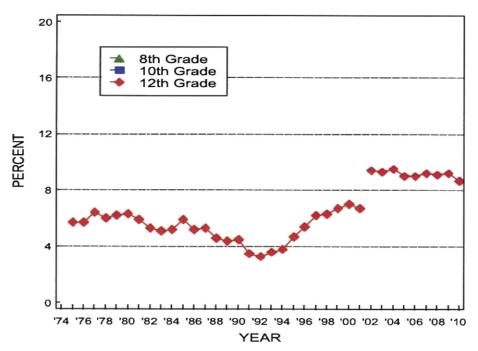


FIGURE 54.2 Narcotic use other than heroin (% who used any narcotics other than heroin in last 12 months). *Johnston, L.D., O'Malley, P.M., Bachman, J.G., Schulenberg, J.E.,* 2011. *Monitoring the Future national results on adolescent drug use: Overview of key findings,* 2010, *Institute for Social Research, The University of Michigan, Ann Arbor.*

rates to substance abuse treatment facilities for prescription opioid abuse increased from 18 300 in 1998 to approximately 105 680 in 2008. Between 2004 and 2009 there was a 98.4 increase in emergency department (ED) visits involving misuse or abuse of pharmaceuticals. Of the 1 244 679 ED visits in 2009 almost one half (595 551) were related to pain relievers. Sproule and colleagues in 2009 evaluated a sample of 571 opioid detoxification admissions over a 5-year period. The number of admissions related to controlled-release Oxycodone increased from 3.8% in 2000 to 55% in 2004. Legitimate prescriptions were the primary source of the opioids and the prescription opioid users reported higher levels of pain, comorbid substance use disorders (SUDs), and psychiatric symptoms. Excluding alcohol, tobacco, sedatives, and psychotropic drugs, opioid analgesics have become the common class of drugs associated with unintentional, fatal poisoning, greater than heroin, and cocaine.

SUDs are more common in many medical populations such as hospitalized patients, patients who have suffered major traumas and in patients treated for depression. Patients in these medical populations tend to develop acute and CNCP and, therefore, the prevalence of SUDs among these individuals treated for pain is high. Chronic pain is also common in patients seeking chemical dependency treatment.

The reported prevalence of OA in CNCP patients ranges from less than 1 to 40%. The wide range of

prevalence in different studies may be the result of the type of population sampled (primary care versus pain clinic) and whether patients were prescreened for history of SUD. A recent structured, evidence-based review of studies examining the abuse/addiction rate and aberrant drug-related behaviors (ADRBs) in patients receiving opioids for CNCP by Fishbain and colleagues in 2008 suggested that clinically significant abuse or addiction occurs in about 1/500 persons with no prior history of SUD and in about 3-4/100 of all persons prescribed COT for CNCP. Abuse/addiction rates appear to be highest in persons with history of SUD. ADRBs are more commonly observed than addiction and may reflect a range of issues including misunderstanding of instructions; self-medication of mood, sleep or other symptoms; elective use for reward/ euphoria; or diversion for criminal intent and addiction. Urine drug screening (UDS) data were examined and revealed that 20.4% of CPPs had no prescribed opioid in the specimen. Illicit drugs were revealed in 12.7% of cases. The authors concluded that only a small percentage of CPPs exposed to COT will develop abuse or addiction.

The prevalence of "true" addiction in pain patients receiving prescription opioids is unknown in part related to confusion in terminology (addiction, tolerance, and physical dependence) and the population sampled. For instance, a pain clinic population would most likely have a higher proportion of patients with

co-occurring psychiatric disorders than a primary care population or a sports medicine clinic. A number of studies relied upon questionnaires and interview protocols that may have been inadequate or not sufficiently sensitive to render the diagnosis of addiction and had sample sizes that were typically small and unrepresentative.

RISK FACTORS FOR ADDICTION

Risk for addiction consists of a convergence of a number of factors related to the host (genetic predisposition and comorbid psychiatric conditions), environment (occupation, peer group, culture, and social stability), and the agent (availability, cost, speed of entering the brain causing euphoria, and the efficacy of the agent as a tranquilizer) (Fig. 54.3).

There is evidence indicating that risk for OA has considerable genetic origins. For example, one study by Tsuang and colleagues in 1998 demonstrated that 54% of the accountability for OA was due to genetic variance and that 38% of the accountability was explained by genetic variance specific to opioids. Other host factors include the extent of psychiatric comorbidities. Depression and anxiety disorders are common companions to chronic pain. Estimates of co-occurring depression in the pain population range from 30 to

over 80%. Anxiety disorders range from 7 to over 60%, and posttraumatic stress disorder (PTSD) ranges from 9 to 33% in patients attending pain clinics. Pain patients with psychiatric and SUD comorbidities have a propensity to use opioids for long term as compared to those patients without a documented history of mood disorders or addiction, and patients diagnosed with a psychiatric disorder are more likely to abuse/misuse opioids than those without a psychiatric disorder.

There is some evidence that healthy social support may reduce the vulnerability to substance abuse and reduce relapse. Inadequate social support may be an important environmental risk factor in the development and maintenance of addiction/abuse in pain patients receiving opioids. If behavioral health/substance abuse treatment resources are scarce, self-help groups such as Alcoholics Anonymous or Narcotics Anonymous may provide needed support to reduce the probability of relapse.

Availability of the agent is an important factor in the development of addiction. Over the past decade there has been an extraordinary increase in the retail sales of opioids (http://www.deadiversion.usdoj.gov/). For example between 1997 and 2006 there has been a 196% increase in the retail sales of morphine, 274% increase in Hydrocodone products, 732% increase in Oxycodone, and over 1000% increase in methadone sales. The 2010 SAMSHA NSDUH report indicated in 2008–2009 among

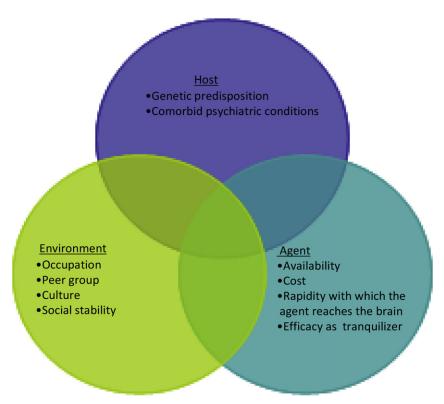


FIGURE 54.3 Risk factors for addiction.

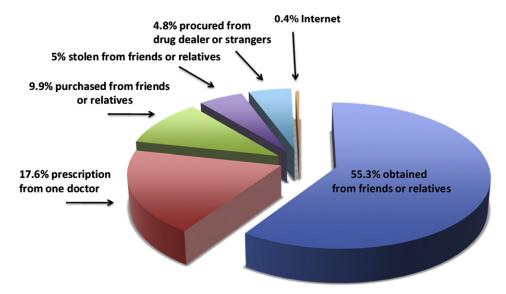


FIGURE 54.4 Source where pain relievers were obtained. Substance Abuse and Mental Health Services Administration., 2010. Results from the 2009 National Survey on Drug Use and Health, vol. I. Summary of National Findings (Office of Applied Studies, NSDUH Series H-38A, HHS Publication No. SMA 10-4856 Findings). Rockville, MD.

individuals 12 years or older who used pain relievers for nonmedical purposes 55.3% of this population acknowledged that they obtained the drugs most recently used from friends and family for free, 17.6% obtained the drugs from a prescription from one doctor, 9.9% purchased them from a friend or relative, 5% stole them from friends or relatives, 4.8% procured them from a drug dealer or stranger, and 0.4% bought them on the Internet (Fig. 54.4).

Other possible risk factors for opioid abuse include pain exaggeration, occult etiology for pain, poor function due to pain, age, psychological comorbidities, history of preadolescent abuse, cigarette dependency, PTSD, and family history of SUD. Cannabis use may also be a possible risk factor. Reisfield and associates in 2009 conducted a literature review of studies on COT, which included measures of ADRBs. Prevalence of cannabis use in patients prescribed COT ranged from 6.2 to 39% (5.8% in general US population). Cannabis use was significantly associated with present and future ADRBs.

The susceptible pain patient with genetic predisposition to addiction, undiagnosed or poorly treated comorbid psychiatric disorders, lacking social support, and having easy access to opioids may be especially at risk for the development of OA.

DIAGNOSING ADDICTION IN THE OPIOID-TREATED PAIN PATIENT

Considerable research has been devoted to identifying and assessing risk factors for addiction in pain

patients receiving opioids. Addiction is a chronic, neurobiological disease state produced by repeated exposure to a drug that activates the brain reward system leading to loss of control over drug use. Drugs with addictive qualities act through the "reward circuits" located within the mesocorticolimbic dopamine systems that include projections into the nucleus accumbens, amygdala, and prefrontal cortex. Addictive drugs produce reward, pleasure, or euphoria. Susceptible individuals repeatedly exposed to a drug with addictive qualities develop a biological adaptation or learning that leads to craving, compulsive use, and continuation despite physical or mental harm created by the drug.

Rendering a diagnosis of addiction in patients treated with opioids is complex and can be confusing due to the tendency to interchange the terminology of addiction and dependence. The World Health Organization (WHO) and the American Psychiatric Association (APA) adopted the term substance dependence, over what was historically termed drug addiction. The influential Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV-TR), published in 2000 established seven criteria for substance dependence (addiction). Only three criteria are required to make the diagnosis of dependence (addiction) (Table 54.1). As noted by Heit in 2003, five of these criteria are commonly experienced by the nonaddicted pain patient: tolerance, physical dependence/ withdrawal, used in greater amounts or longer than intended, unsuccessful attempts to cut down or discontinue use, and considerable time spent obtaining the substance or recovering from use. Pain patients

TABLE 54.1 DSM-IV-TR Criterion for Dependence (Addiction)

- Tolerance
- · Physical dependence/withdrawal
- Used in greater amounts or longer than intended
- Unsuccessful attempts to cut down or discontinue
- · Much time spent pursuing or recovering from use
- · Important activities reduced or given up
- Continued use despite knowledge of persistent physical or psychological harm

*3/7 required for diagnosis

*5/7 common in nonaddicted pain patients

Heit, H.A., 2003. Addiction, physical dependence, and tolerance: precise definitions to help clinicians evaluate and treat chronic pain patients. Journal of Pain and Palliative Care Pharmacotherapy 17 (1), 15–29.

appropriately using opioids over time will develop tolerance and can experience withdrawal symptoms if a dose is missed or due to end-of-dose failure. These behaviors can be misinterpreted as reflecting the condition of addiction. Patients may also display ADRBs reflective of the development of addiction or possibly suggestive of misuse for purposes of self-medicating an untreated or poorly controlled mood disorder (chemical coping), inadequate pain control (pseudoaddiction), tolerance, or criminal intent (diversion).

A consensus panel from the APS, the AAPM, and the American Society of Addiction Medicine (ASAM) was convened in 2001 to develop less ambiguous definitions of dependence and addiction in the pain population to avoid stigmatizing the legitimate pain patient and causing the undertreatment of pain. Consensus recommendations included:

1. Addiction – "Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving."

This definition emphasizes the "four Cs" (adverse Consequences, Control, Craving, and Compulsivity) as critical markers of addiction. Physical dependence and tolerance are not required in formulating the diagnosis of addiction and are considered states that occur naturally when using prescribed opioids.

2. *Physical dependence* – "Physical dependence is a state of adaptation that is manifested by a drug class

specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist." Dependence often occurs in the abuse of highly addictive drugs, but not always such as in cocaine. Physical dependence is common in many classes of drugs that are used for long term such as beta-blockers, antidepressants, and corticosteroids, as well as opioids. The development of physical dependence in patients receiving opioid therapy can be mistaken as suggestive of addiction, for example when a patient reports withdrawal symptoms when missing a dose or due to end-of-dose failure or verbalizes concern to their physician about renewing opioid prescriptions on a timely basis to avoid withdrawal. If a patient develops withdrawal symptoms this may be viewed by an untrained clinician as a sign of addiction in the absence of other critical behaviors such as craving and compulsive use.

- 3. Tolerance "Tolerance is a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time." Patients receiving COT often require an increasing dose of the opioid to maintain the initial therapeutic response of analgesia and improved function. The opioid-tolerant patient will show a pattern of gradual increase in need for titration of dose. Tolerance and withdrawal symptoms are critical features of some addictions such as alcoholism but for prescribed medications such as opioids, these symptoms can be normal.
- 4. Pseudoaddiction The consensus panel also added the term "pseudoaddiction" to describe an iatrogenic condition when relief-seeking behaviors occur if pain is undertreated. These behaviors may include clock-watching, doctor shopping, or drug seeking and even illicit drug use or engaging in deceptive acts to procure opioids all to alleviate pain.

The DSM-V is currently being developed. In this new version OA and dependence will be combined under the heading "opioid-use disorder" (Table 54.2).

The criteria for diagnosing opioid-use disorder are similar to DSM-IV except that tolerance or withdrawal "is not counted for those taking medications under medical supervision such as analgesics, antidepressants, anti-anxiety medications, or beta-blockers." This change in taxonomy hopefully will aid in distinguishing addiction from tolerance and dependence in the patient legitimately using therapeutic opioids.

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TABLE 54.2 DSM-V Opioid-Use Disorder

A maladaptive pattern of substance use leading to clinically significant impairment or distress, as manifested by two (or more) of the following, occurring within a 12-month period:

- Recurrent substance use resulting in a failure to fulfill major role obligations
- Recurrent substance use in situations in which it is physically hazardous
- Continued substance use despite having persistent or recurrent social or interpersonal problems
- Tolerance, as defined by either of the following:
- A need for markedly increased amounts of the substance to achieve intoxication or desired effect
- Markedly diminished effect with continued use of the same amount of the substance (*Note: tolerance is not counted for those taking medications under medical supervision such as analgesics, antidepressants, anti-anxiety medications, or beta-blockers*)
- Withdrawal, as manifested by either of the following:
 - The characteristic withdrawal syndrome for the substance (refer to Criteria A and B of the criteria set withdrawal from the specific substances)
 - The same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms (*Note: withdrawal is not counted for* those taking medications under medical supervision such as analgesics, antidepressants, anti-anxiety medications, or beta-blockers)
- The substance is often taken in larger amounts or over a longer period than was intended
- There is a persistent desire or unsuccessful efforts to cut down or control substance use
- A great deal of time is spent in activities necessary to obtain the substance, use the substance, or recover from its effects
- Important social, occupational, or recreational activities are given up or reduced because of substance use
- The substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance
- Craving or a strong desire to urge to use a specific substance

http://www.dsm5.org

GUIDELINES

Several guidelines were developed to promote "responsible practice" in prescribing opioids for chronic pain. The "Model Policy for the use of Controlled Substances for the Treatment of Pain" from the Federation of Medical Boards was published in 1998 and revised in 2004. "Cautionary Guidelines for the Use of Opioids in Chronic Pain" were proposed by the American Academy of Addiction Psychiatry (AAAP) in 2009 in response to

the "liberalizing" of opioid prescribing attributed to older guidelines from American pain societies. The APS and the AAPM commissioned an expert panel to systematically review the prevailing literature and developed the evidence-based "Clinical Guidelines for the use of Chronic Opioid Therapy in Chronic Noncancer Pain." The "Model Policy" recommended completing and documenting medical history and physical examination (PE), written treatment plan, obtaining informed consent, and if the patient is at high risk for medication abuse or has a history of substance abuse a written treatment agreement should be used. The policy also suggested a periodic review of treatment goals and progress toward these goals, use of consultants particularly in high-risk patients, and outlined the content of appropriate medical records. The AAAP guidelines were enacted "to limit the over-prescription of opioids and problems associated with dependence and abuse." The AAAP policies also encouraged obtaining a full medical history, completing a PE, and monitoring and risk assessment. The AAAP recommended against high doses of opioids and cautioned that chronic, high-dose opioid therapy might lead to opioid-induced hyperalgesia as well as risk of medical complications/adverse effects and deaths, particularly when opioids are used in combination with sedatives–hypnotics. If the patient's pain appeared disproportionate to objective findings nonopioid therapies might be more appropriate and if the patient displayed any type of ADRBs the physician should consider detoxifying the patient from opioids.

The APS and AAPM guidelines are more expansive and were meant to be evidence-based, but most of the recommendations were based on expert consensus. Of the 25 recommendations from this panel, none were rated as supported by high-quality evidence, and only four could be supported by moderate-quality evidence. While also recommending conducting a thorough physical and history along with risk stratification and use of UDS, these guidelines provided more comprehensive and detailed strategies for patient selection, risk stratification, monitoring, informed consent, and specifics on initiation and titration of opioids and guidelines for discontinuation of opioid therapy. Nonopioid alternatives or co-interventions, both pharmacologic and nonpharmacologic and the management of opioid related adverse effects, and opioid rotation were addressed. "High-dose opioid therapy" was defined as greater than 200 mg daily of oral morphine or equivalent. It was advised that when this threshold is reached there should be heightened scrutiny regarding the appropriateness of opioid therapy. Lastly, the panel suggested that patients with a history of drug abuse, significant psychiatric comorbidities, or ADRBs may be considered for COT with the stipulations of increased monitoring and cotreatment with behavioral health or addiction specialists.

UNIVERSAL PRECAUTIONS AND RISK STRATIFICATION

There is limited and weak support for the efficacy and effectiveness of long-term opioid therapy in providing significant pain relief as indicated in a 2010 Cochrane review by Noble and colleagues. The APS/AAPM expert panel concluded that while the evidence was extremely limited, there was consensus that COT could be an effective treatment for carefully selected and monitored patients with CNCP. Prevailing evidence suggests that preselected patients treated with opioids have an extremely low prevalence of addiction. Deterring abuse of prescription opioids requires due diligence in risk assessment and stratification.

On the basis of time-tested concept of "universal precautions" developed for risk assessment in infectious disease, Gourlay, Heit, and Almahrezi in 2005 developed universal precautions in pain management (Table 54.3).

Applying these universal precautions the authors recommended that patients can be stratified into three different risk categories. Low-risk patients defined as having no personal or family history of SUD, no or minimal concomitant psychopathologies can be followed in a primary care setting. Moderate-risk patients having a past history of SUD, strong family history, and past/current psychiatric history should have specialist support. High-risk patients are those who are actively addicted and/or have unstable, major psychiatric comorbidities. These patients should be referred to specialty pain management centers that can provide the highest level of surveillance and integrated

TABLE 54.3 Universal Precautions

- · Formulate diagnosis with differentials
- · Psychological assessment including risk of addictive disorder
- Informed consent
- Treatment agreement
- Pre- and post-intervention assessment of pain level and function
- · Trial of opioid therapy and/or adjunctive medication
- Reassessment of pain score and function routinely
- Regularly assess the "four A's" (analgesia, activity, adverse affects, aberrant behaviors)
- Periodic review of pain diagnosis and the development of comorbid conditions including addictive disorders
- Documentation

Gourlay, D.L., Heit, H.A., Almahrezi, A., 2005 Mar–Apr. Universal precautions in pain medicine: a rational approach to the treatment of chronic pain. Pain Medicine 6 (2), 107–112.

treatment. Subsequently in 2006, Gourlay and Heit emphasized a patient-centered model promoting the assessment and management of treatable, concurrent disorders including pain, drug misuse/abuse, addiction, and other psychiatric disorders. This encourages patients being treated in a less stigmatizing, more humane manner, and enhancing the opportunity for diagnosing and treating complicating disorders such as addiction and psychiatric comorbidities.

MANAGING PAIN WITH OPIOIDS: MAXIMIZING BENEFIT AND MINIMIZING RISK

Chronic Disease Management and the Patient-Centered Medical Home

There is utility in considering both pain and addiction as chronic diseases, as this allows for the opportunity to employ a chronic disease management model that has been highly effective in other chronic disease states (diabetes, asthma, and heart disease) that are also highly prevalent and costly.

In managing chronic diseases, risk stratification is established and monitoring and modification of treatment is determined by the patient's responsiveness to treatment as measured by certain markers (e.g. HbA1c, lipid levels, blood pressure readings, etc.). In the CPPs receiving opioid therapy these markers would include measures of ADRBs suggestive of misuse or abuse of opioids, pain intensity and measures of functionality and response to opioid therapy, and mental health screening. In patients with pain and co-occurring substance abuse, the level of surveillance and types of interventions would be determined by these various measures.

The basic elements of managing patients with opioids and chronic pain from a chronic disease management perspective include risk assessment, intervention, and monitoring.

Risk Assessment

Risk assessment includes the use of validated screening tools, UDS, and mental health screening.

RISK ASSESSMENT TOOLS

Genetic predisposition (family history), personal history of SUD, and the severity of psychiatric comorbidities have been postulated as the predominant risk factors for opioid abuse/misuse.

On the basis of known ADRBs a variety of screening tools have been developed for both prescreening patients being considered for opioid therapy and patients currently using opioids. Prescreening tools include a Screener and Opioid Assessment for Patients with Pain (Butler and colleagues, 2004); Opioid Risk Tool (Webster and Webster, 2005); Diagnosis, Intractability, Risk, Efficacy (Belgrade and colleagues, 2006); and Drug Abuse Screening Test (Skinner, 1982). Assessments employed for monitoring patients currently on chronic opioids include the Pain Assessment and Documentation Tool (Passik and colleagues, 2004) and the Current Opioid Misuse Measure (Butler and colleagues, 2007). These assessment tools have methodological weaknesses including limited generalizability to other clinical settings, as they were mostly validated in pain clinic settings and concern regarding reliability in self-administered versus clinician-administered versions.

URINE DRUG SCREENING

UDS is commonly utilized to assess abuse potential and adherence in pain patients receiving opioid therapy. The APS/AAPM consensus clinical guidelines recommended that patients at high risk or who are engaged in ADRBs (strong recommendation, low-quality evidence) and patients at low risk (weak recommendation, low-quality evidence) have periodic UDS. A number of studies have demonstrated that a significant percentage of patients receiving prescription opioids have abnormal UDS. While an aberrant UDS may be suggestive of abuse or addiction, it does not diagnose addiction, physical, or psychological dependence. The absence of a prescribed opioid on UDS usually is considered to be an indicator of diversion. However, one must consider hoarding behavior for two additional reasons: the patient is fearful of not having access to opioids in the future or the patient is considering suicide.

MENTAL HEALTH SCREENING

A comprehensive risk assessment program should include mental health screening in light of the high prevalence of concomitant mood disorders in patients with chronic pain. Opioids have anxiolytic and possible antidepressant properties and may be used for purposes of chemical coping. Chemical coping refers to reliance on the opioid to promote emotional stability. There is also substantial literature on the risk of suicide in pain patients. Diagnosing depression in the pain population is complex as there is potential for symptom overlap between pain and depression, particularly in the somatic domain (sleep disturbance related to pain and opioid-induced inhibition of rapid eye movement (REM) and non-REM phases of sleep, weight, and appetitive changes secondary to inactivity, change in libido, and/or energy related to opioid-induced hypogonadism) that may lead to misdiagnosis. There are a number of validated tools for assessing depression and anxiety which vary in length and specificity.

Effective risk assessment relies upon a combination of UDS and screening for ADRBs and mood disorders.

Interventions

Treatment decisions are determined by the initial risk stratification. On the basis of Gourlay and colleagues risk categories, patients at low risk can be followed in primary care with less intense monitoring (i.e. less frequent office visits) and more liberal dosing of opioids. Patients at moderate risk will require closer surveillance, more limited access to opioids initially, and co-treatment with other specialists (such as mental health practitioners and addiction medicine practitioners). Patients at high risk would benefit from referral to a specialty pain management program. However, in many instances, there is limited or no availability of specialty pain management especially in more rural areas.

Patients with high levels of depression and/or anxiety based on mental health screening would also benefit from referral to behavioral health. Rational pharmacotherapy targeting pain, sleep, and mood disorders, along with cognitive behavioral therapy and exercise is essential for all patients suffering from chronic pain independent of their risk profile.

In cases where the patients are actively abusing their medications, referral for substance abuse counseling and/or inpatient detoxification may be required. The screening, brief intervention, and referral to treatment (SBIRT) initiative was developed by SAMHSA and the Center for Substance Abuse Treatment (CSAT) as a comprehensive, integrated public health approach to facilitate early detection, intervention, and referral for treatment services for individuals with SUD. SBIRT is intended to be integrated into a system of services utilizing community resources. There is an SAMHSA sponsored web page that helps locate treatment providers and facilities in local regions (http:// findtreatment.samhsa.gov). Utilizing the SBIRT service program patients referred for brief treatment or for specialty treatment self-reported a dramatic improvement in general health, mental health, employment, living situation, and criminal behavior.

Monitoring

Once risk stratification has been conducted and the intervention for the patient has been established, monitoring is crucial. In low-risk patients, who are responding effectively to the treatment interventions, the level of monitoring can be fairly infrequent. For patients at moderate or high risk for either abusing medications or experiencing high-levels of depression with a risk for suicidal ideation and/or attempts, the level of surveillance is more frequent until these conditions stabilize. At each monitoring, medical record audit

should be conducted to determine whether there have been any ADRBs (ED admissions for pain, frequent phone calls to the clinic, doctor shopping, etc.). The PE and repeat SUD/mental health screening is also an important part of responsible monitoring of patients being prescribed opioids for long term. Routine UDS is recommended, particularly for the patients at high risk for abusing their medications. There has been some dispute regarding the frequency and overall utility of UDS. Random UDS is reasonable in this patient population, but the clinician should take steps to be fully educated on the interpretation of UDS, and have a plan established when UDS is suggestive of diversion, hoarding behavior, or addiction.

Figure 54.5 outlines an algorithm of the basic principles of risk stratification, intervention, and monitoring.

Patient-Centered Medical Home

Theoretically complex cases of patients with chronic pain, co-occurring psychiatric disorders that are at high-risk for abuse would be treated in an integrated pain clinic with access to behavioral health and addiction specialists. In practice there is a paucity of these specialty clinics. The majority of these patients are managed in busy primary care practices that lack the needed resources to effectively manage this patient population. The Patient-Centered Medical Home (PCMH) was developed by primary care organizations in 2007 to promote comprehensive primary care that fosters a collaborate relationship between an individual patient and their personal physician, and when appropriate the family and community. The basic principles of PCMH include that each patient has a personal physician

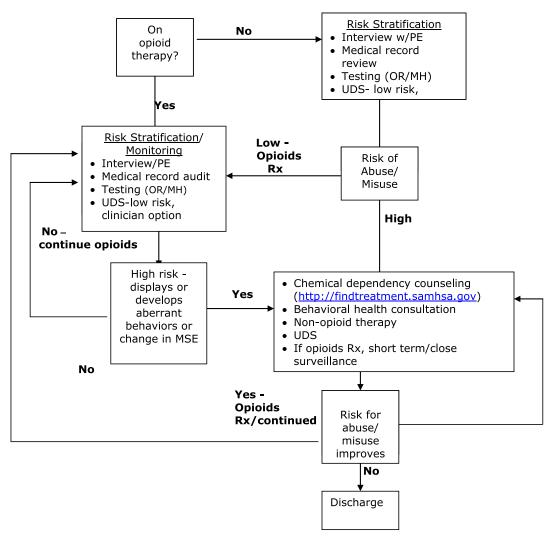


FIGURE 54.5 Algorithm for risk stratification, monitoring, and triage. UDS – urine drug screening, PE – physical exam, OR – opioid risk, MH – mental health.

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directing medical practice through a team, is whole person oriented, provides coordination of care across a healthcare system, ensures quality and safety, promotes enhanced access to services, and reimbursement for PCMH reflects added value. SBIRT has been utilized in this model for substance abuse with promising results. The PCMH model has great potential in managing patients with chronic pain on opioid therapy and reducing the risk of abuse, addiction, and diversion.

STRATEGIES TO DETER OPIOID ABUSE AND DIVERSION

There have been a number of strategies developed in an attempt to deter misuse and abuse of prescription opioids and also to discourage diversion. These include changes in pharmacologic formulations, federal policy, and monitoring programs.

Abuse-Resistant/Abuse-Deterrent Opioid Formulations

Due to the substantial evidence of rising abuse and diversion of opioids, new formulations have been developed to dissuade abuse. These include: (1) abuse-resistant formulations that use a physical barrier mechanism such as a gel to reduce the ability to extract active opioids or alter a tampered capsule or tablet unusable for injecting or snorting; (2) agonist–antagonistic formulations combine an antagonist, typically Naltrexone, with the opioid such that if an opioid is crushed, chewed, or chemically altered the antagonist is released reducing euphoria and tendency for abuse; and (3) aversive agents such as niacin are released if the prescribed opioid is used in excess.

Prescription Monitoring Programs

A number of states have developed prescription monitoring programs (PMPs) to assist regulatory agencies and physicians in the detection of prescription drug abuse or diversion. Initially the objective of these PMPs was to detect and prosecute individuals involved in diversion, which is defined as unlawful transferring of a regulated pharmaceutical from legal means to the illicit marketplace. Data are collected from physicians who are prescribing the medications and pharmacies which fill the opioid prescriptions. The specifics and roles of the PMPs vary from state to state, including which schedule(s) of drugs is monitored, frequency of data collection, and which parties have access to the information (physicians, pharmacists, or Department of Justice).

While there are limited data on the success of the PMPs, it appears that these programs may be helpful in reducing abuse and diversion.

Risk Evaluation and Mitigation Strategy

The FDA amendments act of 2007 extended this agency's authority over drug products that have been demonstrated to carry risk for patients. Under this act the FDA has the authority to require pharmaceutical companies submitting certain drug approval applications to submit proposed risk evaluation and mitigation strategy (REMS) as part of the application. The FDA may require REMS when it's determined that there is a necessity to ensure that the benefit of a pharmaceutical outweighs its risk.

While the specifics of REMS for opioid analgesics are currently being debated, the possible elements of proposed REMS include specialty training and/or certification of both prescribers and persons dispensing the drug (pharmacists and hospital personnel), prescribers and dispensers are familiar with the educational materials on risk of the drug and conditions for safe use, a plan for communicating the risks of a drug, and an implementation system and developing a database of all enrolled entities (prescribers, pharmacies, practitioners, and healthcare organizations).

SUMMARY

There has been much deliberation regarding the prescription of opioids to patients with CNCP. The main focus of concern has been the potential of vulnerable patients exposed to opioids becoming addicted, thus complicating their care. However, there are a variety of risks involved when opioids are prescribed to this patient population. Types of risk include:

- Addiction addiction in pain patients on opioid therapy is characterized by "four C's" – continued use in spite of harm (adverse Consequences); impaired control over use (Control), compulsive use (Compulsivity), and preoccupation with the use for non-pain relief purposes (Craving).
- Misuse patients misusing medications are not necessarily engaging in behavior reflective of addiction but may be chemically coping (i.e. using pain medications for mood modulation, disassociation in cases of PTSD) or in many cases attempting to remedy their sleep disorder.
- Suicide patients with chronic pain have a high comorbidity of depression and in many of these cases engage in suicidal ideation. Patients with pain and depression are at high risk for potential suicidal

gestures. Patients may hoard their medications (evidenced by UDS indicative of no opioids being used) for purposes of self-harm.

- Undertreatment of pain oftentimes patients are concerned about becoming addicted when prescribed opioids. In these instances, patients will under use their medications or refuse the use of opioids thus leading to poor pain control and suffering.
- Diversion diversion is the transfer of a prescription drug from a legitimate to an illegitimate conduit of distribution or use.

Prevailing evidence suggests that addiction in patients on COT is relatively low, particularly in individuals with no current or past history of SUD and negligible psychiatric comorbidities. The incidence of misuse is unknown but most likely substantial given the high comorbidity of chronic pain and psychiatric disorders and the mood modulating effect of opioids. While practitioners are concerned about their patients becoming addicted to prescribed opioids or criminal diversion of opioids, many patients with chronic pain suffer from depression and pain may be an independent risk factor for suicide with drug overdose as a common plan. When dispensing potentially lethal quantities of opioids, mental health screening and monitoring should be a routine practice. A patient displaying evidence of moderate to severe depression which is unresponsive to appropriate antidepressant therapy or endorses suicidal ideation necessitates immediate referral to a mental health facility for co-treatment. Lastly, there is a great deal of stigma associated with CNCP patients receiving COT. Patients often feel overly scrutinized by their healthcare providers, pharmacists, friends, and family. The national attention devoted to concerns of abuse of prescription analgesics may fuel a legitimate patient's fear of becoming addicted to prescribed opioids. Low-risk pain patients that might otherwise benefit from opioid therapy may under use or refuse prescribed opioids. In these cases, additional patient education on the indications and proper use of opioids and addressing the patient's fear of becoming addicted is needed with special attention to defining the concept of addiction as compared to tolerance and physical dependence.

Recent guidelines on opioid prescribing have been published and there has been a great deal of research devoted to developing abuse-deterrent opioid formulations and risk assessment tools and utilizing medical informatics to reduce opioid abuse. When prescribing opioids due diligence includes not only assessing and monitoring for signs of addiction, but also evaluating and addressing the other potential risks (misuse, suicide, under utilization of opioids, and diversion). Employing a chronic disease management model that

includes risk stratification, intervention, and monitoring within a PCMH allows the clinician an opportunity for early detection of potential complicating conditions and corrective action.

SEE ALSO

Screening and Interventions in Medical Settings Including Brief Feedback-focused Interventions

List of Abbreviations

AAAP American Academy of Addiction Psychiatry **AAPM** American Academy of Pain Medicine **ADRB** aberrant drug-related behavior APS American Pain Society **CNCP** chronic non-cancer pain COT chronic opioid therapy CPP chronic pain patient ED emergency department **NSDUH** National Survey on Drug Use and Health OA opioid addiction **PCMH** patient-centered medical home physical examination PE PMP prescription monitoring program **PTSD** posttraumatic stress disorder REMS risk evaluation and mitigation strategy SAMHSA Substance Abuse and Mental Health Services Administration SBIRT screening, brief intervention, and referral to treatment **SUD** substance use disorder

Further Reading

urine drug screening

UDS

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Relevant Websites

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http://www.findtreatment.samhsa.gov - SAMHSA.

http://www.dawninfo.samhsa.gov – SAMSHA Drug Abuse Warning Network.

http://www.oas.samhsa.gov/nsduh/reports.htm-SAMSHA National Survey on Drug Use and Health.

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The Treatment of Insomnia in Substance-Abusing Patients

Subhajit Chakravorty

Philadelphia Veterans Affairs Medical Center, Philadelphia, PA, USA

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INTRODUCTION

Insomnia has been diagnosed in prior literature using either the International Classification of Sleep Disorders, second edition (ICSD-2), or the Diagnostic and Statistical Manual for Psychiatric Disorders, version IV, third revision (DSM-IV-TR). The ICSD-2 criteria for insomnia includes a complaint of difficulty in initiating sleep, maintaining sleep or waking up too early, or sleep that is nonrestorative or poor in quality. This sleep difficulty occurs despite adequate opportunity and circumstances for sleep. In addition to the above, at least one or more complaints of daytime impairment are required, including fatigue or malaise, attention, memory or concentration problems, social or vocational dysfunction, mood disturbance or irritability, daytime sleepiness, poor motivation or energy, proneness for errors or accidents at work or while driving, tension, headache or gastrointestinal symptoms, and concerns or worries about sleep. These insomnia symptoms in substance use disorders (SUDs) must be present for at least 1 month, with abuse or dependence on a drug that is known to alter sleep during intoxication or withdrawal. Further, this insomnia is not better explained by another sleep disorder, medical or neurological disorder, or mental disorder.

The DSM-IV includes a similar criteria for insomnia associated with an SUD. The sleep-related complaints include a difficulty initiating or maintaining sleep, or nonrestorative sleep. These insomnia symptoms may last for a month or more in duration and sufficiently severe to warrant independent clinical attention and is not better accounted for by a sleep disorder that is not substance induced. In addition, the disturbance should not occur exclusively during the course of a delirium, and there is evidence from clinical data that either these symptoms developed during or within a month of substance intoxication or withdrawal. In addition, the consequence of this sleep disturbance is clinically significant distress or impairment in social, occupational, or

other important areas of functioning. Despite the differing classification systems, the common elements include symptoms associated with difficulty with sleep at night, and/or the presence of unsatisfactory sleep quality, with associated impairment in functioning. Insomnia lasting more than a month has previously been termed as chronic insomnia.

The evaluation and treatment of the insomnia in SUDs are important from a treatment perspective for multiple reasons. First, insomnia in recovering alcoholdependent patients may be associated with relapse back to alcohol use. Second, the presence of insomnia in alcohol-dependent patients may be an indication of an underlying comorbid and untreated psychiatric disorder, for example, a major depressive disorder that may impede the recovery process. Third, the insomnia symptoms may conversely mimic symptoms of depressive and anxiety disorders leading to an overdiagnosis and treatment of mood and anxiety disorders. Fourth, the presence of sleep continuity disturbance during recovery, especially in middle-aged patients with multiple medical comorbidities such as obesity and hypertension, should trigger an evaluation for underlying intrinsic sleep disorder like obstructive sleep apnea syndrome.

Insomnia is usually assessed with the use of subjective rating scales or objectively using an actigraph, or rarely using an in-laboratory polysomnogram. An actigraph is a wrist or ankle device that measures sleep indirectly, in the participant's domestic setting, based on the absence or presence of body movements during certain times of the day, in conjunction with the use of sleep logs. In addition to assessing for the presence of insomnia at home, the actigraph may be helpful to assess for sleep disorders involving a circadian mismatch, which may include sleep problems associated with going to bed too late or too early. Some of the subjective scales that have been used to assess for insomnia include the Pittsburgh Sleep Quality Index and the Insomnia Severity Index. An overnight polysomnogram, although a gold standard for the assessment of insomnia in research studies, is clinically useful only for evaluation of certain intrinsic sleep disorders such as obstructive sleep apnea syndrome and for research purposes.

The medications approved by the Food and Drug Administration (FDA) for insomnia include benzodiazepines, the newer non-benzodiazepine Gamma-amino butyric acid (GABA) receptor agonists, the melatonin receptor agonist ramelteon, and the histamine receptor antagonist doxepin. The medications in the benzodiazepine class include temazepam, triazolam, and flurazepam; those in the non-benzodiazepine GABA-receptor agonist class include zolpidem, zaleplon, and eszopiclone.

Despite the presence of multiple medications for the treatment of insomnia, there are some inherent problems associated with treatment of insomnia in those with SUDs. First, there may exist hesitancy on the part of many healthcare providers to provide medications for insomnia in sobriety. In a survey of 311 addiction medicine practitioners, Friedmann and colleagues found that 64% of the practitioners recommended medications to patients complaining of insomnia during recovery from alcohol abuse or dependence. Second, the use of benzodiazepine, as well as the non-benzodiazepine GABA-receptor agonists is usually avoided for the treatment of insomnia in addictive disorders. This practice is commonly used because of the concern over the risk of initiating dependence to these medications in these patients, a concept that needs further research. Thus, the interventions evaluated in prior research have included the use of other sedating and non-addictive psychotropic medications, melatonin, and light therapy. It is important to keep in mind that although some of these prescribed medications may be helpful for the insomnia, most of them have been prescribed on an "off-label" basis, that is, they are not approved by the FDA for this specific indication.

Behavioral therapies for insomnia are a current standard of care for chronic or psychophysiologic insomnia, as well as for insomnias comorbid with other disorders. Although these interventions may be ideally suited for insomnia comorbid with SUDs, unfortunately they have been inadequately investigated. With these considerations in mind, we will review the treatments for insomnia in the specific substance use categories.

METHODS

We reviewed the databases, Pubmed and ISI – Web of Science, for previous literature on treatment interventions involving insomnia in substance-abusing patients. Pubmed was chosen as a database, because of its extensive repository of literature. The ISI – Web of Science database was additionally selected because of its extensive indexing of pharmacologic literature.

The search criteria on Pubmed for the individual drugs consisted of the following: alcohol or alcoholism AND "sleep initiation or sleep maintenance disorder" (for alcohol abuse or alcohol dependence); cocaine and "sleep initiation or sleep maintenance disorder" (cocaine) or "cocaine" AND "Sleep"; "amphetamine related disorders" AND "sleep" (for amphetamines); "opiate related disorders" AND ("sleep" OR "sleep initiation or maintenance disorder") (for opiates); ("cannabis" OR "marijuana") AND "sleep", as well as, "marijuana abuse" AND "sleep initiation and maintenance disorders" AND "therapeutics" (for cannabis);

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"treatment" AND "nicotine" AND "insomnia,"(nicotine); "lysergic acid dethylamide" AND "sleep" (for LSD); (("central nervous system depressants") OR ("hypnotics and sedatives")) AND "abuse" AND "sleep initiation and maintenance disorder" (for sedative or hypnotic medications). The search criteria on the ISI web of science was similar, with the search pattern being treatment*insomnia*drug (ISI), where the drug was each individual category of drug, as mentioned above. All the studies were restricted to adult human subjects, for all the years existing in the database, and excluding animal studies.

RESULTS

Insomnia Associated with Alcohol Dependence

Insomnia has been associated with chronic alcohol dependence in one past epidemiological study. Active drinking in alcohol-dependent patients has been shown in prior studies to prolong sleep onset latency (SOL), decrease the total sleep time, and produce changes in the sleep architecture including a decreased rapid eye movement (REM) sleep duration. During withdrawal from alcohol after prolonged heavy use, there is a further increase in the SOL, with a decreased latency to onset of REM sleep. Delirium Tremens is an extreme form of alcohol withdrawal characterized by agitation, hallucinations, and arousal of the sympathetic system. Sleep disturbance during Delirium Tremens may consist of an increase in stage 1 sleep (light sleep), along with abnormalities of REM sleep. This acute withdrawal phase may last until 3 weeks, and with continued sobriety the patient enters abstinence. During abstinence, the prevalence of insomnia may range from 25 to 72% of the recovering patients and may persist for up to 3 years. This insomnia manifest with subjective complaints and polysomnographic abnormalities of an increase in the SOL, a decrease in the sleep efficiency, REM sleep abnormalities, and a decrease in the slow wave sleep duration.

The underlying biochemical abnormalities associated with prolonged alcohol use and withdrawal may cause or aggravate the insomnia symptoms, although this mechanism is incompletely investigated in humans. Alcohol modulates the excitatory and inhibitory neurochemical systems in the brain. Prolonged alcohol use is associated with an upregulation of the inhibitory GABA neurotransmitter system, and a compensatory downregulation of the excitatory glutamate (NMDA) neurotransmitter system. On cessation of heavy and/or regular alcohol use, alcohol withdrawal symptoms may be precipitated which may be associated with the unopposed activity of the excitatory glutamatergic

system. Medications in the benzodiazepine class are GABA mimetic, including lorazepam and are commonly used to treat alcohol withdrawal. These medications decrease the alcohol withdrawal symptoms and have been shown to improve sleep in some studies.

A range of interventions have been evaluated for the treatment of insomnia in these patients. Please see Table 55.1 for the list of medications that have been evaluated for the treatment of insomnia in this population. Most of these medications have harnessed a common associated adverse effect, i.e. sedation, to treat the insomnia. We will attempt to evaluate these interventions in more detail below.

Pharmacologic Interventions

1. Anticonvulsant Medications: Medications in this class are prescribed for multiple indications including seizures, pain, and headaches. Gabapentin and carbamezapine have been the most investigated medications in this class. Gabapentin is a medication prescribed for seizures and in certain pain

TABLE 55.1 Therapies Investigated in the Treatment of Insomnia in Alcohol Dependence

Therapies investigated

- 1. Pharmacologic treatments
- A. Antidepressant medications

Trazodone

B. Mood stabilizer/anticonvulsant medications

Gabapentin

Carbamezapine

C. Antipsychotic medications

Quetiapine

D. Immunomodulator medications

Etanercept

E. Benzodiazepine medications

Triazolam

F. Other medications or compounds

Melatonin

L-Tryptophan

Acamprosate

Magnesium

Chlomethiazole

2. Non-pharmacologic treatments

Cognitive behavioral therapy for insomnia

Bright light

syndromes. This medication has been investigated during alcohol withdrawal and during sobriety, using a dose range of up to 1500 mg day⁻¹. Brower and colleagues evaluated the efficacy of gabapentin on insomnia in alcohol-dependent participants using a randomized placebo-controlled trial. Subjective and objective sleep improved in both the groups over the 6-week treatment duration. However, gabapentin, in comparison to placebo, over the 6-week treatment duration was associated with delayed onset of relapse to heavy drinking (Relative Risk = 0.25, p = 0.04). In another study, the relative efficacy of gabapentin and lorazepam on subjective sleep was assessed during a 12-day period, consisting of an initial 4-day treatment for alcohol withdrawal with either gabapentin or lorazepam, and a 8-day follow-up period subsequently. Then results did not show any difference in the efficacy between gabapentin and lorazepam during the treatment phase. However, in patients with a history of multiple previous detoxifications (≥ 2 detoxifications), gabapentin was more efficacious than lorazepam in improving the insomnia during and after the treatment phase. In another study involving patients in alcohol withdrawal, the same investigators evaluated the effects of carbamezapine and lorazepam for symptoms of mood, anxiety, and sleep quality. Results were significant for an improvement in the sleep quality and anxiety in the carbamezapinetreated patients (as compared to lorazepam-treated patients).

2. Antidepressant Medications: Trazodone, a serotonin reuptake inhibitor with H_1 antihistaminic and α_1 adrenergic antagonistic properties, is commonly prescribed on an "off-label" basis for insomnia associated with alcohol dependence in recovery. Friedmann and colleagues have shown that this medication is the hypnotic of choice in the majority (37.6%) of the addiction treatment providers for recovering alcoholic patients. The initial starting dose (mean \pm S.D.) for the providers in this study was 61.1 ± 28.1 mg, and the duration of treatment (mean \pm S.D.) was 47.8 \pm 36.4 days. The efficacy of trazodone has been evaluated in two randomized placebo-controlled studies. In the first study conducted by Le Bon and colleagues, recently detoxified alcohol-dependent participants were assessed for objective sleep after 4 weeks of treatment. Trazodone as comparison to placebo, improved the continuity of sleep through the night, with a decrease in the wake time after sleep onset. In a larger study of alcohol-dependent patients with insomnia during the post-detoxification phase, the effect of trazodone on sleep was evaluated over 12 weeks, with a follow-up in 12 weeks after discontinuing the study medication. Trazodone (N = 88), as compared to placebo (N = 85), improved the sleep quality at the 1-month and the 3-month follow-up assessments, with a moderate effect size between baseline and 1-month follow-up (Effect Size, Cohen's d = -0.50), and a large effect size between baseline and 3-month follow-up (Effect Size, Cohen's d = -0.93). However, no difference was seen in the sleep quality between the trazodone and placebo after stopping the medications for 12 weeks. Interestingly, trazodone treatment (as compared to placebo) was associated with a relatively lesser improvement in the proportion of days abstinent during the treatment phase, and an increase in the number of drinks per drinking day, during follow-up after completion of the treatment phase. 3. Neuroleptic Medications: These medications are

primarily used to treat psychotic symptoms associated with schizophrenia or for psychiatric stabilization during a manic or a mixed episode associated with bipolar disorder. Among these medications, Quetiapine has shown the most promise for the treatment of insomnia. Quetiapine is a second-generation antipsychotic medication and an antagonist at the Dopamine (D_1) , serotonin $(5-HT_2)$, histamine (H_1) , and alpha-adrenergic (α_1) receptors. This medication has shown some benefit in the improvement of sleep, mood, and craving for alcohol during acute residential rehabilitation addiction treatment in a case series conducted by Sattar and colleagues. In a retrospective study of data in alcohol-dependent Veterans in outpatient treatment, Monnelly and colleagues evaluated the effect on alcohol-related variables for patients prescribed quetiapine for improving sleep quality. Their results showed that quetiapine-treated Veterans (as compared to other medications) showed a higher number of days abstinent from alcohol, a lower number of hospitalizations, and with a trend toward significance for a higher number of days to relapse.

4. Benzodiazepine Medications: These medications are usually avoided in this population, with the exception of detoxification from alcohol use. In an open label study, the effectiveness of triazolam in treating insomnia was evaluated in 12 alcoholic patients after 5–15 days from their last drink, and with a median dose of 0.75 mg at bedtime. Subjective sleep with triazolam treatment (as compared to their baseline values) showed the following findings: an increase in the sleep depth and sleep duration and a decrease in the number of awakenings and anxiety levels. The most common adverse effect on the triazolam was grogginess and disorientation to time. 5. Etanercept: Prior studies have shown the presence of REM sleep abnormalities including, an earlier

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onset, and architectural abnormalities during recovery and an increase in levels of acute inflammatory markers such as tumor necrosis factoralpha (TNF- α). Etanercept, a protein that binds and inactivates the TNF- α in circulation, is FDA approved for the treatment of rheumatoid arthritis. Irwin and colleagues conducted a randomized, double-blind, placebo-controlled, crossover trial of 18 recovering alcohol-dependent participants. Results form this study showed that a single Etanercept dose (in comparison to placebo) was associated with a decreased amount of REM sleep; further, the percentage of REM sleep was inversely correlated with the circulating level of circulating levels of soluble TNF receptor II. The clinical consequence of this finding is currently unknown. 6. Acamprosate: Alcohol withdrawal symptoms may occur on cessation of prolonged alcohol use. These symptoms may be associated with unopposed activity of the excitatory glutamatergic system. Acamprosate, one of the FDA approved medications for the treatment of alcohol dependence, is a modulator of the glutamatergic system. In a randomized, placebo-controlled trial, Staner and colleagues investigated the effects of acamprosate on objective sleep during the immediate phase of alcohol withdrawal. Treatment with acamprosate (as compared to placebo) was associated with a decreased wake time after sleep onset, a higher amount of slow wave sleep, and an increase in the latency to REM sleep. However, there was no interaction between treatment groups and time. 7. Melatonin and Its Analogs: Melatonin is secreted from the pineal gland and has been used exogenously as a chronobiotic agent with minimal hypnotic properties. During alcohol withdrawal and early abstinence, decreased levels of the following indices have been seen: blood level of melatonin; a delay in the rise of the melatonin level; the peak level of melatonin in the blood at night. These findings may translate into a weaker drive to fall asleep and a tendency to fall asleep later in the night. Melatonin is freely available as a health food supplement over the counter in stores across the United States. There are no studies, to the best of our knowledge, which have evaluated the role of melatonin on sleep in the recovering alcoholdependent patients. Ramelteon, a selective agonist at the Melatonin 1, and 2 receptors, is currently FDA approved for the treatment of insomnia. Brower and colleagues conducted a recent case series of five alcohol-dependent patients with insomnia during recovery, treated with ramelteon for 4 weeks, at a dose of 8 mg at nighttime. Results showed that ramelteon treatment was associated with an

improvement in the total sleep time and a decreased latency to falling asleep.

8. Magnesium: Magnesium is an ion that is involved in multiple integral functions in the body. In an openlabel trial, Hornyak and colleagues treated 11 patients in subacute alcohol withdrawal with 30 mmol of magnesium daily for 4 weeks. Results showed that magnesium treatment was associated with a decrease in objective SOL, and an improvement in the sleep quality. A subset of 7 out of the 11 participants reported an improvement in their periodic limb movement index (PLMI) during sleep, while the other subset of 4 participants had an increase in their PLMI. Future studies will need to clarify the role of magnesium in sleep, if there is one.

9. Clomethiazole: This medication with hypnotic properties is commonly used in some European countries for the treatment of alcohol withdrawal symptoms. There is minimal data on clomethiazole's effectiveness in improving sleep in alcohol dependence. Further, clomethiazole has a narrow therapeutic index and thus may be fatal in an overdose.

Non-Pharmacologic Interventions

1. Cognitive Behavioral Therapy for insomnia (CBTi): This treatment brings together multiple nonpharmacologic interventions for insomnia. According to Perlis and colleagues, the first line treatments are stimulus control therapy (SCT) and sleep restriction therapy (SRT), and education on sleep hygiene (SH) as an adjunctive treatment. The second line interventions include cognitive therapy and relaxation training. SCT attempts to strengthen the association between bedroom or the bed and sleep, a relationship that is problematic in patients with insomnia. This intervention can be implemented by using the bed for sleep or for sex, and discontinuing other non-sleep-related behaviors in bed or the bedroom. SRT attempts to initially contract the time in bed to the actual duration spent asleep in the bed at night, thereby reducing the time spent lying in bed awake. The sleep time is then gradually increased to levels optimal for the patient. The SH techniques include avoiding nicotine and caffeine prior to bedtime, and turning the clock away from line of vision. The *cognitive therapy* component consists of targeting the negative or dysfunctional thoughts and beliefs that lead to an increase in arousal around bedtime and thus interfere with sleep. Relaxation techniques are useful in patients with a high level of somatic arousal/anxiety at bedtime. They may include interventions such as diaphragmatic breathing and progressive muscle relaxation.

Behavioral therapy including CBTi with modifications for alcohol-dependent patients has been shown to be efficacious and is the recommended intervention for patients, whenever possible. 2. Bright Light Therapy: Another non-pharmacologic approach to the treatment of insomnia involves the use of this modality. Bright light therapy has primarily been used in the treatment of Seasonal Affective Disorders, as well as Circadian Rhythm Sleep Disorders. This non-pharmacologic treatment may improve sleep during withdrawal or initial phase of recovery, by improving the sleep quality and sleep architecture, and decreasing the SOL, as shown by Schmitz and colleagues. Further investigations including those comparing it to inactive interventions as well as studies with a larger sample size are needed to clarify the role of this intervention (Table 55.2).

Insomnia Associated with Cocaine Dependence

The emerging picture of sleep disturbance in cocaine dependence and withdrawal appears to be unique. Sleep disturbance investigated prospectively for 3 weeks of abstinence is significant for a mismatch between subjective and objective sleep measures. In one of the more comprehensive investigations involving a 23-day inpatient study, Morgan and colleagues investigated

TABLE 55.2 Medications Investigated for Insomnia with Use of Drugs Other Than Alcohol

Medications investigated

A. Cocaine

Modafinil

Lorazepam

Tiagabine

B. Other stimulants

Mirtazapine

Modafinil

C. Opiates

Quetiapine

Amitritylline

Lorazepam

Buprenorphine

D. Cannabis

Mirtazapine

E. Nicotine

None

sleep disturbance and its relationship with abstinence and cocaine binge sessions, using subjective and objective measures. Sleep evaluated between 14 and 17 days, showed a mismatch between subjective and objective measures. Specifically, participants rated their subjective sleep as the best, whereas the objective electrophysiological sleep measures were at their worst during this period. In addition, vigilance tests were seen to correlate positively with the electrophysiological sleep measures, and negatively with the subjective measures. They used the term "occult" insomnia for this phenomenon.

Modafinil is a wake-promoting medication, with a mechanism of action currently unknown, and is approved by the FDA for treatment of sleepiness associated with adequately treated obstructive sleep apnea, narcolepsy, and in shift work disorder. Modafinil has also been shown to be efficacious in promoting abstinence from use in cocaine dependence. In a recent placebo-controlled trial for 16 days, Morgan and colleagues evaluated the effect of modafinil treatment on subjective and objective sleep in cocaine-dependent participants. Modafinil (as compared to placebo) was associated over time with improved total sleep time, and stage 3 sleep at night. Subjective sleepiness was decreased in the morning and afternoon during the second and third weeks of the study.

In another human laboratory study, the differential efficacy between lorazepam and tiagabine (as compared to placebo) in improving sleep and sleep-related cognitive functioning was assessed. Tiagabine is an anticonvulsant medication with hypnotic properties, with possible mechanism of action through GABA reuptake inhibition into the presynaptic neurons. Lorazepam and Tiagabine were both helpful in improving sleep latency and sleep efficiency, although there were differences. In comparison to placebo, lorazepam use was associated with an increase in stages 1 and 2 of sleep, a suppression of slow wave sleep, a decreased sleep-dependent learning and increased impulsivity, as compared to Tiagabine; however, Tiagabine improved slow wave sleep.

Insomnia Associated with Use of Other Stimulants

The insomnia associated with methamphetamine use or withdrawal has been minimally investigated. Medication interventions evaluated during methamphetamine withdrawal have included mirtazapine and modafinil. Mirtazapine is an antidepressant with hypnotic properties, which causes a central presynaptic α_2 -adrenergic receptor blockade, leading to a downstream increase in serotonin and norepinephrine. Modafinil on the other hand is a wake-promoting medication

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prescribed for sleepiness associated with multiple intrinsic sleep disorders.

In a study conducted by McGregor and colleagues, treatment of methamphetamine withdrawal with modafinil (N=14), in comparison to mirtazapine (N=13) was associated with relatively lower sleep-related disturbances, and a lower severity of methamphetamine withdrawal symptoms.

Insomnia Associated with the Use of Opiates

A limited number of studies have investigated the sleep disturbance associated with the use of opiates, including use during methadone maintenance. In a double-blind crossover trial of 42 healthy adults, Dimsdale and colleagues evaluated the effect of sustained-release morphine and methadone on sleep architecture. Results showed that both the medications (as compared to placebo) were associated with an increase in stage 2 sleep, a decrease in slow wave sleep, and without any change in overall sleep efficiency. There was no difference between the two opiate medications.

Sleep disturbance is a common complaint in treatment-seeking opiate-dependent patients reporting to the clinic for addiction treatment. Sleep-related complaints that may occur during opiate withdrawal include a difficulty falling asleep, an inadequate sleep quality, or sleep quantity. In a human laboratory study evaluating the sleep in recently sober opiate-dependent patients, methadone treatment was associated with an increase in the deeper stages of sleep, a concomitant decrease in the superficial stages of sleep, and with a reversal of sleep architecture during detoxification. The sleep continued to improve over time during protracted abstinence. Predictors of sleep disturbance in patients maintained on methadone as seen in prior studies have included the following variables: benzodiazepine abuse, nicotine dependence, presence of psychiatric disorder, and bodily pain. Interestingly, 62% of the treatment-seeking opiate-dependent patients reported self-medicating themselves for their sleep disturbance in another study.

No specific treatment targeting the insomnia in opiate dependence was seen in the literature. Prior studies showed that treatment with Quetiapine or low doses of amitriptyline and lorazepam improved subjective sleep during opiate withdrawal. Wallen and colleagues have also shown that patients undergoing detoxification treatment with buprenorphine reported an improvement in their subjective sleep disturbance.

Insomnia Associated with the Use of Cannabis

The use of cannabis has been associated with an improvement in subjective sleep quality and ease of

falling asleep at lower doses, with deterioration of sleep measures at higher doses. On polysomnographic sleep studies, short-term use of cannabis has been associated with an increased slow wave sleep and a decreased REM sleep duration. Tolerance developed to the slow wave sleep effects on prolonged use over time. Changes seen in objective sleep during recent abstinence from heavy cannabis abuse may include an increase in the SOL, a decrease in the sleep efficiency, and a shorter latency to REM sleep. In one study conducted by Haney and colleagues, treatment with mirtazapine improved objective and subjective sleep measures during cannabis withdrawal, although mirtazapine use was associated with increased caloric intake.

Insomnia Associated with Nicotine Use or Withdrawal

Nicotine use or withdrawal is commonly associated with sleep-related disturbances including difficulty falling asleep, sleep fragmentation, a decreased sleep efficiency, and an increase in daytime sleepiness. Currently, no medication exists for the treatment of insomnia associated with active nicotine use or withdrawal from nicotine, to the best of our knowledge. To complicate this issue further, interventions used to treat nicotine dependence for example, nicotine replacement therapy, bupropion and varenicline may be associated with insomnia.

Recommendation for Management of Insomnia in Substance-Abusing Patients

To the best of our knowledge, no specific guidelines exist for the treatment of insomnia in the substance-abusing population. Many of the guidelines for the evaluation and treatment of chronic insomnia are applicable to the comorbid insomnia associated with the SUDs. These guidelines will be categorized into recommendations for evaluation and management.

Insomnia complaints in the substance population should prompt a thorough evaluation of the substances used, another intrinsic sleep disorder e.g. obstructive sleep apnea and circadian rhythm sleep disorders masquerading as insomnia, medical and psychiatric disorders. A sleep log or sleep diary should be used by the patient to document his/her sleep-wake patterns and naps, and the day-to-day variability in the sleep at home for at least the previous 2 weeks duration. Additional objective evaluation of the sleep-wake pattern for insomnia and circadian rhythm sleep disorders may be conducted using an actigraph. A polysomnogram is not usually recommended for the evaluation of insomnia routinely. A polysomnogram is usually

ordered to screen for an underlying intrinsic sleep disorder, e.g. breathing-related sleep disorders (obstructive or central sleep apnea), periodic limb movement disorder, or nocturnal seizures.

Inadequate sleep hygiene, which may be comorbid with insomnia in patients with addictive disorders, is best treated with behavioral therapy. Circadian rhythm sleep disorder as a comorbid disorder may present with insomnia and sleepiness and is best treated with a chronobiotic agent like melatonin, bright light therapy, or possibly behavioral intervention like chronotherapy. Breathing-related sleep disorders, including snoring and obstructive sleep apnea, which may be aggravated with the nasal congestion from the cigarette smoking, may mimic insomnia symptoms, and are best treated with weight loss, positive airway pressure therapy, and smoking cessation. Other understudied causes that may precipitate or perpetuate insomnia in this population are environmental and social factors, e.g. living in shelters, living alone, presence of high expressed emotions in the family during active use and recovery.

The aim of the insomnia treatment should be to improve the qualitative and/or quantitative sleep, along with any associated symptoms of sleep-related impairments. An initial approach for insomnia treatment should be behavioral, whenever possible. These behavioral approaches may include any one of the following: stimulus control therapy, sleep restriction therapy, relaxation therapy, or the above in any combination with cognitive therapy. The rules of good sleep hygiene should be independently recommended to all the patients presenting with insomnia. Pharmacological treatment when considered necessary should be considered for the shortest possible duration, with medications tailored to the patient's clinical profile, personal preferences and cost, or as an adjunct to behavioral treatments for the insomnia. Hypnotic agents without a known addiction potential like ramelteon may be a reasonable option. Over-the-counter medications like diphenhydramine are not recommended because of the relatively unknown efficacy. Further, the associated central anticholinergic side effect of medications like diphenhydramine, may place the patient at an increased risk of cognitive impairment. Medications in the benzodiazepine category are best avoided.

DISCUSSION

Insomnia is prevalent in the SUD population. Patients should be encouraged to remain abstinent or clean from substances of use. This insomnia may improve with sobriety or time spent remaining clean in many SUD

patients, while in others it may persist for longer periods of time, for reasons currently unknown and may be a risk factor for relapse in certain drug use disorder like alcoholism. The presence of persistent insomnia beyond the withdrawal phase and the first month of recovery may thus warrant treatment intervention. Literature exists predominantly for insomnia related to alcohol misuse, followed by cocaine, opiates, and nicotine. The complaint of sleep disturbance in opiate-dependent patients stabilized on methadone should trigger an evaluation for covert benzodiazepine use, the presence of comorbid psychiatric disorders, and an evaluation of underlying pain disorders which may interfere with sleep.

Other causes of insomnia may include inadequate sleep hygiene, circadian rhythm sleep disorders, sleep-related breathing disorder, restless leg syndrome, and periodic limb movements in sleep. This distinction is important as the treatment will differ by diagnostic category and may explain the lack of efficacy of standard hypnotic medications in certain participants.

The American Academy of Sleep Medicine (AASM) recommends an initial trial of behavioral therapy, with or without the cognitive component for chronic insomnia whenever possible. If behavioral therapy is not an option or has failed, pharmacotherapy may be attempted, tailored to the patient's individual clinical profile. However, none of the medications mentioned above have been approved by the FDA for the treatment of this comorbid insomnia and are currently used on an "open-label" basis. Most of the prior drug treatment studies for insomnia in addictive disorders have used small sample sizes or have not been replicated. In recovering alcohol-dependent patients, the most evaluated medications include gabapentin, quetiapine, and trazodone. However, the relationship of the improvement in insomnia with improvement in the alcohol use disorder is currently unknown. In cocaine-dependent patients, modafinil, a wakepromoting medication appears to have efficacy in improving sleep at night and sleepiness during the daytime; these findings may however need to be replicated. Medications in the benzodiazepine class are not recommended because of their abuse and dependence potential. The role of non-benzodiazepine class of hypnotic medications, e.g. ramelteon, zolpidem, or eszopiclone, in recovery is currently unknown. Future studies should assess in detail the other causes of insomnia mentioned above, the efficacy of cognitive behavioral therapy for insomnia in different populations of SUD, the safety and the role of non-benzodiazepine GABA-receptor agonists and ramelteon in insomnia associated with substance-abusing patients, and the role of combined behavioral and pharmacologic treatment.

FURTHER READING 525

List of Abbreviations

CBTi cognitive behavioral therapy for insomnia

GABA gamma-amino butyric acid **FDA** Food and Drug Administration

REM rapid eye movement SOL sleep onset latency SUD substance use disorder TNF-α tumor necrosis factor-alpha

Further Reading

Perlis, M., Jungquist, C., Smith, M.T., Posner, D., 2008. Cognitive Behavioral Treatment of Insomnia – A Session-By-Session Guide. Springer.

Relevant Websites

http://pubs.niaaa.nih.gov/publications/arh25-2/110-125.htm – Alcohol's Effect on Sleep in Alcoholics, from NIAAA.

http://pubs.niaaa.nih.gov/publications/aa41.htm – Alcohol and Sleep, from the NIAAA.

http://www.cet.org/- Center for Environmental Therapeutics - Information on Bright Light Therapy.

http://www.oasas.state.ny.us/admed/fyi/fyiindepth-insomnia.cfm – Insomnia and Alcohol and Substance Abuse.

http://www.sleepeducation.com/Disorder.aspx?id=55 – Insomnia due to Drug or Substance.

http://www.sleepnet.com/definition.html – Sleep terminology: multiple websites exist on the Internet, one of which may be.

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Medication for Cravings in Substance Use Disorders

Ashwin A. Patkar*, Jonathan C. Lee^{\$}, Douglas M. Burgess**

*Duke University Medical Center, Durham, NC, USA *Farley Center at Williamsburg Place, Williamsburg, VA, USA ***University of Missouri, MO, USA

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MEDICATION FOR CRAVING AND MOOD

Neurobiology of Cravings

Drug addiction or substance dependence is a chronic, relapsing disorder characterized by the following: (1) compulsion to seek and take the drug, (2) loss of control in limiting intake, and (3) emergence of

a negative emotional state when access to the drug is prevented. According to the United Nations International Drugs Control Programme and World Health Organization, "drug craving is a desire for the previously experienced effects of a psychoactive substance. This desire can become compelling and can increase in the presence of both internal and external cues, particularly, with perceived substance availability. It is characterized by an increased likelihood of

drug-seeking behavior or, in humans, drug-related thoughts."

Craving is related to preoccupation/anticipation in the different stages of the addiction cycle driven by impulsivity with positive reinforcement and compulsivity with negative reinforcement and automaticity. The stages of addiction cycle include binge/intoxication, withdrawal/negative effect, preoccupation/anticipation (cravings), and transition to addiction. Craving has been difficult to measure in human clinical studies and has not always clearly correlated with relapse.

Animal models of craving can be divided into two domains. Type 1 craving is induced by stimuli that have been paired with drug self-administration, such as environmental cues. Type 1 craving is known as conditioned positive reinforcement in experimental psychology. In animal models, a cue previously paired with access to a drug can reinstate responding to a lever that previously has been extinguished. Type 2 craving occurs after a state of protracted abstinence in a drug-dependent individual. Type 2 craving is a state change characterized by dysphoria and anxiety. In animal models, this type of craving is described as residual hypersensitivity to states of stress and environmental stressors that lead to relapse and drug-seeking behavior.

It is in the extended amygdala that memories relating to drug abuse are transformed into craving to use a drug again. Chronic drug use and conditioning may bring about changes that can be detected by brain scans, and these changes might be reversible through medication and psychotherapy. The extended amygdala may link environmental stimuli to both the rewarding effects of drugs and withdrawal. Inactivation of the basolateral nucleus of the amygdala in rats disrupts the association of environmental stimuli with the rewarding effects of food, water, and sex. Neurobiological mechanisms and brain changes in the extended amygdala are likely associated with eating disorders, pathological gambling, and other behaviors driven by reward, withdrawal effects, and elements in the environment.

Animal studies suggest that drug-induced reinstatement (Type 1) is localized to the medial prefrontal cortex–nucleus accumbens–ventral pallidum circuit mediated by glutamate. For instance, craving and cues related to nicotine and cocaine can lead to activation of the prefrontal cortex and anterior cingulate gyrus per brain imaging studies. Cocaine craving is also associated with increased dopamine release in the striatum as well as opioid peptides in the anterior cingulate and frontal cortex. In a study using positron emission tomography (PET), regional cerebral blood flow (CBF) was measured in limbic and comparison brain regions of 14 detoxified male cocaine users and 6 cocaine-naïve comparison subjects during exposure to both nondrug-related and cocaine-related videos and during resting baseline

conditions. The cocaine video led cocaine users to experience craving and showed a pattern of increases in limbic (amygdala and anterior cingulate) CBF and decreases in basal ganglia CBF relative to their responses to the nondrug video. This response did not occur in the cocaine-naive comparison subjects. These results show that limbic activation is one component of cue-induced cocaine craving (Figure 56.1).

Alcohol craving is associated with higher opioid peptide activity in the striatum but lower dopaminergic activity. According to brain imaging studies, there are baseline decreases in dopamine function (e.g. D2 receptors) and orbitofrontal function during chemical dependence; however, acute craving can lead to reactivation of dopamine function in the reward pathway. In summary, the prefrontal cortex, which includes the orbitofrontal, medial prefrontal, and prelimbic/cingulate, and the basolateral amygdala play a significant role in drugand cue-induced craving.

Neuropharmacological and neurobiological studies using animal models for cue-induced reinstatement include the basolateral amygdala with a possible feedforward mechanism through the prefrontal cortex system involved in drug-induced reinstatement. Neurotransmitters involved in cue-induced reinstatement are

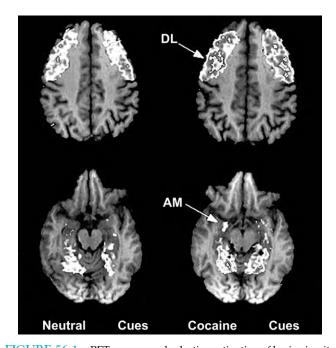


FIGURE 56.1 PET scans reveal selective activation of brain circuits during cocaine craving. On the right, scans from volunteers who experienced cue-induced cocaine craving show activation of the dorsolateral prefrontal cortex (DL) and the amygdala (AM). When these volunteers were exposed to neutral (nondrug-related) cues, this activation was not seen. Adapted from Volkow ND, Wang GJ, Telang F, et al. (2006) Cocaine cues and dopamine in dorsal striatum: mechanism of cravings in cocaine addiction. J Neurosci 26: 6583–6588.

Neurochemical neurocircuits in drug reward

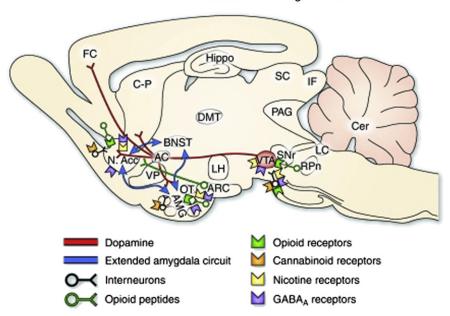


FIGURE 56.2 This sagittal section through a representative rodent brain shows receptors and pathways in the neurocircuitry of addiction. Blue arrows represent interactions within the extended amygdala system, which is correlated with drug reinforcement. AC, anterior commissure; AMG, amygdala; ARC, arcuate nucleus; BNST, bed nucleus of the stria terminalis; Cer, cerebellum; C-P, caudate-putamen; DMT, dorsomedial thalamus; FC, frontal cortex; Hippo, hippocampus; IF, inferior colliculus; LC, locus coeruleus; LH, lateral hypothalamus; N Acc., nucleus accumbens; OT, olfactory tract; PAG, periaqueductal gray; RPn, reticular pontine nucleus; SC, superior colliculus; SNr, substantia nigra pars reticulata; VP, ventral pallidum; VTA, ventral tegmental area. Koob, G.F., Volkow, N.D., 2010. Neurocircuitry of Addiction. Neuropsychopharmacology Reviews 35, 217–238.

characterized by glutamatergic projection from the frontal cortex to the nucleus accumbens that is modulated by dopamine activity in the frontal cortex. Cueinduced reinstatement involves dopamine modulation in the basolateral amygdala and a glutamatergic projection to the nucleus accumbens from both the basolateral amygdala and the ventral subiculum.

Stress-induced reinstatement of drug-related responses in animal models depends on the activation of both corticotropin-releasing factor (CRF) and norepinephrine in portions of the extended amygdala (central nucleus of the amygdala and the bed nucleus of the stria terminalis). Compulsive drug-seeking behavior is driven by the ventral striatal–ventral pallidal–thalamic–cortical neurocircuitry (Figure 56.2). Per alcohol dependence models, protracted abstinence involves overactive glutamatergic and CRF systems.

Due to acute and chronic neuroadaptation in the brain from addiction, craving can maintain addictive drug-seeking behaviors and lead to relapse even after a prolonged period of abstinence. Therefore, treatment that diminishes cravings (preoccupation/anticipation) of alcoholics and addicts can decrease the likelihood of relapse. In the future, neuroimaging studies may be used clinically not only to provide data on the reactivity of the neurocircuitry but also to correlate data with treatment efficacy and risk of relapse.

Future molecular targets for preoccupation/anticipation (craving) include activation of cystine–glutamate exchange (such as by *N*-acetylcysteine), which has been shown to prevent cocaine-induced escalation and behavioral sensitization as well as diminishing conditioned response to drug cues in humans.

MEDICATIONS FOR ALCOHOL CRAVING

- Disulfiram
- Naltrexone
- Acamprosate
- Combination therapy
- Emerging therapies
 - Topiramate
 - Ondansetron
 - Kudzu extracts

Alcohol dependence is a chronic relapsing disease that is treated using a combination of psychosocial and pharmacological treatments. Development of medications to treat alcoholism has focused on reducing craving and consumption of alcohol, treating withdrawal symptoms, preventing relapse, and treating associated psychiatric disorders. Animal models have provided the basic foundation of understanding alcohol-related drinking,

craving, dependence, and relapse. The alcohol-drinking behaviors are mediated through interactions of multiple neurotransmitter systems related to the reinforcing effects of alcohol. These systems affect the corticomesolimbic dopaminergic pathway, which is important in the rewarding effects of alcohol.

Disulfiram

Disulfiram is a form of aversive therapy that has been available since the 1940s. Disulfiram interferes with the metabolism of alcohol by irreversibly inhibiting aldehyde dehydrogenase, leading to the accumulation of acetaldehyde, which results in flushing, sweating, nausea, and tachycardia. Secondary mechanism of disulfiram is on the central nervous system to inhibit dopamine-β-hydroxylase from converting dopamine to norepinephrine, which potentially increases dopamine levels and may decrease cravings.

Serious adverse reactions include hepatotoxicity, optic neuritis, peripheral neuropathy, and psychotic reactions. Common side effects include metallic aftertaste, dermatitis, and transient sedation.

The efficacy of disulfiram is limited due to generally poor compliance when patients take it at their own discretion. Disulfiram is more effective when given in a monitored or witnessed setting for a highly motivated individual. Preliminary evidence shows that disulfiram may reduce alcohol cravings and increase consecutive days of abstinence among patients with alcohol dependence and comorbid psychiatric disorders.

Contraindications to disulfiram include use of alcohol-containing products or metronidazole. Relative contraindications include coronary artery disease, severe myocardial disease, and hypersensitivity to rubber (thiuram) derivatives.

Use disulfiram with caution in patients with hepatic cirrhosis or insufficiency, cerebrovascular disease or cerebral damage, psychoses (present or past), diabetes mellitus, epilepsy, hypothyroidism, and renal impairment. Disulfiram belongs to pregnancy category C. Patients must be reminded to carry a card to alert medical personnel in emergencies.

Disulfiram is available in oral daily dosing form at 250 mg daily (range 125–500 mg day⁻¹). Potential drug interactions of disulfiram include warfarin, isoniazid, phenytoin, and any nonprescription medication containing alcohol. Prior to prescribing disulfiram, the patient's liver function should be evaluated and subsequently monitored. Due to possible disulfiram–alcohol reaction, disulfiram should not be taken for at least 12 h and ideally 2 weeks after drinking alcohol. Patient needs to be instructed to avoid alcohol in the diet (vinegars and sauces), over-the-counter medications, and toiletries.

Naltrexone

Naltrexone has been shown to decrease drinking frequency and the likelihood of relapse to heavy drinking. The US Food and Drug Administration (FDA) approved naltrexone for the treatment of alcohol dependence in 1994. It is thought that the competitive antagonism of naltrexone to opioid receptors blunts the release of dopamine related to alcohol consumption, which results in decreased craving and diminishes the rewarding effects of alcohol use. According to animal models, naltrexone is thought to block the release of β -endorphins in regions related to alcohol reward.

Before and during treatment with naltrexone, liver function should be monitored. Take special precautions before starting naltrexone in patients with hepatic disease, renal impairment, and history of major depression or suicide attempts. Naltrexone is classified as pregnancy category C. In the event of emergency, patients should carry a wallet card to alert medical personnel that they are taking naltrexone. Common side effects of naltrexone include nausea, vomiting, decreased appetite, fatigue, somnolence, headache, anxiety, and dizziness.

Clinicians need to be mindful of the potential of naltrexone to precipitate withdrawal in patients with opioid dependence as well as inhibiting the effects of opioid analgesics for acute and chronic pain management. Patient should be free of opioids for 7–10 days before starting naltrexone. If there is a risk of precipitating opioid withdrawal, a naloxone challenge test can be performed.

Oral Naltrexone

Naltrexone is available in an oral 50 mg daily dosing. Alcoholics who are more greatly driven by reward craving experience increased level of stimulation while drinking alcohol and are more likely to respond to naltrexone. Variance of alleles in the μ -opioid receptor also affects the efficacy of naltrexone, such as seen in subjects of European descent on naltrexone with one or two copies of the 118G variant allele had lower rates of relapse and took longer to return to heavy drinking than those subjects who were homozygous for this allele; however, this has not been observed in all clinical trials. Alcoholics who have a family history of alcoholism seem to have a greater reduction in alcohol consumption compared those who have no known family history.

The efficacy of naltrexone has been proven in a metaanalysis of 27 randomized controlled trials (RCTs) that showed that short-term treatment with naltrexone decreased relapse (risk ratio of 0.64) with a number needed to treat (NNT) of 7.

The Combining Medications and Behavioral Interventions for Alcoholism (COMBINE) trial evaluated the

efficacy of naltrexone, acamprosate, or both, in comparison with each other and placebo, with health care provider-delivered medical management, and with or without a specialized alcohol counselor, delivered combined behavioral intervention. Patients who were treated with naltrexone plus medical management – or naltrexone, medical management, and combined behavioral intervention – had a greater percentage of days abstinent than those receiving placebo and medical management only. In addition, naltrexone reduced the risk overtime of heavy-drinking days.

However, not all clinical trials of naltrexone have seen significant improvements in drinking treatment outcomes. Per meta-analyses in 2002 and 2004, naltrexone has modest efficacy in preventing relapse to drinking. A recent multisite-clinical trial reported that a higher dose of naltrexone (100 mg day⁻¹) with medical management to increase compliance did significantly reduce alcohol use but with a small effect size.

Injectable Naltrexone

To increase compliance, a long-acting injectable naltrexone has been shown to decrease the event rate of heavy-drinking days (25% in 380 mg group versus 17% in 190 mg group). Compared with oral naltrexone, extended-release naltrexone reduces peak levels and fluctuations in plasma levels to minimize the side effects and elevates trough levels to improve efficacy. The administration of long-acting naltrexone along with psychosocial support has been associated with improvement in drinking outcome measures, especially among patients who are abstinent entering treatment.

The dosing of extended-release naltrexone is 380 mg given as a monthly intramuscular injection. It is important to monitor the muscle mass and skin of the injection site. Potential contraindications to injectable naltrexone include hemophilia and bleeding problems. There have been cases of reaction at the injection site, allergic pneumonia, and suicidal ideation with extended-release naltrexone.

Acamprosate

Acamprosate is thought to antagonize *N*-methyl-Daspartate (NMDA) glutamate receptor sites or via modulation of glutamate neurotransmission at metabotropic-5-glutamate receptors to balance the gamma-aminobutyric acid (GABA) and glutamate neurotransmitter systems. These mechanisms of action are thought to reduce symptoms, such as insomnia, restlessness, anxiety, and depression, from protracted abstinence from alcohol. Acamprosate has been reported to reduce neuronal hyperexcitability during alcohol withdrawal. In a more recent animal clinical trial, the proposed

mechanisms of action by acamprosate on the neurotransmitter systems have not been observed in the therapeutic dose range used to decrease alcohol use. Acamprosate reduces responses to alcohol cues in alcohol-dependent animals.

Acamprosate has been shown in multiple European studies and in a meta-analysis in 2004 of 17 clinical trials to increase the proportion of dependent drinkers who maintain abstinence for several weeks to months. The results of the meta-analysis demonstrated that 36% of patients taking acamprosate were continuously abstinent at 6 months versus 23% of those patients taking placebo. However, two US clinical trials did not confirm efficacy of acamprosate. Secondary analyses in one of the trials showed possible efficacy in patients with baseline goal of abstinence. Differences between the European and US clinical trials include more severe alcohol dependence and longer period of abstinence prior to initiating acamprosate in the European studies. US clinical trials had a higher level of psychosocial interventions compared to European trials. A more recent meta-analysis of three significant European trials showed that the rates of complete abstinence as well as percent days of abstinence and time to first drink were significantly greater with acamprosate treatment.

Acamprosate is available in oral form at 666 mg three times daily dosing. Acamprosate is contraindicated in severe renal impairment with creatinine clearance less than 30 ml min⁻¹. Precautions need to be taken for patients with creatinine clearance 30–50 ml min⁻¹ (dose adjustment to 333 mg PO TID), depression, and suicidal ideation. Acamprosate is classified as pregnancy category C. There have been rare events of suicidal ideation and behavior related to acamprosate. Common side effects include diarrhea and somnolence. There are no known clinically relevant drug interactions.

Combination Therapy

The combination of naltrexone and acamprosate has been shown to be well tolerated and safe. However, the results of the combination have been mixed on whether it is superior to naltrexone alone. Some studies have shown superior efficacy; whereas, the COMBINE trial did not observe improved efficacy in combining naltrexone and acamprosate versus naltrexone alone.

Topiramate

Topiramate is an anticonvulsant that is not FDA approved for alcohol dependence but is an emerging therapy that has growing evidence to support its use for treating alcoholism. The mechanism of topiramate includes inhibition of extrasynaptic GABA_A receptors,

L-type calcium channels, voltage-dependent sodium channels; and antagonism of α -amino-3-hydroxy-5-methylisoxazole-4-propionic acid (AMPA) and kainate glutamate receptors. Topiramate has been shown to reduce alcohol use in animal models.

Topiramate has been studied at doses of 200–300 mg day⁻¹ with efficacy in reducing the percentage of heavy-drinking days. In these studies, abstinence was not required prior to start of topiramate. There has also been evidence that topiramate is more effective than placebo and indistinguishable from diazepam for treatment of alcohol withdrawal.

The dosing range of topiramate is between 25 and 300 mg day^{-1} with a target dose of $\geq 100 \text{ mg day}^{-1}$. Due to potential side effects, such as paresthesia, cognitive difficulty, taste distortion, and anorexia, topiramate should be titrated slowly, such as over several weeks to target dose. Less common adverse reactions include myopia, increased intraocular pressure, glaucoma, and nephrolithiasis.

Ondansetron

Ondansetron is a serotonin-3 (5-HT $_3$) antagonist used as an antiemetic. Preclinical trials support the off-label use of ondansetron based on evidence that 5-HT $_3$ receptors in the brain may affect the reinforcing effects of alcohol. Clinical trials in humans show that ondansetron reduces alcohol preference and desire to drink. Studies of ondansetron have shown decreased drinking behavior especially in the subpopulation of early onset alcoholics. Ondansetron has been studied at doses ranging from 1 to 16 $\mu g~kg^{-1}$ with maximal efficacy at 4 $\mu g~kg^{-1}$.

Kudzu

Kudzu is a Chinese herbal root. According to animal studies, extracts of kudzu, which contains a variety of isoflavones (e.g. puerarin, daidzein, and daidzin), have been shown to decrease alcohol consumption. In a small human naturalistic double-blind placebo-controlled trial (n=14) for "heavy" alcohol drinkers (each subject served as their own control), there was a significant reduction in the number of beers consumed without a significant effect on the urge to drink alcohol for participants who received kudzu extract (puerarin) 1000 mg capsules three times daily for 1 week. There were no reported side effects of kudzu treatment.

The kudzu extract diadzein has been isolated as an aldehyde dehydrogenase 2 (ALDH-2) inhibitor, which has been shown in animal models to reduce excessive drinking. Synthetic versions of this selective ALDH-2 inhibitor are being investigated as potential medications to suppress relapse in abstinent alcoholics. More clinical trials will need to be conducted to better understand the

efficacy of kudzu extracts or synthetic variants for treatment of alcohol dependence.

MEDICATIONS FOR OPIOID CRAVING

- Opioid full/partial agonists
 - Methadone
 - Buprenorphine
- Naltrexone
- Emerging therapies

Understanding the neurobiological underpinnings of the endogenous opioid system as well as opioid addiction continues to be a rapidly evolving field in substance abuse treatment. Continued use of opioids is often reinforced through the euphoric effects (positive cravings) as well as the relief of withdrawal symptoms (negative cravings). Functional magnetic resonance imaging (fMRI) has demonstrated increased blood flow to regions of the orbitofrontal and inferior frontal cortex with projections from the mesolimbic dopaminergic system. This system in the brain is believed to play a large role in conditioning and reward processes. Single photon emission computed tomography has demonstrated decreased baseline dopamine type 2 receptors in the left caudate nucleus of opioid-dependent individuals compared to controls. Additionally, opioid-dependent individuals have higher levels of right putamen dopamine release in response to cue-exposure. This finding is significant because chronic craving and anhedonia have been positively correlated with dopamine release. Given the central role of craving in perpetuating opioid use, medications that target negative and positive cravings are commonly used.

Opioid Partial/Full Agonists

Opioid agonists have been used in the treatment of opioid addiction since the early 1960s. More recently, the partial opioid agonist buprenorphine has also gained an increased role within opioid maintenance. The main therapeutic effect of full and partial opioid agonists is relief of the physiological withdrawal symptoms associated with rapid discontinuation of opioids. These medications also serve to blunt the euphoric effects associated with illicit opioid use.

The most commonly utilized full agonist is methadone, a long-acting opioid, which acts as a high-affinity agonist at mu- and delta-opioids receptors as well as an antagonist at NMDA receptors. Methadone is rapidly and nearly completely absorbed in the intestines and accumulates in tissues throughout the body where it remains protein bound and is slowly released. It is extensively metabolized through the cytochrome P450 system before being excreted in the urine.

While general consensus supports the use of methadone as a safe and effective treatment for opioid-dependent individuals, there has been some disagreement about its effect on cravings for opioids. A review article in 2011 looking at the impact of methadone maintenance on heroin craving found 16 articles that met inclusion criteria. Among these articles, seven reported reduced opioids craving, four found continued risk of heroin craving, four found no effect on craving, and one study found that methadone could increase heroin craving.

Originally synthesized in 1974, buprenorphine acts as a partial agonist at the mu-opioid receptor and an antagonist at the k receptor. It was originally used in pain management but gained traction within addiction treatment during the 1990s. As a partial agonist at the k receptor, buprenorphine offers the advantage of a decreased risk of respiratory suppression while still controlling withdrawal symptoms. As a result of extensive first pass metabolism, buprenorphine has poor bioavailability when swallowed, but this is greatly improved when absorbed sublingually. Buprenorphine is lipophilic, highly protein bound within the serum and readily crosses the blood–brain barrier. It is primarily metabolized in the liver via the cytochrome P450 3A4 enzyme system and is eliminated in urine and feces.

In 2010, an article reviewing opioid agonist medications found six studies that looked at the relationship between subjective heroin craving and treatment with buprenorphine. While none of the studies used cue-elicited paradigms or neuroimaging, four studies found clinically significant reductions in subjective heroin craving. The remaining two studies found that low doses of buprenorphine (8 mg or less) may not be effective in craving reduction. However, these studies also found that higher doses of buprenorphine (greater than 8 mg) had a significant impact on craving reduction. This suggests that buprenorphine is effective in reducing opioid cravings at doses greater than 8 mg.

There is an excellent evidence supporting the efficacy of buprenorphine or the combination of buprenorphine and naloxone for the treatment of opioid withdrawal. Furthermore, opioid maintenance with buprenorphine is a safe and effective treatment for opioid dependence leading to rapid adoption of sublingual buprenorphine and naloxone or sublingual buprenorphine alone for the treatment of opioid dependence in real world clinical practice.

Naltrexone

Naltrexone is an opioid antagonist approved by the FDA in 1984 for the treatment of individuals with opioid addiction. It is available in oral form or as a long depot

injection and has a relatively lengthy duration of action. It has been found effective in treating specific groups of highly motivated individuals such as nurses, physicians, and prisoners in release programs, but this was believed to be independent of anti-craving effects. Traditionally, there has been little data to support the use of naltrexone in directly curbing opioid cravings. It may be due to the advantage of naltrexone over placebo stems from its use as a form of "behavioral pharmacotherapy" within an opioid abstinence program.

Recently, data for impact of naltrexone on opioid cravings have been mixed. Two studies using visual analog scales to rate subjective cravings found that naltrexone at 50 mg day⁻¹ did not reduce heroin craving. In contrast, Krupitsky et al. presented results in 2010 from a multicenter randomized double-blind placebo-controlled trial that looked at the effect of an extended-release naltrexone preparation compared to placebo in patients receiving biweekly drug counseling sessions. While it was not the primary outcome, the authors reported significant declines in subjective reporting of opioid cravings. Another study found that a very low dose of naltrexone (0.125 or 0.250 mg day⁻¹) administered during opioid withdrawal was effective in reducing subjective craving scores by 37% across days 1 through 6. Given the mixed results, further studies are needed to clarify the role of naltrexone in treating opioid cravings.

Emerging Therapies

Several other medications have been proposed for targeting craving among opioid-dependent individuals. While there is some preliminary data to support these medications, the research is still in its early phases and more data are required before they should be considered in the clinical treatment of opioid dependence.

Lofexidine is a centrally acting α -2 receptor agonist that reduces opioids cravings. The effect of lofexidine has been observed using a small (RCT) with a dosage of 2.4 mg twice daily in opioid-dependent individuals. It has been found that this agonist receptor, lofexidine, stabilized on combination with naltrexone for 4 weeks before being randomized to naltrexone plus lofexidine or naltrexone plus placebo. While the study only contained 18 individuals, it found an attenuated stress and drug cue-induced opioid craving response in the laboratory in patients who continued with lofexidine.

Given dopamine's role in the neurobiology of cravings, dopamine antagonists have been proposed as potential medications to target craving in opioid-dependent individuals. However, a study that included 17 detoxified heroin-dependent patients found that 2 mg of haloperidol daily had no effect on subjective craving.

In animals, rapamycin has been shown to inhibit the mTOR (serine-threonine kinase enzyme that controls cell growth) pathway. It has been postulated that inhibition of this pathway may interfere with synaptic plasticity and thus the memory formation and conditioning associated with heroin cue craving in addicts. Shi et al. (2009) found that a single-high dose of 5 mg rapamycin was effective in reducing the craving but not anxiety associated with drug-induced cues.

Memantine is a noncompetitive NMDA receptor antagonist used primarily in the treatment of Alzheimer's disease. In rodents, it has been shown to interfere with morphine-conditioned place preference. Studies in humans have demonstrated a slight decrease in cravings without impacting the reinforcing effects of heroin. These results were found using memantine at doses of 30 and 60 mg.

MEDICATIONS FOR STIMULANT CRAVINGS

- Modafinil
- *N*-acetylcysteine
- Stimulant Agonists
- Mecamylamine

While both cocaine and methamphetamine act by directly stimulating the ventral tegmental/nucleus accumbens reward pathway, they accomplish this in slightly different ways. Cocaine inhibits dopamine reuptake transporters resulting in increased synaptic dopamine levels. Similarly, methamphetamine inhibits dopamine reuptake but also acts on presynaptic neurons causing an increased release of dopamine. Stimulants have also been shown to impact norepinephrine, serotonin, glutamate, and GABA concentrations in the brain. While there are currently no medications with FDA approval for the management of stimulant-use disorders or cravings, trials continue to be performed on many promising agents.

Modafinil

One of the more promising medications for targeting cocaine cravings is modafinil, which has several mechanisms of action that overlap with the neurobiology of stimulant addiction. The mild stimulant properties may aid in reducing withdrawal symptoms while increased extracellular glutamate levels may serve to partially counteract glutamate depletion associated with chronic stimulant use. Additionally, modafinil decreases GABA activity and binds dopamine and norepinephrine receptors. Finally, there is some data suggesting that modafinil blocks the euphoric effects

of cocaine. Malcolm et al. conducted a small open label trial that found cravings for cocaine were significantly reduced in individuals treated with modafinil at 400 and 800 mg. Several other studies conducted in laboratory settings have also demonstrated decreased cocaine self-administration when modafinil was administered at 200 and 400 mg day⁻¹. Despite preliminary optimism, the results of initial outpatient RCTs have been mixed. A double-blind placebo-controlled trial conducted by Dackis et al. randomized participants to a single morning dose of modafinil 400 mg or matched placebo. They found a reduced percentage of cocaine positive urine drug screens but no improvement in craving, treatment retention or withdrawal.

The results are equally mixed for utilizing modafinil in the treatment of methamphetamine users. One RCT of methamphetamine-dependent HIV positive gay men found that 60% of the participants who finished the trial reduced their methamphetamine use by over 50%. Impact on cravings was not statistically significant. Conversely, another RCT looking at modafinil in methamphetamine users found no benefits over placebo among a number of measures including cravings. Given the mixed results, further RCTs are needed to evaluate the potential role of modafinil in stimulant misuse.

N-acetylcysteine

N-acetylcysteine (NAC) is a medication with preclinical trials and several pilot studies support its use in the treatment of cocaine users. NAC is believed to exert its effect by increasing extracellular glutamate by stimulating cysteine-glutamate antiporters. A double-blind crossover pilot study conducted on 15 participants looked at response to NAC 600 mg administered every 12 h or placebo during two identical 3-day hospital stays. The medication was well tolerated and resulted in a significant decrease in self-reported desire to use, decreased interest in response to cocaine slides and decreased time spent watching cocaine slides. While the results were relatively modest, they warrant further exploration with larger RCTs.

Stimulant Agonists

Several stimulant agonists have also been studied for the treatment of cravings. While some trials have shown reduced cocaine and stimulant use in individuals treated with methylphenidate or dextroamphetamine, the vast majority of these studies have either not reported impact on cravings or found no significant improvement compared to placebo. The added abuse potential associated with using agonist-like agents limits their clinical utility in the management of stimulant cravings (Table 56.1).

 TABLE 56.1
 Medications With Efficacy in Treatment of Cravings

	Medication	Mechanism of action	Typical adult dosage	Before prescribing	Side effects	Contraindications	Precautions	Evidence level*
alcohol	Disulfiram	Inhibits aldehyde dehydrogenase and dopamine-β- hydroxylase	250 mg daily (range of 125–500 mg)	Evaluate liver function and warn patient to avoid alcohol in the diet, over-the-counter medications and toiletries	Common: sedation, dermatitis, metallic aftertaste. Serious: hepatotoxicity, optic neuritis, peripheral neuropathy, and psychosis	Absolute: use of alcohol-containing products or metronidazole. Relative: CAD, severe myocardial disease	Hepatic cirrhosis or insufficiency, cerebrovascular disease, psychoses, diabetes mellitus, epilepsy, hypothyroidism, and renal impairment. Pregnancy category C	Level C
	Naltrexone	Blocks opioid receptors	Start at 25 mg daily and increase to 50 mg daily after 4 days	Must be opioid-free for at least 7 days prior to initiating therapy. Consider naloxone challenge. Evaluate liver function	Common: nausea, decreased appetite, fatigue, and dizziness. Serious: precipitation of severe opioid withdrawal, hepatotoxicity	Ongoing opioid use, acute hepatitis or liver failure	Severe liver disease, renal impairment, depression. Pregnancy category C	Level A
	Injectable naltrexone	See above	380 mg injected once monthly	See above	See above. Also injection site reaction or infection, muscle and joint pain	See above. Also inadequate muscle mass	See above. Also bleeding problems	Level A
	Acamprosate	Unclear — affects glutamate and GABA neurotransmitter systems	666 mg three times per day. Reduce to 333 mg three times per day in patients with moderate renal impairment	Evaluate renal function	Common: Diarrhea, sedation. Serious: suicidal ideation	Severe renal impairment	Moderate renal impairment, depression. Pregnancy category C	Level C

(Continued)

 TABLE 56.1
 Medications With Efficacy in Treatment of Cravings—cont'd

	Medication	Mechanism of action	Typical adult dosage	Before prescribing	Side effects	Contraindications	Precautions	Evidence level*
Nicotine	Transdermal nicotine	Direct nicotinic- receptor agonist	Greater than 10 cigarettes per day: start 21 mg day ⁻¹ . Less than 10 cigarettes per day start 14 mg day ⁻¹ . Maintain at starting dose for 6 weeks and then titrate down, holding at each subsequent dose for 2 weeks	Evaluate for unstable angina or previous adverse reactions	Common: skin irritation, headache, heart palpitations, nausea, and insomnia	Severe arrhythmias, MI within 2 weeks, severe angina	Pregnancy category D	Level A
	Nicotine gum	Direct nicotinic- receptor agonist	Greater than 25 cigarettes per day: start 4 mg every 1–2 h. Less than 25 cigarettes per day: start 2 mg every 1–2 h. Maintain at initial dose for 6 weeks then taper down by increasing time between administration	Evaluate for unstable angina or previous adverse reactions	Common: headache, diarrhea, and nausea	Severe arrhythmias, MI within 2 weeks, severe angina	Pregnancy category unknown	Level A
	Nicotine lozenge	Direct nicotinic-receptor agonist	Greater than 25 cigarettes per day: start 4 mg every 1–2 h. Less than 25 cigarettes per day: start 2 mg every 1–2 h. Maintain at initial dose for 6 weeks then taper down by increasing time between administrations	Evaluate for unstable angina or previous adverse reactions	Common: headache, diarrhea, and nausea	Severe arrhythmias, MI within 2 weeks, severe angina	Pregnancy category unknown	Level A

Nicotine nasal spray	Direct nicotinic- receptor agonist	1–2 sprays per nostril every hour. Each spray delivers nicotine 0.5 mg. Maximum 80 sprays (40 mg day ⁻¹)	Evaluate for unstable angina or previous adverse reactions	Common: nasal irritation, rhinorrhea, headache, diarrhea, and nausea. Serious: bronchospasm	Severe arrhythmias, MI within 2 weeks, severe angina	Pregnancy category D	Level A
Nicotine inhaler	Direct nicotinic- receptor agonist	6—16 cartridges per day. Titrate to effect. Each cartridge designed to deliver nicotine 4 mg	Evaluate for unstable angina or previous adverse reactions	Common: cough, mouth/throat irritation, headache, diarrhea, and nausea. Serious: bronchospasm	Severe arrhythmias, MI within 2 weeks, severe angina	Pregnancy category D	Level A
Varenicline	Mixed agonist/ antagonist at α4β2 nicotinic acetylcholine receptors	Start 0.5 mg daily for 3 days then increase to 0.5 mg BID for 4 days then increase to 1 mg BID. If CrCl < 30, maximum dose is 0.5 mg BID. Treat for 12 weeks. May repeat treatment for an additional 12 weeks if unsuccessful.	Evaluate kidney function and psychiatric history	Common: nausea, vomiting, insomnia, headache, and vivid dreams. Serious: depression, agitation, suicidality, and Stevens—Johnson syndrome	None	History of psychiatric disorder, renal impairment. Pregnancy category C	Level A
Bupropion	Mechanism of action in smoking cessation unknown. Inhibits reuptake of norepinephrine and dopamine	Start 150 mg daily for 3 days then increase to 150 mg BID. Initiate 7 days prior to smoking cessation	Evaluate for MAOI use within 14 days, seizure disorder, bulimia or anorexia	Common: dry mouth, headache, nausea, anxiety, and insomnia. Serious: worsening depression, suicidality, psychiatric disturbance, and seizures	Seizure disorder, MAOI use within 14 days, anorexia, bulimia	Lowered seizure threshold, psychiatric disorders. Pregnancy category C	Level C
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MEDICATIONS FOR STIMULANT CRAVINGS

	Medication	Mechanism of action	Typical adult dosage	Before prescribing	Side effects	Contraindications	Precautions	Evidence level*
Opioid	Methadone	Full μ opioid- receptor agonist and NMDA antagonist	Schedule II controlled drug: prescriber must obtain separate registration as a narcotic treatment program. Initial dose not to exceed 30–40 mg. Titrate gradually against withdrawal symptoms. See local protocols for further guidance	Obtain baseline ECG, evaluate liver and kidney function	Common: sedation, constipation, nausea, and sweating. Serious: respiratory depression, QT prolongation, and cardiac arrhythmias	None	Reduce dose for hepatic or renal impairment. Caution in QT prolongation, pulmonary dysfunction or use of other narcotics. Pregnancy category C	Level A
	Buprenorphine	Partial agonist at the μ opioid-receptor and an antagonist at the k receptor	Schedule III controlled drug: prescriber must meet qualification criteria and have a specific DEA number: 4–16 mg day ⁻¹ orally – see local protocols for further guidance	Make sure patient has not taken short-acting opiates for 12–24 h and methadone for greater than 48 h to avoid precipitating withdrawal	Common: sedation, constipation, nausea, sweating, and opioid withdrawal. Serious: respiratory depression, hepatotoxicity, and angioneurotic edema	None	Avoid abrupt cessation, caution with pulmonary problems or other narcotics. Pregnancy category C	Level A
	Naltrexone	Blocks opioid receptors	Start at 25 mg daily and increase to 50 mg daily after 4 days. Some evidence suggests low dose (0.125–0.250 mg day ⁻¹) is effective during withdrawal period	Must be opioid-free for at least 7 days prior to initiating therapy. Consider naloxone challenge. Evaluate liver function	Common: nausea, decreased appetite, fatigue, dizziness. Serious: precipitation of severe opioid withdrawal, hepatotoxicity	Ongoing opioid use, acute hepatitis or liver failure	Severe liver disease, renal impairment, depression. Pregnancy category C	Level B
	Injectable naltrexone	See above	380 mg injected once monthly	See above	See above. Also injection site reaction or infection, muscle and joint pain	See above. Also inadequate muscle mass	See above. Also Bleeding problems	Level B

^{*} Evidence Level A: Systematic reviews (SRs) or large (n > 200) randomized controlled trials (RCTs); Evidence. Level B: Small (n < 200) randomized controlled trials (RCTs) or large (n > 200) RCTs with major methological limitations; Evidence. Level C: Observational (cohort) studies, open label trials, case reports or small (n < 200) RCTs with major methodological limitations.

Note: cannabis and stimulants were not included, as data on treatment of cravings remains unclear.

Mecamylamine

Laboratory studies that demonstrated nicotine increases cue-induced cravings prompted exploration of mecamylamine, a nicotine antagonist, for the treatment of cocaine cravings. However, results of RCTs have been mixed and nicotine agonists are not currently used in the clinical management of cocaine cravings.

Emerging Therapies

Perhaps reflecting the paucity of effective pharmacologic treatments available for the treatment of stimulant-use disorders, a number of additional agents have been found to have limited or mixed benefit in treatment outcomes. At this time, none have demonstrated significant effect on cravings for stimulants.

MEDICATIONS FOR NICOTINE CRAVING

- Nicotine replacement therapy
- Combination therapy
- Varenicline
- Buproprion
- Alternative therapies

For those attempting to abstain from nicotine, relief from craving is among the most common reasons for seeking treatment from a health professional. Success in quitting can be predicted by the average intensity of cravings within the first days or weeks of abstinence. Additionally, intense acute cravings have been linked to an increased likelihood of relapse. Given the association between nicotine cravings and the odds of a successful quit attempt, pharmacologic interventions aimed at reducing cravings have received special attention in the treatment of nicotine dependence.

Nicotine Replacement Therapy

There are many forms of nicotine replacement therapy (NRT) including patches, gum, lozenges, nasal spray, and oral inhalers. These modalities have been shown to be effective and increase quit rates by 50–70% regardless of setting. While all forms of NRT work as direct nicotine agonists, different delivery systems result in variable pharmacokinetics and effects on cravings.

Transdermal nicotine patches supply a basal rate of nicotine release. They are available at doses of 7, 14, and 21 mg day⁻¹. The general recommendation is to initiate therapy with 14 mg day⁻¹ if patients are smoking less than 10 cigarettes per day and 21 mg day⁻¹

if patients are smoking 10 or more cigarettes per day. Patients are maintained on their starting dose for 6 weeks before being tapered down to each lower dose where they are maintained for 2 weeks. The most common side effects include nausea, heart palpitations, headaches, and local site irritation. While this strategy has been shown to reduce background craving, it has little effect on cue-induced craving.

The other forms of NRT result in acute peaks in serum nicotine that more closely mimic the effects of smoking. These modalities have been shown to reduce cue-induced craving and, to a lesser extent, background craving. Furthermore, the speed at which the nicotine is delivered correlates with the time to craving relief.

Combination Therapy

Combining NRTs to target background and cueinduced craving has also been studied. Combining NRTs is generally well tolerated and results in a clinically significant decrease in relapse. Schneider et al. compared four combinations of nicotine treatments: 2/4 mg gum + 15 mg patch, 2/4 mg lozenges + 15 mgpatch, inhaler + 15 mg patch, and 10 + 15 mg double patch. They used the Smoker Anchored Withdrawal Grid to monitor craving and withdrawal over a 5-day period. This study in 2008 found that "urge to smoke" and "total withdrawal" scores increased from baseline in the double patch group but not in the combination groups. They also found that scores for "craving" and "miss a cigarette" did not rise in the lozenge/patch group but did in the other groups. While these results are suggestive of the efficacy of combination therapy, this study looked at short-term results and only included 27 participants. In 2008, Shah et al. conducted a large systematic review comparing therapy with patch alone to combined NRTs. They found the aggregated relative risks of abstinence using combination therapy were 1.42 (95% CI 1.21–1.67), 1.54 (1.19–2.00), and 1.58 (1.25–1.99) at 3, 6, and 12 months, respectively. The reported adverse effects were minimal. Doses varied among studies but this data supports the use of NRTs in combination.

Varenicline

Varenicline (Chantix in USA, Champix in Canada) is an orally administered agent that acts as a mixed agonist/antagonist at $\alpha 4\beta 2$ nicotinic acetylcholine receptors (nAChRs). Nicotine abstinence reduces dopamine release in the mesolimbic area of the brain resulting in withdrawal symptoms and cravings. Varenicline acts to stimulate dopamine release while simultaneously blocking nicotine receptors and has been shown to be significantly more efficacious than placebo for smoking

cessation. Gonzales et al. in 2006 conducted a double-blinded randomized control trial and found that a 26.3% greater chance of continuous abstinence from smoking after 9 weeks of treatment with varenicline at 1 mg twice per day versus placebo. As a secondary outcome, the study also found reductions in background cravings as well as withdrawal symptoms. This finding has been replicated in other studies; however, varenicline has not been shown to be effective in modulation of cue-induced cravings.

Of note, varenicline has a black box warning to monitor for serious neuropsychiatric events, such as behavior change, agitation, depression, and suicidality as well as worsening of preexisting psychiatric illness. The FDA announced in June 2011 that the use of varenicline might be associated with a small, increased risk of certain cardio-vascular adverse events in patients who have cardiovascular disease. Further analyses need to be conducted to understand the full implications of this warning.

Bupropion

Several large clinical trials have demonstrated that bupropion is an effective treatment that improves the chances of successful quit attempts. Despite its efficacy in the treatment of nicotine dependence, its mechanism of action in smoking cessation remains unclear. There is some data suggesting that 300 mg day⁻¹ of bupropion might help to reduce nicotine craving and withdrawal. PET imaging has also demonstrated less metabolic activity in the anterior cingulate cortex of patients treated with bupropion relative to those who were not. However, among placebo-controlled trials, which account for the effect of abstinence, the preponderance of evidence suggests that bupropion does not impact nicotine cravings. Alternative explanations for the effectiveness of bupropion include treatment of depressed mood, irritability, difficulty in concentrating, and increased appetite.

Alternative Medications

Although not considered to be a first line agent, there is data supporting the use of clonidine in the treatment of nicotine dependence. Clonidine is believed to indirectly reduce cravings through the attenuation of withdrawal symptoms. However, its effects are doserelated and only achieve statistical significance when at least 300 mg day⁻¹ is administered. The side effects at this dose preclude common usage.

Nortriptyline also has a role in the treatment of nicotine dependence. While the exact mechanism of action for the effectiveness of nortriptyline is unknown, it does not appear to alter cravings.

MEDICATIONS FOR CANNABIS CRAVING

- Dronabinol
- Buspirone
- Divalproex
- Emerging Therapies

Marijuana (Cannabis sativa) is a plant whose psychoactive properties have led to widespread use throughout the world. Although it contains approximately 70 cannabinoid compounds, D⁹-tetrahydrocannabinol (D⁹-THC) acting on presynaptic cannabinoid receptors (CB₁), is thought to produce the mood alterations, feelings of euphoria and cognitive impairments associated with marijuana use. While not traditionally believed to be a substance resulting in true addiction, recent consensus has shifted. It is now known to activate the mesocorticolimbic system, a property common among all drugs of abuse. In addition, there is a well-described withdrawal syndrome associated with cessation of cannabis use. Cue-induced craving for cannabis has been studied using fMRI. This has demonstrated activation of the ventral tegmental area, thalamus, anterior cingulate, insula, and amygdala, which are the areas shown to play a central role in the neurobiology for cravings of other drugs of abuse. Despite its recent acceptance as a more traditional drug of abuse, there are currently no FDA-approved medications for the treatment of cannabis-use disorders.

Dronabinol

Dronabinol, oral D9-THC, acts as a direct cannabinoid receptor agonist. In human laboratory settings, doses of 60 mg day⁻¹ have been shown to modestly decrease cravings for marijuana while simultaneously easing symptoms of withdrawal. It was found to be particularly effective when combined with lofexidine, an α (2)-adrenergic receptor agonist. Lofexidine was administered at a dosage of 2.4 mg day⁻¹. While the combination was found to reduce cravings, this was a short-term study with marijuana withdrawal and relapse as the primary outcomes. Follow-up studies confirmed the effectiveness of dronabinol in outpatient settings among nontreatment-seeking individuals. However, the impact on cravings was not assessed. While these results are promising, further research is needed before dronabinol should be routinely used in the clinical management of cannabis-use disorders.

Buspirone

There is an early evidence to support the use of the anxiolytic agent buspirone in the treatment of marijuana

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cravings. A 2006 open-label trial explored buspirone at flexible doses up to 60 mg day⁻¹ in 11 participants. While the study is limited by sample size and the open label design, there was a statistically significant reduction in frequency and duration of craving. There was also a 76.9% reduction in use reported by participants per the Time-Line Follow-Back method. A placebo-controlled trial of buspirone in individuals with cannabis dependence is needed before routine use is warranted.

Divalproex

Divalproex, an anticonvulsant and mood stabilizer showed preliminary promise in reducing cravings during abstinence among cannabis-dependent individuals. A study by Haney et al. (2004) looking at the effect of THC and divalproex on cannabis withdrawal found divalproex at a dosage of 1500 mg day⁻¹ reduced subjective cravings for marijuana. However, it also increased subjective reports of anxiety, irritability, and fatigue. Another blinded study using divalproex during abstinence found no significant difference from placebo. Based on these results, the use of divalproex for treatment of marijuana cravings is not indicated.

Emerging Therapies

While pharmacologic treatments for cannabis dependence are not as extensive as other substances of abuse, an increased understanding of the endocannabinoid system in the brain and recognition of the addictive nature of marijuana has resulted in a burgeoning area of research. Current preclinical studies have identified several compounds that warrant further study including the benzoflavone moiety from menthol extracts of passiflora incarnate Linnaeus, nicotinic $\alpha 7$ receptor antagonists and inhibitors of endocannabinoid-metabolizing enzymes. Any potential clinical use of these agents remains years away.

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JCL declares that he has no competing interests. DMB declares that he has no competing interests.

SEE ALSO

Evidence-Based Treatment, Improving Medication Use in Addictions Treatment, Cue Exposure Treatments for Substance Use Disorders, Behavioral Treatments for Smoking, Methadone Maintenance, Antagonists for the Treatment of Opioid Dependence, Buprenorphine for Opioid Dependence, Medications to Treat Addictions: Nicotine Replacement, Non-nicotine Medications, Pharmacotherapy of Cocaine Dependence, Agonist-Like (Substitution) Treatment for Cocaine and Other Stimulant Dependence, Alcohol Detoxification, Naltrexone and Opioid Antagonists for Alcohol Dependence, Acamprosate for Alcohol Dependence, Disulfiram for Alcohol and Other Drug Use, Anticonvulsant Medications for the Treatment of Alcohol Dependence, Medication Development for Amphetamine Dependence, Medications for Treatment of Marijuana Dependence

List of Abbreviations

ALDH-2 aldehyde dehydrogenase 2

AMPA a-amino-3-hydroxy-5-methylisoxazole-4-propionic acid

CBF cerebral blood flow

CRF corticotropin-releasing factor

COMBINE Combining Medications and Behavioral Interventions for

Alcoholism

D⁹-THC D⁹-tetrahydrocannabinol FDA Food and Drug Administration

fMRI functional magnetic resonance imaging GABA gamma-aminobutyric acid

NMDA N-methyl-D-aspartate
NAC N-acetylcysteine
NNT number needed to treat
NRT nicotine replacement therapy
PET positron emission tomography
RCTs randomized controlled trials

5-HT₃ serotonin-3

Glossary

Acamprosate *N*-methyl-D-aspartate (NMDA) glutamate receptor site antagonist used in the treatment of alcohol-use disorders.

Buprenorphine medication that acts as a partial agonist at the muopioid receptor and an antagonist at the k receptor used in the treatment of opioid-use disorders.

Bupropion antidepressant with efficacy in the treatment of nicotine dependence.

Buspirone serotonin 5-HT_{1A} receptor partial agonist.

Craving the desire for previously experienced effects of a psychoactive substance.

Disulfiram medication that inhibits aldehyde dehydrogenase leading to an aversive reaction to alcohol.

Dronabinol a direct cannabinoid receptor agonist.

Kudzu Chinese herbal root with an emerging efficacy in the treatment of alcohol-use disorders.

Lofexidine α2-adrenergic receptor agonist.

Mecamylamine nicotine receptor antagonist.

Memantine a noncompetitive NMDA receptor antagonist.

Methadone direct opioid agonist used in the treatment of opioid dependence.

*N***-acetylcysteine (NAC)** medication believed to increase extracellular glutamate by stimulating cysteine-glutamate antiporters.

Naltrexone competitive-opioid receptor antagonist used in the treatment of alcohol- and opioid-use disorders

Ondansetron serotonin-3 (5-HT₃) antagonist with some efficacy in the treatment of alcohol-use disorders.

Rapamycin medication that inhibits mTOR, a serine–threonine kinase enzyme involved in regulation of cell growth.

Topiramate anticonvulsant used in the treatment of alcohol-use disorders.

Type 1 craving a craving induced by stimuli paired with drug administration.

Type 2 craving dysphoria and anxiety following protracted abstinence.

Varenicline mixed agonist/antagonist at $\alpha 4\beta 2$ nicotinic acetylcholine receptors (nAChRs).

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http://www.nida.nih.gov/nidahome.html - National Institute on Drug Abuse.

http://www.kap.samhsa.gov/products/manuals/tips/numerical.htm
 Substance Abuse and Mental Health Services Administration
 Manual for Treatment Improvement Protocol.

http://www.samhsa.gov/ - Substance Abuse and Mental Health Services Administration.

Vaccines for Addictive Disorders

Muthu Ramakrishnan*,\$, Berma M. Kinsey*,\$, Thomas R. Kosten*,\$, Frank M. Orson*,\$

*Veterans Affairs Medical Center, Houston, TX, USA \$Baylor College of Medicine, Houston, TX, USA

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INTRODUCTION

Every individual is composed of unique biological and physiological characteristics, which govern the individual's drive to eat and drink and do other things for stimulation or pleasure. The use of opium, wine and beer, coca leaves, and tobacco has been well documented in human history. In the case of morphine and cocaine, the active drug substances were extracted from plants in 1803 and 1855 respectively, and subsequently prescribed as a temporary relief for acute pain and local anesthesia. As time passed, these drugs began to be used illegally for nonmedicinal recreational purposes.

Generally, drugs of abuse can be delivered by various routes such as smoking, nasal or oral ingestion, or intravenous injection. From the peripheral blood circulation, a drug is distributed to various organs of the body and is metabolized with a specific plasma half-life (e.g. about 60–90 min for cocaine, see Table 57.1). During this period a portion of the drug also rapidly crosses the blood–brain barrier (BBB) and enters the central nervous system (CNS). Since drugs

of abuse are small lipophilic molecules (with a molecular weight <500 Da) that may have a chemical structure similar to that of neurotransmitters (such as dopamine), they bind and activate various receptors. This leads to overstimulation of neural circuits, resulting in strong signals to the brain's reward pathways that give a relaxed sensation of pleasure or escape from reality, driving some individuals to more frequent drug intake and addiction to the drug of abuse. Such substance abuse eventually boomerangs as the addict starts to suffer from the escalating socioeconomic and health problems caused by the abuse. (For any further details concerning the addiction of these drugs please refer to Heroin Addiction, Cocaine Addiction, and Methamphetamine Addiction.)

Current medications, such as methadone for heroin addiction, as well as addiction treatment programs are widely available in developed countries, but they are often not sufficiently effective in reducing drug intake, even for the motivated patient who is dependent on a drug. (Further details can be referred in Methadone Maintenance, Antagonists for the Treatment of Opioid

TABLE 57.1 Summary of Chemical Structures of Common Substance Abuse

	Cocaine	Nicotine	Methamphetamine	Morphine
Structure	H ₃ C CH ₃	H CH ₃	H-CH ₃	HO N-CH ₃
Molecular weight	333	162	149	303
Bioavailability	33% oral, 60–80% smoking	20-40% Oral	63% Oral, 100% iv	25% Oral, 100% iv
Half-life (h)	1	2	9-15	2–3
Metabolism	Hepatic	Hepatic	Hepatic	Hepatic 90%
Excretion	Renal	Renal	Renal	Renal 90%, biliary 10%
Active metabolites	-	_	Amphetamine, 4-hydroxyamphetamine	Morphine-6-glucoronide
Inactive metabolites	Ecgonine, benzoylecgonine	Cotinine	_	Morphine-3-glucoronide
Binding receptor	Dopamine transporter	Acetylcholine	NMDA	Opioid
Clinical status of vaccines	Phase I, Phase IIa, Phase IIb completed	Phase I, Phase II, Phase IIb	Preclinical	Preclinical

Dependence, Buprenorphine for Opioid Dependence, Medications to Treat Addictions: Nicotine Replacement, Non-nicotine Medications, Pharmacotherapy Cocaine Dependence, Agonist-Like (Substitution) Treatment for Cocaine and Other Stimulant Dependence, Medication Development for Amphetamine Dependence) In addition, the pharmacological antagonists used against drugs of abuse may enter the CNS and create unwanted side effects. Recent vaccine strategies for specific drugs can produce either active antibodies directly in humans or monoclonal antibodies through cell cultures, which are then passively administered to humans. These specific antibodies in the peripheral circulation can sequester an abused drug in the bloodstream and reduce its entry to the brain. Antibodies are large molecules that cannot cross the BBB unless there is inflammation or the presence of a specific binding receptor at the BBB to deliver the antibody by receptor-mediated transcytosis. Therefore, immunotherapy has been proposed as a safe and viable approach for treating addictive disorders. Though passive administration of humanized or chimeric monoclonal antibodies against such drugs could be used, patients would need frequent injections to maintain a sufficiently high concentration of antibodies in the peripheral circulation to sequester the drug. In

addition, this treatment strategy would involve some risk of developing an immune response to the administered antibody, as well as being cost-prohibitive for delivery of monoclonal antibodies at sufficiently high concentrations. Improved vaccination therapy has the potential to be a promising and cheaper alternative to address many of the treatment problems for drug addicts.

VACCINE CONSTRUCTION

An initial and repeated systemic exposure to foreign antigens will usually result in the adaptive immune system detecting and clearing them away. However, addictive drugs are too small to provoke any immune response. The goal of antidrug vaccines is to stimulate the immune system to produce antibodies that recognize only the specific drug or selected metabolites and to create enough high-affinity circulating antibodies to bind and thereby prevent drug entry into the brain. The optimal development of a vaccine construct involves the covalent linkage of a representative drug of abuse (the hapten) through a spacer (linker) arm to a suitable high molecular weight immunogenic carrier molecule (see Fig. 57.1). Generally, nonhuman proteins

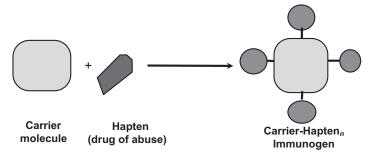


FIGURE 57.1 Preparation of immunogens by covalently coupling a hapten with an immunogenic carrier molecule.

such as bovine serum albumin (BSA), ovalbumin, or Keyhole Limpet Hemocyanin (KLH) have been initially used as immunogenic carrier proteins in small animals. For human vaccines, proteins such as cholera toxin B and tetanus toxoid, which are approved by the FDA, have been used.

There are many linkers available, but drugs of abuse are generally small with few functional groups (see Table 57.1), thereby limiting the options. Ideally, the attachment of a linker to a hapten should allow retention of the stereochemical and electrostatic properties of the drug molecule. When a successful haptenprotein construct is made, the immunogen is injected after being mixed with an adjuvant such as alum. It is expected that the covalently linked drug will be taken up by antigen presenting cells for display to B cells and T-helper cells, so as to activate the humoral response and produce high levels of specific antidrug antibody.

ANTIBODY THEORY AND **EXPECTATIONS**

When a conjugate vaccine elicits an immune response, the immune system produces polyclonal antibodies against the hapten molecules. Antibodies will also be elicited against epitopes from the carrier protein, and sometimes against the linker, which will not contribute to the antidrug effects of the vaccine. Immunoglobulins (Ig) M and G are the two common antibody isotypes produced during the typical systemic polyclonal response. Initially, the immune system produces large 900 kDa pentameric IgM molecules with 10 antigen-binding sites, but subsequently, IgG antibodies dominate the response. The 150 kDa IgG protein is a Y-shaped molecule having two light and two heavy chain components giving two antigen-binding sites on the two arms of the Y structure. To understand the quantitative and qualitative properties of antibodies against haptens, a simple 1:1 binding equation can be written as shown below, treating the human body as one closed

compartment where [Ab]_{free} and [D]_{free} correspond to the concentration of the specific antibody-binding sites and the concentration of abused drug present in the serum (excluding the distribution to various organs for simplicity). Both entities have their own input and elimination half-life.

$$[Ab]_{free} + [D]_{free} = \frac{k_a}{k_d} [Ab - D]_{bound}$$
 Eq. 1

A differential equation can be written for the association and dissociation of the complex [Ab-D]_{bound} where k_a and k_d are the association and dissociation rate constants, respectively.

$$\frac{d[Ab - D]_{bound}}{dt} = k_a[Ab]_{free} \times [D]_{free}$$
 Eq. 2

$$\frac{d[Ab - D]_{bound}}{dt} = k_a[Ab]_{free} \times [D]_{free}$$
 Eq. 2
$$\frac{d[Ab - D]_{bound}}{dt} = k_d[Ab - D]_{bound}$$
 Eq. 3

Affinity :
$$K_D = \frac{k_d}{k_a}$$

To block the pharmacological effects of the drug, the vaccine needs to stimulate the production of drug-specific antibodies at a higher concentration [Ab]_{free} than the drug-intake antibodies [D]_{free}. The drug plasma concentrations ([D]_{free}) vary based on the dose amount, dose frequency, route of administration, and pharmacokinetic elimination profile. Most abused drugs show pharmacological activities in the range of 0.5 µM plasma concentration, which is equivalent to 0.25 µM of specific IgG antibody (two binding sites per molecule that interact independently with a small molecular weight drug), or \sim 37.5 µg ml⁻¹ of IgG. This is substantially higher than the amount of antibody elicited by ordinary vaccines against various microbiological pathogens and toxins such as influenza and tetanus. For example, only ~1-2 μg ml⁻¹ of specific antibody is sufficient to prevent

Besides large quantities of specific antibody, a fast rate of complex formation (k_a) is required to capture the drug in peripheral blood circulation before it can enter into the brain. The often misunderstood dissociation constant (K_D) is an equilibrium, time independent dissociation constant equaling the ratio of the rate constants expressed as k_d/k_a [M], and higher antibody affinity means lower values ranging from 10⁻⁶ to 10^{-12} M. Since the dissociation constant (K_D) is indirectly proportional to k_a , it is expected that an optimal antibody has a strong ability to bind to the drug rapidly (high k_a), and to hold the drug firmly for a long time (low k_d). With the understanding of these qualitative properties of antibodies coupled with the quantitative information from a variety of species, such as [Ab]_{free}, [D]_{free}, [Ab–D]_{bound} that can occur when the drug enters a body, it is possible to derive a mathematical model to determine the antibody response goal for vaccines to treat drug abuse. Though such thorough studies with polyclonal antibodies have not yet been performed to our knowledge, we have performed some simulations to understand how much antibody needs to be produced to achieve different levels of drug binding. Based on this about 20–40 μg ml⁻¹ high affinity antibody is required to bind 50–90% of 0.5 μM drug.

The rationale of developing vaccines for abused drugs has been understood for a long time, but only recently has the field made some significant progress toward transferring the use of this concept from the bench to the patients. The rest of this article will focus on reviewing the vaccine development and clinical status of some of the common drugs of abuse such as morphine, methamptamine, cocaine, and nicotine.

For more details regarding the neuropharmacology of drug abuse, please refer Neuropharmacology of Cocaine and Amphetamine, Neurobiology of Methamphetamine, Neuropharmacology of Cannabinoids, Neuropharmacology of Benzodiazepines, Neuropharmacology of Ecstasy (MDMA) and Other Designer Drugs, Neuropharmacology of Lysergic Acid Diethylamide (LSD) and Other Hallucinogens, Neuropharmacology of Inhalants.

MORPHINE AND HEROIN

Morphine is a narcotic alkaloid drug isolated from the opium poppy, which led morphine and similar drugs to be known as opioids. Traditionally, morphine has been widely used as an analgesic to relieve acute pain and induce deep sleep, but its overconsumption can lead to addiction. Morphine can be synthetically diacetylated to form heroin, which is a similar but more potent drug due to its rapid uptake by the CNS. Both heroin and morphine are regulated in the United States as Schedules I and II controlled substances, respectively. Heroin, being more lipophilic, is rapidly absorbed into different organs, and it has a higher permeability into the CNS than morphine. These drugs bind to several opioid receptors and alter the synaptic levels of dopamine neurotransmitters. Morphine is morphine-3-glucoronide metabolized into morphine-6-glucoronide by glucoronosyltransferase and the 6-metabolite still retains the narcotic activity of the parent morphine. The first antidrug vaccine was developed in the early 1970s against morphine. The preferred site for covalent modification of morphine turned out to be the 6-hydroxyl group. The 6-succinylmorphine conjugate vaccines produced antibodies that recognized both heroin and morphine, as heroin is rapidly hydrolyzed in circulation and in the CNS to the active 6-acetyl form as well as to morphine itself. Rabbits and one rhesus monkey were successfully vaccinated against morphine and heroin, but until recently these efforts were not taken any further, due to the successful introduction of methadone and other pharmacological antagonists for opiate addiction in developed countries. However, there has been a dramatic increase in the abuse of heroin in the Far East and Russia in recent years, with the concomitant spread of blood-borne or sexually transmitted diseases such as HIV/AIDS. This socioeconomic threat, along with the high cost of methadone and other treatment programs that are not affordable for many abusers, eventually reenergized the enthusiasm for opiate vaccine development.

Recently, Anton and Lef of the Laboratory of Molecular Neurobiology and Addictive Neurochemistry in Mexico attained high polyclonal antibody levels in rodents using 6-succinylmorphine attached to a derivative of tetanus toxoid as a carrier protein. These antibodies were able to bind both morphine and heroin at high-dose levels. Similar studies in our laboratory have demonstrated that morphine conjugate vaccines are able to elicit high levels of antibodies that inhibit the nocioceptive action of morphine as measured by hotplate and tail-flick assays in mice.

METHAMPHETAMINE

Methamphetamine is a highly addictive human-made stimulant drug that induces euphoria. A 2008 survey by The National Institute of Drug Abuse (NIDA) reports that 850 000 Americans aged 12 and above had abused methamphetamine at least once in the previous year and several law enforcement agencies in the United States of America noted that methamphetamine abuse may be their greatest drug threat. Though methamphetamine can be prescribed at very low doses, it is abused at higher doses by routes such as oral,

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snorting, or injection. The small and lipophilic nature of methamphetamine allows it to easily cross the BBB and block the monoamine transporters, thereby increasing dopamine concentration in the CNS as well as blocking dopamine reuptake from synaptic vesicles. It is primarily excreted by the kidneys unchanged, but is also metabolized to amphetamine, which is itself a powerful stimulant, and to the inactive 4-hydroxyamphetamine. In contrast to many other abused drugs, both methamphetamine and its metabolite amphetamine have long-lasting plasma half-lives of about 9–15 h. In addition, they are both optically active molecules with the dextro isomer (right handed) being biologically more potent than the *levo* one (left handed). Hence, in designing immune conjugates it is imperative to retain the correct stereochemistry to provoke the immune system to produce appropriate antibodies. Since the presence of methyl groups and chiral carbons are important for the biological properties of methamphetamine, the phenyl group of methamphetamine has been a major site for covalent modification for optimal hapten development.

Most of the work on methamphetamine has been in preclinical animal studies and currently there are no active vaccine formulations or human clinical trials in progress. Owens and colleagues at the University of Arkansas developed a vaccine by conjugating a methamphetamine hapten with a six carbon spacer group at the para position of the phenyl ring (S-(+)-4(5-carboxypentyl)methamphetamine) to KLH. The vaccine elicited methamphetamine-specific antibodies in rats and it was shown that repeated administration of methamphetamine did not affect the generation of antibodies. In subsequent studies, the same group raised monoclonal antibodies (mAbs) against methamphetamine and demonstrated that passive administration of these mAbs reduced self-administration behavior and locomotor activity in rats. Currently, this group is actively involved in developing a humanized version of their successful animal mAbs, particularly focusing on the mAbs with slow dissociation constants for passive immunization of methamphetamine abusers. Many other groups also continue to work to optimize an effective vaccine formulation, in order to initiate the first human clinical trials against methamphetamine abuse.

COCAINE

Cocaine (benzoylmethylecgonine) is a bicyclic alkaloid extracted from the leaves of Erythroxylum coca and it is a psychoactive substance (see Table 57.1) listed as a Schedule II agent by the Drug Enforcement Agency. In 2008, over 5.3 million Americans aged 12 and older abused cocaine, leading to many chronic health

consequences and criminal activities. It is commonly consumed as the hydrochloride salt by inhalation or injection or as the free base (crack) by smoking. Immediately after direct absorption to the systemic circulation, cocaine rapidly distributes to the peripheral system, and subsequently a small fraction reaches the CNS. Cocaine binds to the dopamine transporter, inhibiting reuptake of dopamine and artificially elevating signaling from this messenger system. In the periphery, it is metabolized primarily in the liver, where the methyl ester is hydrolyzed by human carboxylesterase (hCE1), which hydrolyzes the methyl ester of cocaine, whereas the benzoyl ester is either hydrolyzed by hCE2 in the liver or by butyrylcholinesterase in plasma, leading to the major inactive metabolites, benzoylecgonine (BE), ecgonine methyl ester, and ecgonine that are excreted by the kidneys. The N-methyl group can also be removed to produce norcocaine. Both the methyl and benzoyl esters of native cocaine are essential for the drug's activity. Hence, it is desirable that the antibodies produced by vaccination recognize native cocaine and do not bind significantly to the inactive metabolites.

In 1993, a viable cocaine vaccine was developed by the Janda group at Scripps Research Institute. They first attached a six carbon linker to the carboxylic group of BE without altering its stereochemical properties and then coupled it to the carrier protein KLH using carbodimide chemistry. When rats were actively immunized with this construct, they produced cocaine antibodies with about 1 μM affinity, and locomotor activity (restless movement from place to place) and stereotyped behavior (repetitive meaningless gestures or movements) ordinarily induced by cocaine injection were suppressed. In addition, reduced cocaine levels in the brain tissues were observed in the immunized rats following acute administration of cocaine. Later, in 2001, the same group developed a more stable immune conjugate by altering the labile ester group to an amide, which increased the hapten-protein stability for sustained production of antibodies. Even though an initial blockade of cocaine levels in the brain was obtained using this vaccine, the low antibody titer values in the range of 12 800–25 600 were not sufficient to reduce cocaine entry to the brain following repeated doses.

In another effort in 1996 led by Barbara Fox from ImmuLogic Pharmaceuticals, a conjugate vaccine was developed by coupling 20–27 molecules of a cocaine derivative (succinyl norcocaine) per molecule of BSA. This elicited high antibody titers (>100 000) to cocaine derivates for up to 4 months and showed that 0.7 mg ml $^{-1}$ of antibodies was sufficient to bind 8.7 μM cocaine. Interestingly, their data from competition enzyme-linked immunosorbent assay showed that the antisera also bound the pharmacologically active metabolites norcocaine and cocaethylene (a toxic derivative

produced when ethanol is consumed with cocaine) but showed a minimal recognition of pharmacologically inactive metabolites such as ecgonine methyl ester and benzovlecognine. However, these studies did not answer whether the addicted animal learned to compensate for the immunization by taking more drugs or if vaccination discouraged cocaine intake even if more drug were readily available. These questions were partly addressed in 2000 by the same group by passively administering anti-cocaine mAb in a rat self-administration model $(1 \text{ mg kg}^{-1} \text{ training dose})$. The addicted behavior for cocaine intake was significantly reduced only when the drug-specific mAb levels were greater than $50 \,\mu\mathrm{g}\,\mathrm{ml}^{-1}$. In the same study, 2 weeks after addicted rats (n = 8) were given a vaccine consisting of succinyl norcocaine conjugated to recombinant cholera toxin B (TA-CD), they produced serum antibodies against cocaine in the 80–700 µg ml⁻¹ range, and antagonism of cocaine self-administration was apparent in the animals whose antibody levels were high enough. A similar study by the Janda group using the vaccine they had developed came to essentially the same conclusions. In an active vaccination study performed by Landry (Columbia University) on three Rhesus monkeys of mixed age and sex, a correlation was reported between the increased titer values of anticocaine antibodies and the proportional degree of antagonism of cocaine behavioral effects with no serious adverse consequences, suggesting the potential efficacy of anti-cocaine vaccination for humans.

Based on these preclinical findings, both Phases I and II human clinical trials were carried out using the TA-CD vaccine. The phase I study was carried out on 34 cocaine abusers with three injections over 2 months to assess the immunogenicity and safety of the vaccine in humans. As noted in preclinical animal studies, the human subjects tolerated the vaccine with no serious adverse effects and produced anti-cocaine antibodies at levels that correlated with the vaccine dose. Later, to determine the optimal dosing requirements, a 14-week Phase IIa study was carried out in 18 cocaine abusers at two different dose levels (100 μ g × 4 injections, or $400 \,\mu g \times 5$ injections). It was found that the patients who received a total dose of 2000 µg had a significantly higher antibody titer after 6 months. In Phase IIa studies carried out with a group of 109 cocaine abusers of a heterogeneous outpatient population who were enrolled in a methadone treatment program had no immune deficiency. They were chosen because their methadone treatment schedule meant that fewer patients would be lost because of noncompliance. After five vaccinations, 98% of subjects produced anti-cocaine antibodies, and about 38% of the subjects produced antibodies at $\geq 43 \,\mu \text{g ml}^{-1}$. The high responders had significantly more cocaine-free urine samples than the rest of the subjects once the antibody levels were high enough. It is not clear why the rest of the subjects were unable to produce the required antibody target level, and unfortunately few of the subjects reached the primary end point of abstinence from cocaine for three consecutive weeks. Nevertheless, the use of cocaine vaccines will be more promising if high persistent levels of antibodies can be reached by improvements in vaccine construction and better adjuvants.

NICOTINE

Nicotine is an addictive alkaloid drug found in Solanaceae plants such as tobacco. It is commonly consumed through cigarette smoking and causes about 90% of lung cancer cases in the United States of America and about 10% of overall deaths in the world. Though adults are legally allowed to smoke despite the known health consequences, nonsmokers are also affected through secondary smoke. As a result of smoking one cigarette, about 1-2 mg of nicotine is absorbed in the mucosal surfaces of the respiratory tract of the smoker. From there it enters the bloodstream and rapidly distributes to other organs including the brain. In the brain it binds to the nicotinic acetylcholinergic receptors and causes the release of many chemical messengers such as acetylcholine, epinephrine, and dopamine. With a half-life of 2 h in the human body, nicotine is primarily metabolized in the liver by the enzyme cytochrome P450 to the pharmacologically inactive molecule cotinine, which has a plasma half-life of about 16 h. Nicotine is a small optically active molecule with two rings and an asymmetric S-configuration. It lacks suitable functional groups for direct conjugation (see Table 57.1), and hence an appropriate linker must be added carefully to avoid altering the stereochemical properties of native nicotine.

In 1973, a group led by Langone at Brandeis University reported the first nicotine-protein vaccines by synthesizing 3-succinylmethylnicotine and adding it to large carrier proteins. Immunizing rabbits with these conjugates along with complete Freund's adjuvant generated antinicotine antibodies. Though the initial aim was to raise antinicotine antibodies suitable for use in quantitating nicotine and its metabolites by radioimmunoassay in tissues and biological fluids, later efforts were focused on the development of nicotine vaccines. Several other groups have continued developing nicotine derivatives with different linker sizes and linker attachment sites. Additionally, various carrier proteins (KLH, recombinant cholera toxin B, Pseudomonas exoprotein A, virus-like particles formed from the bacteriophage Qb) have been exploited to optimize nicotine vaccines. Studies have been successfully performed on rodents with these various constructs that demonstrated the elicitation of endogenous antinicotine antibodies with different titer values. These studies showed that the nicotine concentration was significantly higher in the serum than in the brain compared to the unvaccinated control mice and furthermore demonstrating that the antinicotine antibodies retained the nicotine in the peripheral circulation without permitting it to enter into the CNS.

At present, there are three pharmaceutical companies that have completed Phases I and II human clinical trials for nicotine vaccines: NicVAX from Nabi Inc. (USA), NicQb from Cytos AG (Switzerland), and TA-NIC from Celtic Pharma (UK). All three vaccines were sufficiently immunogenic and were well tolerated in Phase I clinical trials without any cross reactivity with endogenous neurotransmitters. In a large Phase IIb doubleblind placebo-controlled clinical trial of NicVAX with 301 heavy smokers (average of 24 cigarettes per day), the vaccine was effective in promoting and sustaining continuous abstinence from smoking at 12 months after vaccination in only 18% of subjects as compared to 6% in the placebo group. Interestingly, the successful quitters from the trial were predominantly those who produced high levels of antibodies against nicotine and its metabolites. Similarly, in a 6-month NicQb Phase II trial with 341 smokers, 57% of NicQb-vaccinated subjects mounted high-level antibody responses and quit smoking from the second until sixth month as compared to 31% of placebo subjects. Similar results were obtained with TA-NIC, which clearly demonstrates that the effectiveness of active immunization against nicotine is directly proportional to the amount and persistence of antinicotine antibodies.

BENCH TO PATIENT TRANSITION

Vaccination for addictive disorders is primarily seen as a treatment to block the entry of drugs of abuse into the CNS. Novel vaccine formulations for different drugs of abuse have been successfully developed, and proof of concept data has been obtained in preclinical animal studies showing successful production of antidrug antibodies and significant reductions in drug-promoted behavior in the animals. The TA-CD vaccine against cocaine has completed the Phases I and IIa clinical trials and advancement to a Phase III trial is in progress. The vaccine was shown to be safe without significant side effects, but the efficacy of vaccination was limited and dependent on the magnitude and kinetic parameters of the antibodies elicited. In the recent Phase IIa TA-CD clinical trial only about 38% of patients produced high anti-cocaine antibody titers and efficacy was also limited to 2 months in terms of a reduction in cocaine use. Similar observations have been documented from the clinical trials of nicotine. Since a single cigarette contains a relatively lower dose of nicotine than the usual single doses of other abused drugs, the required level of antinicotine antibody to prevent relapse from a one-time exposure may be lower than for other drugs. Several preclinical animal studies have shown efficacy with a moderate level of antibodies even with a large excess of a single drug administration. However, recent human clinical trials showed only a moderate efficacy with a large variability in the magnitude of the immune response and it remains unclear why some subjects produced more antibodies than others. Currently, the field is focused on trying to unravel the biological and genetic variations behind the addiction. Recently, using a rat animal model for addiction, the teams of Pier Vincenzo Piazza and Olivier Manzoni, at the Neurocenter Magendie in Bordeaux, demonstrated that in addicted rats, the transition to cocaine addiction permanently impairs long-term depression of the neuronal response in the nucleus accumbens (a center in the brain associated with addiction behavior) and thereby disturbs the synaptic plasticity between the neurons. In contrast, the nonaddicted rats, which received similar cocaine doses, the long-term depression of the neuronal response was reversible. It will be interesting to see whether the vaccination of addicted animals can encourage recovery from the loss of long-term depression.

Recent advances in adjuvant research in finding improved immunostimulants for suitable drug conjugate vaccine formulations hold high promise to help achieve sustained high-level production of antidrug antibodies. However, inclusion of any novel adjuvants for humans apart from the currently approved agents can be expected to delay the vaccine applications as safety and other regulatory concerns have to be addressed. Despite the dramatic high throughput technological inventions with various bioanalytical platforms, there is still a limitation on the ability to investigate and understand the biophysical properties of antibodies, such as kinetic parameters, produced by human subjects or in preclinical animal models. There is also not much information available regarding the influence of the number of haptens covalently linked per carrier protein and its variability in the vaccine formulations between different laboratories.

In contrast to pharmaceutical companies that produce small drug molecules and therapeutic proteins, only a few pharmaceutical companies have the resources and expertise to produce any new vaccine product that could meet the demanding regulatory requirements. The vaccine process development includes transferring the technology from basic research laboratory to a good manufacturing environment to produce each and every vaccine dose precisely equivalent and safely transportable. With the recent progress on addiction

vaccines for cocaine and nicotine toward larger clinical trials, other drug vaccines in the field will have to address such manufacturing issues as well. While nicotine and cocaine are the two major drugs of abuse advancing rapidly toward clinical use, other drugs such as heroin, morphine, and methamphetamine are still in the preclinical phase. We have recently initiated a larger six-site Phase III clinical trial with the TA-CD cocaine vaccine. In addition, NIDA has funded \$10 million grant to Nabi pharmaceuticals for conducting Phase III clinical trials on NicVAX.

It is difficult to speculate regarding the implications of the progress with cocaine and nicotine vaccines for heroin, morphine, and methamphetamine vaccines, which are all still in the preclinical stages. However, it is interesting to note that the majority of the cocaine and heroin are degraded by hydrolysis with a serine hydrolase enzyme carboxylesterase 1 (hCE1), which is readily available in liver, kidney, and small intestines and by butyrylcholinesterase in the bloodstream for quick degradation. This is not the case in other drugs discussed here (see Table 57.1). The enzyme hCE1 hydrolyzes the methyl ester of cocaine to benzoylecognine and methanol, and the hCE2 hydrolyzes the benzoyl ester of cocaine to ecognine methyl ester and benzoic acid. In the case of heroin, hCE1and hCE2 hydrolyze the acetyl groups of heroin to 6-monoacetylmorphine. However, only hCE2 hydrolyzes 6-monoacetylmorphine to morphine, which is the parent molecule still having high BBB permeation. In the case of methamphetamine, the presence of methyl group increases the lipophilicity for high BBB permeation and also makes it less susceptible for enzymes such as monoamine oxidase, which keeps the drug intact with a long circulation half-life. In addition, its demethylated metabolite amphetamine is another active stimulant with a long circulation time of about 9 h. In a successful scenario for addiction vaccine development, it remains challenging for the vaccine community to design an immunogen to perturb the immune system to produce antibodies capable of binding all forms of native and active metabolites.

Transfer of active immunotherapeutic strategies from bench to clinic for treating and/or preventing addictive disorders may also present many complicated ethical decisions involving the addicted patients or their family members, government, and other social welfare organizations as well. It is important to realize that the current immunization strategies attenuate the effects of abused drugs for a few to several months unlike typical preventive vaccines against viruses or bacteria. Improved vaccines may have much more prolonged therapeutic efficacy. Addressing the safety and efficacy of active immunizations, particularly in the context of preventive efforts with more persistent

vaccine responses could be cumbersome and timeconsuming.

In brief, the development of vaccines for substance abuse was hypothesized in the early 1970s that and only in the recent years has the field moved from laboratory bench into patients. However, it is unlikely that any treatment in this field will work for everyone unless we completely understand the biological basis of addiction. Until then the vaccines for addictive disorders will still be a work in progress.

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SEE ALSO

Methadone Maintenance, Antagonists for the Treatment of Opioid Dependence, Buprenorphine for Opioid Dependence, Medications to Treat Addictions: Nicotine Replacement, Non-nicotine Medications, Pharmacotherapy of Cocaine Dependence, Agonist-Like (Substitution) Treatment for Cocaine and Other Stimulant Dependence, Medication Development for Amphetamine Dependence

List of Abbreviations

BBB blood-brain barrier

BE benzoylecgonineBSA bovine serum albumin

CNS central nervous system

hCE human carboxylesterase

Ig immunoglobulin

KLH Keyhole Limpet Hemocyanin

mAb monoclonal antibody

NIDA National Institute of Drug Abuse

Glossary

Adjuvant a chemical or mixture of agents that activates immune cell signaling nonspecifically to enhance immune responses.

Affinity a measure of the strength of antibody binding to an antigen or epitope of a target molecule to a single binding site.

Avidity a measure of overall stability of an antigen—antibody complex, which is governed by the intrinsic antibody affinity to the antigen to a single binding site and valency (number of binding sites) of the antibody and the geometric arrangement of the interacting components.

Blood-brain barrier a complex physical barrier that protects the brain from the entry of unwanted chemicals from the blood into the brain. The efflux and influx transport of various chemicals across

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- the barrier is tightly regulated by the brain capillary endothelial cells.
- Carrier protein attachment of molecules too small to elicit an immune response by themselves (Haptens) to these proteins allows the immune recognition of these structures.
- **Epitope** the chemical structure of a molecule that physically and specifically interacts with the binding site of an antibody or other immune recognition molecule.
- **Hapten** these are small molecules (e.g. drugs of abuse), which are molecules too small to elicit an immune response by themselves.
- **Neurotransmitters** these are endogenous signaling molecules, which communicate between the neurons by activating specific receptors.

Further Reading

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Relevant Website

http://drugabuse.gov/nidahome.html - National Institute on Drug

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Medications for Behavioral Addictions

Liana R.N. Schreiber*, Brian L. Odlaug^{\$}, and Jon E. Grant**

*University of Minnesota Medical Center, Minneapolis, MN, USA *Department of Public Health, University of Copenhagen, Copenhagen, Denmark **Department of Psychiatry & Behavioral Neuroscience, University of Chicago, Chicago, IL, USA

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INTRODUCTION

Pathological gambling, kleptomania, trichotillomania (TTM), pyromania, and intermittent explosive disorder (IED) are all formally recognized by the Diagnostic and Statistical Manual of Mental Disorders – 4th Edition (DSM-IV) as impulse control disorders (ICDs) Not Elsewhere Classified. Although compulsive buying, compulsive sexual behavior (CSB), Internet addiction,

and pathological skin picking (PSP) are not formally recognized by the DSM, they are generally included as ICDs Not Otherwise Specified. The hallmark characteristic of an ICD is an inability to resist urges to engage in behaviors that are excessive and harmful to oneself or others. ICDs are fairly common among both adults and adolescents. A study of 791 college students found that 82 (10.4%) met criteria for at least one lifetime ICD, demonstrating the common nature of these disorders in

the general population. ICDs generally have the following features in common: (1) repetitive or compulsive engagement in a behavior despite adverse consequences; (2) diminished control over the problematic behavior; (3) an appetitive urge or craving state prior to engagement in the problematic behavior; and (4) a hedonic quality during the performance of the problematic behavior. These features have led to a description of ICDs as "behavioral addictions." Some of the ICDs (pathological gambling, kleptomania, pyromania, compulsive buying, CSB, and internet addiction) seem to fit the conceptualization of behavioral addictions better than other ICDs (TTM, PSP). In particular, IED may in fact have even less in common with other ICDs. The degree to which ICDs overlap in terms of clinical, genetic, phenomenological, and biological characteristics is not completely understood. Future research should help clarify whether only certain ICDs share a common pathophysiology or whether only certain individuals with certain ICD share the same pathophysiology. See Table 58.1 for summary of double-blind treatment studies for ICDs.

PATHOLOGICAL GAMBLING

Clinical Characteristics

Pathological gambling (PG) is characterized by persistent and recurrent maladaptive patterns of gambling behaviors. Approximately 0.4–1.6% Americans meet criteria for a PG diagnosis. Gambling often starts in adolescence or young adulthood and develops into a problem several years later. The gender ratio of males to females with PG appears to be 2:1. Women tend to develop PG at a quicker rate than men, while men begin gambling at a younger age. Male pathological gamblers appear more likely to report problems with strategic or "face-to-face" forms of gambling, for example, blackjack or poker. Female pathological gamblers tend to report problems with nonstrategic, less interpersonally interactive forms of gambling, for example, slot machines or bingo. High rates of bankruptcy have been linked with PG. In addition to financial problems, impaired functioning, decreased quality of life, marital problems, and legal problems are associated with PG. If left untreated, PG appears to be a chronic, recurring condition.

Individuals who struggle with PG may also be dealing with another psychiatric condition. Common lifetime comorbid disorders include mood (20–55.6%), substance use (35–76.3%), and other ICDs. Suicide attempts are also common in PG with one study reporting attempts in 58 (17%) of 342 individuals. Studies have also found high rates of co-occurring personality disorders.

Pharmacological Treatments for Pathological Gambling

Opioid Antagonists

Mu-opioid receptor antagonists inhibit dopamine release in nucleus accumbens and ventral pallidum through the disinhibition of gamma-aminobutyric acid (GABA) input to the dopamine neurons in the ventral tegmental area. The hypothesis underlying the use of opioid antagonists was that decreased dopamine in the nucleus accumbens and motivation circuit would dampen excitement and cravings related to gambling behavior. Although modulation of drive and subsequent behavioral output by dopamine, endorphin, and GABA have been investigated, the specific mechanisms remain incompletely understood, particularly as related to pathological gambling.

Two opioid antagonists have been investigated in the treatment of pathological gambling: naltrexone and nalmefene. Two of the three double-blind studies of naltrexone (studies randomized 45 and 77 subjects into a 12-week and 18-week study, respectively) found that subjects significantly improved on measures of gambling behaviors and urges when compared to placebo. A study randomizing 52 subjects to receive naltrexone or placebo for 11 weeks in addition to cognitive behavioral therapy (CBT), however, found that groups did not significantly differ in measures of gambling frequency or expenditures.

Nalmefene was found to be effective in reducing PG symptoms in two double-blind studies. A 16-week study found that nalmefene produced significantly greater reductions in gambling symptoms than placebo in 207 gambling subjects. Another larger study of 233 PG subjects treated for 12 weeks found that overall nalmefene was not superior to placebo. However, with analyses limited to subjects taking 40 mg of nalmefene daily, results indicated that the active medication group reported significantly fewer gambling urges compared to those on placebo.

Antidepressants

The hypothesis underlying the examination of antidepressant medications for PG is based on its hypothesized neurobiology. Low levels of the serotonin metabolite 5-hydroxyindole acetic acid (5-HIAA) and blunted serotonergic response within the ventromedial prefrontal cortex (vmPFC) have been associated with impulsive behaviors. Individuals with PG show relatively diminished activation of the vmPFC during a simulated gambling task, and severity of gambling problem correlated inversely with signal intensity within this brain region. Decreased serotonin function within vmPFC may therefore engender disinhibition and contribute to pathological gambling. Thus, drugs

 TABLE 58.1
 Double-blind Treatment Studies of Impulse Control Disorders

Double-blind treatment studies		Duration (weeks)	Outcome
Pathological gambling			
Opioid antagonists			
Naltrexone (ReVia)	45	12	Naltrexone group significantly improved compared to placebo
Naltrexone (ReVia)	77	18	Naltrexone group significantly improved compared to placebo
Naltrexone (ReVia)	52	11	Naltrexone group did not significantly differ from placebo
Nalmefene (Revex)	207	16	Nalmefene resulted in significant improvement compared to placebo
Nalmefene (Revex)	233	12	Nalmefene did not result in significant improvement compared to place be in an intent-to-treat analysis; $40~\mathrm{mg}$ resulted in significant improvement when only those who reached target dose were analyzed
Antidepressants			
Fluvoxamine (Luvox)	15	8*	Fluvoxamine superior to placebo
Fluvoxamine (Luvox)	32	24	Fluvoxamine not statistically significant from placebo except in young males
Paroxetine (Paxil)	45	8	Paroxetine group significantly improved compared to placebo
Paroxetine (Paxil)	76	16	Paroxetine and placebo groups with comparable improvement
Escitalopram (Lexapro)	4	8	Significant improvement for escitalopram subjects while placebo group had a relapse of gambling symptoms
Sertraline (Zoloft)	60	24	Sertraline did not significantly differ from placebo
Bupropion (Wellbutrin)	39	12	Bupropion did not significantly differ from placebo
Mood stabilizers			
Lithium carbonate SR (Lithobid SR)	40	10	Lithium produced significant improvement in reducing PG symptoms and severity compared to placebo
Atypical neuroleptics			
Olanzapine (Zyprexa)	21	7	Olanzapine did not significantly differ from placebo
Olanzapine (Zyprexa)	42	12	Olanzapine did not significantly differ from placebo
Glutamatergic agents			
N-acetylcysteine (NAC)	27	6	59.3% of subjects were rated as responders in the OL. In the DB, $83.3%$ on NAC still met responder criteria at study endpoint compared to $28.6%$ on placebo
Kleptomania			
Antidepressants			
Escitalopram (Lexapro)	15	17	Escitalopram produced no significant differences compared to placebo
Opioid antagonists			
Naltrexone (ReVia)	25	8	Naltrexone was statistically superior to placebo in reducing stealing behavior
Compulsive buying			
Antidepressants			
Fluvoxamine (Luvox)	37	13	Fluvoxamine and placebo groups with comparable improvement
Fluvoxamine (Luvox)	23	9	Fluvoxamine and placebo groups with comparable improvement
Citalopram (Celexa)	15	9	63% were rated as responders in the OL. In the DB, 63% of the placebo group relapsed compared to none of those on citalogram

(Continued)

TABLE 58.1 Double-blind Treatment Studies of Impulse Control Disorders—cont'd

Double-blind treatment studies		Duration (weeks)	Outcome
Escitalopram (Lexapro)	17	9	73% of OL sample were rated as responders. 67 and 63% from the placebo and active medication group, respectively, relapsed during the DB phase after being rated as an OL responder
Compulsive sexual behavior			
Antidepressants			
Citalopram (Celexa)	28	12	Citalopram significantly reduced desire for sex, masturbation frequency, and weekly hours of pornography use compared to placebo. Sexual risk decreased in both groups, but no significant difference was found between groups
Trichotillomania			
Antidepressants			
Clomipramine (Anafranil) Desipramine (Norpramin)	13	5*	Significant improvement with clomipramine compared to desipramine
Clomipramine (Anafranil)	16	9	67% of the clomipramine group were rated as 'very much improved' on the CGI compared to none assigned to placebo. This difference only approached significance
Fluoxetine (Prozac)	15	6*	Fluoxetine failed to show significant improvement compared to placebo
Fluoxetine (Prozac) Clomipramine (Anafranil)	12	10*	Fluoxetine and clomipramine produced similar positive results
Fluoxetine (Prozac)	23	12*	Fluoxetine produced no significant improvement compared to placebo
Opioid antagonist			
Naltrexone	17	6	Naltrexone produced significant improvement only on one measure of symptomology compared to placebo
Atypical neuroleptics			
Olanzapine (Zyprexa)	25	12	Olanzapine resulted in significant improvement compared to placebo
Glutamatergic agents			
N-acetylcysteine (NAC)	50	12	NAC was statistically superior to placebo in reducing TTM symptomatology
Pathological skin picking			
Antidepressants			
Fluoxetine (Prozac)	17	10	Fluoxetine produced significant improvement compared to placebo
Fluoxetine (Prozac)	8	6	53.3% were rated as responders based on the YBOCS-PSP in the OL. In the DB, fluoxetine maintained positive results while the placebo group returned back to baseline severity
Citalopram (Celexa)	45	4	Citalopram was not statistically superior to placebo on a visual analog scale
Mood stabilizers/Anticonvulsants			
Lamotrigine (Lamictal)	35	12	Lamotrigine did not significantly differ from placebo. Lamotrigine responders had impaired cognitive flexibility and delayed reach times at baseline compared to lamotrigine nonresponders
Intermittent explosive disorde	er		
Antidepressants			
Fluoxetine (Prozac)	100	14	Fluoxetine demonstrated superiority to placebo
Mood stabilizers/Anticonvulsants			
Divalproex sodium (Depakote)	116	12	Significant changes were seen only in IED subjects who had a Cluster B personality disorder
Levetiracetam (Keppra)	40	10	Levetiracetam was not superior to placebo

 $^{^{\}star}$ indicates subjects were put in each agent for x number of weeks.

targeting serotonin neurotransmission may be effective in the treatment of pathological gambling.

pharmacologic The majority of double-blind treatment studies for PG have assessed the efficacy of antidepressants with mixed results. While a 16-week, cross-over study of 15 pathological gamblers found that the fluvoxamine group had significantly greater improvement of gambling symptoms compared to placebo, a 6-month study of 32 pathological gamblers found fluvoxamine to be no more effective than placebo. In the latter study, however, high treatment discontinuation (90.6%) and placebo response rates (59%) complicated study findings. Mixed results have also been found for paroxetine. Paroxetine was found to significantly decrease gambling urges and behavior in 45 pathological gamblers participating in an 8-week study. In contrast, results from a larger study of 76 participants with PG indicated that paroxetine was not superior to placebo on any outcome measure in a 16-week trial. These negative findings, however, may be due to a high placebo response rate. Of those randomized to placebo, 48% responded compared to a 59% response rate in the treatment group.

Research has found escitalopram to be a superior treatment to placebo. A 12-week, open-label study investigating escitalopram in pathological gamblers with co-occurring anxiety disorders found that of the four subjects who were responders during the open-label phase (6 of 13 subjects, 46.2%, with PG and high levels of anxiety responded to escitalopram during the open-label portion) and randomized into the 8-week, double-blind discontinuation period, three subjects randomized to active medication continued to maintain improvement in both gambling and anxiety symptoms. The one subject assigned to placebo returned to baseline levels within 4 weeks.

In contrast, other studies have found sertraline and bupropion, a nonserotonergic antidepressant, were not superior to placebo in treating pathological gambling. Researchers found that sertraline and placebo yielded similar response rates in 60 pathological gamblers participating in a 6-month study. Seventy-four and seventy-two percent of those randomized to sertraline and placebo, respectively, were rated as responders.

In the only study examining a nonserotonergic antidepressant, 39 PG subjects were randomized into a 12-week, flexible dose study of bupropion. The study found no significant differences between subjects assigned to bupropion compared to those assigned to placebo in terms of gambling behaviors and thoughts, or time or money spent on gambling per week.

Mood Stabilizers

Only one randomized, placebo-controlled trial of a mood stabilizer has been performed in PG. In a double-blind, placebo-controlled study of 40 PG subjects with bipolar spectrum disorders (bipolar type II, bipolar not otherwise specified, or cyclothymia), sustained release of lithium carbonate was shown to be superior to placebo in reducing PG symptoms during 10 weeks of treatment. Although a majority (83%) of subjects in the treatment group displayed significant decreases in a clinical rating of gambling urges, thoughts, and gambling behaviors in the past week, no differences were found in self-reported amount of money lost, episodes of gambling per week, or time spent per gambling episode.

Atypical Neuroleptics

Olanzapine, an atypical neuroleptic, was investigated in two double-blind studies. A 7-week trial of 21 subjects with PG found that there were no significant differences in gambling urges or behaviors when comparing active treatment to placebo groups. Similarly, olanzapine failed to demonstrate statistical significance compared to placebo in a trial of 42 individuals with PG enrolled in a 12-week trial.

Glutamatergic Agents

Positive results have been found with *N*-acetylcysteine (NAC) – a glutamatergic modulator. Statistical analysis of an 8-week, open-label trial of NAC followed by a 6-week, double-blind discontinuation phase with 27 subjects revealed that those randomized to receive NAC had significantly reduced gambling thoughts and behaviors and an improved level of functioning. Furthermore, approximately 83% of individuals on NAC were rated as 'responders,' compared to 30% assigned to placebo.

Treatment Summary

Several findings emerge from these pharmacological studies:

- 1. Although several different classes of medication appear to show some efficacy in treating PG, only opioid antagonists have demonstrated the successful replication of a positive, randomized, placebocontrolled study. Based on the present data, opioid antagonists should be considered first-line pharmacological treatment for PG.
- **2.** Data for the glutamatergic modulator, *N*-acetylcysteine, and for lithium are encouraging and should be further investigated.
- **3.** Although the majority of pharmacological studies have focused on antidepressants, the results have been inconclusive. Escitalopram, however, may be effective for pathological gamblers with high levels of anxiety.

- **4.** Atypical antipsychotic treatment studies suggest that these medications provide no greater benefit than placebo.
- 5. An exploration of the clinical characteristics of pathological gamblers in which a specific pharmacological treatment is advantageous is necessary to assess reasons as to why some agents are efficacious in some individuals with PG and not in others.

There are also numerous limitations to the current knowledge regarding pharmacological treatment of PG. No comparison studies of medications have been performed in a randomized, placebo-controlled design. No studies have examined which intervention (pharmacotherapy versus psychotherapy) is more effective or whether combination treatment is more beneficial. In addition, no study has examined whether certain individuals with pathological gambling would benefit more from medication or from psychotherapy.

KLEPTOMANIA

Clinical Characteristics

Individuals who struggle with kleptomania repetitively and uncontrollably steal items that are not needed for personal use and may hoard, give away, return, or throw away the stolen items. Although epidemiological research has found that 11.3% of individuals have shoplifted at least one time in their life, no studies have examined the prevalence of kleptomania in the population. One study of 791 college students, however, found that 3 (0.38%) met DSM-IV criteria for kleptomania. Studies of individuals arrested for shoplifting have suggested that 3.8-24% may meet criteria for kleptomania. The majority of individuals with kleptomania appear to be female. Typically, onset of kleptomania is during adolescence. Individuals with kleptomania report significant guilt over their behavior, and the majority have been apprehended at some time due to their stealing.

Studies have found that psychiatric comorbidity with affective disorders, substance use, and anxiety disorders is common among individuals with kleptomania. Additionally, individuals with kleptomania often meet criteria for another ICD. Family studies have found that first-degree relatives of individuals with kleptomania have higher rates of alcohol use disorders compared to control groups.

Pharmacological Treatments and Recommendations

Although research has only recently explored pharmacologic treatment for kleptomania, these studies have shown a similar response between substance use disorders and kleptomania. Historically, the use of serotonergic medications for substance use disorders has not been impressive. Similarly, a recent controlled study of a serotonergic medication (escitalopram) in the treatment of 24 patients with kleptomania was largely unsuccessful in reducing stealing behavior. After 7 weeks of open-label treatment, escitalopram reduced shoplifting urges in 19 (79%) of the participants. Fifteen responders were then randomized to a 17-week, double-blind discontinuation phase where they received either active medication or placebo. At the end of this portion of the study, no significant differences were seen between active medication and placebo, that is, 50% of those on placebo and 43% on active medication maintained their improvement from the open-label portion of the study.

There are no medications currently approved for the treatment of kleptomania, but medications that have shown promise in treating substance use disorders have also shown promise in treating kleptomania. Given their ability to modulate dopaminergic transmission in the mesolimbic pathway, opioid receptor antagonists (naltrexone) have also been investigated in the treatment of kleptomania.

A recent double-blind, placebo-controlled study evaluating the efficacy of naltrexone in the treatment of kleptomania demonstrated its benefit in reducing stealing urges. As in the case of substance use disorders, naltrexone appears to target urges in kleptomania. Twenty-five subjects with kleptomania were enrolled. Significantly better results were observed for those assigned to naltrexone on the primary efficacy variable. Remission of kleptomania symptoms was seen in eight naltrexone subjects (66.7%) and one (7.7%) placebo subject. Although the study was only 8 weeks in duration, a naturalistic outpatient study demonstrated that subjects treated with naltrexone monotherapy for up to 3 years continued to report overall improvement.

There is limited treatment research on kleptomania and future research needs to continue to investigate possible pharmacological treatments for kleptomania. Future research investigating kleptomania and its relationship to substance use disorders holds significant promise in advancing prevention and treatment strategies for addiction in general.

COMPULSIVE BUYING

Clinical Characteristics

It is estimated that about 5.8% of US adults report shopping or spending behavior that could be classified as compulsive buying. Although there are no agreed upon diagnostic criteria, core features of the disorder PYROMANIA 559

are a preoccupation with buying, spending more than one can afford on unneeded items, or shopping for longer durations of time than originally intended. Most individuals with compulsive buying are women with an onset of the behavior during late adolescence or early adulthood. Items typically are unused, given away, or returned to the store. Compulsive buying regularly results in large amounts of financial debt, marital or family disruption, and even legal consequences.

Pharmacological Treatment and Recommendations

Antidepressants are the only pharmacological therapy investigated for the treatment of compulsive buying, and the effectiveness of medications has been examined in four double-blind, randomized, placebo-controlled trials. In the first of two double-blind studies, 37 subjects were treated with fluvoxamine for 13 weeks. Only 9 (45%) of 20 patients assigned to medication were responders, and this rate did not differ significantly from that in the placebo group (8 of 17 were responders). In the second double-blind study, 23 subjects were treated with fluvoxamine for 9 weeks following a 1-week placebo lead-in phase. No differences in response rates were observed between the groups treated with active drug or placebo.

The third controlled study was a 7-week open-label study of citalopram that randomized the responders to 9 weeks of double-blind medication or placebo. Subjects taking active citalopram demonstrated statistically significant decreases in terms of the frequency of shopping as well as the intensity of thoughts and urges concerning shopping.

The final double-blind study found that escitalopram was not effective for the treatment of compulsive buying. Seventeen participants were randomized into a 9-week, discontinuation period after being rated as responders in a 7-week, open-label study. During the discontinuation phase, 63% and 67% of the escitalopram and placebo groups, respectively, relapsed.

There is only scant evidence concerning effective treatments for compulsive buying. Based on available data, citalopram appears promising for this disorder. It is unclear why citalopram may be effective while other selective serotonin-reuptake inhibitors (fluvoxamine, escitalopram) fail to demonstrate benefit.

COMPULSIVE SEXUAL BEHAVIOR

Clinical Characteristics

CSB is characterized by recurrent and intense sexual fantasies, urges, or behaviors and clinically significant

distress or impairment in functioning associated with sexual fantasies, urges, or behaviors. The prevalence rate of CSB in the general population is unknown; however, one study of college students found that 3.7% reported symptoms consistent with CSB. The gender distribution of CSB is unknown, but the majority of treatment-seeking individuals with CSB are males with an onset during late adolescence. The sexual urges and behaviors are often distressing and uncontrollable, triggered by certain mood states (most commonly sadness or depression), and result in a negative mood state and feelings of shame.

Psychiatric comorbidity may also be an issue for individuals struggling with CSB. Studies have found that individuals with CSB often have co-occurring substance use disorders. Family history of addiction is also common with one study indicating that 40% of individuals with CSB had at least one chemically dependent parent.

Pharmacological Treatments and Recommendations

Although a variety of medications have been examined in case reports (e.g. naltrexone, antidepressants, and mood stabilizers), only one double-blind, placebocontrolled study has been published. Compared to placebo, citalopram significantly reduced the desire for sex, frequency of masturbation, and hours of pornography use per week in 28 gay and bisexual men randomized in a 12-week study. High-risk sexual behavior did not differ between groups.

Treatment recommendations are difficult to make given the extremely limited amount of information regarding pharmacotherapy for CSB. There is a substantial need for more systematic studies of the treatment of this disorder.

PYROMANIA

Pyromania is characterized by deliberate and purposeful fire-setting on more than one occasion. The frequency of pyromania within the United States is not well established but one study found pyromania in 1% of college students. A review of 282 arsonists' hospital records found that about 24% who had committed other nonviolent crimes and about 12% who had committed other violent crimes met criteria for pyromania. Within a psychiatric population, studies have found that approximately 6% and 3% meet lifetime and current criteria, respectively, for pyromania. A clinical study of 102 psychiatric inpatient adolescents observed that 6.9% met criteria for current pyromania. Pyromania in

adults appears to be more common in males. Although many individuals with pyromania report pleasure while setting fires, the majority feel severe distress after setting a fire.

No double-blind studies for pyromania have been published. Medications described in case reports that have been demonstrated to be beneficial in the treatment of pyromania include topiramate, escitalopram, sertraline, fluoxetine, lithium, and a combination of olanzapine and sodium valproate. An equal number of medications, however, have failed to show benefit: fluoxetine, valproic acid, lithium, sertraline, olanzapine, escitalopram, citalopram, and clonazepam. Another case report, illustrating the treatment of an 18-year-old male with pyromania, described the use of a combination of topiramate with 3 weeks of daily CBT.

Pyromania is a largely unrecognized disorder that causes significant psychological, social, and legal repercussions. Because few individuals volunteer information regarding their fire-setting, it is important that clinicians recognize the disorder and screen patients appropriately. Various treatments have been helpful in case studies but more research examining etiology and treatment is needed.

INTERNET ADDICTION

Clinical Characteristics

Internet addiction is characterized by excessive preoccupations, urges, or behaviors regarding Internet use resulting in impairment or distress. Internet addiction appears to have three subtypes: excessive gaming, sexual preoccupations (cybersex), and text messaging. The estimated international prevalence rates of Internet addiction is 1.5–8.2%. Within the United States, prevalence rates range from 0.3 to 6%. These rates, however, are derived from studies using a variety of methodologies and, thus, may not correctly reflect the true prevalence of the disorder.

Neuroimaging studies suggest that online gaming cravings activate areas of the brain implicated in substance use disorders. Personality may also play a role in the development of Internet addiction, such as tendency toward novelty seeking and harm avoidance. A recent study in China found that being male, drinking behavior, family dissatisfaction, and recent stressors are predictive of Internet addiction in adolescents. Several cross-sectional studies have found high rates of affective disorders, anxiety disorders, and attention deficit hyperactivity disorder within this population.

Pharmacological Treatments and Recommendations

Although there are no double-blind, placebocontrolled pharmacotherapy studies in the medical literature, two open-label treatment studies have been published. One study examined methylphenidate in 62 children with Internet addiction and co-occurring attention deficit hyperactivity disorder. After 8 weeks of treatment, frequency of Internet use and duration of use both decreased significantly. In another open-label study, escitalopram treatment resulted in a significant decrease in the number of hours spent on the Internet.

With no available placebo-controlled trials, medication treatment recommendations are not possible at this time. Double-blind, placebo-controlled trials are needed.

TRICHOTILLOMANIA

Clinical Characteristics

Approximately 0.5–3.9% of people in the United States have TTM, a disorder characterized by the repetitive, intentional pulling of hair causing noticeable hair loss and resulting in clinically significant distress or functional impairment. TTM is more common in females (~90%) and typically starts in early puberty (11–13 years old). Hair may be pulled from any area of the body but is most commonly pulled from the scalp and eyebrows. One epidemiological study of 1697 individuals with TTM found that about 80% reported that their hairpulling caused social anxiety, and of those who scored high on a hair-pulling severity measure, about 49% avoided social situations and 35% claimed hair-pulling interfered with daily occupational tasks. Hair-pulling is often hidden from family, friends, and treatment providers and people with TTM may go to great lengths to disguise their problem, such as having an elaborate hairstyle or wearing wigs and makeup.

Pharmacological Treatment

In comparison to the other ICDs, there are a number of controlled pharmacological trials that have been performed in TTM. Five of the eight double-blind pharmacological studies examined antidepressants. One study examined clomipramine compared to desipramine in a 10-week double-blind, cross-over (5 weeks for each agent) design (following 2 weeks of single-blind placebo lead-in). Twelve of thirteen subjects had significant improvement on clomipramine. In contrast to the previous study, clomipramine did not yield a significantly greater response to treatment when compared

to CBT and placebo in 16 subjects randomized into a 9-week, placebo-controlled, parallel-treatment study. Although clomipramine resulted in a greater decrease in symptoms compared to placebo, these differences were not significant. CBT, however, resulted in a significantly greater reduction of TTM symptoms compared to clomipramine.

Study of Fluoxetine in Three Randomized Trials with Conflicting Results

In one study, fluoxetine (doses ranged from 20 to 80 mg day⁻¹) was compared with placebo in an 18-week double-blind cross-over study (with a 5-week washout period between treatment arms; 6 weeks on each agent). No significant differences were found between fluoxetine and placebo on measures of hairpulling urges, frequency, or severity. In a study comparing fluoxetine with clomipramine (mean dosage of 75 mg day⁻¹ for fluoxetine and 200 mg day⁻¹ for clomipramine), a 2-week placebo lead-in was followed by a double-blind, randomized 20-week crossover design (10 weeks on each agent). Both clomipramine and fluoxetine demonstrated a similar positive treatment effect. A third controlled study used a doubleblind, placebo-controlled crossover design with 16 subjects treated with 12 weeks of each agent (taking up to 80 mg day⁻¹ of fluoxetine) separated by a 5-week washout period. Fluoxetine failed to show significant improvement compared to placebo.

In a study of the opioid antagonist, naltrexone was compared to placebo in a 6-week randomized, double-blind parallel study. Of 17 subjects who completed the study, 10 received placebo and 7 received naltrexone 50 mg day⁻¹. Significant improvement was noted for the naltrexone group on one measure of TTM symptoms. Two other measures of symptom improvement, however, showed change in the anticipated direction for the naltrexone group but failed to reach statistical significance.

The atypical neuroleptic, olanzapine, was examined in a double-blind, placebo-controlled study of 25 subjects treated for 12 weeks. Those on active medication had significantly greater improvement on measures of TTM severity compared to placebo, and 85% on active medication (compared to 17% on placebo) were rated as full responders.

In the largest pharmacological study of TTM, *N*-acetylcysteine, a glutamatergic agent, was examined in a 12-week, placebo-controlled study of 50 subjects with TTM. The study found that subjects receiving *N*-acetylcysteine had significantly greater decreases in TTM symptoms and a greater percentage of subjects (56%) assigned to NAC were rated as much or very much improved compared to placebo (17%).

Treatment Summary and Recommendations

Data regarding effective pharmacological treatments for TTM are rather sparse. There is some hint that *N*-acetylcysteine and the atypical neuroleptic olanzapine may have some benefit for TTM, but there is conflicting data supporting the use of serotonin-reuptake inhibitors. Naltrexone may offer some promise in treating TTM, but further research is needed in this area before clear recommendations can be made regarding pharmacological interventions.

PATHOLOGICAL SKIN PICKING

Clinical Characteristics

Individuals with PSP repetitively or compulsively pick their skin, resulting in tissue damaging. The area usually picked is the face, but any body part can be a focus. Prevalence rates of PSP are not well established. A large epidemiological study of 2513 individuals found that between 0.2 and 1.4% of US adults satisfied criteria for PSP; however, a smaller community sample found a prevalence rate of about 5%. Typically, PSP is more common among females. Picking may consume a significant portion of time and frequently leads to infections and significant scarring. Individuals with PSP often have a co-occurring psychiatric condition. Lifetime substance use (38%), affective (28.6–36.4%), and obsessive-compulsive disorder (15.2–19.0%) are common.

Pharmacological Treatment and Recommendations

Only four placebo-controlled, double-blind studies have been completed for PSP, and three of the studies have used selective serotonin-reuptake inhibitors. One study of fluoxetine in 21 subjects with PSP found that, among the 17 completers (6 fluoxetine, 11 placebo), the fluoxetine group improved significantly more than the placebo group after 10 weeks of treatment. However, subjects responded on only one of the three measures in the intent-to-treat analysis and full remission was not observed.

In a second fluoxetine study, 15 subjects were given 6 weeks of open-label fluoxetine followed by a 6-week double-blind discontinuation phase for responders (classified as 30% improvement from baseline severity scores). At the end of the 6-week open-label treatment phase, eight subjects (53.3%) were considered responders. The four subjects randomized to fluoxetine maintained their improvement during the double-blind discontinuation phase while the placebo group returned to baseline levels of picking severity.

In a double-blind study of 45 PSP subjects treated with citalopram for 4 weeks, scores on the Yale-Brown Obsessive Compulsive Scale modified for PSP decreased significantly for the citalopram group but not for the placebo group. However, there was no significant medication effect on the primary outcome measure – a visual analog scale of picking behavior.

One placebo-controlled, double-blind study has evaluated the anticonvulsant, lamotrigine, and found that it was not superior to placebo on any measure of PSP severity in 35 subjects randomized in a 12-week study. Detailed analysis, however, indicated that lamotrigine responders demonstrated impaired cognitive flexibility and delayed reaction times at baseline compared to lamotrigine nonresponders. This suggests that there may be different cognitive subtypes of PSP and that lamotrigine may be effective only in a certain type of PSP.

Although limited, the published pharmacological studies suggest that serotonergic antidepressants may be effective for treating PSP but the overall benefit appears limited.

Further research on this treatment and others is needed for more conclusive results. The lamotrigine study suggests that improved understanding of the pathophysiology of PSP may result in more targeted treatment strategies.

INTERMITTENT EXPLOSIVE DISORDER

Clinical Characteristics

It is estimated that about 4–7.3% of people in the United States have IED, a disorder characterized by recurrent, significant outbursts of aggression resulting in assaultive acts against people or property that are disproportionate to outside stressors. Clinical studies have found that the majority (77–88%) of individuals with IED are male. The first outburst typically occurs in early adolescence with individuals usually meeting IED criteria between ages 14 and 18 years. In general, outbursts last about 30 min and people with IED report significant psychosocial impairment resulting from their behavior and describe their behavior as distressing and problematic. Less than 30% of people with IED, however, have ever received treatment.

In a national survey of 9282 US adults, of the 7.3% who met a lifetime diagnosis of broadly defined IED (having at least three attacks within a lifetime and at least one in the past 12 months), about 82% of individuals with IED have co-occurring lifetime psychiatric disorders, most commonly any mood (37.4%), anxiety (58.1%), and substance use disorders (35.1%).

Pharmacological Treatment and Recommendations

Although there have been several treatment studies of aggression, only three placebo-controlled double-blind pharmacological studies of IED have been published. One study of 100 subjects with IED treated for 14 weeks found that fluoxetine reduced frequency and severity of impulsive aggression and irritability.

A 12-week study of divalproex sodium – a mood stabilizer – in 96 subjects with Cluster B personality disorder, 116 with IED, and 34 with posttraumatic stress disorder found that divalproex had no significant influence on aggression in the subjects with IED.

A third study found that levetiracetam – a mood stabilizer – was not superior to placebo on measures of aggression, hostility, or patient-rated improvement in 40 subjects with IED randomized in a 10-week, variable dose study.

Fluoxetine appears to be a potentially effective treatment option for IED. Given the paucity of treatment studies for IED, however, no clear treatment recommendations for IED can be offered.

CONCLUSIONS

Relatively little is known about behavioral addictions compared to other psychiatric illnesses. Most research has focused on PG, but research concerning clinical and biological/genetic characteristics of all types of behavioral addictions is greatly needed to better inform researchers, clinicians, and the general public. Large, randomized, placebo-controlled studies are especially needed to gain knowledge about beneficial treatments. Taken as a whole, pharmacological treatment studies have suggested that opioid antagonists may be useful for some behavioral addictions (PG, kleptomania), while serotonergic antidepressants may be useful for others (such as IED, PSP, CB, and CSB); however, the data are limited and results should be interpreted with caution. Data from glutamatergic agent studies warrant further research in their use for the treatment of PG and TTM. Further exploration of atypical antipsychotics for the treatment of TTM is also needed. Data regarding lithium, antiepileptic, and stimulant medications are extremely limited and inadequate to reach any clinical judgments. Closer examination of the heterogeneity across and within these disorders and how that heterogeneity impacts pharmacological treatment is an area for further research. Advances in these areas will hopefully increase public awareness of these disorders, serving to improve the lives of those both directly and indirectly affected by behavioral addictions.

FURTHER READING 563

SEE ALSO

College Student Gambling: Etiology, Consequences, and Prevention Strategies, Psychological Treatments for Pathological Gambling

List of Abbreviations

5-HIAA 5-Hydroxyindole acetic acid **CB** compulsive buying

CSB compulsive sexual behavior

CBT cognitive behavioral therapy

DB double blind

DSM-IV Diagnostic and Statistical Manual of Mental Disorders – 4th Edition

GABA gamma-aminobutyric acid

ICDs impulse control disorders

IED intermittent explosive disorder

OL open label

PG pathological gambling

PSP pathological skin picking

NAC N-acetylcysteine

TTM trichotillomania

vmPFC ventromedial prefrontal cortex

YBOCS-PSP Yale Brown Obsessive Compulsive Scale for Pathological Skin Picking

Glossary

- **Atypical neuroleptic** a drug used to treat psychiatric conditions, such as schizophrenia and bipolar disorder, which block receptors in the brain's dopamine pathway.
- **Comorbid** the presence of one or more diseases in addition to a primary diagnosis.
- Double-blind a research technique in which neither the subject nor the researchers administering the treatment condition know if the subject is receiving the active treatment or the placebo and is done to eliminate biased results.
- **Glutamatergic agent** a drug that modifies glutamate activity in the brain.
- **Impulsivity** an innate tendency toward reacting in a hasty and spontaneous way to internal or external stimuli with a lack of consideration to negative consequences.
- **Open-label** a research method in which subjects and clinicians know which medication the subjects are receiving.

Opioid antagonists a drug that interferes with the binding of opiates to the brain's opioid receptors.

Placebo an inert medication given to a subject that functions as a control to the medication being tested.

Serotonin-reuptake inhibitor a drug that functions as a neurotransmitter uptake inhibitor on the brain's serotonin receptors.

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Relevant Websites

http:/aic.uchicago.edu - Impulse Control Disorders Clinic.

http://www.stoppicking.com – StopPicking is an online behavioral program designed to help reduce skin picking.

http://www.trich.org - Trichotillomania Learning Center.

http://www.ocfoundation.org - International OCD Foundation.

http://www.stoppulling.com – StopPulling is an online behavioral program designed to help reduce hair pulling.

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Health Care Reforms and Treatment for Substance Use Disorders

Paul M. Roman

Owens Institute for Behavioral Research, University of Georgia, Athens, GA, USA

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INTRODUCTION

Throughout most of the world in the twenty-first century, governments are involved with multiple aspects of the administration of health care and the financing of health care delivery. Thus the breadth and depth of health care available and accessible in a given setting reflect public policy in that setting. Public policy, in turn, is a reflection of national politics, the evolutionary pattern of legislation, and societal values which guide choices between alternatives.

In the United States, health care policy has emerged rather haphazardly, with a largely *laissez faire* environment dominating up until the first half of the twentieth century when a host of demographic and technological changes transformed health care possibilities and expectations. Beginning after World War II, concern over reform and reorganization of health care entered the political arena. A bifurcation emerged, centering around the possibility of the Federal government as a single payer for health care, an idea to which its opponents promptly and effectively attached the term, "socialized medicine." Some version of proposed expansion of Federal financial and administrative control of medical care has been represented in a long sequence of proposals and changes that have occurred over the past 70 years.

Historically, the treatment of addiction has had little relation to changes in health care policy. The treatment of substance use disorders (SUDs) in the US is a relatively new entry into the medical care arena, having undergone many transitions and changes since its inception in the 19th century. From the nineteenth century onward, psychoactive substance use has been seen as a public matter affecting the public good. As such, it has been the target of a series of legislative actions and public policies that have been very specifically addressed to psychoactive substances, including their distribution, use, and resultant needs for interventions directed at some users. Such interventions have combined various forms of treatment and punishment.

SUBSTANCE USE DISORDERS AND THE CONTEMPORARY US MEDICAL CARE SYSTEM

The linkage between SUDs and the medical care system has tightened considerably over the past four decades. Coincidentally, in the twenty-first century reform of the overall US health care system appears to be underway on a potentially large scale. This coincidence of increased medicalization of SUDs and health care reform has led to the possibility of a major transformation of the treatment of SUDs in the US. The main vehicle is the passage and implementation of the Patient Protection and Affordable Care Act of 2010, generally known as the Affordable Care Act (ACA). Despite its Congressional passage and being signed into law, the ACA is presently threatened by a number of court challenges as well as both legislative and state level efforts to slow or prevent its complete implementation.

It is however very unlikely that all of the changes underway will be completely reversed. These unknowns may not be fully resolved for more than a decade, and may undergo constant change as the US social system responds to internal demographic and technological change as well as external pressures created by a globalized economy, and completely unpredictable transformations in world politics and the physical environment.

Intended outcomes of this transition for SUDs treatment in the US is the expansion in the availability and accessibility of treatment and a distinctive integration of SUDs treatment into the American health care system such that it achieves the long-aspired goal of being addressed as "a disease like any other." Thus, while most of the attention to this wave of health care reform is upon policy specifics, America may indeed experience a major symbolic and definitional transition regarding SUDs.

The specific provisions of ACA increase Medicaid coverage, which is presently a large-scale payer for treatment of SUDs, but within a much lower income range than that mandated by ACA. Further, the provision of mandatory health insurance of nearly the entire population substantially broadens the potential target

population who may be treated for SUDs without substantial out-of-pocket payment. Under the provisions of the law, group health insurance plans must include "mental health and substance use disorder services, including behavioral health treatment," along with nine other categories of care.

Finally, many different provisions of ACA mandate the integration of all medical services, drawing together much of what is currently "specialty care" (which includes treatment for SUDs), with one of the ideals being the "medical home" where all care is coordinated, duplication eliminated, efficiency in service delivery enhanced, reduced demands for patient skills at "navigating the system," and reduction of futile referrals for needed care through "hand-offs" are ineffective. But far and away the most significant aspect of ACA for the treatment of SUDs is the fact of its specific inclusion in the legislation, and what this means as the culmination of the long struggle for the treatment of substance dependency as "a disease like any other."

PARITY LEGISLATION

A unique force in the projected future of the SUDs treatment specialty must be added to considerations of the impact of health care reform. Shortly before the ACA legislation was passed, Congress enacted and the President signed into a law the Mental Health Parity and Addiction Equity Act of 2008, also known as the Wellstone-Domenici Act. The purpose of this Act, referred to here as WDA, is to require that employers who offer health insurance coverage for mental health and SUDs provide coverage that is no more restrictive than coverage for medical and surgical problems.

This legislation complements the broadened coverage and integrative prescriptions of the ACA, with parity of coverage also reinforcing SUDs as "diseases like any other." In contrast to the ACA, there are at present no predictions of legal challenges to the parity law, although there are few specific tools for guiding its implementation and enforcement. But regardless of the fate of the ACA in the courts or in legislatures, it is difficult to conceive of the reversal of mandated parity in financial coverage for SUDs (as well as psychiatric disorders).

For the treatment of SUDs, the greatest significance of both the ACA and the WDA lies in the fact that these are the first pieces of major Federal legislation that have included mention and discussion of SUDs as an integral part of the health care arena. According to A. Thomas McLellan, Director of the Treatment Research Institute and former Deputy Director of the White House Office on National Drug Control Policy, in the formulation of ACA, treatment of SUDs was not only made normative,

but was seen within the frame of cost savings whereby early interventions in SUDs prevent or reduce needs for later medical care investments. Within WDA, the platform for articulating the concept of parity in coverage was the comparative costs of other medical care. These "firsts" represent a major step toward the institutionalization of treatment for SUDs as a standard expectation within all relevant medical care settings.

THE HISTORICAL PLATFORM FOR SUDS IN TODAY'S HEALTH CARE REFORM

Discussing these projected changes in isolation could be accomplished simple description of the technical provisions of the ACA, but this is likely to be quite meaningless without considering the sociohistorical and political context. Understanding the significance of these reform actions takes us across American history to examine the precursors of today's health care reform in terms of earlier social policies that defined the social impacts of psychoactive substance use and SUDs. An important dimension of this history is that while those involved in the treatment of SUDs have long urged for parity and have been constantly challenged by the imbalance between perceived need for treatment of SUDs and the actual utilization of treatment, there has not until recently been internal pressure to "desegregate" or integrate specialty care for SUDs into mainstream medical care. There is substantial experience with both payment problems and the relative quantity of treatment delivery, but integration is involving and will continue to demand the charting of new territory and the facing of unexpected challenges.

This history begins in Colonial America where psychoactive substance use was initially outside the purview of social concern and beyond the reach of social policy, except for issues related to taxation of production and distribution of beverage alcohol. Drug users were unknown and those whose drinking was viewed as problematic was largely limited to persons who were nonproductive and became wards of the community. A physician and American Founding Father, Benjamin Rush of Pennsylvania, might be counted as a first advocate for "health care reform" for alcoholism by his articulation of a disease conception of the apparently uncontrolled use of distilled liquor. While invariably documented today as the "founding" of modern addiction treatment, there is little evidence of Rush's influence on this score among his own contemporaries.

The next phase saw a slow but soon-to-be dramatically escalated wave of social concern about the dangers and social costs of alcohol use, culminating in National Prohibition, a distinctive social policy almost completely eliminating the legal manufacture or distribution of

beverage alcohol. During the nineteenth century, three "reform" movements highlighting treatment have been documented, none of which yielded lasting effects. First was the invention in Boston of a self-help effort for chronic inebriates who would "take the pledge," and who came to refer to themselves as "Washingtonians." This group established a hospital-like setting for those most devastated by their alcohol consumption. Remnants of that institution still survive today.

Their practices have some clear parallels with the twentieth century technology of Alcoholics Anonymous, but there is no evidence of a connection. Second, activists in New York State developed a major publicly supported sanitarium for chronic inebriates that operated briefly, but which failed as a reform movement when the State Legislature specifically concluded that it was a waste of public dollars to support treatment for this self-indulgent and indolent behavior. Third, a specific residential treatment program for both alcohol and opiate dependence was launched in the 1890s by a physician, Leslie Keeley, which evolved quickly into a "chain" of treatment centers, said to have treated a total of 300 000 patients. The regimen, typically viewed as chicanery by contemporary historians, involved a combination of a secret medication, group discussions, and posttreatment mutual support follow-up in local Keeley Clubs. The Keeley Institutes survived only a short time after Leslie Keeley's death, apparently due more to organizational and financial issues than to perceived failure of the treatment. While no heritage of this effort is claimed, it was remarkably similar in structure to treatment efforts that were to dominate the second half of the twentieth century. Combined treatment of both alcohol and opiate problems in the same setting is especially notable.

Social policies about other psychoactive substances have followed pathways both different and parallel to those directed at alcohol. During the Temperance Movement, moderate concerns about the quasi-medical use of opiates and cocaine led to modest social reactions in the late nineteenth century that is a source of scholarly debate as to whether this "wave" sprung from the widespread use of opiates and other drugs to treat injury and disability resulting from the Civil War. It is noteworthy that Leslie Keeley, who offered opiate-dependence treatment, had been a Civil War surgeon, and likely a substantial number of his patients were veterans of that conflict.

Another brief emergence of medically based treatment (but far from a health care reform was the use by physicians of morphine and heroin (a 1890s invention) as treatments for what was essentially morphine addiction in the late nineteenth and early twentieth centuries. This substitute treatment was eventually forced out of existence by the 1914 Harrison Act,

motivated by the spread of opiate addiction away from the white middle class and into marginalized minority and immigrant populations. This Act ended open traffic in opiates and cocaine, even though programs offering morphine treatment to addicts persisted until 1920 in a few relatively isolated settings. This essentially began the American Drug Prohibition experiment which remains very much alive in the twenty-first century, with efforts and investments that dwarf the earlier prohibition of alcohol.

During the 1920s and 1930s, all forms of medically oriented treatment for all SUDs were essentially defunct, save for some isolated and low visibility private sanitaria. About 20 years after the initiation of Drug Prohibition, the constitutional amendment that had established Alcohol Prohibition was repealed. American culture was placed in limbo about the meaning of alcohol, for the Repeal process was not based on alcohol's safety or the benefits of its use, but on the uncontrollability of its manufacture and distribution. Eventually, the idea of the dangers of alcohol to all users slowly became supplanted by rediscovery of an earlier idea of "alcoholism," its adoption being greatly facilitated by the coincidental invention of an apparently successful "treatment" that became the program of Alcoholics Anonymous (AA).

THE BEGINNINGS OF PARITY FOR SUDs TREATMENT

The overview of the history of health reforms related to SUDs proceeds most clearly from this point if reforms related to alcohol and drugs are viewed separately for most of the twentieth century. The initial drive for the inclusion of alcoholism within health care cannot be labeled as a call for health care reform, but indeed as oriented to inclusion and a very simple form of "parity." Stemming from recently formed (and recently named) AA and reflecting its commitment through its traditions to avoid public involvement, the National Council on Alcoholism Education (NCAE) emerged as a public relations arm of AA, but totally without formal connection or identification. As a potent alternative, it was identified and affiliated from its founding with the Yale Center on Alcohol Studies, bringing creditability and respectability through this Ivy League connection. NCAE was launched in 1944 by Mrs Marty Mann, one of the first women to recover through AA (subsequently renamed the National Council on Alcoholism (NCA) in 1957 and given the expanded label of National Council on Alcohol and Drug Dependence (NCADD) in 1990). Mann had a previous career in public relations and was a deft and effectively aggressive leader of the organization for over 30 years.

Promoting medical parity for the treatment of alcoholism in the 1940s and 1950s was remarkable in several respects. First, its revolutionary nature must be recognized, in that NCAE was formed only 11 years after the repeal of National Prohibition. The revolutionary aspect lies in its redefinition of the alcohol problem as being something other than alcohol itself, but a disease affecting an apparently limited number of people. This contrasted with the official vision of 1933 and before held by the Federal and state governments that beverage alcohol endangered the life of anyone who consumed it. At the same time, the activities of NCAE and its descendant organizations began what was a successful movement to construct a substantial but segregated treatment system for SUDs.

This movement for "parity in recognition" lacked substance in that few if any specific treatments for alcoholism were being promulgated to the medical community by NCAE. The only treatments within its armamentarium were detoxification and AA. The process pursued during this period might be accurately labeled as destigmatization. NCAE's mechanisms were centered on public visibility through the establishment at the community level of local committees or councils, with a core of local AA members encircled by nonalcoholic representatives of the local clergy, physicians, other professions, and often local government.

Much of the publicity centered on the possibilities of recovery, but steered away from specific recruitment to AA. Through the councils' membership and the staging of public presentations, the middle class and respectable nature of the people involved was implicitly emphasized, contradicting the entrenched image of the alcoholic as a "Skid Row" public inebriate without employment, family or even a stable residence.

An early effort to counter this image while creating a new platform for identifying alcoholics began through NCAE as "industrial alcoholism programming." Leaders of the Yale Center of Alcohol Studies had developed "The Yale Plan for Business and Industry" as a means for providing assistance to employees with alcohol problems (largely through AA affiliation) before their behavior led to job termination, a colorful history that has been described by social historians Harrison Trice and Mona Schonbrunn. Between 1948 and 1958, Yale and NCAE employed a colorful and charismatic consultant, Ralph "Lefty" Henderson, who crisscrossed the country as a speaker at local NCAE councils, and visitor to workplaces in an effort to implement Yale Plan strategies. Adoption by workplaces was modest, but became the target of substantial publicity, sometimes accompanied by the endorsement of corporate executives who were willing to be identified as recovered alcoholics. The focus upon the employed alcoholic was a dramatic symbolic opportunity to reconfigure the national image of the "typical alcoholic" as someone like one's neighbors and friends, not the smelly panhandler in the central city. At the same time, the well-being of communities' public inebriates was on the agenda of NCAE. The goal was toward some form of rehabilitation or betterment, first addressing the decriminalization of public intoxication. Instead of public inebriates passing repeatedly through the "revolving door" of the local jail, local communities were urged to establish treatment centers and halfway houses for these individuals wherein opportunities for AA attendance and affiliation were among the offerings. Other than AA, a sharply distinctive treatment technology was not evident.

The movement for official decriminalization spurred through Federal legislation became for a time a centerpiece in the 1950s and 1960s of what was now NCA. This can be viewed as a deliberate effort at health care reform in that it essentially eliminated jail sentences as the societal "cure" for repeated public drunkenness and instead moved toward rehabilitation as the target (Beauchamp, 1980). There was however no suggestion of integration of this treatment with the broader health care community. It was a continuation of a pattern that led to the construction of a substantial but segregated treatment system for SUDs.

To a degree, local law enforcement agencies reacted positively to the removal of their responsibility for public inebriates in their jails. It is unlikely however that decriminalization offered a substantial contribution to a new view of "alcoholism as a disease like any other." This legislative action did not construct a new or potent constituency that would advocate for NCA's goal for "recognition parity."

FORMALIZING TREATMENT FOR SUDs

Two developments that enhanced a broader base for advocacy were the "Minnesota Model" of treatment delivery and a modest but visible success in the development of workplace alcoholism programming. The Minnesota Model can be viewed as a specific step toward a health care "reform" in that it provided a very specific example of the kind of treatment that was being advocated, and at the same time provided for a very tight coupling of the AA model into a professional treatment regimen. Because of the centrality of AA principles within the Minnesota Model, this also set the stage for substantial involvement of recovered alcoholics in the treatment process, which might be viewed as a long-term latent goal of NCAE activity.

A parallel emphasis on medical involvement can be seen in the technology of industrial alcoholism programs.

As mentioned, these had diffused modestly, but following Henderson's work, a specific workplace-oriented department was established within the national offices of NCA, which served the purpose of facilitating the diffusion and implementation of workplace programs at the level of local NCA councils. As the social historians Trice and Schonbrunn describe, these programs had a "reform" and "mainstreaming into medical care" element through the standard placement of the industrial alcoholism program within the company medical department, and program implementation required the full endorsement and active involvement of the company's medical director.

The innovative nature of this placement is not obvious unless one considers obvious alternative placements in universally present safety or labor-relations units, which would have cast totally different images over these programs than that garnered by medical department placements. A further near-universal feature of the workplace program was the employment of a recovered alcoholic as the day-to-day program coordinator, usually drawn from company ranks. NCA's activities in the promotion of workplace-based programs culminated in 1968 in a widely publicized announcement at the 28th World Congress on Alcoholism in Washington DC that the US Federal Government was initiating an employee alcoholism program for all of its civilian employees.

On the last day of 1970, President Nixon reluctantly signed what was called (after the late Senator Harold Hughes of Iowa) the Hughes Act, which established the National Institute on Alcohol Abuse and Alcoholism (NIAAA) within the National Institute of Mental Health, in turn within the National Institutes of Health (NIH). Beyond establishing a modal NIH research institute, this legislation eventually led to what was relatively massive funding for the Federal support of treatment and prevention activities. Included was the national program to advance the diffusion of employee alcoholism programs, and resources were promptly marshaled to support a national campaign that would succeed in mandating health insurance coverage for alcoholism treatment.

THE ORGANIZATIONAL BASIS FOR INTEGRATION OF SUDS INTO MEDICAL CARE

NCA's activism at the national and local levels can be credited with this massive reform. Beyond the many steps necessary to pass this legislation through both branches of Congress, a cherished story is the personal influence used on Nixon by several leading industrialists who were NCA activists and also in recovery. The ingredients of "having a seat" at the NIH, funding for treatment, and insurance coverage for treatment that could be tapped via referrals from workplaces all contributed to a solid platform for institutionalization of alcoholism treatment in American society that was not to be reversed, although its support would suffer multiple setbacks in the decades that followed.

The 1970s and 1980s were marked by large-scale growth in alcoholism treatment and an apparent success at destigmatizing alcoholism. One of the main mechanisms was for famous figures to come forward and announce their successful recovery to the public, eventually including Betty Ford, the wife of the President.

It was however another President, Ronald Reagan, who succeeded in a first setback for this apparently successful health care reform movement by transferring most of the funding authority for the support of SUD treatment from the Federal Government to the states. This change, along with what proved to be a temporary removal of NIAAA from NIH, was implemented throughout the 1980s. Most of the alcoholism treatment was centered on the 28-day Minnesota Model, which proved to be highly vulnerable to a confrontation with newly emergent "managed care" in the late 1980s and early 1990s. With employers clamoring for a reduction in what were believed to be externally mandated increases in health care costs, managed care found funding for alcoholism treatment to be a "sitting duck" for cost-cutting. Among its vulnerabilities was the lack of data to support the need for the 28-day inpatient experience, in contrast to briefer and less expensive outpatient care. Further, the absence of differential diagnoses of alcohol problems coupled with the prescription of the 28-day regimen for practically everyone proved indefensible. Thus the second setback to the earlier "reform" was a sharp reduction in the availability of Minnesota Model treatment, the promotion of a relatively vague alternative of brief outpatient treatment, and sharp limits on reimbursement for alcoholism treatment.

At this point in history, the 1990s, the permanent merger of alcohol and drug treatment interests began, initially fitful and with some resistance (particularly from those identified with alcoholism treatment who likely foresaw downward mobility for themselves and increased stigmatization for their target disorder), but from then to the present, the closest approximation of a "single voice" across alcohol and drug treatment interests has emerged. Before turning to those developments and their role in health care reform, a brief review of drug treatment developments during the twentieth century is in order.

TOWARD INSTITUTIONALIZING TREATMENT FOR ILLEGAL DRUG DEPENDENCE

The use of science to discover effective treatment for opiate addiction began in earnest in the late 1920s, and its limited visibility came with the post-World War II establishment of the US Public Health Service Hospital in Lexington, KY. This hospital served as a prison for addicts who had been arrested in venues across the country and as a research laboratory pursuing two goals: establishing the safety of newly invented pharmaceuticals through using the addicts as experimental subjects, and searching for a nonaddicting substitute for the treatment of opiate addiction. Many other research studies on addiction-related phenomena were conducted, and the Lexington laboratories became the precursor of the research laboratories presently operated by the National Institute on Drug Abuse. The establishment of this "treatment" center (and a sister "hospital" in Fort Worth), eventually included experiments at group therapy and a therapeutic community. "Lexington" brought intentional medical labels to the programs, but not necessarily to the clients. Records of publicity from that era clearly describe a dark and ominous (and not necessarily hopeful) medium-security prison setting.

By the 1960s, increased diffusion of "drug panic" related to heroin use in northeastern urban settings set the stage for what might be seen as a dramatic reform, the emergence of methadone treatment for heroin addicts. Other than self-motivated abstinence preceded by "cold turkey" detox, this was a clearly articulated medical means for addicts to become patients and to become abstinent from opiates. Because it continues an opiate addiction, methadone maintenance has never found strong societal acceptance. However it distinctively introduced "treatment" with physicians and nurses. There were however no serious suggestions of a reform that would "mainstream" methadone maintenance into the health care system.

During this period, two other treatment technologies were present, but of low visibility. These were Narcotics Anonymous, a self-help program in many ways identical to AA, and therapeutic communities, which were partly descended from the controversial Synanon organization, and which had a distinctive set of procedures for rehabilitation within a nonmedical and notably non-spiritual residential setting of up to 2-years-duration. While offering alternatives to methadone maintenance, neither of these programs attempted any kind of integration with the broader health care system.

During the 1970s, National Institute on Drug Abuse(-NIDA) emerged in 1974 as a parallel organization to

NIAAA, with the same authorities for the distribution of funds to support treatment. The activities did not overlap however, for much of the NIDA supported activity within drug treatment occurred close to the criminal justice system, and new treatment centers came to be dependent upon referrals from criminal justice. By contrast, NIAAA was struggling to disengage itself from the formerly criminal Skid Row public inebriates, to the point of initially labeling its workplace programming efforts "Project 95" to describe its targeting of the 95% of American alcoholics who are not on Skid Row. Thus, while there was little of the "medicalization fanfare" accompanying the low-key establishment of NIDA, its presence within NIH was a step toward an institutionalized presence in the mainstream health care enterprise that would not be reversed.

The 1970s also saw the explosion of marihuana and psychedelic drug use among middle class youth, as well as the partly-phantom crisis of opiate addiction and other drug abuse among returning Vietnam veterans. This greatly increased the public consciousness and confusion about nonalcohol psychoactive substances. Various forms of emergency care for overdoses and "bad trips" were evident, but there was no surge toward increasing treatment capacity for SUDs on the basis of this highly visible experimentation or veterans' addiction. Instead it shaped public sensitivities in the direction of support for increased social control and surveillance, and the vigorous reemergence of the War on Drugs in the 1980s.

NIDA experienced with NIAAA the disappearance of its treatment funding authority, but gained new prominence through the highly aggressive actions toward drugs encouraged by President Reagan. In addition to the great waves of interdiction on all borders and throughout the world, drug users in the workplace became specific targets through "drug-free workplace" legislation. Mandatory drug testing, particularly of job applicants, diffused very rapidly and served to undermine the constructive orientations in employee programs that had been initiated and supported by NIAAA. Exclusion and punishment rather than treatment became the bywords of the War on Drugs, but the presence of NIDA ironically allowed for spillover opportunities of increased funds that actually ended up supporting SUD treatment.

CREATION OF A SCIENTIFIC FOUNDATION FOR TREATING SUDS

Bringing together the alcohol and drug strands of reform history in the 1990s, it has been mentioned that the two specialty interests merged, precipitated by the establishment of a merged Federal block grant and other treatment grant support within the new Substance Abuse and Mental Health Services Administration, merging of alcohol and drug "authorities" at the state level, and eventually, providing the range of services for all drug dependence in the same centers, partly driven by the observation that most clients abused multiple substances. This in turn created a "spillover" of therapies that had been developed for alcohol problems such that the predominant treatment model became a substance-free, 12-step orientation model with the goal of long-term abstinence. There is now a single SUD treatment industry, but it is not unified and in fact lacks a unifying professional or trade association or other organizational mechanism that would allow for collectively addressing the challenges of the ACA.

During the 1990s, SUD treatment has been significantly transformed, with several events that can be seen as setting the stage for integration with the broader medical community. These include the evidence-based practice (EBP) movement, medication-assisted treatment of SUDs (especially buprenorphine), the chronic brain disease definition of SUDs, wraparound service adoption and Screening, Brief Intervention and Referral to Treatment (SBIRT)

The essential necessity of adopting EBPs was presented to the specialty in a unilateral fashion following a 1998 commissioned report from the Institute of Medicine. This report made clear that there was a very poor information transfer from treatment research to SUD treatment practice, not unlike other branches of health care where the emphasis upon EBP has become institutionalized. Part of the solution for the SUD specialty was the creation by NIDA of an extensive Clinical Trials Network (CTN) that recently celebrated its 10th anniversary. Utilizing 12 university centers and more than 140 SUD treatment organizations, the CTN conducts intensive clinical trials of treatment technologies either unique to or adapted to SUD treatment and endeavors to diffuse resulting new practices through "blending products" and through a Substance Abuse and Mental Health Services Administration (SAMHSA) supported network of organizations, the Addiction Technology Transfer Centers. The CTN has the potential as both an internal integrative mechanism for the SUD treatment specialty, as well as being an external integrative mechanism into broader health care. It was modeled in part after several mechanisms implemented by the National Cancer Institute, and without doubt serves to legitimize SUD treatment within the broader medical community represented at NIH.

Of the EBPs that have been subject to trials by the CTN and other researchers, the set that offer the most

mainstreaming potential are medications developed and refined for the treatment of SUDs. Here medical management of both alcohol and opiate dependence through naltrexone and detoxification/maintenance for recovery from opiate addiction with buprenorphine are notable links to mainstream medicine, both required supervision by a physician. Using "medication-assisted treatment" to address SUDs may prove a critical link for commonality with the broader medical community.

A Federal initiative launched in 2000 that has specifically established that linkage is the structure within which buprenorphine is delivered to opiate-dependent patients. Rather than adding this to treatments available within methadone clinics, a structure was established that essentially mandates integration with mainstream medicine (particularly primary care) as a precondition for buprenorphine treatment. The intent is to increase utilization of medication-assisted treatment through providing privacy and confidentiality within typical office treatment that may not be available in a methadone clinic. Physicians must be certified by SAMHSA following a training course before they are licensed to distribute buprenorphine (or other drugs for opiate detoxification or maintenance). In order to avoid "pill mills," each physician was initially limited to 30 patients simultaneously, a number later increased to 100 patients. It is expected that counseling will accompany buprenorphine administration. Physicians working within SUD treatment programs can of course use this setting for buprenorphine treatment, although the intention of these regulations was to maximize involvement of the broader medical community.

MECHANISMS FOR MAINSTREAMING AND INTEGRATION OF SUDS INTO MEDICAL CARE

Mainstreaming SUDs into medical care also involves labels. Accompanying the use of medications in treatment has been a pervasive emphasis in publicity about SUD treatment that addiction is a chronic brain disorder, affecting individuals through their lifetimes, and characterized by relapse. Steady promotion of this concept as if it were unequivocally grounded by research findings is a major dimension of an effort (especially within NIDA) to characterize SUDs for legitimate inclusion within general medical care. This description as a chronic disorder also increases the necessary scope of treatment. While earlier discussion described the promotion of alcoholism as "a disease like any other," this is much more specific and perhaps medically compelling. However such discussion, regardless the apparent authority of the source, does not necessarily transform the substantial attitudinal residue among both the public and medical professionals that alcohol and drug dependence are bad habits, describe individuals' moral weakness, or an engrained pattern of selfmedication for an underlying psychiatric disorder.

Another mechanism for integration is embedded in a widely adopted wraparound services that are found in some form in most SUD treatment programs. This concept originated with the Addiction Severity Index developed by Thomas McLellan and his colleagues at the University of Pennsylvania. The fundamental idea is that among SUDs, opiate addiction in particular is characterized by a deterioration of the overall social ecology of the addict's life, with the SUD embedded in medical, psychological, financial, legal, familial, educational, residential, and employment problems. Without addressing the complex of these other issues, treatment of the SUD will have a minimal impact and any success at abstinence will likely be short lived. Inclusion of medical problems as a wraparound service need is a clear bridge to integration with broader health care.

Perhaps the most prominent mechanism geared toward integration is SBIRT. This concept originated with the work of Michael Fleming and others at the University of Wisconsin that produced the dual findings that primary care physicians could effectively identify alcohol problems within their routine practices, and a brief intervention accompanying such identification could have a useful impact on drinking behavior. The SBIRT mechanism now includes a further step of referring to specialty SUD treatment those patients whose problems clearly extend beyond a brief intervention. A somewhat different version of SBIRT uses the brief intervention as a motivator for referral to specialty treatment without the identifying agent attempting an intervention to address the SUD. True to its invention, the heaviest emphasis at present centers on the SBIRT mechanism and its implementation in primary care practice, with reimbursement now available when the full procedure is utilized. This involvement of primary care physicians is a strong example of an integrative bridge of SUD treatment into general medical care.

Other SBIRT implementation settings include emergency rooms and general hospital treatment settings. Research has demonstrated substantial presence of untreated SUDs in both of these settings. Success in primary care and general hospitals rests on the skills of the physicians or nurses in motivating either behavior change or referral action. SBIRT implementation in emergency rooms offers multiple challenges between delivering the immediately needed treatment and the engagement for effective delivery of treatment for SUDs for patients who may be short-term, or who end up in care in some unit well beyond the scope of the emergency service.

Despite some efforts that have not received Federal support, there has been minimal progress in integrating SBIRT into the workplace. Extending back to the early efforts of NIAAA, potential platforms for the use of SBIRT are possible within some forms of employee assistance programs (EAP) where self-referred employees undergo diagnostic interviews with adequately credentialed personnel. SBIRT might also be successfully implemented within wellness programs that are common in larger workplaces. Epidemiological data confirm that the majority of those with untreated alcohol use disorders are gainfully employed, yet the implementation of SBIRT in these settings is yet to become a priority interest in the overall effort toward integrating SUD treatment into general medical care.

BARRIERS TO THE INTEGRATION OF THE TREATMENT OF SUDs INTO MEDICAL CARE

Having reviewed the changes and initiatives that have formed bridges for integration of SUD treatment into mainstream health care, the issue to be addressed is the manner in which the ACA will affect the treatment of SUDs. In this section, examples of problematic areas for integration are considered, including workforce issues, "co-occurring disorders," and acceptance and engagement by physicians and nurses in SUDs treatment.

Is the current treatment workforce eligible for integration into mainstream medical care? Parts of the ACA appear to address this, stressing the need for credentials that extend beyond the training of a substantial minority of the SUD treatment workforce. At the same time, within social work, clinical psychology, nursing, and medicine, there is very little in terms of in-depth training that could either be made available to the current workforce or adequately train a new workforce, which in turn would be expected to be attracted to the engagement in SUD treatment. Thus the current workforce may not be able to meet the requirements of practice within an integrated setting where they likely will be required to deal with multiple medical situations not seen in current specialty SUD treatment. At the same time, no strategic plan appears to be in place to either upgrade their training or train and attract a replacement workforce.

An ongoing example of a facet of integration within the currently segregated SUDs treatment specialty is what is commonly labeled as "co-occurring disorders." At first blush, this would appear to encompass consideration of any ongoing medical problem that is a "preexisting" condition or perhaps even extends to physical and psychological disabilities. However, it refers in fact only to psychiatric disorder that is believed to exacerbate the SUD. This topic is typically addressed separately from the wraparound services discussed previously.

Attention to this limited set of problems is implicitly viewed as a feature of modern, evidence-based treatment in contrast to the 12-step-dominated treatment of the past. Within the unwritten but potent cultural lore of 12-step programs, depression and anxiety, sometimes in severe forms, are viewed as part of the process of recovering from a SUD. The implicit belief is that these problems are the result of the long process of deterioration accompanying the development of the addiction, and that they are natural and to-be-expected experiences for many. As one sustains abstinence and moves toward sobriety through the steps, these conditions will "fall away" and thus do not need ancillary treatment.

The new science-driven treatment dismisses these assumptions as foolish and dangerous, perhaps typical of the outmoded past. Today these co-occurring problems must be addressed in treatment plans. It is argued that either successful treatment of the "other" condition must precede addressing the SUD, or that treatment of both conditions must occur simultaneously. This of course raises complex challenges for the competencies that are available in a treatment setting, leading in many cases to the need for external referral. The issue of third-party coverage for such care may also be complicated, although within the lore of the treatment specialty, it is often observed that the diagnosis of co-occurring disorder is a boon for payments in that the psychiatric diagnosis may create eligibilities for reimbursement that are more extensive than those available to cover the treatment of the SUD. Alternatively, a dual diagnosis may also for an extension of treatment after payments for the treatment of the SUD have been exhausted.

Ideally, this reimbursement problem may be resolved by full implementation of parity legislation. Beyond that resolution, however, the current segregated SUD treatment specialty is not sanguine about its success in addressing what it has called co-occurring disorders. Not surprisingly, comparative data often reveal the worst prognoses for those with these dual diagnoses. Thus there is little argument that within the context of segregated treatment, the limited definition of co-occurring disorders has produced operational and logistic problems that are not yet even close to resolution.

Integration of treatment as outlined by ACA is however a definite challenge to this operational definition of disorders that "co-occur" with SUDs. Without a complete cataloging, it is evident that a multitude of disorders may co-occur with SUDs, particularly closely linked problems such as diabetes, stomach ulcers, circulatory problems, and respiratory issues. It has long been a contention of the SUDs treatment community that the broader medical care community, particularly primary

care physicians, will readily treat the physiological and disabling consequences of substance abuse and addiction, but will not address, diagnose or treat the abuse or addiction itself. Integration and medical home concepts supposedly will bring this bifurcation to an end. Addressing these as co-occurring conditions with SUDs has not been addressed. One can speculate about the need for treatment teams bridging the skills needed for these co-occurrences, the issues of authority in such teams, matters of priority, and the braiding or unraveling of reimbursement.

One of the greatest challenges for the integration of SUDs treatment into mainstream health care under ACA is the engagement of the entire health care workforce, but especially physicians and nurses. Medical and nursing education is completely inadequate in its past and present coverage of SUDs. There has long been evidence of negative attitudes toward SUDs among physicians and nurses, not only sharing negative stereotypes with the general public but having had negative socialization experiences where patients with SUDs have been recalcitrant, resistant to treatment, and chronic relapsers. It is clear that within integrated systems of care such as medical homes, leadership positions will go to physicians and nurses. Without their active support and involvement, adequate and appropriate attention to SUDs may be at risk. Most of these professionals currently lack any in-depth training in the nature of SUDs or the effective technologies of SUDs treatment. This is perhaps the most threatening artifact of the decades of segregation of SUDs treatment from mainstream medical care. There appear to be no plans whatsoever for the training of these populations or for the supplementation of medical and nursing education to include adequate coverage of SUDs.

CHALLENGES IN THE IMPLEMENTATION OF HEALTH CARE REFORM AND THE TREATMENT OF SUDs

As a concluding set of observations, it is important to reverse the focus and consider some potential ways in which the integrated treatment of SUDs might affect mainstream health care, including the concept of wraparound services, long-term follow-up, and the recovery movement.

As more acute diseases are successfully contained, the fact emerges that most of the American population will eventually cope with a chronic illness, in many cases leading to death. Through its concept and implementation of wraparound services, SUD treatment has valuable lessons to transfer to the care of other chronic disorders. There is ample documentation of the life

difficulties that all sorts of patients experience in attempting to sustain the gains from treatment. As SUD treatment becomes integrated into general medical care, the logic of wraparound services can be transferred to those with other chronic conditions whose problems in their life ecology can undermine treatment gains. Wraparound services do not require added services beyond skilled selection and referral to external agencies specializing in meeting these needs.

The principle of investing in long-term follow-up originates with AA, has long been accepted among SUD treatment specialists, and today is incorporated into most of SUD treatment. Among the very few changes observed in the AA culture over the decades was a transition from the use of the term "recovered alcoholic" to "recovering alcoholic." The positive idea of continuous growth in ongoing 12-step participation is intermingled with the subtle warning that changes in lifestyle and other transitions can lead to relapse. The fit with the nature of chronic disease is obvious, almost all of which have a lifestyle change component associated with maximizing long-term health. Among those who have experienced SUD treatment, continuous recovery experiences can lead to a positive "recovery" identity which can be supported and encouraged by medical personnel without requiring their active involvement in added therapy.

Over the past decade, the long-term recovery concept has been broadened and investments in treatment by SUD specialists have been enhanced by a new "recovery movement." Partly consistent with the model of SUDs as lifelong chronic diseases, the recovery movement emphasizes the need for involvement in communities of others in recovery in order to sustain gains. While building upon and to a degree incorporating some of the concepts of 12-step programs, the recovery movement attempts to be nondoctrinaire and totally inclusive of persons will a wide range of treatment experiences. Spreading this notion to other chronic diseases could be a very low cost means of mobilizing community-based interests and resources that sustain the investments made in the gains accomplished by treatment.

List of Abbreviations

AA Alcoholics Anonymous
ACA Affordable Care Act
CTN Clinical Trials Network
EBP evidence-based practice
NCA National Council on Alcoholism

NCAE National Council on Alcoholism Education

NIAAA National Institute on Alcohol Abuse and Alcoholism

NIDA National Institute on Drug Abuse NIH National Institutes of Health FURTHER READING 577

SAMHSA Substance Abuse and Mental Health Services

Administration

SBIRT Screening, Brief Intervention and Referral to Treatment

SUDs substance use disorders WDA Wellstone-Domenici Act

Glossary

- **Affordable Care Act** it is believed that the ACA will reinforce the parity law, ensuring that all Americans are able to get the SUD care that they require.
- Mental Health Parity and Addiction Equity Act of 2008, also known as the Wellstone-Domenici Act under this Federal law, insurance companies will not be able to limit benefits for the treatment of substance use disorders. This bill was a major legislative project of the late Senator Paul Wellstone and former Congressional Representative Jim Ramstad, both of Minnesota, and both publicly announced recovering alcoholics. It was the only amendment attached to the history-making \$780B "bailout" bill passed by Congress to stimulate the American economy.
- Parity equality, parity is the recognition of substance use disorders as equivalents to physical illnesses. Historically, many health insurers have limited benefits for SUDs and psychiatric disorders to a much lower level than those available for physical conditions. Consequently, many people choose not to seek treatment, and brief therapy becomes the only option for those who do get help.

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Improving the Quality of Addiction Treatment

Kim A. Hoffman, Dennis McCarty

Oregon Health & Science University, Portland, OR, USA

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IMPROVING THE QUALITY OF ADDICTION TREATMENT

Treatment for alcohol and drug use disorders varies. Addiction treatment is the product of tens of thousands of practitioners with idiosyncratic approaches to counseling; most counselors practice without professional licensure and receive little supervision. For decades, the primary training for many alcohol and drug counselors has been personal experience in recovery rather than professional training in graduate schools. Most counselors work in independent not-for-profit corporations that specialize in treating alcohol and drug use disorders. The 13 000–14 000 specialty clinics in the United States tend to be small with a median daily caseload of 30 patients. Services are not standardized across clinics or within clinics

across counselors. Treatment outcomes, moreover, appear to be relatively unpredictable and outcomes tend to be similar when examined by treatment modality, level of care, and patient attributes. Addiction treatment's reliance on counselors without professional licensure practicing in small independent specialty clinics with little supervision and few standardized practices contributes to concern that quality of care is uncertain. From an external perspective, the delivery of addiction treatment appears to be haphazard. It is not surprising that many observers are skeptical of the value of addiction treatment and demand evidence of treatment effectiveness. Persistent skepticism challenges the field of addiction treatment to document the quality and effectiveness of care, and to demonstrate the personal and social value of investments in addiction treatment.

Improving the quality of care is a challenge. There is a need for quality treatment but typical approaches to quality assurance are reactive - licensure, accreditation, credentialing, and practice standards. Recent approaches to treatment quality emphasize strategies to continuously improve treatment processes. Examples of process improvement from the Network for the Improvement of Addiction Treatment (NIATx) and related initiatives illustrate the application and impacts of quality improvement. Performance measurement becomes the hurdle program management must identify useful measures of performance that link to patient outcomes. The environment for addiction treatment is changing rapidly. In 2025, addiction treatment may be more fully integrated with primary care, use population measures of health, and rely on emerging electronic technology.

NEED FOR QUALITY ADDICTION TREATMENT

In the United States, about 23 million individuals 12 years of age and older meet diagnostic criteria for alcohol and drug use disorders. The estimated cost of untreated addiction sums to more than \$180 billion a year (i.e. lost productivity, law enforcement costs, health care expenses, and entitlement payments). In addition to the financial costs, untreated addiction increases medical risks and death, family and social problems, and reduces quality of life. Conversely, individuals who initiate and maintain stable recovery benefit through improved health, increased employment, and enhanced well-being. Society benefits through reductions in crime and the burden of caring for individuals and their families disabled by addiction. For all of these reasons, it is incumbent upon the field to deliver the highest quality treatment.

STRATEGIES TO PROMOTE QUALITY CARE

Quality of addiction treatment has been a concern since states began building addiction treatment systems in the 1960s and 1970s. Quality assessment has evolved from a focus on licensure to accreditation and credentialing to development of practice standards and, more recently, to the use of process improvement.

Licensure

States license professions and services to protect consumers. The enabling legislation that created state programs for alcohol and drug treatment typically includes licensure requirements and strengthen community confidence in the credibility and quality of addiction treatment services. Licensing regulations specify health and safety standards (e.g. screens for windows, width of door ways), and staffing requirements (e.g. staff to patient ratios, hours of staff training, and supervision). Because state licensing regulations typically date to the 1970s, they reflect the dominant models of care at that time (i.e. residential and inpatient care and the use of staff with personal experience in recovery and without professional graduate education). States typically license addiction treatment programs and facilities rather than practitioners. Practitioner licensure is a relatively new development for addiction treatment professionals. State standards are idiosyncratic to each state and there is little consistency across states. State licensure sets minimum standards to operate a business in the state.

Accreditation

Because of the variability in state licensure requirements, trade groups established service standards that were consistent across the membership and more stringent than state licensure requirements. Accreditation offers consumers increased confidence in the credibility and quality of the services provided, and may offer a competitive advantage over nonaccredited services. Accreditation requires organizations to meet specific standards of care and business operations (e.g. treatment services provided and documentation required, facility requirements, human resources, safety and infection control, patient rights, and performance improvement). Survey teams of professionals from other accredited organizations conduct site visits to determine if applicant organizations meet the accreditation standards. Organizations are typically visited every 2 or 3 years in order to maintain accreditation.

In the behavioral health field, the most prominent accreditation organizations include the Joint Commission (the Joint Commission on Accreditation of Health Care Organizations) and CARF International (formerly the Commission on Accreditation of Rehabilitation Facilities). The Joint Commission dates its efforts to standardize hospital services to the founding of the American College of Surgeons in 1913 and the subsequent creation of the Joint Commission on Accreditation of Hospitals in 1951; accreditation of mental health and addiction treatment services began in 1972. CARF International began in 1966.

The 2007 National Survey of Substance Abuse Treatment Services (N-SSATS), an annual census of addiction treatment facilities, reports that the Joint Commission accredited 21% of the nation's 13600 addiction

treatment facilities and CARF International accredited 20%. A handful of facilities reported accreditation from the Council on Accreditation (5%) and the National Council on Quality Assurance (3%). The Joint Commission accredited more facilities operated by federal agencies (80%), general health care organizations (67%), and mental health programs (36%) than freestanding addiction treatment centers (17%). Similarly the Joint Commission was more likely to accredit inpatient services (79%) than methadone (33%) and outpatient services (20%). CARF dominated the accreditation for methadone (51%). Overall, 95% of the addiction treatment facilities responding to N-SSATS reported being licensed or accredited.

Credentialing and Privileging

Health care organizations usually verify that the practitioners they hire are appropriately trained and qualified. Background checks confirm that practitioners completed training in accredited professional programs and have professional licenses. Without appropriate credentials, practitioners cannot be granted practice privileges within the health care organization. Addiction treatment organizations, however, may be less likely to complete formal verification of counselor training because many of the counselors they hire are not licensed to practice independently.

Practice Standards and Clinical Guidelines

Clinical guidelines and practice standards usually emerge from professional trade organizations to establish standards of care and promote consistency across practitioners in the delivery of care. The American Psychiatric Association, for example, developed guidelines for the treatment of alcohol and drug use disorders.

The most important standard of care may be the National Voluntary Consensus Standards for the Treatment of Substance Use Conditions: Evidence-Based Treatment *Practices* issued by the National Quality Forum in 2007. The recommendations, applicable to all members (national consumer advocacy groups, health professional trade associations, health systems, health plans, groups that purchase health plans, pharmaceutical companies, and research institutes), identify four domains (and sub-domains) of expected services for addressing addiction: (1) identification of substance use conditions (screening and case finding, diagnosis and assessment); (2) initiation and engagement in treatment (brief intervention, promoting engagement, and withdrawal management); (3) therapeutic interventions to treat substance use illness (psychosocial interventions and pharmacotherapy); and (4) continuing care management of substance use illness. As a result of the National

Quality Forum's standards, health care plans and health care organizations are expected to screen for alcohol and drug disorders, initiate care, and use evidence-based practices for the treatment of addiction. The standards specifically recommend pharmacotherapy for adult patients with no medical contraindications and diagnosed with opioid, alcohol, and/or nicotine dependence; the standards stipulate that medication should be provided in combination with psychosocial treatment. If fully implemented, the standards could facilitate the integration of addiction treatment into general medical care.

Process Improvement

Quality assurance through the use of licensure, accreditation, credentialing, and practice guidelines tends to be a reactive process. When systems fail to meet standards, corrections are made. Quality improvement is a proactive process that shifts the focus from correcting errors and mistakes to preventing errors and mistakes. Systems are developed to minimize the potential for error and seek continued improvements in the quality of care (fewer mistakes). Quality improvement also shifts perspective from organizational needs (i.e. maintain accreditation) to consumer needs (i.e. how do we serve patients more efficiently and effectively) and requires attention to patient expectation and satisfaction. Quality improvement is now an important facet of accreditation and a central part of quality care.

QUALITY IMPROVEMENT AND HEALTH CARE

The Institute of Medicine's Committee on the Quality of Health Care in America challenged the US health care system to improve health care delivery systems, prioritize patient needs, implement evidence-based decision making, continue efforts to improve patient outcomes, and reduce inefficiencies. Their report, Crossing the Quality Chasm, encouraged the US health care system to adopt six aims to guide quality improvement efforts: (1) safe care - avoids injuries to patients from the care intended to help them; (2) effective care - provides services based on scientific knowledge to all who could benefit and refrains from providing services to those not likely to benefit; (3) patient-centered care – is respectful of and responsive to individual patient preferences, needs, and values and ensures that patient values guide all clinical decisions; (4) timely care - reduces waiting time and sometimes harmful delays for both those who receive and those who give care; (5) efficient care – avoids waste, in particular waste of equipment, supplies, ideas, and energy; and (6) equitable care - consistent high quality across gender, ethnicity, geographic location, and socioeconomic status. A 2005 Institute of Medicine report extended the *Crossing the Quality Chasm* structure to alcohol, drug, and mental health treatment and recommended efforts to (1) promote patient-centered care, (2) foster the adoption of evidence-based practices, (3) develop and use process and outcome measures to enhance the quality of care, and (4) mandate the use of quality improvement measures.

The Institute of Medicine reports catalyzed the application of process improvement within US health care systems. Systems of care are expected to collect data that document the effectiveness of care delivery and use the data to proactively manage care so that processes of care become more efficient and more effective. These expectations are generalizing slowly to the delivery of behavioral health care and to treatment for alcohol and drug use disorders.

IMPROVING THE DELIVERY OF ADDICTION TREATMENT

The Institute of Medicine's six dimensions of quality care apply to treatment for alcohol and drug use disorders. Delayed care is less effective; delays reduce rather than improve motivation for treatment. Treatment systems and providers should identify and address disparities in access and retention so that underserved groups have equitable access to care. System changes can promote the adoption of evidence-based practices including the use of behavioral and pharmacological therapies. Enhanced retention reduces no-show rates and improves counselor productivity and efficiency. Attention to patient needs leads to changes from systems that benefit practitioners (e.g. 50-min sessions between the hours of 9:00 and 5:00 on weekdays) to more accessible services (e.g. early morning and evening services including weekends). Despite the promise of process improvement, the application to addiction treatment remains novel. NIATx is helping addiction treatment organizations and systems improve the quality of care.

NIATx

In 2003, the Center for Substance Abuse Treatment (CSAT) and the Robert Wood Johnson Foundation (RWJF) collaborated to bring quality improvement to addiction treatment. Their aims included improved access and retention, and as a result, improved efficiency and effectiveness. The vehicle for their initiative was the NIATx at the University of Wisconsin – Madison. NIATx provides training to participating agencies in implementing a simplified version of the Institute for Health care Improvement's hospital improvement support

system. NIATx combines the process improvement tradition of Deming and Juran with four quality improvement aims: (1) reduce waiting time to treatment (timeliness); (2) reduce the number of clients who make first contact but do not come in for assessment (noshows); (3) increase the number of clients admitted to treatment (admissions); and (4) retain clients in treatment (continuation).

NIATx uses five principles which evolved through a review of product innovation and process improvement research. The first principle is "Understand and involve the customer." Customer-oriented organizations involve those they serve in developing and assessing improvements, confirming that improvements meet expectations. Customers in the substance abuse treatment realm are not limited to clients; this principle extends to the families of clients, staff working at the site, and even the surrounding community. The second principle, "Fix key problems," links organizational change to agency goals by directing change agents to focus on processes that are critical to the organization. Specific targets vary. Agencies are encouraged to link changes to salient organizational objectives such as reduced staff turnover or improved client retention and, in turn, enhance the agency's business case. The third principle, "Pick a powerful change leader" addresses how to select individuals who will lead change cycles and coordinate change teams. These leaders must have adequate authority and respect from staff to build and motivate change teams. They must also be able to promote buy-in by having a clear vision that is attractive clinic-wide. The fourth principle, "Get ideas from the outside," encourages organizations to seek input from outside their field. In fact, the process improvement movement within the health care field draws heavily on continuous improvement models initially developed to improve manufacturing processes. Change teams are encouraged to seek out creative ideas from other organizations' successes including business practices from other domains such as the transportation and hospitality industries. The last principle is "Use rapid-cycle testing."

Participants use rapid Plan-Do-Study-Act (PDSA) cycles to identify organizational problems and generate solutions (Plan), implement new processes (Do), measure and assess the outcomes (Study), and institutionalize the change or make additional changes (Act). Ideas for change projects can be self-generated by a change team or the result of a "walk through." Walk throughs involve a staff member role-playing as a client in order to gain a customer perspective. For example, during a walk through the staff member will call for an appointment and document what kind of an experience it was and ways to improve it. Another example is arriving for the intake appointment and observing

how they were greeted, how long the intake process took, any redundant paperwork, etc. On the basis of this information, changes are proposed and piloted to assess feasibility and initial effects. Participating agencies strive to use these observations to remove inefficiencies that delay admissions and contribute to missed appointments and early dropout. Strategies include but are not limited to (1) paperwork reduction, (2) motivational interviewing, (3) reminder calls, (4) improved transitions between levels of care, (5) contingency management, and (6) counselor-specific feedback. A cross-site evaluation of NIATx participants found a 37% reduction in days to treatment from 19.6 to 12.4 days across all levels of care. Retention in care also improved; the proportion of clients who completed a first session of care and returned for a second and third session of care increased 18% between the first and second session (72–85%) and 17% between the first and third session of care (62–73%).

NIATx Case Study: Acadia

Acadia Hospital, a freestanding psychiatric hospital in Bangor, Maine, participated in the initial cohort of NIATx members. In 2003, 25% of the clients who called for outpatient care at Acadia attended their assessment appointments, typically 4 days passed between first call for treatment and intake appointment, and only 19% entered treatment. Acadia formed a walk through team and recorded experiences, timelines, and questions encountered from a client perspective. The walk through identified barriers to admission in Acadia's intake procedures; clients were required to place daily calls to the assessment center to schedule appointments to "demonstrate their interest in treatment." Acadia used the NIATx process improvement approach to reduce the time between a first call for service and admission through a series of changes: (1) not requiring patients to call during the waiting period and (2) introducing first-come, first-served walk-in assessments. As a result of the changes, 65% of the approximately 225 clients a month who called for treatment came in for assessment (compared to the 25% baseline) and 52% of the clients (instead of 19%) entered treatment. Other changes, including creating a pool of clinicians to accommodate heavy intake days and expanding the number of hours per day, staff could evaluate clients led a reduction in time to treatment from 4.1 to 1.3 days. Now that Acadia served more clients, they added staff and increased revenue by 56% over 2 years.

NIAT_x 200

NIATx 200 tested the structure of NIATx. A randomized trial of 201 agencies examined the effectiveness of

four combinations of services for adopting and sustaining organizational improvements: (1) learning sessions - biannual meetings where change teams convene to learn and gather support from each other and to receive technical assistance and guidance from outside experts on how best to adopt innovations; (2) interest circle calls - monthly teleconferences where agency change leaders discuss change-related issues and progress (participants share and discuss strategies to improve timeliness, continuation, admissions, dropouts, and transitions); (3) coaching - coaches use site visits, monthly phone conferences, and e-mail to help agencies address key issues, offer process improvement training, and promote appropriate innovation; and (4) all three services (learning sessions, interest circle calls, and coaching). The NIATx 200 website (http://www. niatx200.net) provides useful process improvement tools including (1) a catalog of change ideas and case studies, (2) a toolbox providing just-in-time training on topics such as walk throughs and key innovations, (3) online tools to assess organizational (or project) readiness for and ability to sustain change, and (4) links to relevant process improvement websites.

STAR-SI

The Strengthening Treatment Access and Retention – State Implementation (STAR-SI) program was funded by the Substance Abuse and Mental Health Services Administration's (SAMHSA) CSAT and the RWJF. STAR-SI extends NIATx principles to state-level process improvements and improves delivery of substance abuse treatment. System barriers and broken administrative procedures can often only be addressed at the state level. STAR-SI encouraged states to leverage their position of purchasers of addiction treatment services states to improve practice. Nine state-provider partnerships in Florida, Illinois, Iowa, Maine, New York, Ohio, Oklahoma, South Carolina, and Wisconsin received funding to implement process improvement strategies targeting fiscal, regulatory, and policy changes. An important component of STAR-SI includes designing and testing methods states and other payers use to engage with each other and with providers. The case of Oklahoma provides some insight into STAR-SI's success.

STAR-SI Case Study: Oklahoma

The Oklahoma Department of Mental Health & Substance Abuse Services (ODMHSAS) began its work with six providers to review state processes that impede delivery of care. After identifying issues such as complicated certification rules, contract requirements, and

miscommunication between the state and providers, the partnership used process improvement methods to ameliorate these problems. As a result, redundant paper was eliminated, waiting times to treatment were reduced, and continuation rates increased. Jennifer Glover, director of ODMHSAS reported that the key was changing the nature of the relationship: "Historically, providers have seen the single state agency as an enforcer, rather than as a partner." The collaborative use of change cycles invited provider input in a way that had never occurred before, bringing about a commitment to a "culture of change." In fact, soon after the initiative's success was reported, the governor signed state legislation which required providers to perform "walk throughs," a component that fosters a customer-centered approach to process improvement.

Advancing Recovery

Advancing Recovery was an RWJF initiative using process improvement strategies and system change to promote the adoption of evidence-based practices for addiction treatment. Twelve states or cities (Alabama, Arkansas, Baltimore, Colorado, Dallas, Delaware, Florida, Kentucky, Maine, Missouri, Rhode Island, and West Virginia) formed partnerships with addiction treatment centers to facilitate the use of behavioral and pharmacological therapies through changes in regulation, interagency collaboration, financing, treatment processes, and customer input. Comparing the first and last quarters of the year, Colorado, Dallas, Maine, Missouri, and West Virginia reported a collective 163% increase in the use of medication-assisted treatment and Alabama, Arkansas, Baltimore, Colorado, Kentucky, and Rhode Island increased the use of continuing care 28%. Advancing Recovery illustrates the application of process improvement to system changes for addiction treatment and the potential to leverage change and strengthen the use of evidence-based practices.

A common characteristic of process improvement strategies is the attention to performance measures. Collection and analysis of valid and reliable data can be used to guide and evaluate efforts to promote improvements in the quality of care. Data managers, policy makers, and researchers are increasing attention to data system development to enhance tracking of service quality measures.

PERFORMANCE MEASUREMENT

Process improvement implementations rely heavily on collection and analysis of data. To measure and improve delivery of care, systems must be able to collect information, measure change, and provide feedback. The Health Care Effectiveness Data and Information Set (HEDIS) (a set of performance measures used to compare and evaluate health plans), for example, includes performance measures developed by the Washington Circle to assess the initiation of treatment for drug and alcohol disorders (the percent of patients diagnosed with a drug or alcohol problem who begin care within 14 days of the diagnosis) and engagement in care (percent of those who initiate care who receive two or more units of care within 30 days). The data suggest that health plans have weak showings on these measures. The percent of patients in commercial plans who initiate care has declined from 46% (2004) to 43% (2009) and the percent who engage in care (16%) is disappointing.

Barriers to Performance Measures

Data systems in addiction treatment programs are typically underdeveloped, underfunded, underutilized, and poorly maintained. A key challenge in the assessment of substance abuse treatment is the development of systems and measures to accurately monitor quality indicators. Innovations to improve data system infrastructure are critical for informing decision makers about quality measures. The same innovations seen in the medical field for reducing errors and improving outcomes can be applied in the addiction field. Challenges associated with these improvements include the cost of the technologies and workforce training.

Small numbers are a critical impediment to implementing electronic health records within substance abuse treatment systems: the median number of clients in outpatient treatment is 30, so the per patient costs associated with computerizing records is an economic challenge. In addition, many addiction treatment agencies do not intrinsically value data collection and data-driven decision making; therefore, there may be few perceived benefits to the treatment center other than completing state and federal reporting requirements. In an examination of program use of data for quality improvement, agencies struggled to accurately and consistently provide client-level data that would inform them of their progress on their process improvement goals. Primary barriers to the use of data include lack of expertise and system complexity. In NIATx many counselors had difficulty understanding appropriate outcome measures or did not collect appropriate baseline data. Moreover, data collection was unreliable due to data collection staff turnover and position vacancies. Accurate data collection of measures at the agency is critical to track the progress agencies are making with clients prior to their discharge. Also of interest is what happens to clients after they leave treatment. Does treatment and improved agency processes have an impact on clients post-discharge?

Quality Improvement and Client Outcome Measures

Efforts to track clients after leaving treatment are costly and impractical. A critical public policy issue for studying the quality of substance abuse treatment, nonetheless, is to provide evidence on treatment effectiveness by linking process quality measures with enhanced treatment outcomes.

Improved data reporting through electronic health records and standardized measures is a step toward automated quality monitoring. At present, however, tracking systems generally cannot provide data on outcomes beyond treatment discharge. Research documents the relationship between treatment and improved social outcomes such as reduced criminal activity and health care costs, but little is known of how improvements in the delivery of drug treatment influence these relationships over time. This barrier to progress in the field can be addressed by leveraging technology to link across disparate state administrative databases that capture data on health care utilization, employment, and criminal justice involvement. State data systems offer valuable yet underutilized methods of monitoring provider performance and client outcomes.

Linking state administrative systems facilitates analyses of access to and utilization of addiction treatment services, treatment outcomes, and societal economic impacts. The ability to link records across systems becomes an important source of information to evaluate the longitudinal impact of an intervention. In order to develop appropriate research protocols, researchers working with state administrative datasets need to identify and select the appropriate data sources, determine how to obtain the required data, and understand the advantages and challenges of the selected data sources. Client outcomes are of particular interest to program administrators and state legislators responsible for treatment funding decisions and long-term planning.

ADDICTION TREATMENT QUALITY IN 2025

The addiction treatment system in the United States is likely to change rapidly in the next generation. Efforts to reform health care and to integrate addiction treatment into primary care will change the delivery of care and the assessment of treatment quality. There will be more focus on population measures of effectiveness and greater reliance on electronic technology.

Traditionally, substance use conditions are treated primarily in specialty clinics, separate from general medical practice. Communication about client conditions and status between treatment providers and general health care practitioners is nonexistent and routine screening for substance use disorders is atypical. When health care providers identify problems, moreover, the patient may simply receive a referral, with no follow-up. While treatment has generally occurred outside primary and other health care settings, creative models for integrated care are being developed and may change the assessment of treatment quality.

Integrated Treatment and Parity

In the United States, two federally sponsored studies have increased support for the integration of services. The first, Integration of Mental Health/Substance Abuse and Primary Care, was sponsored by the Agency for Health Care Research and Quality as part of its Evidence Report/Technology Assessment Series. This report found that integrated care led to better outcomes for those with alcohol use disorders and documented that complex, multi-plan payment schedules were an impediment to the implementation of this integrated model.

The second report, Reimbursement of Mental Health Services in Primary Care Settings, was sponsored by the SAMHSA. The goal was to respond to the 2003 President's New Freedom Commission on Mental Health, Transforming Mental Health Care in America, which called for improved integration of physical and mental health. SAMHSA collaborated with the Health Resources and Services Administration, and the Centers for Medicare & Medicaid Services (CMS) to document Medicaid/Medicare barriers to reimbursement of mental health services within primary care. It also detailed recommendations for ameliorating these barriers. Though its focus was on mental health, the barriers to reimbursement for integrated treatment for substance use disorders are similar.

Policy makers have taken note of these and other reports and studies. For example, the Wellstone and Domenici Mental Health Parity and Addiction Equity Act of 2008 increased health plan coverage for addiction treatment: financial co-pays and limits on amount of care for behavioral health services must be similar to those provided for medical care. Enhanced utilization of addiction treatment is likely to amplify concerns about the quality and effectiveness of care. Because the act eliminates barriers to the use of services for substance and mental health disorders, some have expressed concern that these changes may increase health plan costs due to increased service utilization. These fears may be unfounded: a study of the implementation of parity in the plans of federal employees

found only a slight increase in costs to the health plan. Health care reform initiatives may have more extensive impacts.

Health Care Reform

The Patient Protection and Affordable Care Act is reforming health care in the United States. The Act attempts to better control the health care expenses, enhance the quality of health care, and reduce the number of uninsured. When fully implemented in 2014, economists estimate that an additional 30 million individuals will have Medicaid health insurance. It has the potential to catalyze substantial change in the financing of addiction treatment. SAMHSA anticipates that Medicaid and other health plans will be the primary payer for most addiction treatment services. As a result, resources such as the federal block grant could be used to support Medicaid, replacing the current system that directs grants to and contracts with freestanding specialty addiction treatment centers. Health plans are typically selective in their purchase of service contracts and screen for indicators of quality care. Business models for addiction treatment programs are likely to change dramatically; programs that provide evidence of quality care are likely to have competitive advantages. Additionally, treatment organizations and practitioners may be required to meet Medicaid eligibility standards and these standards are likely to require individuals with graduate degrees and professional licensure. This could have a dramatic impact on the workforce in a field where only about 50% of the counselors have graduate degrees.

As the Affordable Care Act impacts the delivery of health care, the organization and financing of addiction treatment services are adapting. Policy makers tout and test pay-for-performance. Providers and practitioners who generate higher rates of sustained recovery will be more competitive in the market. There is likely to be less attention to the quality of treatment processes and more attention to the quality of stable outcomes. Services may shift from an acute care model with a beginning (admission) and end (discharge) for each episode of care to chronic care strategies that emphasize retention in care over prolonged periods of time so that symptoms are monitored continuously and care is intensified as needed. Integration with medical care will be more common. Use of pharmacological therapies will be expected. Medicaid is likely to become the dominant payer for publicly funded addiction treatment. State Medicaid plans increasingly capitate health plans to deliver all required care including treatments for alcohol and drug use disorders. Health plans will be selective in who they contract with and are likely to restrict reimbursement to licensed professionals. With more reliance on professional licensure to identify qualified practitioners, concerns about the quality of treatment may dissipate and attention to the quality of outcomes will increase. Market forces, therefore, are likely to push the addiction treatment system toward the development of outcome monitoring systems. Policy makers are also likely to realize the need to adapt to population perspectives to reduce the prevalence of alcohol and drug disorders.

Population Quality Strategies

Alcohol and drug control policies are enacted to control the supply or demand for drugs and alcohol. A seminal monograph entitled Alcohol Control Policies in Public Health Perspective was one of the first to highlight the influence of national and international governments and agencies on prevention and treatment. Today, substance abuse treatment policies vary widely across the globe. In some countries such as Sweden, substance abuse treatment is outside the health care infrastructure. Other countries, such as the Netherlands, allow for injection rooms for the consumption of prescribed heroin. With the wealth of scientific evidence available today, policy makers can make informed decisions to build public health strategies that reduce alcohol and drug problems. There is no single policy measure that is able to ameliorate all drug and alcohol problems. Most countries are finding that good strategies include incorporating a range of measures.

Drug and alcohol policies include (1) population-based policies, (2) problem-directed policies, and (3) direct interventions. The first group includes actions such as taxation and legal restrictions, education, and media campaigns. Problem policies target alcohol and drug-related problems like drinking and driving. Direct interventions include policies for individual users such as treatment, brief interventions, and harm reduction strategies. Effective policies require strategies to promote efficiency in the organization and delivery of care and enhance the capacity to serve more patients.

E Technology Quality

Patients, policy makers, and other stakeholders expect addiction treatment to keep pace with the latest innovations and trends to deliver quality care. Use of e-technology, for example, may enhance counselor productivity, improve efficiency, and develop the quality of clinician-delivered treatment. Internet applications are emerging for screening, brief interventions, continued monitoring of patients, and delivery of clinical training in evidence-based practices for addiction treatment providers. For instance, online counseling and technology-assisted interventions can improve treatment

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and engagement using e-mail communications. Cognitive behavior therapy seems especially amenable to computerbased therapy. Electronic applications available on the web may also reach users at earlier stages in their disease, reaching subgroups whose pathology has not progressed to more advanced stages. Computer and Internet-based interventions and self-help options have the potential to close the treatment gap, reaching groups that do not seek traditional methods of treatment. Future advances in the delivery of treatment policy should promote the use of such programs into practice, and replace outdated and ineffective modes of treatment. Current policies, however, require face-to-face contact for billable services. Pay-for-performance and performance-based contracting are emerging strategies to alter the financing of addiction treatment services. As addiction treatment services become more integrated with primary care, demands will increase for effective and efficient service delivery.

DISCUSSION

For some who struggle with alcohol and drug use disorders, addiction is a chronic relapsing illness and critics question the effectiveness of the current treatment system. Health care costs substantially increase over the life of individuals with substance use disorders, especially for those with comorbid conditions. Substance use conditions complicate treatment of other medical conditions such as diabetes. Screening and early intervention can prevent substance use problems from escalating. These concerns are advancing to a more holistic and integrated approach to treatment. There is a growing recognition that the field of addiction treatment must document the quality and effectiveness of care. The substance abuse treatment field has reached a critical juncture: new ways of thinking are changing treatment for substance use disorders and, as a result, the organization and delivery of care. The ultimate goal remains improving the quality and effectiveness of addiction treatment.

SEE ALSO

Health Care Reforms and Treatment for Substance Use Disorders, Evaluating Treatment Efficacy, Economic Analysis of Addiction Treatment Programs, Evidence-Based Treatment, Dissemination of Evidence-Based Treatment into Practice, Treatment-as-Usual for Substance Abuse in Community Settings, International Policies to Reduce Alcohol Consumption and Related Harms, International Policies to Reduce Illicit Drug-Related Harm and Illicit Drug Use

List of Abbreviations

CARF Commission on Accreditation of Rehabilitation

Facilities

CSAT Center for Substance Abuse Treatment

NIATx Network for the Improvement of Addiction Treatment
N-SSATS National Survey of Substance Abuse Treatment

Services

ODMHSAS Oklahoma Department of Mental Health & Substance

Abuse Services

PDSA Plan-Do-Study-Act

RWJF Robert Wood Johnson Foundation

SAMHSA Substance Abuse and Mental Health Services

Administration

STAR-SI Strengthening Treatment Access and Retention – State

Implementation

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Relevant Websites

http://www.jointcommission.org – Accreditation, Health Care, Certification; Joint Commission.

http://www.carf.org/home – Commission on Accreditation of Rehabilitation Facilities.

http://www.ihi.org – Institute for Health care Improvement.

http://www.qualityforum.org - National Quality Forum.

http://www.niatx.net - Network for the Improvement of Addiction Treatment.

http://www.samhsa.gov - Substance Abuse and Mental Health Services Administration.

http://www.saprp.org – Substance Abuse Policy Research Program. http://www.ncqa.org – The National Committee for Quality Assurance.

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Evaluating Treatment Efficacy

Sarah B. Hunter, Jeremy N.V. Miles, Susan M. Paddock and Elizabeth J. D'Amico

RAND Corporation, Santa Monica, CA, USA

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STUDY DESIGN CONSIDERATIONS

In this section, we discuss several study designs and the specific issues associated with use of each design.

Randomized Controlled Trial Study Designs: "The Gold Standard"

Historically, substance use treatment efficacy was demonstrated by examining outcomes achieved in controlled research experiments where the observed effects could be attributed to a particular treatment rather than some other confounding factor. More specifically, randomized controlled trial (RCT) has been the favored study design utilized to assess treatment efficacy. In this approach, research participants are randomly assigned to either a treatment condition or one or more comparison condition(s). Common comparison conditions include treatment as usual, a wait list control group,

or some other form of treatment. RCTs are perceived to maximize internal validity, that is, the outcomes that occur can be attributed to the treatment and not to other factors. Evaluating the efficacy of a treatment without randomization is difficult and potentially prone to errors. For example, if we evaluate the efficacy of a treatment program by comparing individuals who decide to attend a treatment program to those who decide not to attend a treatment program, we are at risk of confounding. Specifically, individuals who choose to attend a program or who are nonrandomly assigned to attend a program might differ from those who choose not to attend. These potential differences might therefore determine the outcomes that occur, rather than the differences in the treatment that was received by the two groups. The advantage of randomization is that we know that, on average, the groups assigned to the treatment and comparison condition groups do not differ on these kinds of preexisting characteristics.

Using rigorous experimental designs, such as RCTs, has been emphasized as a necessary step in demonstrating treatment efficacy according to stage-based approaches to behavioral substance use treatment development. Stage-based approaches have been adopted by the US-based National Institutes of Health (NIH) as a strategy to guide research in behavioral treatment development. Utilizing this approach, Stage 1 typically involves piloting and testing the feasibility of a treatment with the aim of understanding the process of the treatment. Stage 2 focuses on evaluating the treatment efficacy by using a rigorous experimental design. After one RCT has demonstrated a treatment's efficacy, the execution of additional RCTs conducted by researchers independent from the treatment developers can help strengthen the evidence for a treatment's efficacy. In Stage 3, treatments that have been shown to be feasible and effective are evaluated to determine if they work in typical treatment settings to demonstrate treatment effectiveness, which indicates that results achieved in the RCT can generalize to typical treatment settings and populations. Tests of effectiveness allow researchers to address the external validity of the treatment, that is, the ability to generalize the study results to other settings and populations.

In response to stage-based approaches to treatment development, there has been a growing emphasis on balancing the need to address internal validity as well as accounting for external validity early on in treatment development and efficacy testing. This has been the result of the recognition that conditions under which many RCTs have been conducted to demonstrate efficacy may not bear much resemblance to real world treatment settings. Therefore, the treatment may not achieve the same outcomes in typical treatment delivery settings. For example, RCTs typically utilize strict inclusion and exclusion criteria that result in the treatment being tested with a small sample of individuals who may be very different from the individuals who are typically treated for substance use problems. For example, many individuals seeking help for substance use problems may have multiple co-occurring conditions that may exclude them from participating in an RCT. In addition, RCTs may also involve treatment delivery using highly skilled clinicians with intensive supervision, which does not always reflect the realities of typical treatment delivery. RCTs with stringent inclusion and exclusion criteria and closely monitored treatment delivery may enhance internal validity by ensuring that the treatment is being tested among a homogenous client population and delivered as intended; however this affects external validity.

Recent work has therefore begun to emphasize blending elements from efficacy and effectiveness designs so that the research findings are more clinically meaningful and the treatments are applicable for delivery in real world treatment settings. For example, many RCTs are now being conducted in real world delivery systems rather than in controlled academic laboratory settings. Other variations of this design include utilizing "real world" treatment staff to deliver the intervention, rather than researchers or highly trained clinical staff who are unlikely to be employed in these settings. Treatments are also being designed to more adequately reflect resources available in typical delivery settings. This has led to a focus on briefer interventions, treatments delivered in group rather than individual formats, and using technology, such as the Web, rather than in-person staff to deliver the intervention.

It is also important to note that RCTs have limitations that do not necessarily ensure internal validity. For example, randomization (and thus internal validity) can be undermined by differential rates of refusal or treatment drop-out. Another threat to RCT internal validity is contamination. In this case, participants do not adhere to their assigned treatment and instead use the treatment provided to participants in the comparison group. Though RCTs are designed so that no systematic differences are expected between participants assigned to the treatment and control groups, it is possible for participants in the treatment and control groups to differ on preexisting, observed characteristics in the sample. When this occurs, different statistical adjustments can be made. Statistical adjustment strategies such as risk, case mix, or covariate refer to methods that are commonly used to account for observed baseline or pretreatment differences between individuals in the assigned study conditions.

Individual versus Cluster Randomized Designs

An approach that preserves the benefit of randomization in real world settings where individual randomization is not feasible is the cluster randomized trial (CRT). A canonical example is when an intervention involves changing the therapeutic environment of a clinic, school, or other higher level unit, such as a public health intervention. In this case, individuals are assigned to the condition based on the group they currently belong to; thus, CRTs have the advantage of greater external validity.

CRTs may also be employed when there is a risk of contamination across conditions. For example, if a trial of an educational intervention is carried out, which involves providing educational materials to participants in an intervention group, and providing different (or no) materials to participants in a control group, then there is a risk that materials may be shared across the groups if there is communication between individuals across

conditions. Similarly, if a trial is carried out to investigate the efficacy of an intervention that is freely available to the public, members of the control group may see their peers using the intervention and choose to use the intervention themselves – one example may be the use of nicotine patches to aid in the cessation of smoking. Thus, CRTs are necessary when an intervention needs to be applied to a group of individuals simultaneously and may be advantageous when there is a risk of contamination.

Researchers conducting and interpreting CRTs must be aware of two issues. The first issue of cluster randomization is the threat of nonrandom assignment at the individual level. In an individually randomized trial, a person is recruited to the trial and is then assigned to a condition. In a CRT, a group is recruited to the trial and then persons are assigned to a condition based on the group (clinic, school, etc.) to which they belong. In this case, allocations are known prior to recruitment. Cluster-specific variation, such as differences in the patient populations across clusters, may therefore unbalance the comparison conditions on important characteristics. Further, in some cases, it may be difficult to conceal the treatment assignment to participants and treatment providers, which can threaten validity. For example, a clinician who is very enthusiastic about a particular treatment that is available in his/her cluster might put particularly strong effort into recruiting participants into the trial. The second issue is the necessity for considerably larger sample sizes because outcomes of individuals within clusters are nonindependent.

Quasi-experimental Study Designs

Quasi-experimental study designs involve the comparison between two or more groups where the assignment to the treatment and comparison groups is not randomized. Quasi-experimental designs are typically done when random assignment is not feasible for practical or ethical reasons. These designs may help inform treatment efficacy but are susceptible to bias due to confounding of characteristics of intervention assignment with the intervention effect. It is important to employ risk adjustment strategies when evaluating treatment efficacy in such studies given the lack of randomization.

Systematic Reviews: Generalizing from the Existing Evidence

A broader assessment, or summary of evidence, can be conducted when a particular treatment has been tested multiple times in various settings. In this approach to evaluating treatment efficacy, a systematic review may be conducted of existing studies to determine the evidence for a particular treatment's outcomes. One approach to

determining efficacy quantitatively through a systematic review is called meta-analysis. In this approach, a common set of metrics across a relevant set of studies is used to gauge the magnitude of a treatment's impact.

Summary

When considering design features for treatment efficacy studies, it is relevant to consider both internal and external validity to best inform the field about what works for substance use treatment. The recent research in the field of treatment efficacy recognizes the importance of balancing internal and external validity in developing and testing behavioral treatments to address substance use. Although randomized controlled study designs are still the gold standard because of their compelling nature to conclude cause and effect, other designs may provide valuable insight into treatment efficacy when an RCT is not feasible.

ANALYTIC METHODS TO EVALUATE TREATMENT EFFICACY

In this section, we discuss common analytic methods used in the substance use treatment field to evaluate treatment efficacy.

Researchers frequently assess treatment efficacy by examining the intention to treat (or sometimes intent to treat; ITT) effect. The ITT effect summarizes the effect of treatment assignment on outcomes by comparing responses from individuals assigned to receive the treatment to individuals assigned to the comparison group(s), regardless of what treatment they actually received. The importance of the ITT effect is typically assessed through statistical testing. The most common testing approach is to specify two hypotheses: a null hypothesis that the outcomes for participants assigned to the treatment and comparison condition(s) are equal and an alternative hypothesis that outcomes across treatment conditions differ from one other. In the case of individual-level RCTs, the simplest statistical analysis that might be appropriate for the data would employ a bivariate test such as a *t*-test or a test of proportions to compare treatment and comparison conditions. However, it is often necessary to conduct more sophisticated statistical analyses to accommodate different study design features or data complications. We highlight some of these below.

Drop-out and Noncompliance to Treatment

One threat to the internal validity of a treatment study is drop-out from treatment and noncompliance. That is, individuals who are assigned to a treatment choose not to take up or complete treatment, despite it being offered and available. For example, in Project Choice, a voluntary after-school intervention, treatment was taken up by approximately 15% of those to whom it was available. In addition, if individuals are randomly assigned to either some form of therapy or a waiting list control, there is a chance that those assigned to therapy may drop out, whereas it is not possible to drop out of a wait list control group because no actual treatment is being provided. This is a problem because drop out might be related, for example, to level of substance use – those who drop out may be functioning less well and finding it difficult to keep appointments and maintain the therapy.

The ITT effect reflects not just the effect of the intervention effect but also the appeal and practicality of the intervention. For example, a high level of noncompliance might suggest that the intervention lacks appeal for its intended target population. The intervention might need to be altered or barriers to its uptake removed. Thus, the ITT effect differs from the effect of the intervention itself. In the presence of noncompliance and drop-out, it may be tempting to analyze the data based on the treatment received – that is, those individuals who were compliant with an intervention would be analyzed as an 'intervention' group, with the 'control' group either remaining the same or including individuals from the treatment group who were noncompliant. However, such an analysis will provide a biased estimate of treatment efficacy because, unlike an RCT, those who decide to take up the treatment versus those who do not would no longer be expected to be balanced on pretreatment characteristics, including unobserved characteristics, which could then induce bias into the assessment of treatment efficacy. Thus, using an ITT approach risks bias in a conservative direction, with the effect of the treatment being underestimated, whereas using a treatment received approach risks overestimating the size of the treatment effect. Researchers would rather underestimate than overestimate effects; hence the ITT approach is preferred.

Yet, researchers often want to estimate treatment efficacy when all clients are compliant with their treatment assignment in order to address the scientific question of the efficacy of the intervention as it was designed. Such an estimate would complement the ITT effect by indicating whether removing barriers to treatment uptake might hold promise for the intervention's efficacy. An alternative treatment-effect estimate that addresses this issue is the complier average causal effect (CACE), which is the estimate of treatment efficacy for those who comply with their treatment assignment. A major challenge with CACE estimation is that complier status for each individual is unknown; someone who is assigned to the intervention condition and receives the intervention could be a treatment complier or someone who always takes up

the intervention, whereas someone who is assigned to the comparison condition and does not use the intervention could be a complier or someone who might never take up the intervention. Thus, several assumptions must be made in order to estimate the CACE such as treatment assignment is random; the outcomes of each individual are not affected by the intervention assignment of any other individuals; some individuals who are assigned to receive the intervention will comply with their treatment assignment and the treatment will only affect outcomes for compliers; and there are no 'defier' individuals who will always do the opposite treatment of what they are assigned.

Covariate Adjustment

For studies that lack balance of observed pretreatment characteristics across comparison groups - regardless of whether or not those studies are RCTs - covariate (or risk or case mix) adjustment of treatment-effect estimates are crucial. Traditionally, the most frequently -used method of covariate adjustment was regression adjustment (i.e. enter risk adjustment variables as predictors into a regression of an outcome of interest on the treatment group indicator). The strengths of covariate adjustment include the ease of incorporating covariates into any regression-based model (e.g. cross-sectional or longitudinal models, or models that account for hierarchical (multilevel) data such as in CRTs). Limitations of covariate adjustment are that covariates are assumed to be related to the outcome in the manner specified by the model (i.e. usually linearly), that the relationship between covariates and treatment outcomes is assumed to be equal in both treatment and control groups, and that there is also a danger of including too many covariates in the model relative to the sample size (over-fitting) if there are numerous covariates of interest.

Propensity Score Adjustment

Propensity score adjustment techniques can avoid some of the limitations of covariate adjustment. The propensity score is the probability of an individual being assigned to a particular treatment condition based on a set of covariates, which are typically pretreatment characteristics in treatment efficacy studies. Recent methods address propensity score estimation for studies with multiple treatment arms; however, for illustration we focus on estimating the conditional probability of treatment assignment for two-arm studies because this study design reflects the vast majority of applications of propensity scoring. The propensity score is estimated by modeling assignment to treatment (versus control) as a function of pretreatment characteristics. Statisticians

have shown that adjusting for the propensity score produces balance between treatment and control conditions with respect to pretreatment characteristics.

Propensity scores can be incorporated into the analysis in several different ways. Early papers on propensity score estimation advocated creating strata according to the quintiles of the propensity score estimates, estimating the treatment effect within each quintile, and averaging results across quintiles to estimate the overall treatment effect. More modern approaches include using functions of the propensity scores as weights in analyses or conducting matched-pairs analyses by matching treatment and control individuals who have similar propensity scores. The latter approach is particularly attractive when one can draw comparison of individuals from a large pool (such as from a large administrative database), but can be more limited for modestly sized treatment-effect studies.

A limitation of both covariate and propensity score adjustment that is especially relevant for nonrandomized studies is that these approaches only control for observed differences between treatment groups, therefore unobserved differences could still exist between groups that are being compared. In such cases when one suspects unobserved yet important differences exist between comparison groups, methods used to estimate CACE, econometric approaches such as instrumental variables, or sensitivity analysis to examine the robustness of treatment efficacy estimates to unobserved bias can be utilized.

Group Treatment

Group treatment is a frequently employed modality for substance use. Participants typically enter group treatment under a rolling (or "revolving" or "open") admissions policy. Treatment groups with rolling admissions ("rolling groups") continuously enroll new participants into the group as space permits. This is in contrast to "closed" groups, in which the same participants are expected to jointly attend group treatment sessions without the addition of new group members. Recent research underscores the importance of accounting for the interrelatedness (correlation) of outcomes for participants attending group treatment, regardless of how participants are admitted into the group. Failure to account for this correlation could lead to biased statistical tests and incorrect conclusions about the effectiveness of the treatment.

The analytic methods necessary to model the correlation among participant outcomes for participants attending closed groups are straightforward compared to what is required for rolling groups. For closed groups, standard implementations of hierarchical (or multilevel) modeling that are widely available in popular statistical

software packages allow the user to specify to which closed group participants belong and to specify random effects terms to model the correlation of outcomes among participants attending the same treatment group. In contrast, rolling admissions induces a far more complex pattern of interrelatedness among participant outcomes because the set of participants in the group can change from session to session. For example, suppose 10 participants attend the first session of a treatment group, and one of these 10 participants is very disruptive and leaves the group after the first session. Then, another participant enrolls at session two after the disruptive participant's departure. Even though these two participants never met, the second participant's outcomes could still be correlated with the disruptive participant's outcomes if the disruptive participant altered the group climate sufficiently enough to affect the group experience for the remaining nine participants, who then interact with the new participant in the second session.

One recent method for rolling group studies is to use multilevel models that capture the overlapping participant attendance across sessions with random session effect terms that are allowed to be correlated. Techniques for modeling correlated random effects include conditionally autoregressive priors, which are frequently employed in the analysis of geographic (spatial) data. In the context of rolling groups, the analyst would specify the closeness of each pair of random session effects. For example, sessions attended by the same 10 participants might be considered very close relative to sessions sharing fewer participants. This method is flexible enough to be applied to data collected either during the course of group treatment or to post-treatment outcomes and to incorporate other application specific concerns, such as concerns about whether treatment efficacy differs for participants who drop out of treatment early or have different patterns of group treatment attendance.

Accounting for Cluster-Level Treatment Assignment

When the unit of treatment assignment is a cluster rather than an individual on whom outcomes are examined, testing for treatment efficacy requires accounting for the fact that individuals within cluster have nonindependent outcomes. This means that there is less information in the data compared to an individual-randomized trial in which outcomes for the same number of individuals could be assumed to be independent from one another. This reduction in information due to cluster-level randomization is called the design effect, or variance inflation factor (VIF), which is approximately equal

to 1 + (m-1)r, where m is the number of individuals per cluster and *r* is the intracluster correlation, which is the proportion of variance in individual outcomes that is attributable to cluster membership. The effective sample size is equal to the raw sample size divided by the VIF. The effective sample size represents the sample size of an individually – randomized trial that would have an equivalent amount of information about the difference between intervention and comparison conditions. Even for small values of r, the VIF will be large when m is large, thereby increasing the numbers of individuals necessary for the cluster randomized study relative to an individually randomized RCT. Thus, the effective sample size is frequently considerably less than the raw sample size. In the worst case scenario, the effective sample size is equal to the number of clusters. Multilevel (or hierarchical or random effects) regression modeling is one analytic approach to account for the nonindependence of outcomes for individuals within the same cluster. Multilevel modeling allows a researcher to estimate the treatment effect at the cluster level, thus aligning the treatment-effect description with the clusterlevel targets of the intervention.

Meta-analysis and Study Pooling

Meta-analysis is a statistical technique that allows researchers to pool the results from multiple studies that set out to test the same hypotheses. Consider an example of 10 RCTs that have been carried out to investigate the efficacy of motivational interviewing for substance use. If each of these hypothetical trials contained 100 participants, we could pool the results of each of these trials to create an effective sample size of 1000 participants. Such a pooled analysis would then result in a larger sample size, which leads to greater power, and a more precise estimate, and also incorporates a wider range of individuals, enhancing the generalizability of the estimates. When studies are pooled, a test of heterogeneity of effect is carried out. This tells us if the variation in effect sizes across studies is greater than would be expected by chance if the studies were sampled from the same population. If heterogeneity exists, this suggests that there are differences between the studies, which means that the intervention was found to be more effective in some of those studies compared to other studies. Heterogeneity can then be investigated through the use of meta-regression analyses, in which study characteristics are used as predictors of study-level outcomes. For example, we might investigate whether trials using motivational interviewing approaches are more effective in adolescents than in adults by using a meta-regression approach. It should be noted that meta-regression approaches are indirect tests of a hypothesis. Therefore, these meta-regression approaches do not provide the same level of evidence as a well-designed RCT that includes both adolescents and adults and compares efficacy. However, if a meta-analysis shows that a treatment is efficacious, it typically shows that the treatment under study is effective across multiple studies. In this way, the results from a meta-analysis may provide stronger evidence regarding the efficacy of a particular treatment than the results from a single RCT.

HOW TO INTERPRET RESULTS

Over the past decade, literature has focused more on interpretation of treatment findings. Although the typical metrics for substance use are externally valid and easy to interpret, for example, the percentage of days abstinent, well-described efficacy studies typically address whether differences are both statistically and clinically meaningful. However, it is important to note that many substance use outcomes that are studied, such as "recovery" and "relapse," have been defined in a number of different ways in the literature and therefore a consistent definition does not currently exist. In this section, we discuss how to interpret results from treatment efficacy studies.

Sample Size Considerations

Sample size can affect a researcher's ability to draw clear conclusions about the outcomes of a study. Determination of sample size should occur before the study begins. Several factors should be taken into account when determining sample size. One factor is the expected size of the treatment effect to be detected by the study, which is called the hypothesized effect size. The hypothesized effect size should represent the difference between the treatment and comparison group(s) that would be meaningfully large enough to influence clinical practice. The number of participants in the study should be sufficiently large to reduce the variation in the treatment-effect estimate so that if there is a difference between study conditions, it can be detected. A second factor that influences the choice of sample size is the form of the treatment-effect estimate. For example, detecting practically meaningful difference between treatment conditions on a difference in proportions in a dichotomous outcome would require a greater sample size than comparing means for a continuous outcome since continuous measures provide more detailed information about an outcome. A third factor that influences sample size is the significance level of the test of treatment efficacy (also called the Type I error), which is often denoted by the alpha level (α). A significance level of $\alpha=0.05$ implies that when the null hypothesis is true (no evidence of a treatment effect), one can expect the test of significance to erroneously reject the null hypothesis 5% of the time. A fourth factor is the statistical power of the hypothesis test. The power of a test is the probability of not rejecting the null hypothesis when in fact the alternative is true, which is called a Type II error. Since the Type I and Type II error rates are related, increasing one typically decreases the other, so investigators need to weigh the relative costs of erroneously rejecting the null hypothesis when the null hypothesis is true versus failing to reject the null hypothesis when the alternative hypothesis is true.

The Meaning of Statistical Significance

Determining whether an effect is statistically significant depends on at least two things: the size of the effect and the number of individuals being studied. Consider an example of an intervention that is able to reduce substance use from 10 to 5%. Given exactly this reduction in every study, a randomized trial with 20 people in each group would give a probability or p-value of 1.000, giving no evidence of any effect. A trial with 200 people in each group (and exactly the same result) would give a *p*-value of 0.086, providing weak evidence of an effect. With 400 in each group, the result would be statistically significant at p = 0.010, and with 800 in each group, p < 0.001. A naïve interpretation of these results would be that the statistically significant results were more important. This is not the case; the more significant results provide better evidence for the effectiveness of the intervention due to having a larger sample size in this case.

If a statistically significant result is not found, we cannot conclude that the null hypothesis can be accepted as the statistical tests used only allow us to conclude that we have failed to reject the null hypothesis. For example, if a study found no effect of an intervention, we cannot conclude that the intervention is ineffective, we can only conclude that we have not found evidence that the intervention is effective. When we search for a needle in a haystack, if we don't find a needle, we can only conclude that we didn't find a needle – not that there is no needle to be found. In other words, if we find a statistically significant result, we have obtained evidence against the null hypothesis (i.e. there is no treatment effect). If we do not find statistical significance, we can only conclude that we have failed to reject the null hypothesis, not that the null hypothesis is true.

Effect Size and Clinical Significance

Statistical significance indicates the probability associated with the null hypothesis, but it does not determine whether the result is important, meaningful, substantive, large enough to care about, or clinically significant. To interpret the effect of an intervention in terms of whether it is sufficiently large to be termed clinically significant, we must describe the magnitude of the effect of the intervention.

Some outcome measures can be summarized by a mean, which allows us to simply calculate an average value for individuals in two groups. Because people can examine their data in different ways, however, we must understand the baseline from which we start to determine a treatment's effect. For example, if we expected that treatment would increase service use, we might find that the mean number of days of service use for a control group was 25, and the mean for the treatment group was 45. We can represent the size of this effect as the difference between these two groups by using days, stating that treatment increased service use by 20 days. Alternatively, we can express the effect of treatment as a ratio, stating that the effect of the treatment was to increase service use by 80% (45/25 = 1.80 or an 80%increase). There is not a one-to-one correspondence between the two measures. In another example, a reduction of 1 drink per drinking day can represent a 17% reduction, relative to a control group which is consuming, on average, 6 drinks per drinking day, but a 50% reduction relative to a control group that consumes, on average, 2 drinks per drinking day. Thus, the baseline from which we start can affect how we evaluate the effectiveness of our intervention.

Effects are often reported using standardized measures. For example, when a difference between two groups with respect to a continuous outcome measure is examined, one might standardize the difference by dividing by the standard deviation (this might be a pooled standard deviation or the standard deviation of the control group). This standardized effect size measure is known as Cohen's d. An effect size measure such as Cohen's *d* allows one to make comparisons across different continuous measures. Specifically, if one study has evaluated a treatment in terms of days in treatment, but a second study has evaluated a treatment in terms of an Alcohol Use Disorders Identification Test (AUDIT) score, the effects of these studies could be compared through the use of Cohen's d. A second use of Cohen's *d* is that it allows one to quantify the size of an effect using a unit-free measure. Cohen applied labels to different effect sizes for Cohen's d, calling 0.2 a small effect, 0.5 a medium effect, and 0.8 a large effect. If a study evaluates a treatment effect and finds an AUDIT score change of 4 units, this is difficult to interpret for anyone unfamiliar with the AUDIT scoring system, but if we are also told that the Cohen's *d* effect size is 0.5, we can interpret the size of the effect and have a somewhat better understanding of the clinical significance of the study. However, Cohen's *d* and similar effect size measures have some disadvantages. The first is that the units of the measure are lost when any effect size measure is standardized. Learning that an intervention doubled the number of days in treatment might be more interpretable than d = 0.5. A standardized effect size measure alone cannot therefore convey clinical meaningfulness. Another problem with standardized effect size measures is that they are determined not only by the size of the effect, but also by the amount of variance in the data. For example, a difference in the number of days in treatment of 1 would result in an effect size of 0.5 (medium) if the standard deviation were equal to 2, but only 0.2 (small) if the standard deviation were equal to 5. These concerns also hold for other types of standardized effect size measures for noncontinuous outcomes.

Another measure of effect size that can be used for either categorical or continuous outcomes (but we will limit this discussion to categorical outcomes) is the number needed to treat or NNT. The NNT is the number of people who need to be treated with the intervention, rather than the control condition, in order that one person sees a benefit. The NNT is considered to be a useful indicator for policy decisions, as it describes the impact at a level of individuals affected. The NNT is calculated as 1/(risk difference). If the risk of relapse is 60% (or 0.6) in the control group and 40% (or 0.4) in the treatment group, the risk difference is 0.6 - 0.4 = 0.2. The NNT is 1/0.2 = 5. Thus, if five people were treated with the intervention, rather than the control condition, we would expect one additional individual to cease use who would not have otherwise ceased use.

Substantive Significance

Just because a treatment shows a statistically significant effect does not mean that is likely to be useful or that policy should change to use that treatment. First, and most obviously, the change in the outcomes associated with the intervention should be sufficiently large – the appropriate effect size should be calculated and presented. Second, determining how large an effect should be to be clinically meaningful is challenging, and other features of the intervention must be taken into account beyond simply the effect size. For example, the costs (both financial and societal) of an intervention as well as of the condition being treated should be taken into account when determining the substantive significance of an intervention. If an intervention had a small effect but could be implemented at low cost and easily, such an effect might be substantively important, or if a condition has very large financial and societal costs, interventions with relatively small effects might result in a large cost saving dollars-wise. In general, researchers have found that every additional dollar invested in substance use treatment saves taxpayers \$7.46 in societal costs (crime, violence, loss of productivity, etc.). Health economists use sophisticated modeling techniques to determine the cost-effectiveness of treatments. For example, the UK Alcohol Treatment Trial (UKATT) compared two treatments: in one group social behavior therapy and network therapy were employed; this was compared with motivational enhancement therapy. No statistically significant differences were found between these two treatments, but analysis of the costs showed that both therapies saved approximately five times as much as they cost, taking into account health, social, and criminal justice services. In addition, the authors concluded that there was a 58% chance that motivational enhancement therapy was more cost effective than social behavior therapy, and a 42% chance that social behavior therapy was more cost-effective than motivational enhancement therapy, thus helping policymakers conclude which treatment is more likely to be cost-effective. In another study conducted in the United States, targeting cannabis use among adolescents, a brief five-session treatment called Motivational Enhancement Treatment/Cognitive Behavioral Therapy-5 or MET/CBT-5 was found to be equally efficacious and more cost-effective compared with other four adolescent treatments that were at least twice as long (MET/CBT-12, Family Support Network therapy, Adolescent Community Reinforcement Approach, and Multidimensional Family Therapy).

CONCLUSIONS

The development of efficacious treatments for substance use requires the use of rigorous analytical methodologies to provide reliable information to guide clinical practice. The use of randomized study designs is typically preferred over nonrandomized designs and there are analytic techniques that can be used to adjust for preexisting differences among comparison groups. When randomization at the individual level is not feasible, cluster randomized designs offer another option to testing treatment efficacy. Blending components from both traditional efficacy and effectiveness studies has increased in the last decade in recognition of the need to build treatments that are appropriate for delivery in real world treatment settings. As the number of research studies increases, the use of systematic review methods, such as meta-analyses, is useful in informing the field about treatment efficacy. Continued use of the aforementioned methods along with further innovation in these areas will help to improve the quality of evidence of treatment approaches to address substance use.

FURTHER READING 597

SEE ALSO

Improving the Quality of Addiction Treatment, Evidence-Based Treatment

Glossary

- **Alpha level** in statistical testing, the probability of rejecting the null hypothesis given it is actually true. It is the cutoff that is selected for determining whether a *p*-value associated with a test statistic is small enough (less than the alpha level) to reject the null hypothesis.
- **Alternative hypothesis** in general, the proposition that the null hypothesis is false. In a typical treatment efficacy study, the alternative hypothesis is that the true (or population) means on some outcome measure for the treatment and control groups is unequal.
- **AUDIT** Alcohol Use Disorders Identification Test. **Case mix adjustment** a statistical procedure used to identify the procedure of the proced
- Case mix adjustment a statistical procedure used to identify and adjust for variation in participant outcomes that stem from observed differences in participant characteristics (or risk factors).
- Cluster randomized trials (CRTs) a randomized trial where units composed of multiple individuals (i.e. a set of providers, institutions, schools, or communities) are randomized rather than individual research participants to study conditions.
- **Cohen's** d a measure of effect size, calculated as the difference between two means divided by the pooled standard deviation.
- **Complier average causal effect (CACE)** the treatment effect for those who comply with their treatment assignment.
- **Confounding** failure to control for the effects of a third variable in an experimental design.
- **Contamination** when an individual assigned to one intervention receives a different intervention.
- Covariate adjustment see Case mix adjustment.
- **Design effect** see Variance inflation factor.
- **Effect size** an effect size is a value that represents the strength of a relationship between two variables in a population (or a sample estimate of that relationship).
- **External validity** the degree to which the results of an experiment can be generalized to the population of interest.
- **Intention to treat (ITT)** an analysis where data from participants are analyzed according to the study condition to which they were assigned, regardless of the treatment actually received.
- **Internal validity** the certainty with which results of an experiment can be attributed to the treatment under study rather than to some other variable.
- **Intraclass (intracluster) correlation coefficient (ICC)** a statistic used in cluster randomized trials that describes how strongly outcomes are correlated for units assigned to the same cluster.
- **Meta-analysis** a systematic procedure for statistically combining the results across many different studies.
- **Null hypothesis** the hypothesis that the treatment has no effect in the study population.
- **Number needed to treat (NNT)** an estimate of how many persons need to receive a treatment before one person would experience a beneficial outcome.
- **Propensity score** the probability of being assigned to a study condition as a function of observed covariates.
- **Quasi-experimental design** a type of design that approximates the control features of a true randomized experiment (RCT) to infer that a treatment under study has its intended effect.
- Randomized controlled trial (RCT) a type of experiment in which participants are assigned to a study condition (i.e. treatment or control) using a random process.
- Risk adjustment see Case mix adjustment.

Sample size the number of participants in a study.

- **Statistical power** the probability, on the basis of observed data, to correctly reject the null hypothesis given a certain effect in the population. Power is expressed as 1β , where β is the probability of a Type II error.
- **Statistical significance** rejection of the null hypothesis when an outcome has a low probability of occurrence (typically 0.05 or less) if in fact the null hypothesis is correct.
- **Study design** a methodology that is used to investigate a treatment-effect relationship.
- **Systematic review** a critical assessment and evaluation across many research studies that address a particular clinical issue. May or may not include a quantitative assessment across studies (meta-analyses).
- **Treatment effectiveness** how well a particular treatment works as demonstrated in "real world" conditions.
- **Treatment efficacy** how well a particular treatment works as demonstrated in an experimental controlled research setting.
- **Type I error** an incorrect decision to reject the null hypothesis when it is true.
- **Type II error** an incorrect decision to fail to reject the null hypothesis when it is false.
- **Variance inflation factor (VIF)** a measure used to determine the extent to which the group assignment in a cluster randomized trial (CRT) has increased the variance of the estimate. It is calculated as (m-1) ICC, where m is the mean cluster size and ICC is the intracluster correlation coefficient.
- **Wait list control** a comparison condition used in experimental studies where participants are assigned to (wait to) receive treatment after the experiment is completed.

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Economic Analysis of Addiction Treatment Programs

Sarah Q. Duffy

National Institute on Drug Abuse, Bethesda, MD, USA

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ECONOMIC ANALYSIS

A major goal of the science of economics is to determine how society can best allocate its scarce resources to produce the array of goods and services that maximize the welfare of the people in that society. Costing, economic evaluation, and cost-function analysis are three types of economic analysis that have been conducted both to inform and to understand the effects of allocation decisions in the addiction treatment field.

The fundamental assumption of economics is that resources, such as raw materials, workers' time, and equipment, used to produce goods and services are limited whereas society's need and desire for those goods and services are not. This means that choices have to be made, either implicitly or explicitly, about what will be produced and how. Under certain conditions a market allocation mechanism, in which individuals make decisions such as what they want to purchase and how much they are willing to pay, how many hours they choose to work in return for wages or salaries, and how to invest their savings to receive the desired rate of return, leads to the optimal array of

goods and services being produced in the most efficient manner possible. The array is optimal in the sense that there is no additional transaction, such as a purchase, investment, or employee hire that can make one person better off without making someone else worse off. Production is efficient because it requires the fewest resources possible, maximizing the amount that can be produced and therefore getting as close as possible to fulfilling society's needs and desires.

The market allocation mechanism can achieve this optimum automatically only in what are known as perfectly competitive markets. In perfectly competitive markets, all individuals involved have complete and accurate information on which to base their decisions, firms can freely enter an industry in which there is excess demand for a product and leave one for which there is excess supply, no buyer or seller is large enough to affect the price of the good or service they produce, and only a single, homogeneous, product is produced. Health care markets in general, and the market for addiction treatment in particular, seldom meet those conditions. Economic evaluation and cost-function analysis have been used to better understand the effects of

these deviations from perfect competition and to help society take actions, through, for example, public policies and purchasing decisions that maximize welfare.

Economic evaluation, which has been conducted frequently on treatment interventions and programs, cost-benefit analysis encompasses (CBA), costeffectiveness analysis (CEA), and cost-utility analysis (CUA). Broadly speaking, these types of analyses help determine whether the benefits of a particular intervention, program, or practice are worth the resources needed to produce it. Cost-function analysis, which has been conducted less frequently on addiction treatment programs but extensively on other health care providers, seeks to characterize the production process - how inputs such as labor and equipment are combined to produce outputs – and to investigate whether or not the process is efficient. In either case, the first step in conducting these analyses is to determine how much it costs to produce treatment. In the addiction treatment field, this is generally done using costing studies.

COSTING STUDIES

Addiction treatment providers generally have not been subject to the same types of financial oversight as other health care providers, in part because they often have been funded by state agencies through grants that allocate a certain number of treatment slots rather than relying on service-based reimbursements from payers such as Medicare. As a result, there is no standard chart of accounts or other generally accepted mechanism by which addiction treatment providers commonly categorize and report their expenses. In addition, any accounting records they do have likely do not include volunteer services, donated space, or other nonpaid inputs used in the production of addiction treatment, or the resources expended by a parent organization, if there is one, that contribute to the production of treatment in an individual program. Although these inputs may not be paid by the treatment program, the time volunteers spend, the space that programs occupy, and the administrative services provided by the parent organization could be used to produce other goods and services that society values, thereby enhancing welfare. It is also essential to account for these costs because others wishing to implement the same program elsewhere may not have access to the volunteers, donations, or parent organization support and would need to pay for them. Some research suggests that these "opportunity costs" may add as much as 15% to the total cost of treatment programs, although that estimate is far from definitive. The lack of a standard chart of accounts and concerns about adequately capturing all relevant costs has led economists studying addiction treatment programs to rely on de novo data collection, often using instruments such as the Data Treatment Cost Analysis Program (DATCAP), the Substance Abuse Services Cost Analysis Program (SASCAP), the Treatment Cost Analysis Program (TCAT), or methods such as microcosting (described below).

The DATCAP is a standardized instrument that can be used by researchers, ideally individuals with a bachelor's or higher degree in economics, to interview program directors or financial officers and to extract information from financial records to ascertain the yearly costs of production. Information is gathered on a comprehensive list of inputs, such as personnel costs, the costs of contracted services such as laboratory services, building and facilities costs, supplies and materials, miscellaneous costs such as staff travel, as well as volunteer and donated inputs. In addition, information on the number of clients and their average length of stay is captured so that per-week estimates and episode costs can be computed. The DATCAP has been used in numerous studies, often to collect cost data for economic evaluations. The DATCAP is from a family of instruments including one used to assess the costs incurred by patients in treatment (Client DATCAP) and the costs incurred by parents and other caregivers of those in treatment (Caregivers DATCAP).

Another tool for determining the economic costs of treatment programs is the Treatment Cost Analysis Tool (TCAT). The TCAT is a Microsoft® Excel-based workbook that allows researchers as well as program directors to enter and analyze cost data. It collects annual cost information on a comprehensive set of inputs, including volunteer labor and donated goods, used to produce addiction treatment, but in somewhat greater detail than the DATCAP. For example, although the DATCAP collects information on depreciation costs for the facility as a whole, the TCAT captures it for some individual items such as computer equipment. The TCAT also explicitly captures overhead costs from facilities that are part of larger parent organizations. The TCAT workbook contains comparison values that can be used for quality control in the data entry process as well as for analysis by program directors. This relatively new tool has been fielded in more than 70 programs nationwide.

The other major instrument for collecting cost data on addiction treatment providers is the SASCAP, which combines a cost survey similar to the DATCAP that obtains annual program cost data from program directors, and a labor allocation survey that collects data from a key informant on how staff members spend their time. These instruments can be administered by individuals without specific economic or accounting training, lowering the costs of data collection compared to the DATCAP. The information can be combined to provide

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not only data on the annual costs of the entire treatment program, but also the costs of distinct services, such as initial assessment and treatment planning, initial medical services, and group counseling, within that program. The SASCAP has been used in a number of treatment programs, including a major study of methadone treatment programs. Work is underway to develop and test a Web-based version, which, if successful, should further reduce the costs of administering the instrument.

The DATCAP, TCAT, and SASCAP all compute treatment costs for the program as a whole or for specific services, the averages of which can be used for a variety of purposes including studies of the costs of the treatment program as well as costs of interventions that are the subject of economic evaluations. Another costing method that is increasingly being applied in addiction treatment intervention studies is microcosting; this method can be especially useful in capturing the full cost of a specific treatment intervention, particularly a new one, and for analyzing the variations in costs across patients. Microcosting entails determining exactly what and how many inputs were used to treat each patient in a study. Although the list of inputs is similar to those identified in other costing methods (e.g. personnel hours, office space, supplies), inputs are tracked for each patient through methods such as activity logs and other detailed data-collection efforts.

This brings more accuracy to the cost estimates and allows better estimates of the variability of those costs across patients. Generally, however, microcosting studies are more expensive than other types of cost studies and can be more intrusive. No studies have yet compared the outcomes from the two approaches in addiction treatment studies to determine how much the results differ and under which conditions.

Table 62.1 displays estimates of the costs of treating clients in US addiction treatment program from selected studies using these methods. Studies using the DATCAP, SASCAP, and TCAT used data from convenience samples; therefore, the reported findings are neither generalizable nor comparable. Only one study to date has provided national estimates of treatment costs, the 1996–97 Alcohol and Drug Services Study Cost Study (ADSS), but that did not use a comprehensive cost-assessment instrument, although the instrument that was used was the basis for the TCAT. Published cost estimates from the ADSS study, which have been inflated to 2002 dollars, are presented for comparison purposes.

The results displayed in Table 62.1 suggest that there are substantial variations in treatment costs across providers. The sources of those variations are poorly understood. Studying such variations is the subject of cost-function analysis, which will be discussed below, following the discussion of economic evaluation.

TABLE 62.1 Illustrative Results from Selected Costing Studies of Addiction Treatment Programs (Standard Deviation in Parenthesis When Reported)

	DATCAP (2006 US		SASCAP (2000 US	
Type of Treatment	dollars)*	TCAT (2006 US dollars)**	dollars)***	ADSS (2002 US dollars)§
Regular outpatient	\$2325/episode (2138)	\$882/episode		\$1433/admission
Intensive outpatient	\$4271/episode (5057)	\$1310/episode		
Adolescent outpatient	\$2954/episode (2678)			
Mixed regular and intensive outpatient		\$1381/episode		
Methadone maintenance	\$7409/episode (4747)		\$4176/patient/year (2560)	\$7415/admission
Adult residential	10, 228/episode (11,354)			\$3840/admission
Therapeutic community	\$21 404/episode (14 125)			
In-prison therapeutic community	\$1747/episode (1078)			

^{*} Data from a convenience sample of treatment programs that had been the subject of a DATCAP analysis (n = 21 nonmethadone OP, 9 intensive OP, 20 adolescent outpatient, 12 methadone maintenance, 22 adult residential, 5 therapeutic community, and 8 in-prison therapeutic community). French, M.T., Popovici, I., Tapsell, L., 2008. The economic costs of substance abuse treatment: updated estimates and cost bands for program assessment and reimbursement. Journal of Substance Abuse Treatment 35, 462–469.

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[§] Data from in-person interviews with the directors from a nationally representative sample of 280 substance abuse treatment facilities. Office of Applied Studies, 2004. Alcohol and Drug Services Study (ADSS) Cost Study. The DASIS Report. June 18.

ECONOMIC EVALUATION

There are several types of economic evaluation, but three commonly used ones to examine addiction treatment programs are CBA CEA, CUA. Although these analyses appear to be very similar, the theoretical basis for them differs, as do the conclusions that can be drawn from them. In addition, the science of each continues to evolve both broadly and within the addiction treatment field, leading to a variety of approaches and continued debates as to the best way to conduct these analyses. Given the state of the science and the quality of the data available to conduct them, these analyses can best be thought of as mechanisms to promote a careful delineation of the costs and benefits associated with programs and interventions. The results of these analyses provide an important piece of evidence that decision makers, such as individuals, third-party payers, program directors, and governments, can use in determining how to invest their scarce resources in purchasing, providing, or funding addiction treatment.

Cost-Benefit Analysis

A CBA involves identifying and valuing in monetary terms all the resources used to produce a good or service and the resulting benefit. It involves the computation of one of two summary statistics, either the benefit—cost ratio or the net benefit. The benefit—cost ratio divides the monetary value of the benefits of the program by the monetary value of the costs. The resulting ratio reveals how much society gains (or loses) in monetary terms from a unit of expenditure on the program. A net benefit ratio simply subtracts the costs from the benefits. Either a benefit—cost ratio greater than one or a positive net benefit signal that society should consider allocating resources to this program, depending on the other possible uses of those resources (which may be even more cost-beneficial).

The results from CBAs are thought by most economists to lead to decisions on resource allocation closest to those that would be made under perfect competition and can therefore be said to be welfare enhancing. This, of course, assumes that the analysis contains values and characterizes all of the major costs and benefits appropriately. Although it sounds simple enough, numerous controversies remain in this field. For example, there is a continuing debate as to whether or not the analysis should include the reduction in goods and services that results because an individual in ill health is not working or is not working up to his potential, because in most economies there are unemployed individuals who could take the job.

Although generally it is possible to delineate and value the costs of producing addiction treatment, it may be more difficult to accurately delineate the other cost implications of the activity (e.g. future treatment utilization) and some of the benefits (e.g. reduced pain and suffering of family members), given available data and methods to elicit those values, although innovations in that area are continuing. Another issue is the length of follow-up. Most studies in the addiction field estimate the benefits of an acute episode of treatment over a relatively short period of time. One study, however, found that allowing for the chronic nature of addiction and modeling the life course yielded cost–benefit ratios that were significantly higher than those of a single treatment episode.

Cost-Effectiveness Analysis

Although it sounds very similar, CEA is quite different from CBA and only yields information leading to welfare-enhancing decisions under certain rather strict conditions, such as that all costs are included in the calculations and that everyone is willing to pay the same amount for an extra unit of benefit. In CEA, the costs of a program contain elements similar to those in a CBA, but only one benefit, such as a specific outcome variable, is examined. Furthermore, that benefit is not expressed in monetary terms but rather in its natural units such as, for example, the longest duration of continuous abstinence measured in weeks. Finally, CEAs usually are done comparing two or more programs or interventions, or a given program and an enhanced version. It is seldom appropriate to say that a particular program or intervention is cost-effective in and of itself. It is only cost-effective in comparison with alternative uses of the resources used to produce it that achieve the same outcome. Many CEAs in the addiction treatment field have been conducted alongside clinical trials that compare a new treatment to treatment as usual, or that compare an existing treatment and its enhancement.

The result from a CEA is also presented as a ratio, called the incremental cost-effectiveness ratio (ICER), which can be interpreted as the extra costs for an additional unit of benefit. This is an important piece of information when one program has better outcomes but higher costs than another program. If one program has both better outcomes and lower costs, it is said to dominate the other program.

Although CEA can be a useful tool to aid narrow decisions about which from among like interventions should be undertaken to most efficiently achieve a specific outcome given a specific program budget, it

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can be problematic when applied to addiction treatment because of the multiple outcomes that addiction treatment can affect. Although a single measure for use in economic evaluations of addiction programs based on Addiction Severity Index data has been developed, it has not been adopted widely. In addition, it is difficult to use the results of a CEA to compare alternative uses of the same resources for very different purposes with different outcome goals. Finally, although it seems that CEA might be preferable because it does not require placing a value on the benefit of a health care organization, that actually is not the case. When the decision maker is presented with a finding that, for example, prize-based contingency management would cost an extra \$258 over the costs of usual care for a 1-week increase in the longest-duration abstinent, the decision maker must decide whether or not the extra week is worth \$258, thereby valuing the outcome.

Cost-Utility Analysis

CUA overcomes one of the identified shortcomings of CEA, the fact that it can be difficult to compare interventions with different outcomes. CUA is the same as CEA except that the benefit is measured in terms of quality adjusted life years (QALYs). A QALYs is a year of life adjusted for the quality or value based on health status. Quality is assessed across the physical, social, and somatic domains, and weights are assigned to the various dimensions. A year in perfect health is assigned a QALY value of 1. A year of less than perfect health is assigned a value below 1. Theoretically, all manner of programs and interventions can be compared based on their ability to increase QALYs. There are several ways to arrive at the weights that quantify the decrement in quality of life experienced among individuals in less than perfect health.

Among the controversies in this line of analysis are whether these weights should be assigned using a generic preference weighting scheme or a diseasespecific weighting scheme, and who should do the weighting. Many of the addiction studies conducted to date have used a generic survey instrument, such as the EQ-5D, administered to individuals in the study population. The EQ-5D asks individuals about problems they are having with items such as physical functioning, pain, emotional distress, and social functioning, and then asks them to rate how good or bad their health is based on a 100 point scale. The information is summarized for different health states and used to create weights for use in the economic evaluation. However, the recognition that drug abuse treatment can affect quality of life beyond the domains measured in generic instruments has spurred the development of a few disease-specific instruments, although they have not been widely used.

Another purported benefit of CUA is that a commonly accepted threshold can be used to determine whether or not it is worth investing in a specific intervention or program; values of between \$50 000 and \$100 000/QALY have traditionally been used as threshold values in addiction treatment and other studies. This range is based on the costs of an additional QALY for patients receiving dialysis, which is viewed as an appropriate benchmark because of the US Medicare Program's decision to cover this intervention for all who need it. However, recent work has called into question the appropriateness of this threshold and debate continues.

A Note on Perspective

One of the design considerations when planning an economic evaluation of a treatment program or intervention is the perspective from which it will be conducted. In other words, whose costs and benefits should be included in the analysis? Given that the main goal of the science of economics is to examine the allocation of resources across society, economic analyses require the use of a societal perspective. This involves accounting for the costs and benefits of an intervention or program regardless of who incurs or receives them whether the payer, provider, other health care providers, the social services system, the patient or family members, the criminal justice system, and so forth. Others argue that it is more appropriate to consider only the provider or payer perspective because they are the ones who decide which programs to offer or reimburse, and, therefore, what interventions and program models will be used in practice. However, limiting the perspective to only one actor can lead to suboptimal choices when, for example, treatments are chosen that minimize the cost to the provider or insurer but transfer costs to others such as patients or the social welfare system. Conducting the analysis from a societal perspective and then reporting the results from that and the other relevant component perspectives, which are encompassed in the societal estimate, is a preferred course of action.

Communicating Uncertainty

Estimating and communicating the variation inherent in the ICER – which is the ratio of two estimated variables – is a relatively new feature in the reporting of economic evaluations of addiction treatment programs and interventions. It is an important methodological advance, however, because it enhances our

understanding of the variation in costs and individual responses to programs and interventions, and provides important information about the strength of the evidence. In the addiction literature this has been done in a number of ways. One example is to estimate a confidence interval around the estimate of the ICER. Another is to generate an acceptability curve, which displays the probability that a given intervention is cost-effective at different levels of the decision makers' willingness to pay for a unit of benefit. It is also possible, when comparing two interventions or programs, to plot the joint distribution of the incremental costs and effects, to get a sense of how dispersed they are.

Also popular is the use of sensitivity analysis to determine the effect of varying key assumptions in the analysis on the results. Each of these methods has its strengths and weaknesses. It is often advisable to report several of these ways of communicating uncertainty, which, taken together, can appropriately characterize the precision of the estimate, the strength of the evidence, and the potential consequences of making the wrong choice.

Study Designs

Economic evaluations of addiction treatment programs have been of two main types: ancillary studies to effectiveness or efficacy trials or outcome studies and simulation studies. Each can provide valuable evidence to inform decisions about the allocation of resources. Those evaluations done alongside clinical trials have the benefit of randomization and of allowing for a very accurate and detailed assessment of the costs of the program or intervention at the time it is being provided to the patient. If conducted early enough, they can also inform the future development of the intervention or program to reduce costs so that it will be more likely to be adopted if it is found to be effective. Results from these studies, however, are limited in the sense that they can be difficult to generalize beyond the types of patients and settings used in the trial. In addition, results may not accurately reflect how the intervention or program would be implemented outside of a trial setting, much like the clinical results from the trial.

Dynamic simulation studies can be useful for examining the long-term effects of interventions and programs, for analyzing the results at the population level, and for including a large number of variables in the analysis. In the addiction field, these have been used for all three types of economic evaluation described here. The types of simulation models used to study addiction treatment interventions and programs typically start with a data set, which may come from survey or administrative data, containing

a variety of variables on the individual person at a specific point in time. At that point in time, each individual in this data set can be in one of a limited number of comprehensive and mutually exclusive states, for example, using a drug and not in treatment, using a drug and in treatment, not using a drug and not in treatment, and not using a drug and in treatment. Each state is associated with a variety of costs, such as the costs of treatment, the consequences of drug use, including criminal justice involvement and other health care utilization. Mathematical equations, combining information on the individuals within the data set (such as their age, gender, drug use history, and treatment utilization, with information, often from the literature, on the probabilities of transitioning among these states over time as a function of these characteristics) are used to develop a path across time of the individual's movement into and out of these states. The estimated trajectories of those who receive treatment are compared with the trajectories of those who do not receive treatment to generate the costs and benefits of the treatment program or intervention.

Results of Economic Evaluation Studies

Table 62.2 displays information on several recent economic evaluation studies of addiction programs and interventions. CBA studies tend to find that addiction treatment is cost-beneficial. CUA studies tend to suggest that effective addiction treatments and improvements to those treatments cost modest amounts per increase in QALYs, although recent studies incorporating uncertainty estimates reveal that the results are often imprecise. This is often because the analyses are conducted on clinical trial samples that may not have been powered for the economic evaluation, but also because of the heterogeneity of costs and outcomes observed across patients. Some of the studies in Table 62.2 also reveal that the analyses yield different results based on perspective. Further work is needed to improve methods, such as assuring that power analyses are conducted to determine the adequacy of the sample size for the economic analysis and to standardize the reporting of studies, including design, perspective, costing methods, and uncertainty estimation, to make the results as useful as possible.

COST-FUNCTION ANALYSIS

As is apparent from the costing study results presented in Table 62.1, the costs of producing addiction treatment vary substantially. This variation may be due to a variety of factors, including differences across

 TABLE 62.2
 Selected Economic Evaluations of Addiction Treatment

Subject	Method	Findings
Publicly funded addiction treatment programs in California*	CBA based on a pre-post study design on data on patients from 43 addiction treatment programs. Benefits, including reductions the costs of medical care, mental health services, criminal activity and transfer payment programs, and increases in earnings, were collected using Addiction Severity Index (ASI) data and administrative data. Direct treatment program costs were estimated using the DATCAP.	Over the 9-month period of the study, treatment cost approximately \$1583 on average while the benefits to society were \$11 487, for a 7:1 ratio of benefits to costs. Sixty-five percent of the total benefit was from reductions in crime costs.
Methadone treatment over the lifetime**	CBA based on a simulation model of the progression of heroin use and treatment, as well as employment, criminal activity, incarceration, and health care use, over the lifetime of a cohort of individuals from 18 to 60. Data are from a variety of national surveys and from published sources.	The benefit—cost ratio for the initial treatment was \$4.86 per dollar spent. Treatment over the lifetime returns approximately \$37 per dollar spent.
Prize-based contingency management plus usual care versus usual care alone for increasing longest-duration abstinent (LDA), negative urines, and length of stay***	CEA based on results from a US RCT of 415 stimulant abusers. Costs were estimated from a provider perspective using a microcosting approach and uncertainty assessed using sensitivity analysis and acceptability curves.	On average, CM cost \$258 for each 1-week increase in LDA, \$146 for each additional stimulant-free urine, and \$398 for each 1-week increase in length of stay. The acceptability curve analysis reveals that CM has a 90% probability of being cost-effective at a willingness-to-pay threshold of \$325 per additional week of LDA.
Motivational interviewing (MI) versus usual care for smoking cessation and relapse prevention§	CEA and CUA based on results from a US RCT of 302 low-income pregnant women in Boston. Costs were estimated from a societal perspective using microcosting methods, and QALYs were derived from the published literature.	MI was dominated by usual care for smoking cessation; for relapse MI cost \$851 per life year saved and \$628 pre additional QALY.
Nine treatment regimens for alcohol dependence: Medical management (MM) plus placebo, MM plus naltrexone, MM plus acamprosate, MM plus placebo plus a combined behavioral intervention (CBI), MM plus naltrexone plus acamprosate, MM plus naltrexone plus CBI, MM plus acamprosate plus CBI, MM plus acamprosate plus CBI, and CBI only Times CBI, and CBI only	CEA using data on 1383 participants in the US Combined Pharmacotherapies and Behavioral Interventions (COMBINE) clinical trial. Outcomes were percentage of days abstinent, avoiding heavy drinking, and achieving a good clinical outcome (abstinent or moderate drinking without problems). Per-patient costs were estimated from the provider perspective based on the number and types of services received, times the cross-site medians of the labor, space, laboratory costs for each service, plus the cost of the medication. Per-patient costs were also estimated from the patient perspective, including time, out-of-pocket, and medication costs. Acceptability curve analysis and sensitivity analysis were used to assess uncertainty.	The treatment regimen that had the highest probability of being cost-effective varied across willingness-to-pay thresholds. From the provider perspective, MM plus naltrexone was most likely to be cost-effective for lower thresholds. while MM plus naltrexone plus acamprosate was most likely to be cost-effective at higher thresholds. Patients had the same ranking, but the threshold at which MM plus naltrexone plus acamprosate had the highest probability of being cost-effective was much lower than that of the provider (\$1500 versus \$7000 per patient with a good clinical outcome).
Twelve-week buprenorphine- naloxone treatment (up to 24 mg day with 1-week taper – BUP) versus brief detoxification treatment using buprenorphine-naloxone (up to 14 mg day tapered to zero on day 14 – DETOX) [‡]	CEA and CUA based on results from a US RCT of 152 adolescent subjects. Costs were estimated from the payer and societal perspectives using the SASCAP, and QALYs were elicited from clients using the EQ-5D instrument. Uncertainty was estimated using acceptability curve analysis.	BUP cost \$1376 per extra QALY and \$308 per extra opioid-free year from the payer's perspective, although the chances of it being cost-effective were only 86%. Point estimates suggest that BUP may be cost-effective from a societal perspective, but the results were statistically imprecise.

(Continued)

TABLE 62.2 Selected Economic Evaluations of Addiction Treatment—cont'd

Subject	Method	Findings
Varenicline plus physician counseling versus physician counseling alone for smoking cessation [#]	CUA using a simulation model based on Japanese epidemiological data, and effectiveness and transition probability information from expert opinion and the literature. Costs were measured from the perspective of the health care system and were based on patient and provider surveys, as well as administrative data.	Varenicline was dominant overall and for men, and cost about \$3000 per QALY (in 2007 dollars) for women, although there was considerable uncertainty around the estimates.

^{*} Ettner, S.L., Huang, D., Evans, E., Ash, D.R., Hardy, M., Jourabchi, M., Hser, Y., 2005. Benefit-cost in the California Treatment Outcome Project: does substance abuse treatment "pay for itself?" HSR: Health Services Research 41, 192–213.

programs in their size, the types and scope of services they produce, local costs of doing business, the types of patients treated, and the efficiency of production. Cost-function analysis, which has just recently begun to be applied to addiction treatment programs, offers a way to examine the causes of this variation. It can also provide important information to policymakers and payers about the appropriate amount to reimburse programs, as well as the optimal size and configuration of these programs.

Derived from the standard neoclassical theory of the firm, cost-function analysis is a type of regression analysis that regresses variables such as the volume of output (e.g. the number of clients treated) and costs of inputs such as wage rates for various types of staff and rental space costs, on the total cost of production. Coefficients on the variables provide an estimate of the effect of a small change in the value of those variables on costs.

Understanding the cost structure of an industry, such as whether or not it displays economies of scale or scope, can inform payment, antitrust, and licensing policies as well as industry production practices. An industry is said to experience economies of scale if the average or per-unit cost of production is lower in firms with higher output levels than it is in firms with smaller output levels. In industries with strong economies of scale, it may be appropriate for policymakers to encourage the formation of a few large firms rather than many small ones, for example, through payment or licensing policies. An industry is said to experience economies of scope if firms that produce multiple products can

produce those products at a lower average cost than would be achieved if different firms produced each product separately. If economies of scope are present in the addiction treatment field, it may be appropriate for policymakers to consider changing regulatory requirements where necessary to make it easier for firms to produce several different types of treatments under the same roof. Also important is understanding another facet of the cost structure of the industry, whether efficiency can be improved by altering the mix of inputs used in the production process. This can be ascertained by examining the coefficients on the input price variables.

Other variables are included in the analysis both to improve the estimates of industry structure coefficients and to understand the effects on costs of those variables. These other variables, which can include information on the types of patients the program treats, its location in a high-cost or low-cost area, or whether or not it is part of a parent organization, may be especially important if the results from these studies are used to determine payment rates or to compare firms on the basis of their efficiency. Failure to account in the analysis for factors that legitimately affect cost differences and that society values can lead to erroneous conclusions and policy actions.

Two studies grounded in economic theory have been conducted on addiction treatment programs, one using data on a nationally representative sample of outpatient nonmethadone facilities from the ADSS study and the other using a large sample of methadone treatment facilities. The outpatient nonmethadone study examined

^{**} Zarkin, G.A., Dunlap, L.J., Hicks, K.A., Mamo, D., 2005. Benefits and costs of methadone treatment: results from a lifetime simulation model. Health Economics 14, 1133–1150.
**** Olmstead, T.A., Sindelar, J.L., Petry, N.M., 2007. Cost-effectiveness of prize-based incentives for stimulant abusers in outpatient psychosocial treatment programs. Drug and Alcohol Dependence 87, 175–182.

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Zarkin, G.A., Bray, J.W., Aldridge, A., Mitra, D., Mills, M.J., Couper, D.J., Cisler, R.A., 2008. Cost and cost-effectiveness of the COMBINE study in alcohol-dependent patients. Archives of General Psychiatry 65, 1214–1221.

[†] Dunlap, L.J., Zarkin, G.A., Bray, J.W., Mills, M., Kivlahan, D.R., McKay, J.R., Latham, P., Tonigan, J.S., 2010. Revisiting the cost-effectiveness of the COMBINE study for alcohol patients: the patient perspective. Medical Care 48, 306–313.

[‡] Polsky, D., Glick, H.A., Yang, J., Subramaniam, G., Poole, S.A., Woody, G.E., 2010. Cost-effectiveness of extended buprenorphine-naloxone treatment for opioid-dependent youth: data from a randomized trial. Addiction 105, 1616–1624.

[#] Igarashi, A., Takuma, H., Fukuda, T., Tsutani, K., 2009. Cost-utility analysis of Varenicline, an oral smoking-cessation drug, in Japan. Pharmacoeconomics 27, 247–261.

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TABLE 62.3 Findings from Economic Cost-Function Analyses

Study

Study of a nationally representative sample of 222 outpatient nonmethadone treatment programs. Explanatory variables included number of admissions, wages (counselor, clerical, and senior administrative), office space, percentage of patients who were white, black, Hispanic, other race, percentage referred by the criminal justice system, percentage who had both drug and alcohol disorders, percentage who injected drugs, percentage who received Supplemental Security Income (SSI) or Social Security Income (SSDI), facility ownership (private for-profit, private nonprofit, government), whether or not the program was part of a larger organization, location in an urban area, and how many special services the facility reported offering.*

Study of 159 methadone treatment programs from several states that participated in the Center for Substance Abuse Treatment's Evaluation of the Methadone/LAAM Treatment Program Accreditation Project.**

Findings

A 10% increase in the number of treatment admissions resulted in a 6.7% increase in total costs, suggesting economies of scale. Facilities with higher proportions of clients with SSI and SSDI had higher total costs.

A 10% increase in patient days resulted in an 8.2% increase in total costs, suggesting economies of

economies of scale only, while the methadone study examined both economies of scale and scope. The results, shown in Table 62.3, suggest that there are economies of scale in both types of treatment programs but little support for the presence of economies of scope in methadone treatment. Few other variables were significantly related to treatment costs.

Although these studies are informative, they do not adequately control for two factors that could affect costs, the omission of which might affect the estimates of economies of scale and scope because of omitted variables bias, but which are also important in their own right: client casemix and the quality of care provided. Casemix

measures are needed to objectively control for differences in the resources that may be required to treat different types of clients. Failure to include such information when using cost-function results to set payment rates, for example, could lead programs to stop admitting clients they believe will cost more to treat, reducing access to those who might need treatment most. Failure to include quality measures could lead programs to use methods that are less costly but not as effective, leading to worse outcomes and lowering the value of society's investment in treatment.

Although Table 62.3 shows that the studies did include indicator variables that might capture some differences in casemix, the field has not carefully conceptualized, developed, or tested a comprehensive measure or set measures for this purpose. The field is also lacking in quality of care measures appropriate for this purpose. Although length of stay often is considered a proxy for quality in addiction treatment, its use in costfunction analysis is especially problematic because a longer length of stay could also reflect inefficiency in the production of treatment. Research designed to fill both of these gaps would enhance the utility of costfunction and other economic analyses, as well as the ability to compare programs for other purposes such as pay-for-performance schemes.

SUMMARY

The basic insight from economics - that limited resources must be allocated carefully to maximize welfare - has led to the development of a variety of analytical approaches to inform allocation decisions. These approaches, including costing studies, economic evaluations, and cost-function analyses, have increasingly been applied to study addiction treatment programs and interventions, and the methods and data available to conduct them continue to improve. Addiction treatment is often found to be cost-beneficial, and effective enhancements to addiction treatment are often shown to improve outcomes or increase QALYs at costs that many would consider reasonable. Studies to date suggest that there is substantial variation in the costs of producing addiction treatment, but the sources of that variation are poorly understood. Although other factors, such as equity and access, should certainly be considered when deciding what addiction treatments to purchase, provide, or fund, careful accounting of the costs of a proposed activity and the outcomes or benefits it produces need to be a cornerstone of any such decision.

Economic analyses, like all analyses, should have clearly defined goals, employ methods and data that are most appropriate to meet those goals, and be

^{*} Duffy, S.Q., Dunlap, L.J., Feder, M., Zarkin, G.A., 2004. A hybrid cost function for outpatient nonmethadone substance abuse treatment facilities. In: Council, C.L. (Ed)., Health services utilization by individuals with substance abuse and mental disorders (DHHS Publication No. SMA 04-3949, Analytic Series A-25). Substance Abuse and Mental Health Services Administration, Office of Applied Studies, Rockville, MD. **Dunlap, L.J., Zarkin, G.A., Cowell, A.J., 2008. Examining variation in treatment costs: a cost function for outpatient methadone treatment programs. HSR: Health Services Research 43, 931–950.

reported in a way that accurately, clearly, and objectively states what was done and what it means. CEAs and CUAs, for example, may be most useful when considering novel treatment interventions or enhancements to existing interventions. They can help identify interventions that are unlikely to be of high value as proposed and point to ways to improve their value. A high-quality analysis would involve determining the most appropriate outcome or outcomes to measure and how to best measure them, assuring adequate statistical power, clearly describing the comparator condition, carefully costing (identifying, quantifying, and valuing) all of the societal resources incurred in the production and participation in each of the treatments and how they vary among patients, and assessing and communicating the statistical significance of the ICER and, in the case of QALYs, its relationship to the chosen threshold value. Theoretically, microcosting is the preferred method for assessing the costs of interventions for CEAs and CUAs, but research is needed to determine if the additional accuracy warrants the significant research resources required to conduct such studies in the addiction field. Studies examining other health care sectors suggest it may not. Simulation analyses that can estimate the effects on ICERs of changes in the model parameters – for example, reduction in the price of pharmaceutical interventions that might be possible when a generic becomes available – can be used to avoid the problem of nipping the diffusion of a promising intervention in the bud because it appears too costly. To enhance the quality and comparability of such studies, research is needed to identify clinical endpoints or other outcomes that could be implemented across studies and in developing a nationally representative cost database that could be used to value treatment inputs.

CBAs may be most appropriate as an aid to determining which of a variety of cost-effective treatments or other interventions to implement given limited budgets. Careful accounting of the costs and benefits that accrue to the entire society is essential in making this determination. Again, results can be reported for different perspectives, but spillovers must be identified and accounted for in the main result. For these types of analyses to fulfill their promise, investments need to be made in understanding and quantifying the nature of the disorder, the long-term consequences of drug use among the treated and untreated populations, and the long-term effects of treatment for diverse populations. Such data currently are lacking.

Undergirding each of these studies needs to be cost data that adequately captures and converts into currency terms the resources used to produce treatment. In the absence of government- or market-mandated reporting requirements such as those that exist in other

industries, it falls to researchers to capture those data using de novo data-collection methods such as the ones described above. Ideally, such data would be pooled to provide industrywide averages that could be used across studies, and that could support careful examinations of the industry's structure and ways to make it as efficient as possible.

SEE ALSO

Treatment-as-Usual for Substance Abuse in Community Settings, Motivational Enhancement Approaches, Evaluating Treatment Efficacy, Therapeutic Communities[®], Methadone Maintenance, Buprenorphine for Opioid Dependence, Naltrexone and Opioid Antagonists for Alcohol Dependence, Acamprosate for Alcohol Dependence

List of Abbreviations

ADSS Alcohol and Drug Services Study

CBA cost-benefit analysis
CEA cost-effectiveness analysis
CUA cost-utility analysis

DATCAP Drug Treatment Cost Analysis Program ICER incremental cost effectiveness ratio

SASCAP Substance Abuse Services Cost Analysis Program

TCAT Treatment Cost Analysis Program
QALY quality adjusted life year

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- http://www.bing.com/search?q=TCU+TCAT&src=IE-SearchBox&FORM=IE8SRC The Treatment Cost Analysis Program (TCAT).

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Ethical Issues in the Treatment of Drug Dependence

Adrian Carter*, Wayne Hall\$

*University of Queensland Centre for Clinical Research, Brisbane, QLD, Australia

\$Queensland Brain Institute, Brisbane, QLD, Australia

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INTRODUCTION

The treatment of drug addiction can involve a range of pharmacological and psychosocial approaches. Pharmacological treatment of drug dependence can be divided into three broad categories: detoxification (supervised withdrawal from the drug of addiction), relapse prevention (prophylaxis against relapse), and maintenance or substitution treatment programs (supervised provision of the drug of addiction or a similarly acting drug (its agonist)). Psychosocial treatments involve cognitive behavioral therapy, therapeutic communities, or social support, and may or may not be provided in conjunction with a pharmacological treatment. Some treatment programs such as needle

and syringe programs (NSPs) do not aim to reduce or stop drug use, but to reduce the harm that drug use causes. These types of treatment are of an approach referred to as *harm reduction*.

The aims or desired outcomes of each of these treatments can vary widely. Treatment may differ in the length of intervention (e.g. short-term detoxification to longer-term relapse prevention, substitution, or maintenance), the requirement of abstinence from addictive drug use, and the degree of clinical engagement. The strengths and weaknesses of each approach to addiction treatment differ but the ethical principles that supervene on the treatment of addiction hold irrespective of the treatment aim or modality.

ETHICAL PRINCIPLES AND SOCIAL FACTORS INFLUENCING THE TREATMENT OF ADDICTION

The treatment of drug dependence should observe the minimum requirements for ethicality of any form of medical or psychosocial treatment. These have often been expressed in four influential ethical principles: respecting the *autonomy* of persons who are being treated, avoiding harm (nonmaleficence), doing good (beneficence), and providing a fair distribution of costs and benefits of drug treatment and drug policy (distributive justice). These four ethical principles also form the basis of important statements of human rights, such as the World Medical Association's Declaration of Helsinki and similar statements by United Nations Organization.

Treatment of drug dependence can involve the use of the coercive powers of the state and the denial of liberty and autonomy because the behavior of drug-dependent people adversely affects others (e.g. criminal acts to finance illicit drug use, violence, or dangerous driving while intoxicated). Treatment of drug dependence also often involves the coordination of several different social systems – the medical or health care system, public health, and criminal justice – which often requires careful justification and balancing of the rights of addicted individuals and the community in developing treatment policy.

Most would agree that individuals should be respected and treated fairly. However, consensus often proves elusive in the case of treatment of drug dependence because of disagreements about what these ethical imperatives require us to do, and where the balance of effort and responsibility lies. These disagreements are often largely driven by different answers given to the following questions: What is the nature of addiction? How does addiction affect those with the disorder? How much autonomy do drug-dependent persons have? To what extent are they able to make decisions about their drug use, consent to enter treatment, choose not to use drugs, be involved in decisions regarding their treatment, and take responsibility for their actions? What are they capable of and responsible for? What are the respective rights and responsibilities of society and drug-dependent individuals?

AUTONOMY AND THE DRUG-DEPENDENT INDIVIDUAL

For most of the last century, drug-dependent persons were seen as autonomous, self-governing individuals who willfully, knowingly, and voluntarily engaged in criminal and immoral behavior (i.e. illicit drug use).

However, in the last decade, the autonomy and responsibility of addicted individuals were called into question by genetic and neuroscientific research on addiction. In 1997, Alan Leshner, the then director of the National Institute on Drug Abuse (NIDA), declared addiction to be a "chronic, relapsing brain disease" caused by the repeated self-administration of drugs that produced enduring changes in brain neurotransmitter systems and left addicted individuals vulnerable to relapse.

Brain imaging studies have shown how prolonged drug use produces long-lasting changes in brain structure and function that undermine voluntary control. These studies have specifically shown that chronic drug use produces a significant decrease in dopaminergic activity that is involved in the disruption of limbic and prefrontal regions. Adaptations in limbic regions emphasize the rewarding effects of drugs and make addicted individuals less sensitive to the rewarding effects of everyday rewarding activities, such as food, work, and relationships. Disrupted functioning in the prefrontal regions focuses addicted individuals' attention on drug use and impairs their ability to control their drug use for months after they become abstinent. Addicted individuals also display cognitive deficits in decision-making tasks.

An explicit aim of advocates of the brain disease model of addiction is to change the way that society deals with addiction. The hope is that public acceptance of addiction as a brain disease will lead to less reliance on punitive measures and more effective and humane medical treatment of addiction. It is also hoped that reduced social stigma would encourage more individuals to seek treatment early and increase funding for medical research and interventions. Despite a decade of the chronic, relapsing brain disease model of addiction, relatively little has changed in societal responses to addiction.

Some social scientists are concerned that the brain disease model of addiction may be used to justify greater discrimination against those with an addiction. If individuals with an addiction are seen as suffering from a brain disease where their behavior was neurobiologically determined, addicted individuals might be deemed incapable of making decisions regarding their drug use. On this view, those with an addiction lack the capacity to make autonomous decisions, and more coercive forms of treatment or invasive interventions with serious risks or side effects could be justified. Such an interpretation could lead to reliance on only mildly effective pharmacological or neurological treatments at the expense of cheaper, more effective social policies that aim to minimize the effects of drug abuse. An uncritical acceptance of this view might also encourage the promotion of expensive and invasive "cures" of addiction of doubtful efficacy to a vulnerable and desperate population.

The ability, or lack thereof, of the drug-dependent individuals to control their drug use is central to ethical debates regarding the treatment of drug dependence. These arguments hinge on whether these individuals are compelled to use drugs. While arguments for compelled behavior can stem from both biological and social causes, arguments for compulsive behavior more often involve appeals to biological causes. Genetic and neurophysiological explanations of compulsive drug use are much more compelling and have the appearance of material fact. The presence of "addictive genes" and pictures of "addicted brains" possess the allure of truth and are easily misrepresented or misunderstood. Results of this kind are often used to portray the addicted person as someone who is "internally coerced by an irresistible force" and therefore lacks autonomy with regard to drug use.

Some bioethicists have used the chronic, relapsing disease model of addiction to argue that people with an addiction lack the autonomous decision-making capacity about drug use. According to these ethicists, addicts are unable to make rational decisions about whether to accept offers of drugs in experimental or clinical research studies. Such arguments would also raise similar doubts about the capacity of addicted individuals to provide free and informed consent to enter any form of treatment that involves maintenance on an agonist drug, such as methadone or buprenorphine: two of the most effective pharmacological treatments available to opioid-dependent individuals.

Such interpretations ignore the limitations of what the neuroscience of addiction is able to tell us. For addiction to completely override autonomy in drug-dependent individuals, the forces of addiction must be demonstrably irresistible and absolute. Observational studies show that this is not the case and evidence from the neuroscience literature is not as clear as some bioethicists suggest. Neuroimaging and cognitive studies show that addicted individuals, as a group, are more likely to show disruptions in brain function, which is thought to be associated with a reduced ability to control drug use and make appropriate decisions. They do not, however, demonstrate an absolute lack of control that undermines decision-making capacity in all addicted individuals.

Many addicted individuals succeed in stopping drug use without further assistance. Others can become abstinent for varying periods as a result of social pressure. The problem with the disease model of addiction, and any of the "lifestyle diseases" such as obesity and diabetes, is that nearly any kind of abnormal behavior will be accompanied by biological changes in the brain that can be detected or measured. Finding such differences does not indicate that they comprise a disease of biological origin. By contrast, those who claim that

addiction is a self-serving excuse for willful and bad behavior ignore the biological correlates of addiction.

The nature of addiction is a much more complex phenomenon than either partial perspective allows. Disease models need to acknowledge that people with drug dependence still maintain a level of autonomy in making decisions about their drug use. Skeptics need to acknowledge that disrupted brain neurobiology does impair the ability of some drug-dependent people to make decisions about their drug use and may indicate the need for pharmacological interventions to support abstinence.

PERSONAL HEALTH AND THE PUBLIC GOOD

The treatment of drug dependence, particularly illicit drug dependence, is motivated by mixed personal, public health, and public order goals that complicate and sometimes compromise treatment. Drug-addicted individuals often enter treatment under some form of coercion, whether it be from friends or family, or as a result of an encounter with the criminal justice system as an alternative to imprisonment. Many drug-dependent persons are unable to pay the costs of their treatment, which is often provided by the government. Taxpayer-funded addiction treatment is usually justified because it is more cost-effective than imprisonment in reducing crime and public disorder.

Treatment often involves interactions between personal and public health systems and the criminal justice system. These different areas (e.g. law enforcement, clinical staff, and public health) have different aims and approaches to health care, with different professional ethical imperatives, that can lead to conflicts in the provision of treatment. Clinical or personal medicine focuses on the treatment and cure of individual patients while public health medicine aims to understand and ameliorate the causes of disease and disability in a population. While the physician–patient relationship is the focus of medicine, public health involves interactions and relationships among professionals and members of the community, as well as government agencies. The involvement of the criminal justice system in coercing patients into treatment and the competing goals of drug treatment of different agencies amplifies opportunities for conflict. The tensions between these goals must be managed by all forms of treatment, including abstinence-oriented treatment, but they present special issues for programs that provide pharmacological treatment of opioid dependence.

Pharmacological treatments, agonist maintenance in particular, can have negative effects on society if drugs for treatment are diverted to the black market. As a result, treatment requires the imposition of restrictions to protect public welfare. Public ambivalence about the ethical acceptability of maintaining "addicts" on "drugs" often leads to restrictive rules and regulations on pharmacological treatment. Some regulations are intended to minimize the risk of nonaddicted persons entering treatment (e.g. by demanding evidence of an extensive history of dependence and documented failure at abstinence treatment). Other regulations aim to prevent diversion of pharmaceutical opioids to the black market where they may result in harm (e.g. overdose deaths, new cases of addiction). Program regulations may also include regular urine testing, punishment for patients who provide a certain number of dirty urine samples (e.g. exclusion from the program), limits on the length of treatment, or an insistence upon achieving a goal of abstinence from all drugs within some arbitrary period (e.g. 1 or 2 years). These regulations may have unintended effects such as decreased program retention, discouraging drug-dependent persons from seeking treatment until their condition is chronic, or forcing stable patients to withdraw from treatment and return to illicit drug use. Ethical treatment of addiction requires program rules and regulations that balance patient and community safety while permitting patients to remain in and benefit from treatment.

DISTRIBUTIVE JUSTICE: BALANCING THE BURDEN OF DISEASE AND TREATMENT

The public benefits that treatment for drug dependence brings are important in obtaining public support, but there is a danger that policies that benefit the majority may impose unfair burdens on a vulnerable minority. An important ethical goal of drug-dependence treatment is ensuring that public policies do not *unfairly* burden or discriminate against a vulnerable minority to serve the public good.

Distributive justice is a difficult and emotively charged issue in the case of addiction because drug use has negative effects on society, and drug policies that aim to discourage drug use may adversely affect dependent individuals. This raises important questions about where the burden of responsibility lies for society and the addicted individual in dealing with drug dependence. For a treatment to be ethical, it is necessary to show that (1) it is effective in reducing negative outcomes for both society and the individual and (2) that the social and political policies that produce and respond to addiction do not unfairly burden the minority who become addicted. The first condition is necessary but not sufficient: it would be unethical, for

example, to use effective pharmacological treatment of opioid dependence to compensate for social policies that fail to address social disadvantage, family history of violence and drug use, and presence of comorbid psychiatric disorders, all of which increase vulnerability to opioid addiction.

Those who receive publicly funded or subsidized treatment arguably have a reciprocal responsibility to engage in a reasonable treatment program, to meet its aims, and to avoid behavior that adversely affects the community. Society is justified in expecting that drugdependent individuals, who engage in treatment, adhere to treatment and not act in ways that adversely affect society. For example, while methadone maintenance treatment has been shown to be relatively safe and effective in reducing opioid use, it can lead to overdose if methadone is diverted to opioid-naïve users. In the United Kingdom during the 1990s, poorly regulated methadone programs led to the diversion of methadone onto the black market, resulting in fatal methadone overdoses of persons who were not in treatment. Risks such as these highlight the importance of delivering treatments in ways that protect both those receiving it and the broader society.

Treatment responses and regulations used to ensure that those who enter treatment meet their obligations must be informed by a broad set of ethical principles. To be ethical, they must

- not unduly violate privacy and autonomy of individuals;
- scale responses to individual lapses to their relative importance in achieving overall treatment goals;
- 3. be mindful and consistent with the ability of individuals to meet their obligations (including actively helping individuals to do so); and
- be sensitive to the situation of the individual, with regard to both internal (neurophysiology and neuropsychology) and external (social) circumstances.

Based on the ethical analysis presented, we believe that the treatment of drug dependence should meet the following ethical guidelines:

- Drug-dependent persons should have equitable access to safe and effective forms of treatment. That is, they should not be discriminated against by virtue of their condition nor should the illegal status of their actions prevent them from access to safe and effective treatment.
- 2. There should be rigorous evidence that the treatment be safe and effective. New pharmacological or neurological treatments for drug dependence need to have their safety and efficacy rigorously assessed before they are widely used.

- **3.** Treatment should be provided safely in well-structured, well-resourced, and well-managed treatment programs.
- 4. Treatment should ideally be individualized to the patient. Addicted persons differ in many ways and addiction is a dynamic process. Different individual's needs will therefore vary and may change over time and circumstances. It is accordingly important that treatment flexibly meets patients' changing needs.
- 5. Treatment staff need to emphasize the importance of the client–carer relationship in providing ethically adequate treatment that respects the autonomy of patients, their privacy, and the confidentiality of information that they provide, and ensures that individuals provide free and informed consent to participate in treatment (see below).
- 6. Treatment should be motivated by an intention to treat the individual. Ideally, treatment that accords with the ethics of personal medical care is also the most successful in meeting the aims of a public health care program because good individual treatment will ensure good program retention and maximize the benefits to the individual and the community that funds his/her treatment.
- 7. Good relationships between clients and staff are important in successful treatment. Attitudes of staff toward clients and their relationship with clients have been found to be the critical factors in determining the success of methadone maintenance treatment.
- 8. Conversely, treatment programs should be regulated in such a way that protects society from further harm. These rules and regulations should be understood by clients and be administered in a fair and reasonable way that aims to protect society and are not used to unfairly punish clients. Drug-addicted individuals should not bear a disproportionate social burden in accepting treatment.

ENTERING TREATMENT FOR ADDICTION

Informed consent is the process by which individuals agree to enter treatment in the full knowledge of its possible risks and benefits, and in the absence of duress or coercion. Informed consent requires that the individual (1) has the capacity to understand treatment and communicate his/her wishes, (2) is free to make decisions (i.e. is not internally or externally coerced), (3) is fully informed of the risks and benefits of the treatment as well as those of other treatment options, and (4) has reasonable access to all effective forms of treatment, where treatment is appropriately operated and resourced.

When drug-dependent individuals enter treatment, they are often in a desperate state. They may be willing to agree to almost anything to get into treatment (e.g. to end their withdrawal symptoms or avoid the negative social consequences of their addiction). For these reasons, individuals in this situation should not be asked to provide detailed consent to a treatment program, apart from indicating their acceptance of the immediate offer of assistance. Clients can only begin to think about detailed requirements of treatment after they have been stabilized in pharmacological maintenance treatment or have completed supervised withdrawal.

When choosing a treatment, it is important that the client understands its effectiveness, benefits, and risks, as well as the requirements of the treatment program. The treatment that is chosen should reflect the aims of the individual rather than those of the staff or the wider community. The staff member's responsibility is to ensure that the client is well-informed about the treatment options that are available, their goals, risks, and benefits, and what the expectations are in entering the program. Ensuring this understanding requires discussions about the pros and cons of abstinence versus maintenance treatment goals, as well as an honest appraisal of the risks and the likelihood of benefiting from both types of treatment (see Table 63.1).

Informed consent to a detailed treatment contract will state the rules and regulations of treatment and an individual's obligations. This may include information on drug testing regimes, responses to positive urine samples, intended length of treatment, costs, where and how often drugs are to be dispensed, other treatment requirements, involvement of the criminal justice system, and rights to privacy and confidentiality, including informing participants of the limits of confidentiality (e.g. that it is mandatory to report child abuse or homicide). Rules and obligations such as this should

TABLE 63.1 The Minimum Requirements for Acquiring Free and Fully Informed Consent to Addiction Treatment

Minimum requirements for informed consent to addiction treatment, include providing information to clients about

- 1. Clinical characteristics and diagnosis
- 2. Treatment recommendations
- 3. Risks and benefits of treatment
- 4. Costs of treatment
- 5. Program rules rights and obligations
- 6. Alternative services and interventions
- 7. Freedom to choose and refuse treatment

Notes: These data are based on research findings from Carter, A., & Hall, W. (2008). Informed consent to opioid agonist maintenance treatment: recommended ethical guidelines. International Journal of Drug Policy, 19(1), 79–89.

be aimed at the treatment of the individual, while still protecting society from harm.

COERCED TREATMENT OF ADDICTION

There is reasonable evidence that persons who enter treatment for drug abuse will benefit from the treatment and that the longer they remain in treatment, the better off they will be. The fact that many drug-dependent persons are ambivalent about entering treatment has led to the use of various forms of formal and legal coercion to encourage treatment entry and retention that vary in the degree to which they contravene an individual's liberty, freedom, and autonomy.

Mild informal coercion, such as social pressure from friends and family to enter treatment, can be effective motivation for addicted persons to enter and complete treatment. Formal, noncriminal coercion by employers and other nongovernmental agencies, such as Employment Assistance Programs, is negotiated between agencies or employers and the individual.

Informal social coercion and formal noncriminal coercion arguably raise few ethical issues in the treatment of drug dependence. In both these cases, the drug-dependent person is *relatively* free to agree to treatment or suffer the threatened consequences (such as loss of employment or relationship). The coercive pressure in these situations does not deprive them of their liberty or deny their autonomy. Legal coercion, or the forced or coerced treatment of addicted individuals by the state, does raise a number of ethical concerns.

The Case for Legally Coerced Treatment

Legally coerced treatment most often involves the use of the criminal justice system to enforce entry to treatment on pain of imprisonment. A major justification for legally coerced treatment is that treating offenders' drug dependence will reduce the likelihood of their re-offending. Studies from both the United States and Australia have shown that treatment for drug addiction significantly reduces criminal and violent behavior by addicted subjects while they remain in treatment. The use of drug treatment programs as an alternative to incarceration has also been motivated by the failure of prison terms to reduce drug use and drug-related crime among drug-dependent people who are overrepresented in prisons.

The advent of HIV/AIDS has provided an additional argument for treating addicted persons who engage in injecting drug use. Keeping injecting drug users (IDUs) out of prison reduces the transmission of infectious diseases such as HIV and hepatitis C virus (HCV). The ethical, correctional, and public health arguments for drug treatment under coercion are reinforced

by the economic argument that it is less costly to treat offenders who are drug dependent in the community than it is to imprison them.

Legal coercion covers a wide range of strategies for getting individuals into treatment programs. The form of legal coercion that has become increasingly popular within the criminal justice system is the use of diversionary programs that offer drug-dependent persons treatment as an alternative to imprisonment at various stages in the criminal justice process. Legally coerced treatment is most often advocated for persons charged with or convicted of an offense to which their drug dependence has contributed. It is generally offered as an alternative to imprisonment to have legal sanctions deferred, reduced, or lifted, or as a condition of parole. Suspension of legal sanctions is usually made conditional upon successful completion of a treatment program, with the threat of imprisonment if the person fails to comply.

When Is Coerced Treatment Ethical?

Careful consideration of ethical issues is critical when the state uses the threat of imprisonment to encourage drug-dependent persons to seek treatment. Coerced treatment of addiction must operate within a constitutional and legal framework that protects the civil liberties of the people being coerced into treatment. It is important that treatment does not override an individual's basic human or civil rights to achieve broader social goals.

Coerced treatment for drug addiction may be justified by appealing to either of two ethical principles: *paternalism* or *the public good*. Addiction is a harmful behavior in which to engage; it adversely affects an individual's health and social welfare and significantly increases mortality and morbidity. Coerced treatment of drug addiction could therefore be justified for *paternalistic* reasons: that is, on the grounds that it is in the best interests of the individual. This would involve coerced treatment for an addicted individual's "own good."

Two forms of paternalism can be distinguished on the basis of the degree of coercion involved. Treatment that is provided against an individual's wishes, where the individual is deemed competent in making this decision is referred to as *hard paternalism*. When an individual is deemed incapable of making a competent decision, treatment is imposed because it is argued that their condition prevents them from making informed decisions on their own behalf. Coerced treatment of this type is referred to as *soft paternalism*. It is soft paternalism that is most likely to be used to justify coerced treatment in the case of addiction.

In many countries, people with serious mental illnesses can be compelled to accept treatment under certain circumstances, usually after some form of judicial review. While there is a strong beneficent justification for providing treatment, respect for an individual's liberty to make their own decisions about treatment generally overrides the beneficent drive to intervene. This would prevent the use of coerced treatment under hard paternalistic justification.

The second principle that can be used to justify coerced treatment of drug dependence is to protect the social welfare or the *public good*. The public good claim for the use of coerced treatment depends on the negative effect of drug-addicted individuals on society (e.g. via drug dealing and other criminal activity to finance their drug use). The justification of coerced treatment to protect the public good therefore becomes a distributive justice issue: that is, providing a fair distribution of the costs and benefits of drug use and drug treatment. This analysis arguably creates an obligation on society to provide treatment, and an analogous obligation on drug-dependent individuals to accept treatment under certain circumstances. This is the most commonly used justification for coerced treatment of addiction.

Some authors reject any form of treatment under coercion for drug addiction. Radical libertarians argue that drug use is always voluntary. Others accept that drug dependence exists, but oppose compulsory drug treatment on the grounds that it does not work. If treatment under coercion was ineffective, then there would be no ethical justification for providing it.

A consensus view on coerced drug treatment prepared for the World Health Organization (WHO) concluded that it was legally and ethically justified only if (1) the rights of the individuals were protected by "due process" (in accordance with human rights principles) and (2) if effective and humane treatment was provided.

Some proponents argue that offenders should be allowed two "constrained choices." The first would be whether to participate in drug treatment. If they declined to be treated, they would be dealt with by the criminal justice system in the same way as anyone charged with the same offense. The second choice would be given to those who agreed to participate in drug treatment: this would be a choice of the type of treatment that they received. There is some empirical support for these recommendations in that there is better evidence for the effectiveness of coerced treatment that requires some degree of "voluntary interest" by the offender.

The requirement of constrained choice of treatment has three implications. First, pharmacological treatments, including substitution or maintenance approaches, should be included in the options that are offered. There has been a tendency for coerced treatment programs to offer only "drug-free" abstinence-oriented treatments that prevents coerced addicted individuals from accessing the forms of treatment that are most likely to benefit them. Second, pharmacological

treatment options should not be the only options available. A range of drug-free treatment options should be available for those who do not wish to use pharmacological treatment. Third, the safety, effectiveness, and cost-effectiveness of whatever forms of treatment are offered should be rigorously evaluated.

Is Compulsory Addiction Treatment Ethically Acceptable?

Compulsory treatment – the unconditional, forced treatment of addicted individuals who have not committed a crime – does not offer a drug-dependent individual any choice. Coerced treatment of this type involves an extreme violation of an individual's autonomy and liberty. Mandatory treatment has generally involved the confinement of individuals in specialized drug-treatment facilities or prison hospitals, usually with the goal of attaining abstinence. Failure to comply with any condition of the program usually results in being readmitted to a secure inpatient facility.

As compulsory treatment involves a maximal deprivation of liberty, it requires a correspondingly greater ethical and legal justification than other forms of coerced treatment. Arguably, this includes stronger evidence that this form of treatment is effective and that the consequences of not treating the person are significant and likely to occur. Given the poor outcomes of compulsory treatment, it is difficult to justify its use for either paternalistic or public good reasons. Importantly, compulsory treatment programs override the autonomy of the individual and arguably constitute a violation of civil liberties in a manner that contravenes the United Nations Declaration of Human Rights. Coercive diversion strategies, by contrast, are less restrictive because they involve constrained choices in which a choice not to enter treatment leaves the person to face the judicial system with their civil and human rights intact.

Ethical Issues in Providing Coerced Addiction Treatment

Ethical issues in coerced addiction treatment also arise from the interaction between the correctional and medical treatment systems. A major problem is the conflicting expectations of correctional and treatment personnel about the effectiveness of drug treatment and their understanding of each other's roles and responsibilities.

Treatment staff regard the drug offender as a client: someone who should be involved in treatment decisions and whose personal information should be confidential. Treatment staff also expect that their clients will have relapses to drug use, which should be dealt with therapeutically rather than punitively. Correctional and

judicial personnel, by contrast, often expect treatment to produce enduring abstinence. They see treatment as something directed by the court and hence regard drug use in treatment as a breach of a court order that treatment staff are legally obliged to report. When these expectations of treatment effectiveness are not met and there is little communication between courts and treatment services, judges and magistrates may become skeptical about the value of coerced treatment and reduce their use of it.

The effective and ethical use of coerced drug treatment accordingly requires a shared understanding of the likely benefits of treatment and a clear statement of the roles of correctional and treatment staff. The latter should include agreement on their respective responsibilities for monitoring and reporting on an offender's progress in drug treatment. These issues should be addressed in written protocols that govern interactions between courts and treatment personnel.

TREATMENT OF VULNERABLE POPULATIONS

Addiction Treatment in Prisons

Few prisons in developed or developing nations provide effective treatment for addiction. When addicted individuals enter prison, they more often than not receive little or no treatment for their condition. Consequently, many are forced to undergo unsupervised detoxification, or "cold turkey." Given the high rates of imprisonment among drug-dependent (in particular opioid) persons, more should be made of the opportunity to offer them treatment while in prison. At a minimum, we should avoid the current practice in many prison systems of compulsory unassisted detoxification. Basic human rights include access to good pharmacological management of withdrawal symptoms on prison entry. A good case can also be made for providing substitution (e.g. methadone or buprenorphine) treatment and other harm reduction programs (e.g. NSPs) in a prison setting with the aims of both benefiting opioid-dependent prisoners and contributing to the good management of prisons. A reduction in bloodborne virus (BBV) transmission within prisons and BBV transmission and relapse to heroin use after release may therefore represent an additional benefit.

The lack of adequate addiction treatment can lead to the use of drugs within prisons, increasing the risks of drug overdose, and HIV and HCV infection. As a UN report noted, by entering prisons, prisoners are imprisoned for their crimes; they should not be condemned to HIV and AIDS by being denied access to effective addiction treatment. Forced detoxification can also lead to overdose if individuals with no opioid tolerance relapse to opioid use in prison or on release, as many do.

Few prisons provide access to sterile injecting equipment for IDUs. This is despite high rates of HIV (10–20%) and HCV (30–40%) infection occurring in prisons. Approximately one-third of the prisoners report injecting drugs while incarcerated and a high proportion share injecting equipment. These individuals are at a very high risk of contracting HIV or HCV. Failure to provide prisoners with the means to avoid these diseases arguably denies them access to health measures available to the rest of society, violating the "principle of equivalence" (the obligation to provide equivalent care to prisoners as available to the general population) and the right to health.

Human Rights in the Treatment of Addicted Pregnant Women

Substance abuse during pregnancy can have adverse effects on both the mother and the developing fetus and may increase the risk of medical complications during birth. Individuals born to substance-using mothers often suffer from significant structural brain abnormalities (e.g. significant neuronal loss and smaller brains) and lifelong cognitive and behavioral deficits for the abuse of drugs such as alcohol (e.g. fetal alcohol syndrome), cocaine, and methamphetamine.

The treatment of substance abuse or addiction during pregnancy raises the challenging ethical issue of balancing the interests of the fetus and the freedom of the mother. Society often imposes limits on the autonomy of individuals when their behavior affects others, such as overriding a competent patient's refusal of treatment to prevent the spread of an infectious disease. However, the case of overriding the autonomy of drug-abusing pregnant mothers to protect the fetus from harm is complicated by the uniquely interdependent relationship between the mother and fetus, and the uncertain legal status of the fetus.

There are two arguments against state-sanctioned coercive treatment and detention of pregnant mothers: (1) the stress and anxiety associated with forced detention or medical intervention, or the experience of intense withdrawal symptoms, can have serious adverse effects on the mother and fetus; and (2) the threat of compulsory treatment programs may deter women from presenting themselves early for prenatal care and preterm health checks to avoid compulsory detention or intervention. Both of these outcomes would adversely affect the health and welfare of the child and mother in ways that may offset any benefits of coerced treatment.

Increasing access to addiction treatment for consenting addicted mothers is a preferable option. Given the

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potential harm from enforced addiction treatment for pregnant women, treatment programs should rely on less restrictive and coercive forms of treatment that do not override the mother's autonomy. Alternative options may include improving engagement with clinicians and education, reinforcing abstinence using vouchers, offers of free prophylactic support to prevent relapse, less punitive responses to positive drug tests, and offers of effective and safe substitution treatments.

CONCLUSION

Drug addiction is a condition that not only causes significant harm to those who suffer from it but also adversely affects society. It is a condition that also raises questions about our ability to control our own actions. If opioid addiction is seen as a failure of individuals to control their behavior, it can lead to a moral condemnation of those who suffer from it. This may affect how we as a society deal with it and in turn may lead to adverse consequences for both the individual and society. Drug addiction often requires a response from many governmental agencies, both medical and judicial, that can affect how treatment is provided and how effective it is.

It is important that the treatment of drug dependence be governed by the primary aim of treating the individual suffering from it. Most of the obstacles to effective treatment are the result of different understandings of the nature of drug addiction and confusion over the aims of treatment. Often the regulations and policies that guide treatment are aimed at controlling and even punishing the individual. Not only are such approaches ethically unsound – in that they violate the individual's right to safe and effective treatment - they are also ineffective from the utilitarian ethical perspective that often motivates the provision of treatment for drug dependence. Treatment that aims to produce a therapeutic benefit for the individual is more effective if it engages the patient in treatment and encourages an individual to change, within the constraints of preventing further harm to society.

SEE ALSO

Harm Reduction Approaches, International Policies to Reduce Illicit Drug-Related Harm and Illicit Drug Use, HIV/AIDS and Substance Abuse, Etiology and Prevention of Stimulants (Including Cocaine, Amphetamines and Misuse of Prescription Stimulants), Etiology and Prevention of Marijuana Use among College Students

List of Abbreviations

AA Alcoholics Anonymous

AIDS acquired immune deficiency syndrome

BBV blood-borne virus
CNS central nervous system
DC drug counseling

DSM-IV Diagnostic and Statistical Manual of Mental Disorders, 4th

Edition

HCV hepatitis C virus

HIV human immunodeficiency virus

IDUs injecting drug usersNA Narcotics Anonymous

NIAAA National Institute on Alcohol Abuse and Alcoholism

NIDA National Institute on Drug Abuse NSPs needle and syringe programs TC therapeutic communities

UDHR Universal Declaration of Human Rights
UROD ultra-rapid opioid detoxification

WHO World Health Organization

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Evidence-Based Treatment

Sandra E. Larios, Jennifer K. Manuel, Howard Newville, James L. Sorensen

University of California, San Francisco, CA, USA

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INTRODUCTION

Substance abuse treatment practices have evolved independent of the mainstream health care community. Traditional health care facilities, like hospitals, were unable to adequately treat addictive disorders, leaving a gap in the treatment. Recovering addicts filled this gap by implementing a peer treatment system. Even as the disease model was applied to addiction, treatment perspectives did not change. Especially since there was little evidence available to determine which practices were effective.

Currently, the field of addiction is experiencing a transition from the use of subjective evidence to a focus on objective evidence. In the past, treatments were designed

based on subjective opinions of what worked best. As the wealth of scientific evidence increases, we are better able to make scientifically informed decisions as to which treatments to employ. In addition, policy factors can also influence treatment decisions. Increasingly, treatment programs relying on government funding are being required to demonstrate that the programs they fund incorporate evidence-based practices.

Evidence-Based Treatments (EBTs) are approaches that have been found to improve patients' functioning after rigorous scientific testing. Through the use of EBTs, we can ensure patients get the best possible services. The use of EBTs combines research with clinical expertise, and takes patient characteristics into consideration when selecting the best interventions.

However, there are barriers to the adoption of EBTs. Many programs have different treatment approaches, and providers may use different treatments within the same clinic. Sometimes providers are committed to their particular treatment models, believing the methods they have used for years to be correct. There is also the tendency to fall back on what we know out of comfort, rather than trying something new and unfamiliar.

In this chapter, we will describe different types of evidence and how it is evaluated to determine whether or not a treatment is evidence based. In addition, we will highlight important methodological issues that arise, describe findings from key studies, and the current state of EBT. Future directions for the field are also presented, focusing on increasing the dissemination and adoption of EBTs.

EVIDENCE-BASED TREATMENT

What Constitutes Evidence for a Particular Treatment?

How is a treatment deemed to be evidence based? There are several methods of evaluating treatments, such as randomized-controlled trials and meta-analyses, which will be described in more detail later in the chapter. Working within the population of substance users, EBTs have been found to be more successful in reducing patients' alcohol and drug use relative to a comparable treatment. Consensus exists, based largely on published studies, that several treatments (e.g. motivational interviewing, cognitive-behavioral therapy, contingency management) are evidence based. As a result, lists of EBTs have been generated by multiple sources. The EBTs included on these lists vary, and treatments that are not deemed evidence based are absent from such lists. There are overarching concerns about the generation of lists of EBTs. It is suggested that treatments be subject to ongoing testing and lists of EBTs should reflect the latest evidence. While scientific evidence is a key component in evaluating treatments, the role of clinical judgment and patient characteristics has also been cited as important factors.

Evaluating Evidence for EBT

Over the years, the EBT movement remains focused on empirical evidence as a guiding force in addiction treatment, but the nature and scope of the relevant evidence continue to evolve. Early conceptions of EBT placed a great deal of emphasis on randomizedcontrolled trials as the only form of methodological evidence worthy of inclusion and limited the use of treatments to only those that had been validated by a randomized-controlled trial, the gold standard of evaluation research. In recent years, other methods have begun to gain acceptance. Efficacy and effectiveness studies, pharmacological studies, and meta-analyses are common types of studies used as evidence for EBTs, and several key contributions of these types are summarized below. When evaluating the validity of these types of studies there are several areas of focus including treatment fidelity, inclusion criteria of the sample, assessment issues, cost-effectiveness, and treatment acceptability. These areas will be discussed in detail.

Efficacy and Effectiveness Studies

In behavioral research, randomized-controlled trials, sometimes called efficacy trials, have become gold standards against which to evaluate treatments. These trials randomly allocate individuals to treatment condition in order to control for factors that could potentially confound study results. There are several benefits to employing a randomized study design. By randomly assigning participants to each group, one can reduce potential confounding factors related to participant characteristics, self-selection processes, or the context in which the intervention is implemented. Randomizing participants can help the researcher better understand if the treatment is causing a behavior change. Recently, however, critics have questioned whether the findings of such tightly controlled studies will translate into routine clinical practice. Instead, many researchers are suggesting effectiveness trials that test interventions in real-world settings, with the patients and providers that are likely to be using the intervention. This design choice consequently limits intervention studies to those that can be realistically administered given staff preferences, time, and resources.

Pharmacological Studies

In pharmacological research, clinical trials also vary in their applicability to real-world settings. The National Institutes of Health identifies four phases of research, each with its own methodological advantages and drawbacks (see Relevant Websites). This type of phased research is typically conducted only after a particular intervention shows preclinical promise in laboratory or animal studies. Within this system, Phase I research involves testing a medication with a small sample. Phase II trials test the intervention with a larger sample to further monitor safety. In Phase III, the drug is tested with an even larger population and compared to another treatment or control condition to determine its comparative efficacy. In Phase IV research, a drug that is already being routinely administered is evaluated for

effectiveness and safety in real-world settings, and the long-term effects are assessed. The findings of such research may be more meaningful given their greater likelihood of being administered in real-world settings.

Systematic Reviews and Meta-Analyses

In recent years, a greater focus has been placed on systematic reviews and meta-analyses. Early on in substance abuse research, researchers synthesized groups of studies by reading the literature and making inferences about overall effectiveness using a narrative style. Those methods sketched the big picture for a particular treatment, but sometimes they lacked scientific rigor and were prone to the biases and preconceptions of the authors. In a more recent development, methodologically driven reviews were conducted that provided more objective summaries of the literature base. One such strategy uses a box tally method, counting the numbers of positive and negative findings published in scientific journals for a particular intervention, and producing a cumulative evidence score either for a given treatment or against a given treatment. Sometimes the box tally method is enhanced by differentially weighting studies based on factors like their methodological quality.

Meta-analysis is a more sophisticated approach to synthesizing multiple studies. The different outcome variables of a group of studies are statistically combined to produce standard measures of effect. These effect sizes can allow researchers to compare different treatments and are less influenced by the bias that can result from having an insufficient number of participants in significance testing. Meta-analysis offers a common metric (i.e. effect size) that can be used as a standard to compare different interventions. Meta-analysis, however, has its own difficulties. For one, outcome studies in substance abuse research use a variety of outcome variables (e.g. abstinence, quantity of use). Statistically combining these diverse measures can be misleading. In addition, there is a bias in research known as the file drawer problem, to leave negative findings in the file drawer and publish only positive findings, resulting in an optimistic picture of effectiveness. Nonetheless, meta-analyses are important tools. An international network of researchers, known as the Cochrane Collaboration (see Relevant Websites), conduct reviews of substance use behavioral and pharmacological treatments.

Treatment Fidelity

An important factor to consider when evaluating EBTs is that of treatment fidelity. Treatment fidelity describes the degree to which treatments are delivered competently and as intended. Poor treatment fidelity can reduce our ability to attribute symptom changes to

the intervention and to replicate and disseminate treatments. Treatment fidelity is particularly important when comparing a novel treatment intervention to treatment-as-usual. Without evidence of treatment fidelity, it can be difficult, if not impossible, to understand differences between treatment conditions. One approach to increasing treatment fidelity is the development of treatment manuals that can be used during implementation. Although treatment manuals can improve treatment fidelity and make implementation easier, there is risk of serious misapplication when the treatments and disorders are highly context dependent and highly variable through time, as they often are in the substance abuse areas. Treatment fidelity is rarely monitored outside of randomized-controlled trials due to the cost associated with supervision, feedback, and fidelity monitoring. Assessing treatment fidelity is further complicated by recent evidence, which suggests that there is little to no correlation between provider selfreport and objective evaluation of providers' behaviors.

Sample Characteristics

One of the most important factors to consider when evaluating evidence for EBTs is the sample under study. Most randomized-controlled trials have strict eligibility criteria for inclusion and can exclude participants who present with complex issues, such as psychiatric disorders, noncompliance, co-occurring medical disorders, and homelessness. Such exclusion criteria may increase the likelihood of a study being successfully conducted, but may also have the unintended consequence of reducing a study's ability to generalize its findings to those individuals who seek treatment. Rates of comorbidity in both clinical and community samples suggest that single-disorder presentations are the exception rather than the rule, and by limiting the inclusion of these individuals into clinical trials we are limited in our ability to say what treatments work for them. A similar argument can be made for the inclusion of women and ethnic minority participants into clinical trials. For a study to have adequate external validity, that is the ability to generalize the study's findings to other populations and settings, the study sample should be similar to the target population. Keeping these issues in mind when evaluating evidence is vital to ensure even the most marginalized populations receive the most effective treatments.

Issues Related to Assessment

When evaluating the evidence presented in research studies, several issues related to the assessment of outcome variables should be taken into consideration. Research studies are usually funded for limited periods of time and logistical and monetary issues make it difficult to follow participants after implementation to evaluate the long-term impact of the intervention. As a result, few intervention studies provide evidence of sustained effects. In addition, some studies only measure specific outcome variables and may not assess the variables a provider or treatment program are interested in. For example, a research study evaluating the efficacy of motivational interviewing for reducing drug use in prisoners may not assess how the intervention impacts recidivism or familial relationships. In combination, not having information about sustained effects and important outcome variables can make it difficult to evaluate which treatments would be the best for a particular patient.

In addition, research studies often require participants to complete extensive assessment batteries prior to receiving treatment. Assessment interviews typically query patterns of alcohol and drug use, as well as potential consequences of use. An unintended consequence of these lengthy interviews is a reduction in substance use by research participants, prior to receiving any treatment. This assessment reactivity is an important consideration when evaluating treatment outcome studies.

Cost-Effectiveness

In recent years, there has been an increased focus on the cost-effectiveness of EBTs. Cost-effectiveness analysis compares a new treatment strategy with current practice and calculates a cost-effectiveness ratio based on several factors including substance use, medical visits, employment, and imprisonment. If a strategy is "cost-effective" it means that the new strategy is a good value. In other words, the new treatment has a greater impact on disease burden, or costs less to achieve the same reduction in burden, and is therefore more cost-effective than the older treatment. Unfortunately, cost-effectiveness studies are costly themselves, so few studies occur. Cost-effectiveness information can be helpful in the evaluation of EBTs, but these studies occur later in the process. Only after an intervention has proven to be effective (usually through a randomized-controlled trial) cost-effectiveness analyses are undertaken.

Acceptability

An important factor to consider when evaluating EBTs is that of acceptability to the providers in the field, to policy makers making funding decisions, and to the patients. Providers are at the frontline of implementing EBTs in clinic settings, and gaining their support is important to assure the success of implementation (*see* Dissemination of Evidence-Based Treatment into Practice to learn more about dissemination of EBTs). Communicating information about EBTs to clinical staff through colleagues rather than from research articles or books tends to increase acceptability. When evaluating the appropriateness of an

EBT for implementation, understanding resistance that might arise is vital. Even where systems are in place to help with the implementation of an EBT, providers may be skeptical in regard to the use of such practices perceived to come from the culture of research, or when imposed by mandate. Treatment manuals can improve treatment fidelity, though perceived rigidity by treatment staff and patients may reduce treatment acceptability. Policy makers are also important to consider when it comes to the acceptability of treatments. Often, there are mandates that require the use of EBTs in clinics receiving state and federal funds and policy makers may wish to decide which EBTs are used and fund clinics accordingly. The treatment to patient match is another important factor to take into account. Finding treatments that are acceptable to patients and fit with the patient's goals can increase the likelihood that patients will stay in treatment long enough to benefit from the EBT.

Having an informed approach to the evaluation of evidence of EBTs that selects and evaluates research methods in service of a given research question – and not the other way around - is essential for promoting an interdisciplinary approach to addiction science. An approach that establishes whether and how a treatment performs under tightly controlled conditions, and if it does, whether it is effective and cost-effective in the usual clinical setting and in a variety of cultures and settings using pragmatic trial designs. Keeping in mind that establishing treatment efficacy with randomizedcontrolled trials is an appropriate use of method to answer a research question, but there are other questions relevant to improving the reach and effectiveness of practice that are better addressed with nonexperimental designs and methods, or that require a combination of the two approaches. In the next section, we will describe key studies that have been used as evidence for EBTs in the field of addictions. These include multi-site clinical trials, meta-analyses, and reviews.

EXAMPLES OF KEY STUDIES AND FINDINGS

Multi-Site Clinical Trials

Several large, multi-site, randomized clinical trials have revealed a good deal about treatment efficacy in the addictions. These studies are typically of high methodological quality. A drawback of the rigorous methodological features, such as having extensive exclusion criteria, can limit generalizability to real-world clinical settings. Several multi-site clinical trials have been particularly informative to the field of substance use and dependence. Five of these flagship studies are described in more detail below: Project Matching Alcoholism Treatments to Client

Heterogeneity (MATCH), Combining Medications and Behavioral Interventions (COMBINE), the Cannabis Youth Treatment study, the Marijuana Treatment Project, and the Clinical Trials Network.

Project MATCH was a collaborative, multi-site trial sponsored by the National Institute on Alcohol Abuse and Alcoholism (NIAAA). The study tested matching hypotheses, which predicted that patients with certain characteristics would fare better in a particular treatment. Participants were assigned randomly to one of three treatments (cognitive-behavioral treatment (CBT), motivational enhancement therapy (MET), or 12-step facilitation (TSF), and their outcomes were compared based on 10 variables. At a 12-month follow-up, participants from all three treatments had more days abstinent and drank fewer drinks per episode when compared with baseline assessments. However, few of the matching hypotheses were supported. Findings indicated that CBT, MET, and TSF were equally effective in improving alcohol outcomes (see Relevant Websites).

The COMBINE study built on the findings of Project MATCH to learn whether combining medications for alcohol dependence (naltrexone and acamprosate) would improve the effectiveness of behavioral interventions. A combined behavioral intervention was created that incorporated aspects of the three treatments used in Project MATCH. In addition, COMBINE tested a Medication Management (MM) intervention, a less intensive treatment that provided support and encouraged medication compliance. Participants in the study were randomly assigned to one of nine treatment combinations. Results from the COMBINE Study showed that adding a brief intervention (MM) to naltrexone could be a cost-effective way of treating alcohol dependence and that a combination of medication and behavioral treatment was more effective than medications alone. The implication of these results is that, via the use of a variation of MM combined with naltrexone, it may be possible to treat alcohol dependence more effectively in primary care settings.

The Cannabis Youth Treatment study aimed to compare the effectiveness and cost-effectiveness of five treatments in real-world settings. Adolescents in the study were randomly assigned to one of five group therapies (MET/CBT 5 sessions, MET/CBT12 sessions, the Adolescent Community Reinforcement Approach (ACRA), Multi-dimensional Family Therapy, and Family Support Network). Results revealed that participants in the five treatments showed significant improvements but the most cost-effective approaches included MET/CBT5, MET/CBT12, and ACRA (see Relevant Websites).

The most recent and largest controlled trial of marijuana treatment in adults (the Marijuana Treatment Project, see Relevant Websites), compared a 9-session combined cognitive behavior treatment with

motivational enhancement and case management to a 2-session motivational enhancement treatment and found that the extended CBT intervention was more effective than brief motivational therapy.

Clinical Trials Network

Multi-site randomized clinical trials can be conducted with high internal validity, but they do not always apply readily to clinical practice. Rigid restrictions in participant inclusion criteria, for example, with administration of interventions by highly trained practitioners (following standardized treatment protocols) can increase our ability to show that a treatment actually caused changes, but these tight procedures decrease the generalizability of findings to community treatment centers. In those settings, patients often have multiple and more severe problems, and providers may have relatively little training. To address the limitation or relevance to the community treatment system, the National Institute on Drug Abuse (NIDA) formed the Clinical Trials Network (CTN). The CTN provides a setting where treatment providers and researchers exchange information and develop research together. Research protocols are tested in front-line clinics, making results more generalizable to community settings. Since its inception, CTN has funded nearly 50 large clinical trials to determine the most effective treatments for drug dependence, testing a variety of interventions (behavioral treatments, medications, telephone support), and in different languages. Dissemination of effective treatments is a principal goal of the CTN. A dissemination library serves as a forum from which dissemination can occur (see Relevant Websites). To facilitate dissemination, the CTN developed the Blending Initiative which is designed to blend resources, information, and expertise in order to encourage the use of current EBT interventions in the drug abuse treatment field.

Meta-Analyses and Reviews

The Mesa Grande (great table) project was an influential review of 361 clinical trials of treatments for alcohol use disorders conducted by researchers at the University of New Mexico's Center on Alcoholism, Substance Abuse, and Addictions (see Relevant Websites). Results showed equal effectiveness for brief interventions, social skills training, community reinforcement approach (CRA), behavior contracting, behavioral marital therapy, and case management in treating alcohol use. Some medications were among the supported approaches, including opiate antagonists (naltrexone, nalmefene) and acamprosate. Confrontational counseling and mandated Alcoholics Anonymous were judged to be ineffective.

When it comes to drug use, contingency management, relapse prevention, CBT, and treatments that

combine CBT and contingency management are all found to be effective. In comparing effect sizes across treatments contingency management interventions showed the greatest effect. There are also differences in effectiveness depending on drug of choice, with marijuana use being the easiest to treat and poly-substance use the most difficult.

To assist addiction treatment professionals and program planners, the Substance Abuse and Mental Health Administration (SAMHSA) has a website that can be searched to identify interventions thought to prevent or treat mental illness or substance abuse. The National Register of Evidence-Based Programs and Practices (NREPP) contain results of a periodic, systematic review of these interventions, and it categorizes approaches into three levels: promising, effective, or model programs. Promising programs may be effective but lack the requisite research. Effective programs are both promising and have sufficient comparative research trials that show that they accomplish their objective related to mental health or substance use. Model programs are both effective and are ready for dissemination, based on both materials and training being available (see Relevant Websites).

Dodo Bird Effect

A common finding in comparative clinical trials, reviews, and meta-analyses in substance abuse is that the treatments being tested all perform equally well. Some have used an analogy between treatment outcome research and the Dodo Bird's race in *Alice in Wonderland*, in which the Dodo bird enthusiastically declares that "everyone's won and all must have prizes". Although some treatments have been found to be ineffective in comparative studies of addiction treatments, most theoretically based or manualized behavioral treatments perform equally well when tested in the field. The findings of equal effectiveness are especially surprising considering that so many treatments have vastly differing assumptions about the recovery process.

EBT IN PRACTICE

In this section, we will briefly discuss a structured approach to applying EBTs in clinical practice. These five steps (Ask, Search, Appraise, Apply, and Evaluate) can help providers interested in determining which EBT would be the most appropriate for implementation. The first step is to formulate a question (ASK), based on the presenting problem of the patient. For example, if a 25-year-old male Caucasian patient presents with methamphetamine dependence and a history of trauma, an

appropriate question would be: Which treatments have been found to be effective to address methamphetamine use for male Caucasian patients with trauma symptoms? A more specific question will help with the remaining steps. For example, determining if the patient is interested in setting a harm reduction or abstinence goal, or whether or not he was interested in outpatient treatment, would help further specify the question. It may be necessary to go back and modify the primary question.

After formulating a question, the second step of the process is to search the literature (SEARCH) and identify articles and other evidence-based resources that answer the question. As was described earlier in the chapter there are Internet resources available (e.g. NREPP), meta-analytic reviews (e.g. Cochrane Collaboration), or large multi-site trials (e.g. Project MATCH) that can help with this step. More examples of EBTs are described in the next section. Once resources have been gathered the third step is to critically appraise the evidence and assess its validity (APPRAISE). Specific considerations for evaluating evidence were discussed earlier in this chapter. After reviewing the available evidence in the fourth step EBT is applied (APPLY). It is through the application of an EBT that practitioners can determine which parts of the treatment, if any, are appropriate and acceptable to both the practitioner and the patient. This is done in the fifth step. The fifth and final step of the process includes reevaluating the application of evidence and areas for improvement (EVALUATE). After applying the treatment you can then go back and reevaluate the effectiveness of the treatment, and then make changes accordingly (Table 64.1).

The practical application of these five steps (Ask, Search, Appraise, Apply, and Evaluate) will vary depending on who employs them. In some clinics, administrators and not providers choose the treatments that will be used with the patients in the clinic. In these situations Appraise, Apply, and Evaluate can still be used by providers to determine if the treatment they have been asked to use is the most appropriate for their patient. At the administrator level, each of the steps can be used to determine which treatments will be used in the clinic. At this level the first step (ASK) will be focused on a large sample instead of an individual (e.g. which treatments have been found to work in outpatient settings to reduce stimulant use?). These steps can be of use in a variety of settings and with providers from different organizational levels.

EXAMPLES OF EVIDENCE-BASED TREATMENTS

As an addictions provider or policy maker it is essential to have at least a cursory knowledge of which treatments have support for their effectiveness. In

TABLE 64.1 Evidence-Based Treatment in Practice

Step 1: Formulate a question (ASK)	Based on the presenting problem of the patient determine which question you wish the Evidence-Based Treatment to address.
	A more specific question will help with the remaining steps.
	It may be necessary to go back and modify the primary question.
Step 2: Search the literature (SEARCH)	Identify articles and other evidence-based resources. Types of resources include Internet resources, meta-analytic reviews, or large multi-site trials.
Step 3: Critically appraise evidence and assess validity (APPRAISE)	Specific considerations for evaluating evidence include methodological quality, treatment fidelity, inclusion criteria, outcome measures used, cost-effectiveness, and acceptability.
Step 4: Apply evidence-based treatment (APPLY)	Use the evidence-based treatment with your patient.
	Through the application of an evidence-based treatment you can determine which parts of the treatment will work to address your formulated question.
Step 5: Reevaluate applied evidence (EVALUATE)	After applying the treatment you go back and reevaluate the evidence taking into account patient and practitioner preferences.

this section, we briefly describe several treatment approaches broadly considered to be evidence-based.

Cognitive-Behavioral Therapy

Cognitive-behavioral approaches start with the belief that learning processes play a vital role in the development and maintenance of addictive behaviors. These are among the most extensively studied of substance abuse treatments. Acknowledging the substantial research that has been conducted on cognitive-behavioral therapy as an empirically supported treatment and that few differences are found when comparing CBTs (see Mesa Grande review above), researchers have recommended that effective elements across cognitive-behavioral approaches be integrated into treatment approaches.

Motivational Interviewing

Motivational interviewing (MI) helps patients to explore and resolve ambivalence about a behavior change, using a brief, client-centered, directive intervention. Practitioners take a nonjudgmental stance and lead patients through the process of exploring their substance use in the light of the patients' personal goals and values. MI has been evaluated extensively and shows moderate efficacy in the treatment of alcohol and drug disorders, as well as in engaging people in other kinds of addiction treatment.

Brief Interventions

Other brief interventions have shown promise in the treatment of substance use disorders. Brief interventions

can have dramatic and long-lasting effects, and increasing the intensity of an intervention does not consistently result in improved effectiveness. Brief interventions are promising because they are inexpensive, allow more people to receive treatment and can be conducted in medical settings where providers have little time to commit to behavioral issues.

Relapse Prevention

Relapse prevention takes into consideration the cognitive and behavioral components within the process of the relapse phenomenon. Two of the most salient features of these interventions are identifying high-risk situations and providing coping skills to manage them more effectively. Relapse prevention is effective in improving clinical outcomes for alcohol use, smoking, cocaine, and poly-substance use.

CRA and Contingency Management

CRA is a treatment, largely based on behavioral therapy, which has been proven to be efficacious among alcohol and drug using individuals. The focus of CRA is to rearrange the contingencies in a substance user's life such that sobriety becomes more rewarding than substance use. CRA patients are often encouraged to examine the antecedents and consequences of substance use, sample sobriety for a prespecified amount of time, improve communication skills, problem-solving, and relapse prevention efforts. In addition, other key components of CRA are job-finding skills and other recreational activities that preclude substance use.

CRA is sometimes used in conjunction with contingency management (CM), another empirically based treatment for substance use disorders. In CM, practitioners provide about 6 months of outpatient therapy in individual counseling sessions, refer alcohol-abusing patients for disulfiram (antabuse) therapy, monitor patients for continuing drug use through the collection of regular urine samples, and reinforce their abstinence by providing contingent vouchers that patients can exchange for retail goods that are consistent with a drug-free life style. CM has been studied extensively in a variety of settings and with numerous substances of abuse.

Pharmacological Treatments

Pharmacotherapy is also available for the treatment of substance use disorders. Disulfiram, or antabuse, has been used in the treatment of alcohol disorders for several decades. A drawback of disulfiram (like many medications) is that it is effective only if taken daily and consistently. Meta-analyses have shown small effects from its use. A medication approved for use more recently is naltrexone, an opiate receptor antagonist that reduces the pleasurable effects of alcohol and, consequently, reduces alcohol cravings. Finally, acamprosate can help people to maintain abstinence after detoxification from alcohol, by normalizing metabolic processes that occur when heavy drinking is discontinued.

Several pharmacotherapies have also been developed to treat opioid dependence. Methadone is an opioid agonist that blocks the pleasurable effects of opiates, such as heroin. Treatment with methadone typically requires visiting a clinic for daily dosing, has been extensively studied, and it is effective and safe. Buprenorphine is the most recently approved medication (2002) for the treatment of opiate addiction. Buprenorphine is a partial opioid agonist that suppresses withdrawal, produces effects similar to other opiates at low doses, and blocks other opiates. Buprenorphine has shown promise in clinical trials. Unlike methadone, buprenorphine does not have to be administered from a specialized clinic; physicians can prescribe buprenorphine directly.

CURRENT STATE OF TREATMENT

While it is difficult to ascertain the extent to which EBTs are utilized by providers in substance abuse treatment settings it appears that some treatments with empirical evidence have been adopted more readily than others. Relapse prevention, cognitive-behavioral therapy, motivational interviewing, and brief interventions are used with some frequency in treatment settings, whereas CM the CRA, and behavioral couples therapy are underutilized in treatment settings (for recent reviews of implementation of EBTs, see Further Reading section). Regarding pharmacological treatments, facilities do report prescribing naltrexone whereas buprenorphine is dispensed with less frequency, presumably because it is a newer medication and requires prescribers to obtain a special waiver. Reported use of EBTs in clinics may be inflated due to social desirability biases. In addition, while providers may report use of an approach in their setting, objective evaluation may indicate otherwise.

There are several potential reasons for the slow adoption rates of EBTs among substance use treatment providers. To begin, there is a large literature noting the gap between research dissemination and clinical practice. Thus, many providers may not be well informed of the treatment outcomes literature indicating that some treatments have been found to be more effective than others. The standard route for dissemination of treatment findings occurs via scholarly journals and scientific conferences, both of which are expensive and time-consuming resources of information. While some providers do have knowledge about EBTs, the efficacy supporting these approaches may not be particularly compelling to providers. Treatment outcomes that are regarded as statistically significant may not be regarded as clinically significant or meaningful by providers. Furthermore, clinical trials have received criticism for their strict inclusion criteria, often excluding particularly complicated or severe patients from their studies. Thus, some providers doubt the efficacy of EBTs in front-line clinical settings.

Adoption of EBTs is further complicated by providers' heavy case loads. Many cite time constraints and clinical burdens as barriers to learning about new treatments. Furthermore, EBTs may be in conflict with the providers' or agencies' theoretical orientation, creating an additional barrier for adoption. In addition, high staff turnover at agencies further complicates training issues. Thus, there are a myriad of reasons for slow adoption rates among providers in substance abuse treatment settings.

Nonetheless, providers indicate a willingness to adopt some treatment methods including TSF, MI, relapse prevention, and cognitive-behavioral therapy. Providers are less willing to adopt contingency management or behavioral couples therapy. Hence, providers may be willing to adopt treatment that they are familiar with or that share similarities to their current clinical practice.

Provider attitudes toward pharmacological EBTs are mixed. Recent surveys of providers indicate that less

than half view the use of medications for substance use disorders positively. In addition, many providers report that they are unaware of the efficacy of newer medications such as buprenorphine. Lack of provider support for buprenorphine has been found to be largely related to lack of information about the medication.

Training Issues in EBTs

Recent research has focused on effective ways of training providers in EBTs. Traditionally, training in EBTs has occurred during brief workshops in which providers participate in both didactic and experiential exercises. Despite the relative ease of brief training, it has not been found to be particularly effective in preparing providers to competently utilize new clinical skills. Recent findings support the use of ongoing training enhancements in addition to the workshop. Enhancements that have been found to be effective in increasing training skills include booster training sessions, feedback from recorded sessions with real or standardized patients, and ongoing consultation with experts in the treatment approach. While these training enhancements are costly and time consuming, they may be necessary components for the successful use of EBTs. To reduce barriers to training, research has also begun to investigate the efficacy of long-distance training methods including web-based and video workshops telecast to remote facilities.

Overall, research studies examining the efficacy of training approaches indicate there are a number of provider factors that impact training gains, including provider motivation level and pretraining general clinical skills. In addition, there is strong evidence that clinical skills decay over time, thus training should be viewed as ongoing rather than time-limited task.

There is considerable evidence for directing implementation efforts at the agency or organization level rather than at the individual providers. Research findings indicate that greater agency involvement and support for the adoption of an EBT are associated with greater provider willingness to utilize a new approach. Involving the entire staff in trainings, the provision of ongoing supervision, meetings for problem-solving difficulties related to EBT implementation, and the consideration of how an EBT may need to be adapted for a particular setting are associated with more successful implementation efforts. For more information about training see Chapter 62 in this volume.

Treatment Adaptations

A recent focus on the implementation of EBTs has centered on treatment adaptations for use with specific populations or settings. Adaptations of EBTs are regarded as a natural process within implementation efforts. Adaptations, while potentially facilitating increased adoption of a particular treatment, also present unique challenges when striving to maintain the integrity of an intervention.

EBT adaptations are particularly relevant when working with minority populations. Applying the adaptations involves a balance between maintaining the integrity of the treatment approach while considering the specific needs and values of diverse ethno-cultural groups. Adaptation efforts usually begin with a treatment approach that has been found to be effective with a population overall. The next step in this process is to garner involvement from the community and with their assistance adapt the EBT and develop a manual. When adapting EBTs for minority populations it is important to consider the impact of factors such as cultural values, religion and spirituality, acculturation, and racism. Often times, adaption occurs based on knowledge from both qualitative and quantitative data. This allows treatments to be systematically adapted while still having a foundation in the EBT, while allowing enough flexibility to meet the specific needs of a population.

Adoption efforts have begun to focus on the implementation of pieces or processes of EBTs rather than the entire treatment. While research findings on the implementation of pieces of an intervention are still somewhat mixed, advocates for this approach indicate that adoption of specific processes of an EBT may facilitate increased adoption among providers. Adoption of a component of an EBT, such as coping skills or communication skills, may allow providers to implement pieces of an EBT that they feel comfortable with, rather than forgoing their previous treatment approaches entirely in favor of a new treatment. While this approach would result in more individualized treatment, research has not yet substantiated pieces of EBTs in isolation.

CONCLUSIONS AND FUTURE DIRECTIONS

In this chapter, we defined the term Evidence-Based Treatment, described how EBTs are evaluated, and discussed the current state of EBTs in the field of addiction. These treatments, which are deemed evidence based after rigorous analysis, offer great promise to providers dealing with a variety of complicating issues.

When analyzing what makes a treatment evidenced based, it is important to consider the means for assessing evidence. Efficacy and effectiveness studies, pharmacological studies, and meta-analyses provide different information about each treatment. However, factors that impact the validity of these studies, such as

treatment fidelity, sample characteristics, assessment issues, cost-effectiveness, and acceptability, need to be considered when evaluating the evidence.

Even though many EBTs are presently available, unsupported methods continue to be used, while other methods with solid evidence are seldom delivered. We cannot expect that the benefits of EBTs will translate into clinical practice on their own. Current clinical practices have become ingrained over time and although treatment manuals and training aids are widely available, many providers are not aware of them. In addition, some providers are skeptical of treatments they perceive to be developed in laboratories, with no applicability to the real world.

Continued outreach to providers can help address barriers to implementation. Face-to-face interactions with providers can clear up confusions, put misconceptions to rest, and give them a say in the practices they implement. EBTs can also be adapted for use with different populations to increase a treatment's realworld effectiveness. To improve the likelihood of treatment adoption, treatment facilities should be fully engaged in the implementation process and provide ongoing trainings since brief training workshops are insufficient to maintain long-term changes. Researchers should address both institutional and provider concerns in order to facilitate the adoption of EBTs and provide ongoing support to ensure providers can deliver the treatment as directed to make sure clinics are seeing the results needed to maintain adoption.

SEE ALSO

Evaluating Treatment Efficacy, Screening and Interventions in Medical Settings Including Brief Feedbackfocused Interventions, Dissemination of Evidence-Based Treatment into Practice, Motivational Enhancement Approaches, Cognitive Behavioral Therapies, Contin-Management, Community gency Reinforcement Approaches: CRA and CRAFT, Behavioral Couples Therapy for Alcoholism, Treatment-as-Usual for Substance Abuse in Community Settings, Treatment for Co-occurring Substance Abuse and Mental Health Disorders, Individual and Group Counseling for Substance Use Disorders, Brief Strategic Family Therapy Drug Abuse: Treatment Adolescent Implementation

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List of Abbreviations

ACRA adolescent community reinforcement approach

CRA cognitive-behavioral treatment community reinforcement approach

CM contingency management

COMBINE Combining Medications and Behavioral Interventions

CTN Clinical Trials Network EBT evidence-based treatment

MATCH Matching Alcoholism Treatments to Client Heterogeneity

MET motivational enhancement therapy

MI motivational interviewing
MM medication management
NIDA National Institute on Drug Abuse

NREPP The National Register of Evidence-Based Programs and

Practices

TSF 12-step facilitation

Glossary

Assessment reactivity a process in which, assessments, such as research interviews, have unintended consequences, such as a reduction in substance use by research participants.

Dissemination a planned process of providing information on the quality, relevance, and effectiveness of the results of programs and initiatives to key personnel.

Dodo Bird Effect a common finding in comparative clinical trials, reviews, and meta-analyses in substance abuse that the treatments perform equally well.

Effectiveness studies experimental studies done under less carefully defined conditions reflecting the variation in real-world clinics are known as effectiveness studies. Effectiveness maximizes external validity.

Efficacy studies laboratory randomized-controlled trials produce knowledge about the efficacy of a treatment, treatments that work under ideal conditions. Efficacy maximizes internal validity.

External validity the main criteria of external validity are the process of generalization, and whether results obtained from a small sample group, often in laboratory surroundings, can be extended to make predictions about the entire population.

Internal validity the approximate truth about inferences regarding cause-effect or causal relationships. The key question in internal validity is whether observed changes can be attributed to your program or intervention (i.e. the cause) and not to other possible causes (sometimes described as alternative explanations for the outcome).

Meta-analysis a quantitative approach in which individual study findings addressing a common problem are statistically integrated and analyzed to determine the effectiveness of interventions.

Practitioner a person who conducts procedures intended to help individuals. Common examples are a counselor, clinician, therapist, or case manager.

Quasi-experimental design a research design that contains some of the controls and manipulations of experimental design, but usually lacks random assignment of subjects. A before–after study is an example of a quasi-experimental design.

Randomized-controlled trial randomized-controlled trials are studies that randomly assign individuals to an intervention group or to a control group, in order to measure the effects of the intervention.

Treatment adaptation the systematic modification of an Evidence-Based Treatment or intervention protocol to consider language, culture, and context in such a way that it is compatible with the client's cultural patterns, meanings, and values.

Treatment adoption the use of an Evidence-Based Treatment in a clinical facility.

FURTHER READING 631

Treatment fidelity strategies that monitor and enhance the accuracy and consistency of an intervention to ensure it is implemented as planned and that each component is delivered in a comparable manner to all study participants over time.

Further Reading

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- Shadish, W.R., Cook, T.R., Campbell, D.T., 2002. Experimental and Quasi-experimental Designs for Generalized Causal Inference. Houghton Mifflin, Boston.
- Sorensen, J.L., Rawson, R., Guydish, J., Zweben, J.E. (Eds.), 2002. Drug Abuse Treatment Through Collaboration: Practice and Research Partnerships That Work. American Psychological Association, Washington, DC.

Relevant Websites

- http://casaa.unm.edu/index.html University of New Mexico Center on Alcoholism, Substance Abuse, and Addictions.
- http://clinicalresearch.nih.gov/how.html How does clinical research work? This website provides a readable overview of research approaches, including the phases of clinical research.
- www.cochrane.org Information about meta-analyses. The Cochrane Collaboration is an international, independent, not-for-profit organization that provides up-to-date, information about the effects of health care readily available worldwide. Its contributors

work together to produce systematic reviews of healthcare interventions, known as Cochrane Reviews, which are published online in The Cochrane Library. Cochrane Reviews are intended to help providers and patients make informed decisions about health care, and are the most comprehensive, reliable, and relevant source of evidence on which to base these decisions.

- http://www.commed.uchc.edu/match/ Project MATCH. The website provides access to products of this multi-site study as well as access to the public access dataset.
- http://ctndisseminationlibrary.org/ Clinical Trials Network Dissemination Library. The library contains journal articles, presentations, reports, brochures, bibliographies, and descriptions of studies being conducted within the NIDA Clinical Trials Network. It provides the public with a single point of access to research findings and other materials that are approved for dissemination throughout the CTN and to the larger community of providers, researchers, and policy-makers.
- http://www.labmeeting.com/papers/author/marijuana-treatmentproject-research-group – Marijuana Treatment Project publications.
- http://www.nrepp.samhsa.gov/index.asp National Register of Effective Programs and Practices. The NREPP system conducts separate reviews for the effectiveness and dissemination dimensions. Each reviewer separately examines the materials provided and rates along structured dimensions the quality of research and the readiness for dissemination. There are specific dimensions for rating interventions (such as reliability of measures, appropriateness of data analysis). Additionally, the NREPP system lists over a dozen categories of intervention.
- http://ncadi.samhsa.gov/govpubs/bkd384/background.aspx Cannabis Youth Treatment Study. The website provides access to products of this multi-site study.

Harm Reduction Approaches

Arthur W. Blume*, Diane Logan\$

*Washington State University, Vancouver, WA, USA \$University of Washington, Seattle, WA, USA

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INTRODUCTION

Harm reduction approaches are strategies that are used to reduce the harmful consequences of addictive behaviors. Harm reduction often includes multiple approaches including pharmacological, psychological, and environmental interventions. Harm reduction approaches typically involve interventions designed to reduce risky behaviors and their consequences. Interest in harm reduction arose partly in response to a body of scientific evidence suggesting that abstinence was not necessarily a realistic goal for people engaging in addictive behaviors, and that many clients preferred moderation goals even after successful completion of abstinence-based treatment programs.

Harm reduction approaches are considered client centered, such that clinical professionals assume a consultant role to work with the client to identify and reach treatment goals collaboratively. Abstinence may or may not be an ultimate treatment goal, but is never a requirement for services and support. In fact, clients often opt for moderation-oriented goals or may not desire to make reductions at all and instead modify behavior to reduce risk without reduction. Harm reduction approaches are used to flexibly respond to whatever the client's goals for change may be.

HISTORY AND DEVELOPMENT

Harm reduction has a history rooted in pharmacotherapy and in activism. The use of methadone constituted one of the earliest forms of harm reduction interventions. Methadone was prescribed to people addicted to heroin as a safer alternative for those unable or unwilling to abstain immediately. Methadone treatment represented a crack in the wall of staunch belief that abstinence from all substances was the only proper means to improve the lives of people engaging in addictive behaviors. A grassroots harm reduction movement later developed in Europe in an effort to leverage compassionate care for people who engaged in

addictive behaviors, especially those who injected drugs. The harm reduction movement was also driven by concerns about the spread of HIV and other blood borne diseases by those who were sharing needles. Harm reduction developed in the United States as an alternative to the disease model of treatment. Harm reduction approaches in the United States were initially met with great scorn by most treatment professionals who subscribed to the disease model and feared that these approaches were enabling people to continue to engage in a chronic progressive disease to their own peril. The fallout from this dispute was immense and eventually included preeminent researchers in the addictive processes.

Researchers began as early as the 1970s to uncover significant evidence that challenged the prevailing belief that addictive processes were chronic and progressive, as well as the precept that only abstinence oriented treatment can be effective to treat addictive behaviors since clients were considered to be powerless over substances and assumed to immediately lose control with any use. The first area of scientific inquiry that challenged these traditional beliefs was research that found that substance use often is influenced by beliefs as much as the actual consumption of behavior. A classic study by Alan Marlatt and colleagues, using what was referred to as the balanced placebo design, demonstrated that if people believed they had been drinking to intoxication, they would often act intoxicated even when they had been drinking nothing stronger than tonic water and were stone cold sober. The converse was true as well: if people were told they had been served nonalcoholic drinks, they displayed none of the intentional behavioral changes expected by a progressive disease model (e.g. loss of control, increasing consumption, inability to stop, etc.) nor were there any changes in social interactions. Instead, individuals attributed physiological reactions to alcohol consumption to external factors (lack of sleep, room temperature, etc.). The study results challenged prevailing beliefs at the time that addictive processes were primarily biological since alcohol-dependent participants demonstrated behavioral loss of control only when they thought they were consuming alcohol. The study results suggested that loss of control was a function of beliefs about substance use rather than actual substance use itself.

The second area of inquiry to challenge prevailing thinking was longitudinal studies that demonstrated that some people were getting better on their own, without treatment; a process known as natural recovery; and that some people were able to achieve moderate drinking after a period of dependence. This research triggered what became known as the controlled drinking controversy and led to brutal attacks by disease model adherents

against addiction scientists such as Mark and Linda Sobell and Marlatt who published empirical evidence to dispute those beliefs. Although the addiction scientists were unfairly targeted for their early research challenging the abstinence-only model, their findings have continued to be supported and expanded since that time. The body of empirical evidence clearly indicates that harm reduction goals are not only attainable but they are also commonly pursued and reached by clients.

The third area of inquiry that supported the development of harm reduction was research that examined what predicts addiction-related consequences. As one might suspect, researchers have found a positive relationship of frequency/amount of the addictive behavior/substance with frequency of consequences experienced. However, the relationship has been less robust than one would intuitively predict, suggesting that the experience of consequences is not just a function of the addictive behavior alone. Indeed, some research has found that other variables (such as beliefs about addictive behaviors) are independent predictors of consequences, sometimes more potent than consumption. These findings suggest the possibility that harmful consequences may be reduced by intervening on cognitive and behavioral processes other than consumption. As will be explained subsequently, harm reduction approaches provide for ways to do so.

Interestingly, traditional disease model treatment facilities have employed harm reduction approaches (although many would not have referred to it as such) for many years during the detoxification process. For several decades, the use of prescribed controlled substances, usually benzodiazepines, has been to reduce the discomfort of withdrawal symptoms. In effect, this would constitute a harm reduction approach similar to methadone treatment, although arguably some of the benzodiazepines have since been found to be at least as risky as the substances for which the person has sought treatment.

INDIVIDUALIZED HARM REDUCTION STRATEGIES

Recent pharmacological advances have been used successfully to reduce the potential harm from substance abuse. Opiate agonists such as naltrexone, as well as other types of substances (such as acamprosate), have been used to successfully reduce substance-related cravings in many patients. Certain antidepressant drugs such as selective serotonin reuptake inhibitors (SSRIs) have been used similarly to control mood-triggered substance use associated with anxiety and depression. In addition, recently vaccinations have been used with some success to interfere with psychoactive properties

(inhibiting the high) of certain substances of abuse to dissuade further use. Readers interested in pharmacological interventions should refer to the numerous chapters specifically written on this topic within the neuropharmacology section of this volume.

Cognitive-Behavioral Harm Reduction Approaches

Addictive processes are not solely responsive to biological processes: Addictive behaviors are also learned and so reducing harmful consequences of addictive processes will involve learning new beliefs and practices. It will also involve the unlearning of old beliefs and habits. Because of the importance of new learning in behavior change, a number of empirically supported cognitive-behavioral intervention strategies are employed in the use of harm reduction.

Behavioral Control Strategies

A variety of behavioral control strategies are used in harm reduction. One strategy is to simply track and count as a means to manipulate the behavior. An example is challenging the clients to see how many sips are taken to finish a glass of wine or beer, and then finding ways to increase the number of sips over time (in effect slowing consumption). Another example would be to have the clients time (or mentally count) the seconds between puffs on a cigarette and then extend the pauses between puffs over time, which naturally reduced the amount consumed and the time spent engaged in the behavior.

Another behavioral control strategy, referred to as alternating, is a process by which a person naturally reduces the frequency in which he or she engages in the addictive behavior by alternating that behavior with something else. An example of alternating is when a person follows consumption of an alcoholic beverage by a nonalcoholic drink. By alternating the addictive behavior with a compatible nonaddictive behavior, the client limits the amount of time engaging in the addictive behavior and reduces its frequency.

A third behavioral control strategy, referred to as switching, induces a client to switch from a higher risk to a lower risk addictive behavior. One example of this approach is to have the client's switch from a pattern of drinking high alcohol content beverages to lower alcohol content beverages, such as from stout beer to lager, or from multiple shot mixed drinks to something with less alcohol. Another example would be switching from heroin to methadone or marijuana. The idea is to reduce the risk of harm by replacing the high-risk behavior with a lower risk one.

Tapering is also a common behavioral control strategy used in harm reduction. Many clients are challenged to meet weekly goals for reduction in the addictive behavior until a particular targeted goal is reached, in effect tapering engagement in the behavior. An example would be a gambler who budgets \$50 US for a night of gambling that week, then next week is budgeted \$40 US, then the following week \$30 US, until finally reaching a personal harm reduction goal of \$20 US per gambling event. The goal is to gradually reduce the behavior slowly over time to eventually meet the ultimate goal set by the client in therapy.

Another highly effective behavioral control strategy is structuring time with activities incompatible with the addictive behavior including healthy alternatives such as exercising and other recreational pursuits. Sometimes an alternative activity may involve a challenging mental task or other goal-directed activity. The alternative activity should be interesting and challenging to the client and it should be something that makes engagement in addictive behavior difficult or uninteresting in comparison.

Cognitive Modification Strategies

As mentioned previously, beliefs about addictive behaviors potently predict outcomes; therefore, effective harm reduction approach will include interventions designed to challenge beliefs that contribute to acting in a risky fashion.

One successful approach is to challenge the client's positive expectancies associated with the addictive behavior. Positive expectancies are the beliefs that clients have about the positive effects or outcomes related to the addictive behavior. Common positive expectancies involve beliefs that the addictive behavior will contribute to increased socialization, power, sexuality, and euphoria. Expectations that the addictive behavior are personally enhancing are particularly potent but can be modified with the use of traditional cognitive therapy methods for challenging irrational or dysfunctional beliefs by means of hypothesis testing and data collection. The therapist works with the client to test the assumptions of positive expectancies, and then helps the client to determine ways for collecting data to support or refute the beliefs. In some cases, it may be possible to challenge positive expectancies by testing the realistic probability of the expected positive outcome by examining previous outcomes. Other beliefs, such as cultural myths related to the addictive behavior or thinking errors that place the client in harm's way, can also be challenged through the use of traditional cognitive modification techniques.

Lifestyle Balance Activities

Another class of harm reduction approach is used to restore and maintain lifestyle balance. Lifestyle balance is determined by examining the time spent in various activities by the client and then assessing whether there are significant imbalances in time spent in work-related activities versus recreation, for example, or if the client is not taking enough time for basic self-care. A lifestyle balance assessment focuses on different domains: family life, physical self-care, emotional self-care, spirituality, etc. If too much time is spent in one sector at the expense of another, in a way that is contrary to the personal professional goals of the client and in a way that is causing personal distress, alternative activities are suggested and the client's schedule of activities may be restructured toward more balance.

In addition to examining how time is committed, personal habits may also be examined, such as those related to nutrition and healthy eating, sleep hygiene, routine dental and medical care, and exercise. Adjustments may be recommended to improve client health. Use of over the counter and prescribed medications may need to be examined to see and determine if there are potential harmful interactions with the substances being used. As an example, cold medicines, acetaminophen, ibuprofen, naproxen, birth control medications, and SSRIs all can react adversely to different substances and their concurrent use is not recommended. Vitamin supplements, on the other hand, may be recommended to supplement the diets of clients at risk (such as thiamine with people who are drinking large amounts of alcohol).

In some instances, the client may have other mental health needs that are necessary to be addressed with concurrent psychological or pharmacological care. Harm reduction approaches often involve the use of multiple services to achieve the goals of treatment, so referral for adjunct psychiatric care is common. Harm reduction approaches are highly compatible with multidisciplinary care and team approaches to treatment are commonly used.

ENVIRONMENTAL STRATEGIES

Harm reduction approaches also may employ interventions targeting the environment to reduce the risk of harm to people with addictive behaviors. Environmental harm reduction interventions have generally targeted four broad areas: accessibility, economics, safety, and social support networks.

Harm reduction approaches designed to improve accessibility often involve policy changes to lower the threshold for accessing services. Lowering the threshold to access may include providing services to people without a condition of abstinence on entry, decreasing the administrative barriers for admission into services, increasing the number of care providers available including nontraditional care, providing transportation to services, and providing multiple services under one roof for ease of access. The philosophy of harm reduction is to make access easy, convenient, and safe for those who need the services.

Harm reduction proponents also have used economic principles in attempts to reduce risks by increasing prices to shape behavior. Researchers have found, for example, that increasing the costs of alcohol and cigarettes can profoundly impact their use, especially among people of limited means. Price increases, reductions of bargain events (such as sales and happy hours), and increased taxes have been used as harm reduction approaches by communities attempting to address heightened public health risks due to drinking and smoking behavior.

Harm reduction approaches designed to improve safety depend upon the nature of the activity. Risky addictive behaviors that are commonly targeted include the use of unclean needles and drinking and driving. Examples of harm reduction approaches targeting those behaviors include use of needle exchanges to reduce the risk of blood borne pathogens such as HIV and hepatitis and free taxi services on campuses or in communities on New Year's Eve to reduce drinking and driving. Marketing campaigns are often employed to inform the public of such programs.

Sometimes marketing campaigns are also used in efforts to shape the behavior of the public. One commonly used method is referred to as social marketing, which advertises social norms in an effort to present data to the public about normative behavior for that particular group. Social norms interventions directed by trained interventionists are empirically supported and can be highly effective. Since overestimations of norms are often associated with increased individual use, challenging and correcting these norm perceptions are generally associated with individual reductions. However, because of the nature of social marketing campaigns, they do not include interventionists who can provide feedback to recipients of the campaign. An example would be a social marketing campaign that shares social norms around marijuana usage in the last month by the students in that school in a poster on campus. The poster is meant to encourage reduction in order to conform to the social norms of the campus. Although advertising norms seems intuitively useful, researchers have not found consistent support that social marketing as an environmental strategy that works broadly or consistently to reduce harm.

Public Policy

Environmental interventions frequently impact public policy, especially if those environmental interventions are enacted at a community, state, or national level. In addition to conducting research that often pushes the boundaries of public policy, many practitioners of harm reduction also choose to intervene on an environmental level by promoting or speaking out against societal laws, policies, and proposals. While it is important to separate research-supported findings from personal opinions, both are vital in educating and influencing policy makers and the public in general. However, when considering controversial topics, this is not necessarily agreed upon perspective even among those from a harm reduction background.

For example, one current controversial topic in the United States is the proposed legalization of illicit drugs. Some harm reduction practitioners argue for legalization of these substances to elevate the behaviors from an illegal and largely underground problem to a visible public health problem that can be addressed without fear of legal jeopardy. Proponents also argue that legalization would improve quality control and generate large amounts of revenue from fees and taxes that could be used to fund prevention and treatment efforts as well as potentially regulate consumer demand. However, not all practitioners of harm reduction agree, having concerns that legalizing drugs would have an impact on perceived norms as well as increased access, both of which were discussed prior as having an adverse effect on use and related consequences. Because harm reduction approaches tend to be highly pragmatic and client centered, the complex intersection of science, practice, and policy tends to impact the work of harm reduction professionals routinely.

Cultural Variables

Culturally relevant harm reduction approaches represent collaborations between harm reduction professionals and the community being served. Because of its strong emphasis on client-centered goals, harm reduction approaches are sensitive to the importance of cultural relevance in helping the clients. In particular, use of the community-based participatory model for collaborations between scientists, practitioners, and the communities they serve is particularly important for achieving the goals of harm reduction therapy. The community-based participatory model suggests that when conducting research and providing services among people who have been historically disempowered within societies, it is critically important to place the needs of client and community at the center of therapy to avoid the potential for disrespect or abuse to either. Harm reduction professionals serve in a scientific advisory role to the client and community. However, decisions about cultural relevance and the ultimate direction of research and services are made by the client and community. The community-based participatory model is particularly effective when working in cultures where collectivism and interdependence are highly valued.

Culturally relevant harm reduction often includes the use of culturally relevant practices as a key component of the intervention. Culturally relevant practices may include traditional spiritual and healing practices, use of traditional language, inclusion of culturally important ceremonies and events, inclusion of culturally historic content including traditional stories, and use of culturally sensitive interpersonal styles. The harm reduction goals chosen by the client will likely be linked in very specific ways to the culture of the community. It is important for the harm reduction professional to be educated by the community about what may be the culturally relevant norms related to addictive behavior being targeted and its treatment. What may be a culturally appropriate goal for harm reduction in one culture may be entirely inappropriate for another.

EXAMPLES OF AGE-SPECIFIC PSYCHOLOGICAL INTERVENTIONS

Older Adults

Harm reduction has been found to be an effective means for improving lives for adults, especially for those who may not be realistic candidates for abstinence-based treatment. Research has found that many adults who enter treatment do not necessarily cease the addictive behavior after discharge, but many do reduce the frequency and severity of their engagement in the behavior. Many high profile treatment outcome studies (e.g. Project MATCH; Project COMBINE) have found that significant numbers of clients reduce but do not cease the targeted behavior.

Adults often experience slips and relapses during the early stages of recovery as they practice the new behaviors learned in therapy. Relapse is a normative part of the change process; it is not surprising that the client will have lapses or slips on the way of achieving their personal goals for recovery. The principles of relapse prevention have found to be efficacious to help the clients achieve their goals, whether those goals are for cessation or reduction of the addictive behavior. When used with people seeking harm reduction goals, relapse prevention has been more correctly referred to as relapse management, since the goal is to minimize the harm of the relapse rather than prevent engagement in the

addictive behavior. The goal of relapse management is to use traditional relapse prevention therapy techniques to moderate addictive behavior.

One effective use of relapse management for harm reduction is to address apparently irrelevant decisions that clients make. Apparently irrelevant decisions are decisions made that may appear benign to the client because the natural consequences of the decision are not fully appreciated. As an example of an apparently irrelevant decision, a client may decide to go fishing with a former drinking companion and not see the risk involved with such a decision. It may be that the client even takes nonalcoholic drinks to consume on the trip but does not adequately assess the risk of observing his friend drinking, or perhaps has not considered the risk of being offered an alcoholic beverage by the friend. In harm reduction therapy, the focus is on preventing apparently irrelevant decisions from leading the client away from his/her goal for treatment.

Another effective method is the use of mindfulness techniques to help the client improve attention and concentration at that moment. Improving the client's moment-by-moment focus will likely improve the client's ability for self-control in the moment, an important skill to hone in order to achieve moderation goals. Mindfulness also has been found to be effective for reducing depression, a condition that often co-occurs with addictive behaviors.

Gradualism

Some researchers and treatment professionals have advocated for a combination of harm reduction approaches with traditional abstinence-based treatment to provide a menu of options for clients when they seek help. Some have argued that clients who initially opt for harm reduction goals may go on to cease the addictive behavior if given the time to reduce the behavior gradually. The idea that harm reduction may gradually lead to abstinence has been referred to as gradualism, often by those who oppose it on philosophical grounds. Proponents of the disease model actively oppose the inclusion of moderation goals into treatment programs and see gradualism as a threat to client health. On the other hand, those who operate under a biopsychosocial model of addictive behaviors see an advantage in having multiple options for treatment for clients that would appeal to a wide range of posttreatment goals and that consider the multifaceted complexity of addictive behaviors.

Harm Reduction Support Groups

Some clients have found an advantage to participate in a support group as they strive to reach harm reduction treatment goals. However, clients have not been able to utilize traditional 12-step support groups with any success because of the belief by many 12-step group members that moderation goals are not acceptable for group members. The incompatibility of harm reduction and 12-step recovery goals has led to the clients seeking harm reduction goals to form support groups, which have a philosophy that moderation rather than cessation is an acceptable and attainable goal for therapy. One example of such a group is called Moderation Management, and they offer face-to-face groups as well as online virtual groups.

Adolescents and Young Adults

Harm reduction approaches have been especially appealing to adolescents and young adults who often have not experienced the severe and longstanding consequences that older adults may have experienced over the course of chronic engagement in addictive behaviors. Since adolescents and young adults have not generally experienced widespread aversive consequences, they generally do not see the need for cessation or abstinence and often will not do well in programs that expect abstinence as a precondition for treatment admission or as an expected treatment outcome. In addition, adolescents and young adults do not fit nicely into the diagnostic categories used for adults to determine addiction severity and often do not respond well to older adult-oriented treatment models. As an example, young adults who have experienced problems with drinking have been routinely referred to Alcoholics Anonymous meetings. However, young adults often have very little in common with the experiences of Alcoholics Anonymous members and usually report that those referrals were unhelpful and unnecessary.

The most extensively studied harm reduction approaches for this age group have been conducted and evaluated in college and university campuses. College students present researchers with accessibility to large samples and multiple options for incentives, as well as high rates of alcohol misuse and related consequences. National surveys estimate past year drinking rates over 80% among college students, with two in three students drinking at least once in the past 30 days and one in three students reporting a heavy drinking episode (five or more drinks in one occasion) within the past 2 weeks. This kind of heavy alcohol use is associated with increases in risks ranging from meeting DSM-IV criteria for alcohol abuse and dependence to myriad alcohol-related consequences. The most common aversive consequences for students include regrettable decisions, blacking out, unprotected sex, and injuries, though many others also experience consequences subsequent to drinking and driving, academic failure, and interpersonal consequences.

Offering college students interventions beyond a just say no message is an important strategy for health and wellness efforts. College students are at a developmental phase described as emerging adulthood, a unique stage between adolescence and adulthood, characterized by increasing responsibility while retaining some of the interdependence of earlier stages. At this phase, students identified as more independent and perceived threats to their autonomy (e.g. through abstinence-only interventions) can be counter-therapeutic and may be inconsistent with perceived campus norms. Furthermore, since many students do not view their alcohol use as a problem, abstinence-only programs and scare tactics may not be personally relevant and appear too extreme to be individually beneficial. Harm reduction approaches, on the other hand, are designed to meet a student where he or she is in terms of substance use.

As discussed above, effective interventions to reduce substance abuse and related harms on college campuses have been extensively studied. The National Institute on Alcohol Abuse and Alcoholism (NIAAA) identified strategies with demonstrated effectiveness in impacting alcohol use and consequences in college students. Each of these strategies, cognitive-behavioral techniques, motivational interviewing, and norms clarification, impact different areas related to decisions about drinking.

Cognitive-behavioral techniques combine accurate information, such as blood alcohol concentration levels and realistic effects of alcohol, with behavioral techniques to assist students in reducing alcohol use. These techniques are designed to provide the students with specific tools strategies to reduce drinking and other substance use, reduce consequences associated with drinking and other substance use, and/or choose or maintain abstinence either short-term or on a permanent basis so that they may choose to implement as appropriate, thereby supporting autonomy. One of the common strategies taught to college students involves use of protective behavioral strategies, or techniques to limit consumption (such as the alternating strategy mentioned earlier in this chapter or adding additional ice to a glass) or minimize related consequences (including not leaving a drink unattended and employing the buddy system). These strategies have been associated with decreases in consumption as well as reduced risk of alcohol-related consequences including unwelcome and unsafe sex.

Motivational interviewing is a clinical intervention that combines a nonjudgmental style while attempting to evoke self-motivated talk about behavior change. The four primary tenets include expressing empathy (understanding the student's perspective and experience), developing discrepancy (typically between the positives expected from alcohol use and the potential negatives that are actually experienced), rolling with resistance (approaching with a nondefensive style and focusing on what is most useful for the student), and supporting self-efficacy (giving the tools to make change while supporting the autonomy and capability of the individual). Motivational interviewing is particularly important with this group, as prior studies have found that information-only interventions do not necessarily lead to behavior change. Thus, using motivational interviewing to help a student identify personal reasons for change increases the likelihood of decreased consumption and consequences.

Norms clarification attempts to correct misperceptions of descriptive and injunctive norms. In other words, students' overestimations of how much their peers consume as well as how much they believe their peers approve of drinking behaviors are related to increased drinking. Providing normative reeducation through use of assessment and personalized feedback has also been associated with decreases in drinking behaviors and consequences.

In a process to determine the best practices for intervening upon college student drinking risks, the NIAAA identified what is referred to as Tier 1 interventions, or approaches that have favorable outcomes with college students in at least two independent studies. Two harm reduction approaches are provided as specific examples that utilize the above strategies: Alcohol Skills Training Program (ASTP) and Brief Alcohol Screening and Intervention for College Students (BASICS).

ASTP combines cognitive-behavioral skills, norms clarification, and motivational enhancement techniques in a group setting. The intervention includes information about alcohol as a drug, tolerance and withdrawal, alcohol expectancies and actual physical effects at varying levels, information about drug interactions, and tips to reduce harms from drinking including drink refusal skills. One of the key components of the ASTP is discussing the point of diminishing returns, or the point at which one more drink will not increase the desirable effects but will heighten the dysphoric outcomes, by referring to research on the biphasic effects of alcohol. Beyond the point of diminishing returns, positive effects such as relaxation and increased social ease will not improve, but negative effects including nausea, black outs, and poor decision-making become more likely. Students are reminded that alcohol is a depressant; thus the only way to avoid all negative consequences and effects is to not drink at all. However, for those who make the choice to drink, the intervention attempts to reduce the associated harms by maximizing positives and minimizing negatives through reduction of peak consumption.

BASICS, on the other hand, incorporates personalized feedback with motivational interviewing and skills training in brief, one-on-one sessions. Typically, a student will complete assessments so the facilitator (who might be a psychology professional, graduate student, or undergraduate peer) can provide feedback of drinking behaviors, perceived and actual norms, expectancies and consequences, and any number of other potentially relevant data to motivate change (e.g. calories consumed from alcohol, money spent on alcohol, etc.). The graphic feedback presents the opportunity to display drinking patterns and misperceptions in new ways for the student. After feedback is provided, a menu of options for behavior change may be offered, if welcomed and appropriate, including harm reduction strategies described earlier. While the goal is to increase motivation to reduce alcohol consumption and its aversive consequences, the intervention is oriented toward what the student sees as most relevant. If a student is experiencing myriad consequences but dismisses them as irrelevant or unlikely to occur again, the facilitator true to the style of motivational interviewing will roll with this perceived resistance and focus on another aspect that is more salient.

Harm reduction interventions for students are also being implemented via web-based or computermediated forms, often using ASTP and BASICS as guides for intervention content. These interventions range from individualized feedback produced from survey questions to interactive atmospheres that teach strategies to avoid alcohol use or misuse. Whether conducted in person or electronically, the goal of these interventions is to reduce the harm associated with drinking. For some students, reducing harm means encouraging and supporting the choice for abstinence. For others, reducing harm means teaching behavioral skills and supporting maintenance of moderate drinking, or it may simply mean increasing awareness of some of the bad and adverse effects of drinking while encouraging contemplation of behavior change sometime in the future.

While the majority of this section has focused on interventions for alcohol use, it is important to note that harm reduction with college students spans a wide range of problematic behaviors including tobacco, marijuana, and other drug use, sex-related behaviors, gambling, and eating disorders. The techniques used for reducing harm subsequent to alcohol consumption also may reduce harm subsequent to other addictive behaviors, enhance personal reasons for change, provide tools to support that change, and educate students on norms and expectancies while respecting the autonomy and individuality of students. In addition, these programs are potentially helpful for use with adolescents and with young adults not attending colleges and universities. However, it is still

somewhat controversial to suggest the use of harm reduction programs with adolescents since addictive behaviors are mostly illegal activities for minors. Some treatment professionals and policy makers see harm reduction programs as condoning illegal activities, whereas harm reduction professionals would argue that reducing risk to adolescents outweighs concerns about legal issues.

SUMMARY AND FUTURE DIRECTIONS

Harm reduction approaches have been found to be helpful for clients who are not willing or able to cease addictive behaviors. The biopsychosocial model of addictive behaviors suggests that effective harm reduction interventions may need to target client physiology, client's cognitions and behavior, or the client's environment. Harm reduction approaches have been empirically supported and have demonstrated efficacy to help people reduce aversive consequences of addictive behaviors as well as reach moderation goals that may eventually lead to cessation (although not necessarily). Harm reduction differs from traditional treatment in that it operates under the assumption that client goals for treatment may vary and may not include cessation of the addictive behaviors. The harm reduction professional defers to the client in establishing the goals for therapy, and serves as an advisor to the client on how to best reach these goals. Harm reduction programs have great appeal to specific demographics of clients, such as to those with cooccurring problems that make behavior change difficult, to youth and young adults who may not see the need for cessation, to older adults who also do not desire cessation, and to groups where moderation may be a culturally relevant value. Researchers continue to test and refine pharmacological and psychological harm reduction methods, and the research they generate contributes to reevaluating and redesigning prevention and treatment methods and to challenge the policies that suggest one size that fits all treatment is appropriate or effective for all clients.

SEE ALSO

Motivational Enhancement Approaches, Cognitive Behavioral Therapies, Mindfulness, Individual Prevention of College Student Alcohol Misuse

List of Abbreviations

ASTP Alcohol Skills Training Program

BASICS Brief Alcohol Screening and Intervention for College Students

FURTHER READING 641

NIAAA National Institute on Alcohol Abuse and Alcoholism SSRI selective serotonin reuptake inhibitors

Glossary

- **Apparently irrelevant decisions** decisions made by clients that often place them at risk for relapse. The client is generally oblivious to the risk at the moment of making the decision; therefore the decision seems apparently irrelevant.
- **Balanced placebo design study** a classic psychological study by Marlatt and colleagues (1973) that demonstrated that an intoxicated behavior may be a function of beliefs about drinking behavior rather than the result of actual drinking experiences.
- Community-based participatory model a model designed to protect traditionally underserved and vulnerable communities from abuses through a collaborative process where the community and professional work together to design and implement research and clinical services conducted within the community that is culturally relevant and appropriate.
- **DSM-IV** Diagnostic and Statistical Manual of Mental Disorders, 4th edition, is commonly used by clinical professionals to diagnose mental health issues. The manual is produced by the American Psychiatric Association and revised periodically through a committee process.
- **Harm reduction** interventions designed to reduce the risk of experiencing harmful consequences from addictive behaviors without a requirement of cessation of the addictive behavior.
- **Natural recovery** the ability of some people to change addictive behaviors on their own without the need for therapy or treatment. **Relapse management** use of relapse prevention strategies for harm

Further Reading

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Relevant Websites

http://www.harmreduction.org/ – Harm Reduction Coalition site. http://www.harmreductionjournal.com/ – Harm Reduction Journal site.

http://www.moderation.org/ - Moderation Management site.

http://www.collegedrinkingprevention.gov/ – National Institute on Alcohol Abuse and Alcoholism College Drinking site.

http://www.soros.org/ - Open Society Foundations site.

http://www.drugpolicy.org/ - The Drug Policy Alliance site.

http://www.ihra.net/ - The International Harm Reduction Association site.

http://peele.net/ - The Stanton Peele Addiction site.

66

Therapeutic Communities

George De Leon*,\$

*National Development and Research Institutes (NDRI), New York, USA

\$NYU School of Medicine, New York, USA

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INTRODUCTION

Drug-free residential programs for substance abuse appeared a decade later than did therapeutic communities (TCs) in psychiatric hospitals pioneered by Maxwell Jones and others in the United Kingdom. The term *therapeutic community* evolved in these hospital settings, although the two models arose independently. The TC for substance abuse emerged in the 1960s as a self-help alternative to existing conventional treatments.

This chapter is abstracted from a comprehensive account of the therapeutic community theory, model, and method provided elsewhere (De Leon, 2000).

Recovering alcoholic and drug-addicted individuals were its first participant developers. Although its modern antecedents can be traced to Alcoholics Anonymous and Synanon, the TC prototype is ancient, existing in all forms of communal healing and support.

Contemporary TCs for addictions are sophisticated human services institutions. Today, the label *therapeutic community* is generic, describing a variety of short and long-term residential and nonresidential programs that serve a wide spectrum of drug-abusing and alcoholabusing clients. Although the TC model has been widely adapted for different populations and settings, it is the traditional long-term residential prototype for adult substance abusers that has documented effectiveness for substanceabusing individuals. The last section of this chapter summarizes the adaptation and modifications of the traditional TC model for various populations and settings.

TRADITIONAL TCs

Traditional TCs are similar to each other in structure, staffing pattern, perspective, and treatment regimen although they differ in size (30 to several hundred beds in a facility) and client demography. Staffs are composed of TC-trained clinicians, with and without recovery experiences, and other human service professionals who provide medical, mental health, vocational, educational, family counseling, fiscal, administrative, and legal services. The recommended planned duration of stay of long-term TCs has gradually decreased across the years from 15–24 months to 9–15 months.

THE TC PERSPECTIVE

The TC perspective or theory shapes its program model and its unique approach, community as method. The perspective consists of four interrelated views of the substance use disorder, the individual, the recovery process, and of healthy living.

View of the Disorder

Drug abuse is viewed as a disorder of the whole person, affecting some or all areas of functioning. Cognitive and behavioral problems are evident, as are mood disturbances. Thinking may be unrealistic or disorganized; values are confused, nonexistent, or antisocial. Frequently there are deficits in verbal, reading, writing, and marketable skills. Moral or even spiritual issues, whether expressed in existential or psychological terms, are apparent. Thus, the problem is the individual, not the drug. Addiction is a symptom, not the essence of the disorder.

View of the Person

In TCs, individuals are distinguished along dimensions of psychological dysfunction and social deficits rather than according to drug use patterns. In many TC residents, vocational and educational problems are marked; middle-class, mainstream values are either missing or not sought. Usually these residents emerge from a socially disadvantaged sector. Their TC experience is better termed habilitation, development of a socially productive, and conventional lifestyle for the first time. Among residents from more advantaged backgrounds, the term rehabilitation is more suitable which emphasizes a return to a lifestyle previously lived, known, and perhaps rejected.

Regardless of differences in social background, drug preference or psychological problems most individuals admitted to TCs share clinical characteristics that center around the immaturity or antisocial dimensions (Table 66.1). Whether they are antecedent or consequent to serious involvement with drugs, these characteristics are commonly observed to correlate with chemical dependency. More important, in TCs, a positive change in these characteristics is considered to be essential for stable recovery.

View of Recovery

In the TC perspective, recovery involves a change in lifestyle as well as in social and personal identity. Thus the primary psychological goal of treatment is to change the negative patterns of behavior, thinking, and feeling

TABLE 66.1 Typical Behavioral, Cognitive, and Emotional Characteristics of Substance Abusers in Therapeutic Communities

- Low tolerance for all forms of discomfort and delay of gratification
- Problems with authority
- Inability to manage feelings (particularly hostility, guilt, and anxiety)
- Poor impulse control (particularly sexual or aggressive impulses)
- Poor judgment and reality testing concerning consequences of actions
- Unrealistic self-appraisal regarding discrepancies between personal resources and aspirations
- Prominence of lying, manipulation, and deception as coping behaviors
- Personal and social irresponsibility (e.g. inconsistency or failures in meeting obligations)
- Marked deficits in learning and in marketable and communication skills

that predispose the individual to drug use; the main social goal is to develop the skills, attitudes, and values of a responsible drug-free lifestyle. Stable recovery, however, depends on a successful integration of these social and psychological goals. Behavioral change is unstable without insight, and insight is insufficient without felt experience. Several key assumptions underlie the recovery process in the TC.

Motivation

Recovery depends on pressures to change, positive and negative. Some individuals seek help, driven by stressful external pressures; others are moved by more intrinsic factors. For all, however, remaining in treatment requires continued internal motivation to change. Therefore, elements of the treatment approach are designed to sustain motivation or to enable detection of early signs of premature termination.

Self-Help and Mutual Self-Help

Strictly speaking, treatment is not provided; rather, it is made available to the individual in the TC through its staff and peers and the daily regimen of work, groups, meetings, seminars, and recreation. However, the effectiveness of these elements depends on the individual, who must fully engage in the treatment regimen. In self-help recovery, the individual makes the main contribution to the change process. In mutual self-help, the principal messages of recovery, personal growth, and "right living" are mediated by peers through confrontation and sharing in groups, by example as role models, and as supportive, encouraging friends in daily interactions.

Social Learning

A lifestyle change occurs in a social context. Negative behavioral patterns, attitudes, and roles were not acquired in isolation, nor can they be altered in isolation. This assumption is the basis for the use of a peer community to facilitate recovery. A socially responsible role is learned by acting the role within a community of similar others.

View of Right Living

TCs adhere to certain precepts, values, and a social perspective that guide and reinforce recovery. For example, there are community sanctions to address antisocial behaviors and attitudes: the negative values of the street, jails, or negative peers; and irresponsible or exploitative sexual conduct. Positive values are emphasized as being essential to social learning and personal growth. These values include truth and honesty (in word and deed), a work ethic, self-reliance, earned rewards and achievement, personal accountability, responsible concern (being one's brother's or sister's keeper), social manners, and community involvement.

The precepts of right living are constantly reinforced in various formal and informal ways (e.g. signs, seminars, in groups and community meetings).

THE TC PROGRAM MODEL

THE TC APPROACH: COMMUNITY AS METHOD

The TC approach can be summarized in the phrase "community as method". Theoretical writings offer a definition of "community as method" as the purposive use of the community to teach individuals to use the community to change themselves.

The fundamental assumption underlying community as method is that individuals obtain maximum therapeutic and educational impact when they engage in and learn to use all of the diverse elements of the community as the tools for self-change.

Thus, community-as-method means that the community itself provides a context for social learning. Its membership establishes expectations or standards of participation in the community. It continually assesses how individuals are meeting these expectations and responds to them with strategies that promote continued participation. The diverse elements and activities of the community can be organized in terms of the TC program model, specific methods, and the program stages that facilitate the process of change.

THE TC PROGRAM MODEL

The TC program model is its social and psychological environment. Each component of the environment reflects an understanding of the TC perspective and each is used to transmit community teachings, promote affiliation, and self-change. The key components of the program model are summarized in terms of its social organization, work, peer, and staff roles.

TC Structure/Social Organization

The social organization of a TC consists of a relatively small staff complemented by a large base of residents or peers at junior, intermediate, and senior levels. This vertical structure arranges relationships of mutual responsibility to others at various levels in the program.

The daily operation of the community itself is the task of the residents, who work together under staff supervision. The broad range of resident job assignments illustrates the extent of the self-help process. Residents perform all house services (e.g. cooking, cleaning, kitchen service, minor repair); serve as apprentices; run all departments; and conduct house meetings, certain seminars, and peer encounter groups.

The TC is managed by the staff that monitor and evaluate client status, supervise resident groups, assign and supervise resident jobs, and oversee house operations. The staff conduct therapeutic groups (other than peer encounter groups) provide individual counseling, organize social and recreational projects, and confer with significant others. They make all decisions about resident status, discipline, promotion, transfers, discharges, furloughs, and treatment planning.

Work as Education and Therapy

Work and job changes have clinical relevance for substance-abusing patients in TCs, most of whom have not successfully negotiated the social and occupational world of the larger society. Vertical job movements carry the obvious rewards of status and privilege. However, lateral job changes are more frequent and permit exposure to all aspects of the community.

Peers as Role Models

TC participants who demonstrate the expected behaviors and reflect the values and teachings of the community are viewed as role models. Thus, all peers and staff are expected to be role models. TCs require multiple role models in order to maintain the integrity of the community and ensure the spread of positive social learning effects.

Staff as Rational Authorities

Staff facilitate community as method, as role models, counselors, and particularly as rational authorities. In their management and clinical functions, staff as rational authorities provide the reasons for their decisions and explain the meaning of consequences. Staff exercise their authority to teach, guide, and correct rather than to punish or control.

THERAPEUTIC COMMUNITY METHODS

In the TC, all activities, planned and unplanned (e.g. interpersonal and social interactions) facilitate recovery and right living. However, planned activities are viewed as interventions or methods, designed to impact both individuals and the general community in specific ways. They can be organized in accordance with their primary purpose, therapeutic–educational change, community enhancement, and community and clinical management.

Therapeutic-Educative Activities (Groups-Counseling)

Therapeutic–educative activities consist of various group processes and individual counseling. They increase communication and interpersonal skills, bring about examination and confrontation of behavior and attitudes, and offer instruction in alternative modes of behavior.

The main groups include encounters, probes, and tutorials. These differ somewhat in format, objectives, but all have the goal of fostering trust, personal disclosure, intimacy, and peer solidarity to facilitate therapeutic change. The encounter is a peer led group that utilizes supportive confrontation. Its basic objective is to heighten individual awareness of specific attitudes or behavioral patterns that should be modified. Probes are staff-led group sessions, which have as their primary objective emotional change and psychological insight. (Marathons are extended group sessions whose objective is to initiate resolution of life experiences that have impeded individuals' development. The use of marathons has sharply declined commensurate with the decreases in planned duration of residential stay.)

Tutorials are primarily directed toward skills training (e.g. management of the department or the reception desk; training in the use of encounter tools). Additionally, cognitive-behavioral tutorials using manualized curricula are employed for targeted clinical areas such as relapse prevention, criminal thinking, and anger management.

Other groups that convene regularly or, as needed, supplement the main groups. These vary in focus, format, and composition. For example, weekly or biweekly "static" (caseload) groups are convened. These home groups consist of the same cadre or composition of peers who address and mutually monitor ongoing clinical progress. Special theme groups relating to gender, ethnic, age-specific, or health issues may use encounter or tutorial formats. Dormitory, room, or departmental encounter groups may address issues of operating the community. In addition, sensitivity training, psychodrama, and emotionality ("feelings") groups are used to varying extents. Like marathons the frequency of these groups has declined significantly commensurate with shorter planned durations of treatment.

One-to-one counseling balances the needs of the individual with those of the community. Peer exchange is ongoing and is the most consistent form of informal counseling in TCs. Staff counseling sessions may be formal or informal and are usually conducted as needed. The focus of staff counseling is to address issues that may impede progress and to facilitate the patient's adjustment to and constructive use of the peer community.

Community Enhancement Activities (Meetings)

Community enhancement activities include the four main facility-wide meetings: the morning meeting, the seminar, the house meeting that meet daily, and the general meeting (which is called when needed). Though different in format and specific purpose, all meetings have the common objective of strengthening community cohesion.

The purpose of the morning meeting is motivational, to instill a positive attitude in the community at the beginning of the day. This meeting is particularly relevant for residents in TCs most of whom have never adapted to the routine of an ordinary day. Led by resident teams, morning meetings occur daily for 30 min and utilize a plan of songs, dance, music, games skits, and inspirational words to achieve its objective.

The afternoon seminar is viewed as a community meeting since it includes all the residents in the program (subsets of all residents are groups). Residents conduct most seminars, although some are presented by staff members or less frequently by outside speakers. Seminar topics directly or indirectly relate to the TC perspective including themes of personal growth, recovery, and right-living concepts (e.g. self-reliance, maturity, relationships). However, topics may include special knowledge themes (e.g. such as the brain and addiction, preparing for re-entry, family genealogy). The educational format of the seminar focuses on impacting conceptual and communication skills.

House meetings take place nightly after dinner, usually last 30–60 min, and are coordinated by senior residents. The main aim of these meetings is to transact community business (e.g. departmental reports, special announcements, phase changes, introduction of new residents, disciplinary issues, etc.), although they also have a clinical objective. In this forum, social pressure through public acknowledgment of positive or negative behaviors is judiciously applied to facilitate both community and individual change.

General meetings are called when needed to address negative behavior, attitudes, or incidents in the facility. All residents and staff members are assembled at any time and for an indefinite duration. Conducted by staff they are designed to identify problem individuals or conditions or to reaffirm motivation and reinforce positive behavior and attitudes in the community.

Community enhancement occurs in a variety of informal activities. These include rituals and traditions, and celebrations (e.g. birthdays, graduations, phase changes), ceremonies (e.g. those relating to general and cultural holidays), and memorial observances for deceased residents, family members of residents, and staff members.

Community and Clinical Management Elements

Community and clinical management elements maintain the physical and psychological safety of the environment and ensure that resident life is orderly and productive. They protect the community as a whole and strengthen it as a context for social learning. The main elements are staff managed and include privileges, disciplinary sanctions, surveillance, and urine testing.

Privileges

In the TC, privileges are explicit rewards that reinforce the value of achievement. Privileges are accorded with overall clinical progress in the program. Staff members deliver all privileges, which may range from telephone use and letter writing early in treatment to overnight furloughs later in treatment. Successful movement through each stage earns privileges that grant wider personal latitude and increased self-responsibility. Displays of inappropriate behavior or negative attitude can result in loss of privileges, which can be regained through demonstrated improvement. The privilege system in the TC teaches that productive participation or membership in a family or a community is based on an earning process.

Disciplinary Sanctions

TCs have their own specific rules and regulations that guide the behavior of residents and the management of facilities. The explicit purpose of these rules is to ensure the safety and health of the community. However, their implicit aim is to train and teach residents through consequential learning. The code of rules may be organized into three levels of severity or strictness reflecting their importance to the health and safety of the community: Cardinal rules (such as no drug use, violence or threat of violence); major rules (such as stealing or vandalizing); and house rules (such as respect for authority, no displays of street code behaviors). Disciplinary actions may also be delivered for resident's persistent failure in meeting community expectations. Examples are nonparticipation in community activities or repeated displays of negative attitudes toward the program.

Delivered by staff members, the disciplinary sanctions employed relate to the severity of the infraction. For example, these may range from written assignments, job demotions, or loss of privileges to administrative discharge. The sanction is usually a written contract with the resident. These agreements make explicit the behaviors addressed, nature, and duration of the consequences. Although contracts may be perceived as punitive, their basic purpose is to promote a learning experience by compelling residents to, attend to their own conduct, to

reflect on their own motivation, and to consider alternative forms of acting under similar situations.¹

Surveillance

The TC's most comprehensive method for assessing the overall physical and psychological status of the residential community is the house run. Several times a day, staff members and selected senior residents walk through the entire facility, examining its overall condition. House runs provide global snapshot impressions of the facility: its cleanliness, planned routines, and safety procedures. They also illuminate the overall morale and psychological tone of the community in the attitudes and social functioning of individual residents and peer groups.

Most TCs implement unannounced random urine testing or incident-related urine-testing procedures. When urine tests are positive for drugs, the action taken depends on several factors (e.g. the drug used, the resident's time and status in the program, the resident's history of drug and other infractions, and the locus and condition of use). Positive urines initiate a disciplinary action or learning experience that includes exploration of conditions precipitating the infraction.

Peer Confrontation: Verbal Affirmations and Correctives

In the TC, verbal affirmations and correctives are the main ways that peers engage in community management. These verbal interactions illustrate examples of peer confrontation in that they provide face-to-face feedback to members as to whether they are meeting community expectations concerning program participation, recovery, and right living. Correctives aim to raise the individual's awareness of behaviors and attitudes that require changing. Correctives range in severity from mild reminders ("pull ups") to stern conversations ("verbal reprimands"). Affirmations aim to encourage or reinforce positive clinical change or personal growth and provide the crucial balance to verbal correctives and staff disciplinary sanctions.

Peer confrontations are intended to facilitate learning for those delivering as well as receiving them. Observing, affirming, reminding, and correcting others reciprocally reinforce self-learning through practice, rehearsal, or role modeling. Thus, verbal affirmations and correctives are quintessential examples of the principle of mutual self-help (see Center for Substance Abuse Treatment 2005a, p. 169).

THE PROGRAM STAGES AND PHASES

Recovery in the TC is a developmental process, one that occurs in a social learning setting. The developmental process itself can be understood as a passage through stages of learning. The learning that occurs at each stage facilitates change at the next, and each change reflects movement toward the goals of recovery. Three major program stages characterize change in long-term residential TCs: orientation-induction, primary treatment, and re-entry.

Stage 1: Orientation-Induction (0-60 Days)

The main goal of stage 1 is to provide new residents with a formal orientation to the TC. The aim of orientation in the initial phase of residence is for the individual to be assimilated into the community through full participation and involvement in all of its activities. Formal seminars and informal peer instruction focus on dissemination of information and instruction concerning program philosophy, rules, house regulations, and community expectations as to participation in the program meetings and group activities.

Stage 2: Primary Treatment (2–12 Months)

The stage of primary treatment consists of three subphases that roughly correlate with time in the program (2–4, 5–8, and 9–12 months). The daily therapeutic–educational regimen of meetings, groups, job assignments, and peer and staff counseling remains the same throughout the year of primary treatment. However, progress is reflected at the end of each phase in terms of three interrelated dimensions of change: community status (role model), development or maturity, and overall psychological adjustment.

Stage 3: Re-Entry (13–24 Months)

Re-entry is the stage at which the individual must strengthen skills for autonomous decision-making and the capacity for self-management and must rely less on rational authorities or a well-formed peer network. The main objective of the early re-entry phase (13–18 months), during which clients continue to live in the facility, is to prepare for separation from the TC. Particular emphasis is placed on life-skills seminars, which provide training for living outside the community. Plans

¹(An evolutionary change in TCs is the abandonment of questionable learning experiences (e.g. shaved heads, stocking caps, wearing signs). These were once rationalized as useful strategies for some clients in addressing the immaturity and social deviancy features of their disorder. Such practices were largely abandoned by the 1980s and are excluded in the practice standards of contemporary TCs. It should be noted that while such practices were unnecessary and appropriately renounced, there is no compelling statistical or clinical evidence that they resulted in harmful outcomes).

are developed for long-term psychological, educational, housing, and vocational objectives. Clients may be attending school or holding full-time jobs, either within or outside the TC.

The objective of the later re-entry phase (18–24 months) is successful separation from the TC. Clients have a "live-out" status; they hold full-time jobs or attend school full time, and they maintain their own households, usually with live-out peers. They may participate in Alcoholics Anonymous or Narcotics Anonymous or attend family or individual therapy sessions. Contact with the TC is gradually reduced to weekly telephone calls and monthly visits with a primary counselor.

Graduation

Completion marks the end of active program involvement. Graduation itself, however, is an annual event conducted in the facility for individuals who have completed the program, usually 1 year after their residence is over. Thus, the TC experience is preparation rather than a cure. Residence in the program facilitates a process of change that must continue throughout life, and what are gained in treatment are tools to guide the individual on a path of continued change. Completion, or graduation, therefore, is not an end but a beginning.

Aftercare

TCs have always acknowledged the client's efforts to maintain sobriety and a positive lifestyle beyond graduation. Until recently, long-term TCs addressed key clinical and life adjustment issues of aftercare during the re-entry stages of the 2-year program. However, funding pressures have resulted in shorter planned durations of residential treatment and the stages and phases therein. This has underscored the necessity for aftercare resources to address both continuing primary treatment as well as re-entry issues. Thus, many contemporary TCs offer post-residential aftercare treatment and social services within their systems, such as intensive day treatment and step down outpatient ambulatory treatment, or through linkages with outside agencies.

WHO COMES FOR TREATMENT?

TCs accommodate a diversity of drug abusers. Males exceed females (70–30%) but the number of female admissions is increasing. Most community-based TCs are integrated across gender, race, or ethnicity, although the demographic proportions differ according to geographic regions and specific programs. Originally

attracting primary opioid abusers the current TC client populations have histories of multiple drug use, including marijuana, cocaine, crack, opioids, alcohol, and prescription medications.

Despite sociodemographic and drug use differences, psychological profiles of admissions appear relatively uniform, as has been shown in a number of TC studies. For example, the character disorder elements and poor self-concept of delinquent and repeat offenders are present, as are the elements of dysphoria, anxiety, and confused thinking seen in emotionally unstable or psychiatric populations. Therefore, in addition to their substance abuse, clients in TCs have considerable degrees of psychological disability.

Similarly, in diagnostic studies, nearly three-fourths of clients admitted to TCs have had a non-drug-related psychiatric disorder in their lifetime in addition to substance-related problems. The most frequent non-drug-related diagnoses were phobias, generalized anxiety, psychosexual dysfunction, and antisocial personality. Serious Axis 1 diagnoses (e.g. lifetime affective disorders) occur in more than one-third of those studied, although the prevalence of schizophrenic diagnosis is low.

Contact and Referral

Approximately a third of adult admissions to community-based TCs have a legal status, in terms of being paroled, probated, or otherwise court ordered to treatment. However, some programs serve legally referred (mandated) clients exclusively. Voluntary contacts with TCs occur through self-referral, social agencies, treatment providers, and active recruitment by TCs. Although most adult admissions to TCs are voluntary, many of these clients come to treatment programs under various forms of perceived pressures originating from conflicts with family members or significant others, employment difficulties, or anticipated legal consequences.

In contrast with adults, a high majority of juvenile admissions to TCs are legal referrals. Thus, for the younger substance abusers, actual legal pressure is a prominent form of external motivation to enter treatment. Their lower internal motivation to change reflects the shorter time-correlated negative consequences of their substance abuse.

Criteria for Residential TC Treatment

Traditional TCs maintain an open-door policy with respect to admission for residential treatment. This understandably results in a wide range of treatment candidates, not all of who are equally ready for, suited for, or motivated to face the demands of the residential regimen. Relatively few are excluded, because the TC policy is to accept individuals who are mandated to or elect residential treatment, regardless of the reasons influencing their choice.

The general consideration concerning suitability for the TC is risk – the extent to which clients present a management burden to the staff or pose a threat to the security and health of the treatment community. Thus, specific exclusionary criteria most often include histories of arson, suicide attempts, and serious psychiatric disorders. Psychiatric exclusion is usually based on documented history of psychiatric hospitalizations or evidence of psychotic symptoms on interview (e.g. frank delusions, thought disorder, hallucinations, confused orientation, signs of serious affect disorder). However, psychotropic medication is more widely used in TCs to accommodate increasing numbers of admissions with comorbid conditions.

Clients taking medication for medical conditions can be admitted, as can disabled individuals or persons who require prosthetics, providing these individuals can participate fully in the program. Physical examinations and laboratory workups (blood and urine profiles) are performed after admission. Because of concern about communicable disease in a residential setting, some TCs require tests for conditions such as tuberculosis, and hepatitis to be performed before clients enter the facility or at least within the first weeks of admission.

Policies and practices concerning testing for human immunodeficiency virus (HIV) and management of acquired immune deficiency syndrome (AIDS) and hepatitis C emphasize voluntary testing with counseling, special education seminars on health management and sexual practices, and special support groups for residents who are HIV positive or who have a clinical diagnosis of AIDS or hepatitis C.

RESEARCH: THE EFFECTIVENESS OF THERAPEUTIC COMMUNITIES

Over the past four decades, a considerable scientific knowledge base has developed with follow-up studies on thousands of individuals treated in TCs worldwide. The main findings and conclusions are briefly summarized from multiple sources of outcome research in North America including multi-program field effectiveness studies, single program controlled studies, meta-analytic statistical surveys, and cost-benefit studies.

The most extensive body of research bearing on the effectiveness of Addiction TC programs has amassed from field outcome studies. These all employed similar longitudinal designs that follow admissions to TCs during treatment and 1, 5 years (and in one study up to 12 years) after leaving the index treatment.

TABLE 66.2 Meta Estimates From Field Outcome Research: Multi-Program Surveys and Single Program Studies

Sources

1. Multimodality/multi-program studies

Drug Abuse Reporting Program (DARP): Simpson, D.D. and Sells, S.B. (1982)

Treatment Outcome Prospective Study (TOPS): Hubbard, R. L., Marsden, M. E., Rachal, J.V., Harwood, H.J., Cavanaugh, E.R., and Ginzburg, H.M. (1989)

National Treatment Improvement Effectiveness Survey (NTIES): (1996)

Drug Abuse Treatment Outcome Study (DATOS): Simpson, D.D. and Curry, S. (Eds.): (1997)

2. Single program field outcome case studies (no comparison condition)

Phoenix House (De Leon, Wexler, and Jainchill, 1982; De Leon and Jainchill, 1981–1982)

Eagleville Residential Program (Barr and Antes, 1986)

Gateway House (Holland, 1983)

Estimates

- ➤ Over 5000 admissions to community-based TCs in North America have entered into multimodality and single program studies (1969–2000) and have been followed 1–12-years post-treatment
- Studies have been conducted by different research teams, across different eras
- Studies have assessed outcomes on multiple variables using similar methodology (e.g. assessment instruments, longitudinal follow-up designs, and statistical analyses)
- Results are strikingly similar yielding "lawful" findings with respect to profiles, outcomes, and retention

Main research questions and findings

➤ Who comes for treatment?

All studies show that TC admissions have poor profiles in terms of severity of substance use, social deviance, and psychological symptoms

▶ What are the outcomes?

All studies show significant decreases in measures of drug use, criminality, and psychological symptoms and increases in employment and/or educational involvement. In studies, which utilize a composite index of favorable or successful outcome over 60% of the intent to treat, samples (dropouts and completions combined) show most favorable or favorable outcomes

Is there a relationship between treatment "dosage" and outcomes?

All studies show that reductions in drug use, criminality, and increase in employment are related to time spent in treatment. Those who complete the planned duration of residential TC treatment show the best outcomes; among dropouts, retention is highly correlated with outcomes.

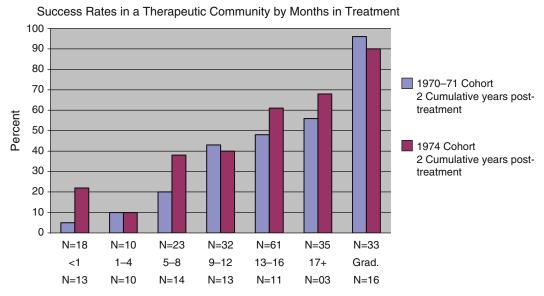


FIGURE 66.1 Success (defined as no drug use and no criminal activity) through all years of follow-up for primary opioid abusers. *Adapted from De Leon* (1984).

Table 66.2 summarizes the major findings from this research expressed as "Meta-Estimates" – the pooled information from the four major national multimodality, multi-year evaluations. Also included in these estimates is the information from three notable uncontrolled "case studies" of single community-based TC programs.

The striking replications across studies (though not shown, often within percentage points on some variables) leave little doubt as to the reliability of the main conclusion from these studies. Namely, there is a consistent relationship between retention in treatment and positive post-treatment outcomes in TCs (Figure 66.1).

Similar conclusions are obtained with the smaller number of controlled and comparative studies involving TC programs. With few exceptions in the studies with a bona fide non-TC comparison condition, the TCs showed significantly better outcomes than the comparison condition. Finally, the main findings from five published cost–benefit evaluations involving TC programs report a significant and positive cost–benefit outcome for TCs. In comparative studies, the TC shows relatively higher benefits particularly as reductions in costs associated with criminal activity and gains in employment.

Overall, the weight of the research evidence from multiple sources (multi-program field effectiveness studies, single program controlled studies, meta-analytic statistical surveys, and cost-benefit studies) is compelling in supporting the hypothesis that the TC is an effective and cost-effective treatment for certain subgroups of substance abusers particularly those with serious social and psychological problems in addition to their drug abuse.

THE EVOLUTION OF THE TC: MODIFICATIONS AND APPLICATIONS

The traditional TC model described in this chapter is actually the prototype of a variety of TC-oriented programs. Today, the TC modality consists of a wide range of programs serving a diversity of patients who use a variety of drugs and present with complex social and psychological problems in addition to their chemical abuse. Client differences as well as clinical requirements and funding realities have encouraged the development of modified residential TC programs with shorter planned durations of stay (3, 6, and 12 months) as well as TC-oriented day treatment and outpatient ambulatory models. Having become overwhelmed with alcohol and drug abuse problems, correctional facilities, medical and mental hospitals, and community residences, and shelters have implemented TC programs within their settings. Most communitybased traditional TCs have expanded their social services or have incorporated new interventions to address the needs of their diverse residents.

These changes and additions include family services; primary health care specifically geared toward HIV-positive patients and individuals with AIDS; aftercare, particularly for special populations such as substance-abusing inmates leaving prison treatment; relapse-prevention training; components of 12-step groups; mental health services, and other evidenced abased practices (e.g. cognitive-behavioral therapy, motivational interviewing). Mostly, these modifications and additions enhance but do not substitute for the basic TC approach, community as method.

Current Applications to Special Populations

An important sign of the evolution of the TC is its application to special populations with substance abuse problems (e.g. adolescents, mentally ill chemical abusers, criminal justice clients, women with children, methadone maintained clients) and special setting (e.g. prisons, shelters, mental hospitals). Research provides impressive evidence for the effectiveness and cost benefits of modified TCs for special populations.

Modifications in practices and in program elements for special populations and settings center on the treatment goals and planned duration of treatment, flexibility of the program structure to accommodate individual differences, and in the intensity of peer interactions. Special services and interventions are integrated into the program as supplemental to the primary TC treatment. An example of the modification of the TC for clients with serious co-occurring psychiatric disorder is outlined in Table 66.3.

THE TC WORLDWIDE

In the past 40 years, the TC for Addictions launched in North America has been adapted worldwide with programs implemented on every continent. These programs reflect cultural and societal differences (e.g. influences of religion, the prominence of the family, the political orientation). To a considerable extent, however, many retain the basic perspective, approach, and elements of the standard TC. A developing research

literature documents the effectiveness and cost benefits for these programs.

TCs worldwide are also undergoing the evolutionary changes described above including modifications for special populations and particularly adapting to fiscal pressures to reduce time in residential treatment. Another notable development is the rapprochement between the addiction TC and the psychiatric TC pioneered by Maxwell Jones that has been prominent in Europe. Both of these TC approaches share many of the common elements of community as method to treat populations with both substance use and personality disorder.

Nevertheless, maintaining uniformity and fidelity of the TC approach in light of these changes remains a challenge. In response to this challenge, the World Federation of Therapeutic Communities (WFTC) that represents regional and individual TC programs worldwide is currently exploring initiatives to develop universal standards for TC practice.

THE TC IN HUMAN SERVICES

The modifications of the traditional model and its adaptation for special populations and settings are redefining the TC modality within mainstream human services and mental health services. Most contemporary TC programs adhere to the perspective and approach described in this chapter. However, the basic peer/social-learning framework has been enlarged to include additional social, psychological, and health services. Staffing compositions have been altered, reflecting the

TABLE 66.3 Modifications of the TC for Co-occurring Disorders

TCs for mentally ill chemical abusers (MICAs)

Clinical issues

The special needs of severely mentally ill chemical abusers center on the themes of the mental illness' symptoms, their fragility to intense social interactions, overall level of social dysfunction, their lower tolerance of structured regimens, their proneness toward social withdrawal, and their need for appropriate utilization of mental health services.

Treatment goals

The basic goals of lifestyle and identity change are viewed as long-term objectives that can be realized dependent upon the functional level of the individual. Realistic goals are the individuals' acceptance of the mutual effects of their substance abuse and mental illness problems, engagement into the change process, learning to use and be effective in the peer community, strengthening daily living skills, commitment to continue drug abuse and mental health treatment beyond the program, and preparation for vocational and educational training. Homelessness is a third major problem for many of these MICA clients. Thus, an additional treatment goal is training clients to seek and secure permanent housing to minimize risk of relapse.

Adaptation and modifications

The clinical issues of the MICA clients shape the key modifications. There is greater focus on individual differences evident in more use of individual psychotherapy, case management, and skills training activities, more flexibility in the daily regimen of activities and in the phase format, a less demanding work structure, use of standard psychotropic medications, moderated intensity of group process, more focus on mental health issues, and greater use of psycho-educational formats. Adaptations in host settings such as hospitals and shelters require intensive cross-training of personnel and accommodation to institutional features.

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fact that traditional professionals – correctional, mental health, medical and educational, family, and child care specialists; social workers; and case managers – serve along with experientially trained TC professionals.

Indeed, the cross-fertilization of personnel and methods between traditional TCs and mental health and human services portends the evolution of a new TC: a general treatment model applicable to a broad range of populations for whom affiliation with a self-help community is the foundation for effecting the process of individual change.

SEE ALSO

Evidence-Based Treatment, Dissemination of Evidence-Based Treatment into Practice, Treatment for Co-occurring Substance Abuse and Mental Health Disorders, Individual and Group Counseling for Substance Use Disorders, Motivational Enhancement Approaches, Cognitive Behavioral Therapies, Community Reinforcement Approaches: CRA and CRAFT, A Decade of Research on Recovery Management Checkups, Self-help Groups, Criminal Justice Interventions

Glossary

- Axis 1 diagnoses the standard Diagnostic and Statistical Manual (DSM 1V) classification of serious psychiatric disorders including for example, substance abuse dependence.
- Community as method unique social–psychological approach of therapeutic communities defined as the purposive use of a community (peers and staff) to teach individuals to use the community to change themselves.
- **Correctives** verbal strategies (e.g. reminders, criticisms) which peer use to help each other remain aware of behaviors and attitudes that they are attempting to change.
- **Street code behaviors** behaviors, attitudes, and values which are common among those in deviant, antisocial, or otherwise negative subcultures such as drug dealers, criminal, or gangs.

TCs therapeutic communities.

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Relevant Websites

http://www.ndri.org/ctrs/ctcr.html – Center for Therapeutic Community Research-Link to NDRI.

http://www.Psychotherapy.net - For obtaining DVD TC series.

Internet Screening and Intervention Programs

Preben Bendtsen*, Kent Johnsson\$

*Linköping University, Linköping, Sweden \$Malmoe University, Malmoe, Sweden

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INTRODUCTION

Substance abuse and addictive behaviors are a widespread problem in all parts of the world and have a significant impact on physical and mental health. Tobacco and alcohol abuse are historically the most common forms of substance abuse followed by drug abuse. More recently, other forms of addictive behaviors have been added to the list, such as eating, sexual, and gambling disorders as well as Internet addiction.

Due to the magnitude of tobacco and alcohol abuse, there has long been an intensive search for cost-effective interventions to tackle the burden these conditions inflict on society. Although the health care system has an important role in offering advice and support for addictive behaviors, a number of barriers have been identified, such as competing demands, lack of time,

insufficient reimbursement, and lack of training, hampering widespread implementation of addictive interventions to all in need of such support or treatment. Since the Internet has the potential to reach a substantial number of people with instant feedback, it is a potentially interesting means of implementing behavioral change interventions.

Access to the Internet is steadily increasing worldwide. In 2011, it was estimated that over a quarter of the world's population uses the Internet. However, access to the Internet varies considerably between continents (from approximately 10 to 80%) and between countries (from less than 1% to more than 97%).

In Europe, nearly 60% of the population uses the Internet, and in the North America the figure is nearly 80%. Thus, it is not surprising that considerable research has focused on how to use the Internet to offer cost-effective interventions for addictive behaviors.

The Internet already encompasses a vast amount of information on addictive behaviors; for example, a search on Google using the phrase "alcohol abuse" revealed 11.6 million results at the beginning of 2011, "drug abuse" revealed 41.8 million results, and "sexual addiction" 5.5 million results. When looking for Internet treatment for addictive behaviors, Google offers 166 000 results.

Between 75 and 80% of Americans and Europeans routinely use the Internet to find health-related information, but only around 10% are looking for information on substance use. There is a strong trend toward patient control of health information seeking, and already a majority of Americans go to the Internet first before seeking the help of a health care provider.

However, the quality of the content of Internet sites designed for promoting behavior change varies considerably and by itself does not necessarily offer the information needed to promote behavioral change. Thus, owing to the vast amount of information on the Internet, it seems to be a challenge for an individual person to find adequate information and help.

As a consequence of this explosion of health information on the Internet, a substantial amount of research has emerged on how to design and deliver specific interventions for a great variety of health conditions. In general, outcome trials have consistently shown a positive change in health behavior compared with controls. A number of reviews and meta-analyses have been performed in this fairly new research area. Nonetheless, most of the research so far has suffered from a lack of consistency on what constitutes an Internet intervention. The lack of accepted standards makes it difficult to compare different studies. Also, a number of methodological problems in Internet research must be taken into account in future research. One important area to consider is recruitment bias when recruiting participants online and retaining a reasonable number of participants throughout the study period.

Some Internet interventions have considerable human involvement with various forms of online support. This kind of intervention is more expensive and implies a smaller reach since the resources needed are similar to traditional face-to-face treatment. Consideration of external validity is important when designing an Internet intervention because what is easy to perform in a smaller study with extra resources might not be possible on a larger scale.

On the other hand, due to the advantages of the Internet with its 24/7 accessibility, without having to schedule an appointment, and thereby lowering the barriers for seeking treatment for certain vulnerable groups, certain researchers argue that Internet interventions might not have to offer the same level of treatment effect as face-to-face interventions since "some help

might be better than none." Instead, Internet interventions can be seen as part of a stepped-care model offering a supplement to traditional treatment.

WHAT IS AN INTERNET INTERVENTION APPLICATION?

Internet intervention applications can be defined as various forms of computer software such as (1) public websites with interactive tests offering personalized feedback on response to some questions, (2) provider-controlled websites where a patient obtains a personal user name and interacts with a therapist online, or (3) software applications on stand-alone computers in a professional's office or in a waiting room. Internet intervention is primarily a self-guided intervention program that is accessible through a website and attempts to create a positive change in a behavior or at least improve awareness and knowledge concerning an unhealthy behavior.

In addition to these computerized solutions, other forms of computerized applications are emerging for additional support, such as short message service (SMS) reminders that could be a daily reminder of a targeted goal (e.g. quit smoking or decrease drinking). The person could also answer these SMSs and, for example, be asked to type the amount of alcohol drunk in the last 24 h and then receive weekly feedback on consumption. Another example of computerized applications where the individual does not interact with a computer is the interactive voice response (IVR) technique. This is an automated phone call in which a person is asked a number of questions and answers by tapping the response into the keyboard of the phone or by talking into the phone and then receives personal feedback based on the answers, with very much the same content as on an interactive website.

Most studies so far have focused on applications reached by a computer with access to the Internet. There is as yet no consensus on a clear terminology when describing what constitutes an Internet-based intervention leading to a lack of clarity and consistency. This is most certainly due to the fast expansion of websites offering help and support, making it impossible for research on scientific evidence to keep up with all the new ways of delivering Internet interventions.

Several terms have been suggested to encompass Internet interventions, such as web-based therapy, e-interventions, e-therapy, cybertherapy, eHealth, and computerized interventions. In an attempt to distinguish between the various forms, it has been suggested that Internet interventions can be organized into four main categories: web-based interventions, online counseling, Internet-operated therapeutic software, and

other online activities. Web-based interventions encompass most Internet interventions developed and implemented so far, but the future might show a different picture with the rapid development of new Internet technologies.

Web-Based Interventions

Web-based intervention in its simplest design could be primarily a self-guided intervention delivered on a computer either as an online website or a preinstalled program on a computer in a health care facility, for example. However, web-based interventions include a great variety of applications from mostly passive educational sites aiming to increase knowledge in order to increase motivation for change to interventions with a more self-guided therapeutic approach partly or mainly with human support delivered over the Internet.

Obviously, program content is vital for the effectiveness of all types of web-based interventions, and not surprisingly there is a considerable variety among Internet interventions with regard to whether the website only offers educational material or specific tools for behavioral change.

The least interactive mode, educational intervention, may still offer some interactivity such as self-assessment or quizzes in which the individual mostly receives a generic automatic response. Research has shown that for some conditions such as risky drinking, this level of intervention might be sufficient for a behavioral change, especially if the information is tailored to the individual user.

In self-guided therapeutic interventions the content is more theory based, often with cognitive behavioral therapy (CBT) as the foremost behavioral change approach. However, the content varies in this kind of intervention and not least in the amount of online activities offered. The intervention might be a single session with brief normative feedback or a multisession intervention where the individual has to create a password and log on at certain intervals. Multisession interventions have the advantage that content can be built up bit by bit in order to enhance the motivation to change behavior. On the other hand, the burden of using the website might be an important barrier to completion of the intervention. In contrast to generic educational interventions, more tailored feedback is commonly offered in self-guided interventions, although the amount varies. Meta-analysis of self-guided therapeutic interventions has shown that this approach is effective for some addictive behaviors.

Human-supported therapeutic Internet intervention adds access to a health professional for support, guidance, and feedback. Most commonly, this is done on an individual level by e-mails, SMS, or webcam sessions. In previous studies, the amount of time the individual had access to a therapist varied from a few minutes to several hours. A recent meta-analysis reveals that human-supported programs could be more effective than self-guided programs. However, educational and self-guided interventions are often open websites that do not require registration and are always open, whereas human therapist interventions require registration and are not as widely accessible, undermining the possibility for widespread implementation.

Online Counseling and Therapy

In its most basic form, a counselor might have a website with some basic information about a certain addictive behavior offering the user contact by e-mail, instant messaging, or some kind of chat forum. Another example is peer-delivered therapeutic support and advice - for example, various 12-step groups who meet online. The website at http://www.aabigbook. com links to online self-help support groups for many forms of addictive behaviors. Although little research has been performed on peer-delivered support and advice, there are a number of obvious reasons why these social networks have become popular. They reduce social desirability, which might lead to increased honesty and thereby self-disclosure of addictive problems. Also, these sites have links to a number of professional lead services both online and face to face.

There are dedicated online counseling websites with virtual clinics that list online therapists. There are also hundreds of independent online therapy or e-clinics and a number of larger e-clinics that are linked to a large number of therapists. These sites mostly offer either written answers to mail questions or a real conversation with a therapist often via a chat room.

Generally, online counseling offers two basic means of communication: individual or group contact. The communication can either be direct online or delayed in time, allowing people to log in when they have time to comment on issues. Although some online websites offer communication via web cameras, written communication has become the most frequently used means of interaction.

Some controversies still exist about this kind of Internet-delivered therapy due to inconsistency in the quality and professional guidelines. Some research has been performed on the effectiveness of this form of Internet-based therapy and has shown that it is possible to accomplish a change in an addictive behavior. However, due to the ever-expanding number of sites offering online therapy for addictive behaviors, it is

difficult to know which sites are of good quality and which are not.

Therapists who want to offer online support must be trained adequately in the challenges of using the Internet. Thus, a face-to-face therapist cannot directly step into cyberspace but needs training in the various means of communicating on the Internet. With the right amount of training, studies have shown that online therapy can establish a close and emphatic alliance between the therapist and client. However, there is a lack of outcome studies, although a few studies have shown online therapy to be effective in addictive behaviors such as smoking cessation.

Internet-Operated Therapeutic Software

Internet-operated therapeutic software refers to more advanced therapeutic software such as gaming programs and virtual environments and to expert systems, including assessments followed by treatment selection and progress monitoring. Among these is the Drinker's Check-up site which contains various decision-making modules that are dynamic in relation to the individual's responses.

Studies have demonstrated the potential effectiveness of Internet-operated therapeutic software for various psychiatric conditions, but not yet for addictive behaviors. However, the cost of developing this kind of application is rather high, and there is a lack of experience among clinicians of the technical possibilities. Nevertheless, the potential for such applications is enormous and in the light of increasingly sophisticated commercial games that have already been developed, technical knowledge and competence are becoming more widespread. This advance might lead to the development of advanced applications for addictive behaviors in the near future.

Other Online Activities

Online support groups have existed for decades. This category of support consists of online activities such as personal blogs and support groups, which can be used as stand-alone functions or added as a supplement to other Internet treatment interventions. Online support groups and networks can be moderated by a facilitator or they can be unmoderated. Social networks and others such as MySpace and Facebook are growing more popular. However, research on such networks is very limited, although anecdotal information is encouraging when it comes to emotional support and information exchange between users. In a review of the effectiveness of virtual communities with regard to interventions for psychiatric and additive behaviors, most such social

networks were offered as part of a complex intervention, and therefore the effect of the network per se was difficult to determine. Thus, the potential of using various kinds of social networks remains to be explored.

ADVANTAGES OF COMPUTERIZED APPLICATIONS

Computer-assisted interventions have several advantages over conventional face-to face counseling. The use of computers decreases the effect of social desirability and increases the amount of information disclosed. Thus, a person might prefer to reveal information of a personal and potentially embarrassing nature to a computer rather than a person.

Another advantage is the access to the Internet 24 h a day, which makes Internet interventions convenient and flexible to use and not confined to a specific physical location. The Internet can reach a large number of people, even those living in remote areas with poor access to health care providers. Furthermore, groups of individuals who might not seek traditional help for an addictive condition might be attracted to using the Internet due to the anonymity offered in most cases. Thus, women and young people have been shown to be more prone to seek help on the Internet, as is the case with traditional treatment services.

The content of an Internet intervention is more stable than a face-to-face intervention and will always be as accurate as constructed. An Internet intervention can be personalized and tailored to match an individual in a more systematic and consequent manner than a face-to-face intervention, although a human interface or contact might be more sensitive and flexible depending on the response from an individual.

The cost of Internet intervention is probably far less than an individual face-to-face intervention, although more cost-effectiveness studies are warranted due to the relatively high cost of developing and maintaining more advanced Internet applications.

METHODOLOGICAL CHALLENGES IN EVALUATING INTERNET INTERVENTIONS

Conducting an effectiveness trial of an Internet intervention poses a methodological challenge. So far, most studies have used conventional methods for recruitment, randomization, and outcomes assessment. Also, many evaluations of Internet interventions for addictive behaviors have been performed on a fairly small number of individuals in special settings, such as college and university students.

Before disseminating Internet interventions on a large scale to a broader audience, however, it is important to know the effectiveness among individuals who enter an Internet intervention site when browsing the web rather than referred by a health care staff professional. Unfortunately, entirely online trials most often have a substantial drop-out rate, making it difficult to analyze the effectiveness.

The transition of relatively small-scale Internet intervention studies to a large-scale implementation reaching a larger segment of the population is an important aspect.

CHALLENGES IN THE DEVELOPMENT OF EFFECTIVE INTERNET INTERVENTIONS

Internet interventions face a lot of challenges, such as supplying the right information for a particular individual, at the right time and place, and providing the best way to guide an individual to a behavior change. Thus, Internet interventions need to be flexible, interactive, engaging, and easy to use for all individuals accessing the intervention. So far, most developers of Internet interventions have been fascinated by the technical possibilities of the Internet reaching a large audience rather than by finding the best way to communicate a health behavior intervention. As a consequence, many websites offering more time-demanding interventions have a problem getting visitors to stay for a longer time and to read all the information or take all the steps necessary for a behavior change to take place. Thus, it is a challenge to design Internet interventions that create interest and engage the users.

Researchers have summarized the directions that must be taken in developing effective Internet interventions; they must be designed to encourage as much as interactive communication as possible; they should work on different platforms, such as computers and smart phones, and attract individuals with various needs and backgrounds. Internet interventions should be designed so that individuals become interested and emotionally involved in performing all steps of the intervention. It has been repeatedly suggested that users of Internet interventions should be involved in the design of new interventions in order to develop more effective and widely implemented interventions.

Interactivity

Many websites offer only information on addictive behavior and are not designed to promote interaction and collaboration. Nonetheless, interactivity (i.e. the user is requested to answer a question or choose between various alternative pathways) probably plays an important role in the effectiveness of an intervention and, in particular, tailored feedback to the individual user. Interactivity has been shown to be related to meaningful participation in both the process and content of communication. Health behavior change has been shown to be largely dependent on social values and networking. Thus, all social Internet-based forums such as blogs might play an important role in the development of effective Internet interventions, although research so far is limited as to the effectiveness of such social networks. In a review of tobacco cessation Internet interventions, only half of more than 100 sites reviewed contained at least one interactive component, although the proportion has been increasing in the last 5 years.

In particular, tailored feedback promotes an interpersonal interaction between the computer and the users that simulates interpersonal communication and thus bridges interpersonal and mass media forms of communication.

Unfortunately, research has shown that many visitors leave the sites before completing them, and so this is a major challenge because many websites are designed to be revisited in order to achieve substantial change. This situation could be remedied by offering follow-up assessments with the provision of a graphic illustration of change over time concerning a certain health behavior or by offering new information each time a person revisits the site. Also, some sites have a certain number of prescheduled CBT sessions that have to be attractive and user friendly in order to inspire the user to revisit or follow the program. Reminders by e-mail have also been shown to increase revisits to websites.

THEORETICAL BACKGROUND, DELIVERY EFFECTIVENESS, AND UNDERLYING COMPONENTS

As in face-to-face interventions, the message in Internet interventions is based on different theoretical backgrounds. One reason why is that most Internet interventions have been transformed from earlier known effective interventions. Most of the Internet interventions are behavioral treatments, including different types of methods, depending on the purpose of the intervention. As the Internet is worldwide, country-specific cultures concerning the goals of the interventions must be taken into consideration when designing Internet interventions. Some cultures do accept, both legally and socially, behaviors that are totally unacceptable in other cultures. Therefore, Internet behavior change models must relate to the local society.

Methods often used in Internet interventions are related to CBT and social learning theory, using feedback, motivational enhancement, skills training, self-monitoring, and self-regulation as components to regulate the behavior. These methods are commonly used in other non-Internet interventions. To avoid client resistance, motivational interviewing, including components such as avoiding direct confrontation and making judgments, often influences the message of the intervention. However, in the Internet-based interventions developed so far for addictive behaviors, it is difficult to find a specific theoretical model that explains behavior change and improvement.

Different well-established theoretical models must be used when designing an Internet intervention, but new models or components not yet defined by behavioral change science may have to be added. These new models should include factors such as the environment, both physical and mental, as well as the website design itself. In face-to-face interventions, we normally have control over factors important for the intervention, but in Internet-delivered interventions we cannot anticipate those factors. The environment could either provide support or be a barrier for behavior change. If the environment is positive and supports the use of the Internet intervention, as well as the behavior change, it could enhance the delivered message.

Websites targeted to influence people to change behavior involve different factors such as appearance, instructions, behavioral prescriptions, content, message, and degree of participation. Several more important factors could probably be added to the list. So even if we attempt to individualize the message in the website, the look and feel of the application attract people differently and thereby dictate the appeal to the user. In the same way, the instructions on the site attract people differently, so it is not only the message that is important but also knowledge about how the receiver can handle the Internet-delivered intervention from a technical point of view.

The main message in trying to encourage the patient to deal with the unwanted behavior has been described as a behavioral prescription. This instructs the user in how to address the targeted problem and should be designed so that it increases commitment and boosts adherence. Supporting techniques such as automated e-mails or mobile phone messages can enhance willingness to take part in the intervention. The single most important component of an Internet application is the actual content of the intervention. As there is a considerable amount of misinformation on the Internet, it is important that the content provided in the intervention is accurate, clear, and simple. The organization delivering the intervention is also an important factor. If the user considers the organization to be serious and trustworthy, this will enhance willingness to accept the information.

As in face-to-face interventions, the length of the Internet intervention is important. If the intervention is too long, the patient may lack endurance, resulting in early withdrawal and poor outcome. Therefore, the main components in the intervention should be at the beginning of the program. Later in the program, it is possible to add complementary information. Another alternative is to create short Internet interventions.

Depending on what kind of behavior change methods are used, there are different aspects of the power of the relationship between the therapist and the person seeking treatment. In dependence treatment, it is claimed that the alliance between the therapist and the person seeking help could be a component as powerful as the method itself. Evidence on the relationship has been proved, showing that a good relationship is worth a lot for the treatment outcome. However, although a certain treatment method, often manual based, has been proved to be effective in several studies, lack of experience and skills by the therapist can reduce the expected outcome. In Internet interventions, the importance of the alliance between therapists and patients is no longer a component that influences the effectiveness of the method. It has been suggested that there may be some kind of alliance between the user and the organization delivering the message. If the organization actively keeps in contact with the person receiving the intervention, this probably could create some kind of alliance or closer relationship.

As described earlier, Internet interventions are not only about behavior change; they also include the sciences of web design, social marketing, computer programming, and technical support. Therefore, many different disciplines have to cooperate to create effective Internet-based interventions in the behavioral change area.

ALCOHOL INTERVENTIONS

Alcohol Internet interventions typically use a range of components such as alcohol self-assessment with personal feedback relating to a certain norm, general information concerning alcohol and health, various forms of interactive chat forums, and links for further treatment. So far, it is not known which components have the most effect, although few visitors to alcohol websites go beyond the first few pages. Also, just answering questions about alcohol consumption appears to reduce drinking levels, which might indicate that the various forms of feedback have no additional impact at least for risky drinkers. More research is needed in order to find the optimal amount of information and intervention needed to reach risky drinkers.

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Many alcohol Internet interventions have been designed for use among college and university students, including various forms of normative feedback. Many of these interventions have been developed as a single-exposure intervention offering a normative feedback that does not require a log on. The effectiveness of such single-exposure interventions among college and university students has been found to be in the same range as a shorter face-to-face counseling session. One example is the website for Thrive, which has been designed for students (http://www.uq.edu.au/healthservice/selfhelp/thrive-alchohol-self-check-survey).

Some of the single-session alcohol interventions have been delivered in a student health care setting on standalone computers in the waiting room. Also, stand-alone computers with a single-session alcohol intervention with normative feedback have been used in waiting rooms in emergency departments and primary health care waiting rooms.

A number of sites have also been developed for the general population. Most require a log on in order for the user to have repeat visits to fulfill an interactive behavior change program over a number of sessions, typically around six sessions. One example is the Down Drink website (http://www. downyourdrink.org.uk). A recurring problem with this intervention design is to get the person to revisit the website at certain set intervals, typically every week. In one trial on Down Your Drink, 60% stayed for 1 week and only 6% for the entire 6 weeks of the intervention. Therefore, the website was redesigned so that the individuals could go through the six sessions at any time, making the site more flexible for the individual user; they were able to navigate freely throughout all parts of the intervention. Other trials have shown that only a small proportion of users visit the part of a website that provides additional information besides an initial assessment. However, individuals looking for more help were more likely to be risky drinkers, and those who clicked on the link for more help were more likely to be abusing or dependent on alcohol.

Most individuals who visit alcohol Internet sites have not seen a health care professional before, and thus the web is the first attempt to learn more about alcohol. Drinkers with high alcohol consumption or more severe problems tend to stay longer and read more of the information provided, including where to find additional help. However, several researchers have found that many individuals using alcohol websites consume just as much alcohol as people seeking treatment in health care, but they do not experience the same level of negative consequences. Men and women seem to use alcohol websites in equal numbers, and in contrast to alcohol treatment services in general, where most of the

attendees are men, the Internet seems to especially attract women with alcohol problems.

In general, alcohol Internet interventions have an effect among risky drinkers without alcohol dependence, but due to the great variety of content, it remains to be shown what is needed to accomplish behavior change. However, with the possibility of an Internet intervention reaching a large proportion of the population, it might be fully acceptable to have a lesser behavior change effect than a face-to-face intervention. Also the Internet intervention on alcohol could be seen as the first part of a stepped-care model.

For people with more severe alcohol dependence, there are dedicated websites with a more extensive online design. The Internet can be used to guide the individual to a face-to-face treatment or telephone counseling. A vast number of such sites are seen in North America with hundreds of independent online therapy or e-clinics and a number of larger e-clinics that are linked to a high number of therapists (e.g. http://www.thecounselors.com and http://www.egetgoing.com). These sites offer either written answers to e-mail questions or a real conversation with a therapist, often via a chat room function. On http://www.aabigbook.com there are links to online self-help support groups for many forms of addictive behaviors, but the effectiveness of such support has not been evaluated in a research study.

TOBACCO INTERVENTIONS

The first computer-assisted smoking cessation intervention was limited to computer-generated printed feedback which was mailed to the participants. However, smoking cessation Internet interventions now include more tailored feedback often with some kind of reminder system, typically e-mail, SMS, or applications for the newer smart phones.

A review of Internet smoking cessation interventions found more than 100 websites and concluded that interactive sites are still underrepresented. Less than half the sites were offering at least one interactive feature. Evaluation of sites with interactive components in the form of e-mail, IVR, and SMS reminders shows promising results compared with just general health information. In a comparison of 10 smoking cessation Internet interventions of various lengths and content, there was some evidence that tailored interactive advice might be more effective than static sites. Some interventions are used as an adjunct to therapist-delivered treatment, whereas others are a fully self-guided intervention. The interventions vary considerably in length, ranging from a single session to several sessions, and even as many as 400 contacts were used in one intervention. A core component in many interventions is CBT, with the addition of chat features or online therapist support in some interventions. This variety of content makes it very difficult to compare the overall effect of Internet-based smoking cessation interventions. This observation also applies to most other Internet interventions for addictive behaviors. When comparing the effectiveness of existing alcohol and smoking interventions, the effect size is small to moderate and somewhat less for tobacco than alcohol. But given the accessibility of the Internet, this might still imply a reasonable reach of the target population. Not surprisingly, studies with treatment-seeking individuals reveal a higher smoking cessation rate than studies recruited from the general population.

Although there are rapid developments in Internet smoking cessation interventions with more sophisticated designs involving interactive components, it is still unclear "what works for whom." Many of the existing stop smoking sites contain a considerable amount of information in contrast to many alcohol sites. It is unclear how much detailed information is needed to help smokers quit. Moreover, smokers might hesitate to use a site with too much information that they regard as irrelevant or difficult to find due to the many options offered. Thus, as well as considering general usability features, it is also important to understand the ways in which individuals use websites when considering changing behavior.

In 2010, there were about 20 controlled trials, including 40 000 participants in various Internet smoking cessation interventions. Due to a great variability in design and outcome, however, there is still inconsistency in the effectiveness and more studies are needed. There is a need for trials focusing on the likely mechanism or components through which these interventions mediate their effects. In another recent review of more than 50 studies, the proportion of effective studies was examined. Overall, the authors found Internet smoking cessation interventions to be effective in particular when they incorporated reminders via e-mail and SMS and provided tailored feedback. Although not all studies have been able to show the effectiveness of Internet interventions, some studies with self-guided smoking interventions have been shown to be effective with a quit rate between 10 and 30% at 1-month follow-up.

Several additional reviews of the literature on Internet smoking cessation interventions have been performed with somewhat varying conclusions. In general, some evidence exists that the intervention needs to be tailored and interactive as opposed to a more static intervention, although not all trials have found this necessary. Adding chat forums or online support has not been shown to be more effective than fully automated interventions. Several studies with online activities

have shown difficulties in getting the participants to use these online tools. In most studies, a very small proportion (around 5%) utilized chat forums and access to an online therapist.

DRUG INTERVENTIONS

Only a few studies have been performed on Internet interventions for drug abuse. Most of these interventions have been used in addition to face-to-face therapy. One study found a positive effect of a computerized CBT delivered in a clinic in conjunction with standard faceto-face treatment. More and more sites are offering self-tests and information about drug abuse and where to find more help. These sites also most often offer either written answers to mail questions or a "real conversation" with a therapist, often via a chat room. So these sites must be classified as online treatment rather than web-based interventions. Because online treatment sites generally suffer from a lack of scientific evaluations and quality control, it is difficult to estimate the results. All the same, they may well serve as an important means of informing users of the Internet about addictive behaviors and where to get more help. Thus, many sites on the Internet offer information about drug abuse but cannot be considered to be a formal intervention. There is a need for more properly designed studies in order to evaluate both the effectiveness of these services and the cost-effectiveness of using the Internet for general information about drug abuse, and the value of various online supports.

OTHER ADDICTIVE BEHAVIORS

Pathological gambling has been shown to be an increasing problem, especially among young people. The Internet has been predicted to be a suitable means of offering interventions based on CBT principles. So far, only one study with 66 participants has been performed for pathological gambling. The intervention consisted of eight modules, four of which had a motivational interviewing focus, and the other four were based on CBT. Each module included exercises that were mailed to the site, and feedback was given within 24 h. The participants were telephoned once each week by a therapist in order to encourage continuous participation, and in total during the 8-week program the time spent with each participant was 240 min. Follow-up at 18 and 36 months revealed a significant decrease in pathological gambling in the intervention group, as well as less anxiety and depression, and increased quality of life. Future studies will reveal whether these results can be replicated, but given SUMMARY 663

the positive results from other addictive behaviors, this will probably be the case.

Treatment for sexual addiction via Internet interventions has not been described in the literature as a stand-alone intervention. There has been some focus on cybersex and its impact on the addicted person and related consequences. However, the interventions used have not been delivered via the Internet. There are websites where you can take part in other peoples' experiences. Those websites also recommend different kinds of non-Internet treatment.

Anabolic steroids are a growing problem for adults and teenagers. On the Internet, there are many websites that provide information about the drug, but no Internet interventions are offered through those sites. In research, the role of the Internet is described more as a tool than as a place where a person could easily buy illegal drugs.

Eating disorders are also a growing problem in many countries, especially among young women. So far the number of studies on these behaviors is far less than for many other addictive behaviors; nevertheless, some comparisons have been made between face-toface CBT interventions and Internet interventions of similar design, with promising results. Typically, Internet intervention for an eating disorder is based on CBT with weekly sessions, including reading material, support group activities, and homework assignments. One study showed that participation in discussion groups with other participants increased the adherence to a program, but for certain individuals this might also exacerbate the eating disorder. Having moderators for discussion boards was suggested as one solution; on the other hand, this adds to the cost of an Internet intervention.

Internet addiction is becoming an increasing problem and is under consideration as a diagnosis in the forthcoming Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) classification. prevalence in Western countries ranges from 2 to 8%, with a higher prevalence among young people. Interactive features on Internet sites such as online games, chat rooms, and bulletin boards have been suggested to add to the risk for addiction. Treatment for Internet addiction encompasses a great variety of psychotherapeutic approaches and medications, and so far the area is in its early stages. The question of whether Internet addiction could be treated online has not been discussed and may seem contradictory, but some attempts will probably be made to use the Internet for treatment of Internet addiction in the future. One Internet site, which has been running for 15 years (http://www.netaddiction.com), provides self-testing for Internet addiction, including cybersex addiction, general information about Internet addiction, and the opportunity to sign on for individual counseling delivered face-to-face or by telephone. However, the effectiveness has not been formally evaluated.

SUMMARY

Traditional treatment for addictive behavior is increasingly being augmented in various ways by applications found on the Internet, and in certain cases it is more or less being substituted by Internet interventions. Websites concerning addictive behaviors offer a wide range of general information, self-tests with tailored feedback, self-guided interventions, therapist-assisted intervention, and guides as to where to find more help. With the fast increase in the number of websites, it has been difficult to evaluate the quality and effectiveness of all new components added over time. Studies so far have mostly focused on alcohol and tobacco abuse and to a minor extent drug abuse, pathological gambling, eating disorders, and Internet addiction, including cybersex addiction, work addiction, shopping addiction, and addiction to prescription and over-thecounter medication. Given the magnitude of addictive behaviors in society and the effects on the individuals' surroundings, there is a need for cost-effective widespread interventions to address the challenge. The results so far are promising, especially on use of the Internet to gain more information about addictive behaviors and participation in self-guided interventions. Online chat and therapy-guided group counseling have been found to be less favored by participants owing to fears of lack of privacy and security.

SEE ALSO

Using the Internet for Alcohol and Drug Prevention, Technology-Delivered Treatments for Substance Use Disorders: Current Status and Future Directions, Brief Feedback-Focused Interventions, Screening and Interventions in Medical Settings Including Brief Feedbackfocused Interventions

List of Abbreviations

CBT cognitive-behavioral therapy IVR interactive voice response

SMS short message service

Glossary

Interactive websites sites that not only contain information that is the same for all visitors but also offer interaction in various ways producing a cause–effect action; for example, answering questions

- and getting personal feedback based on the individual's answers. Another form of interactivity used on websites involves more complex branching logic that responds differently to differing responses from the individual.
- **Internet intervention** primarily a self-guided intervention program accessible through a website that attempts to create positive change in a behavior or at least improve awareness and knowledge about an unhealthy behavior.
- **Internet-operated therapeutic software** refers to more advanced therapeutic software (such as gaming programs and virtual environments) and to expert systems including assessments, followed by treatment selection and progress monitoring.
- Online counseling in its most basic form, a website with some basic information about a certain addictive behavior supplied by a counselor and offering the user contact by e-mail, instant messaging, or some kind of chat forum.

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Relevant Websites

- http://www.aabigbook.com Alcoholics Anonymous, an online counseling site.
- http://www.alcoholscreening.org Alcohol screening site in the United States.
- http://www.alcoholhelpcenter.net Alcohol site and help center in the United States and Canada.
- http://www.minderdrinken.nl Alcohol site in The Netherlands.
- http://www.downyourdrink.org.uk Down Your Drink an alcohol self-help site for the general population.
- http://www.drinkerscheckup.com Drinker's Check-up, an alcohol site in the United States.
- http://www.egetgoing.com eGetGoing, online group therapy.
- http://www.thecounselors.com Online counseling and therapy.
- http://www.infotobacco.com Smoking cessation in Canada.
- http://www.smokehelp.org Smoking cessation in the United States. http://www.smoking-cessation.org – Smoking cessation in the United States.
- http://www.tobaccofree.com Smoking cessation for young people in the United States.
- http://www.netaddiction.com The Center for Internet Addiction.
- http://www.uq.edu.au/healthservice/selfhelp/thrive-alchohol-self-check-survey Thrive. An alcohol site in Australia, mainly for students

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Dissemination of Evidence-based Treatment into Practice

Patrick M. Flynn*, Barry S. Brown\$

*Institute of Behavioral Research, Texas Christian University, Fort Worth, TX, USA

\$University of North Carolina at Wilmington, NC, USA

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INTRODUCTION AND BACKGROUND

The ultimate objective of health services research is to achieve the more effective delivery of health-care services (i.e. to further reduce disease and promote greater well-being). In the area of substance abuse, the objective of health services research has been to increase the capacity of treatment to enable individuals to become drug free and socially productive. Because research advances are seen as being so tightly tied to improving the nation's health, the Congress regularly provides vast sums to support health care studies with such faith in the scientific community that it rarely demands an accounting of sums expended. It seems fair to say that the legislators, like the public they represent, assume the link between knowledge development and improved practice has been well forged and stands

intact. It has become increasingly clear that the link has been imperfectly forged to the extent it has been forged at all. It is noteworthy that recognition of the problem and the call for corrective action as described below has been the work of the federal agencies responsible for the conduct of research and a cadre of the investigators funded. We might first usefully explore the conditions that have existed to permit, if not promote, the gulf between researcher and clinician before examining efforts and issues significant to reducing that gulf.

Research and Clinical Practice March to the Beat of Different Drummers

Research is a slow and deliberative process. The time to the development of new knowledge is measured in years – and even then the answer may not appear definitive. Thus, the time from the recognition of a clinical problem to its solution is unlikely to satisfy the needs of clinical programming. The clinician has to respond to that same identified problem immediately and lack the luxury of years to mount a satisfactory therapeutic process. In addition to proceeding along very different timelines, researchers and clinicians have a need to be responsive to different audiences. Researchers acquire tenure, promotion, prestige, and an increased capacity to garner federal grants based on their ability to add to the scientific literature. Contribution to the scientific literature does not equate to contribution to change and improvement in clinical practice, but it is all that is required of researchers by their peers, supervisors, and funding agencies. Clinicians' capacities to acquire promotion, prestige, and job satisfaction are based on their abilities to contribute to the health and well-being of their clients and to satisfy the demands of payers. Apart from often being housed in different settings, the trade publications and sources of communications for both research and practice are largely separated by language and focus. Thus, research articles focus on methodology, and the vagaries of statistics to explain study findings, while the clinical literature focuses on the intervention and its proper implementa-Effective knowledge transfer requires a minimum that the media and language of communication are held in common by contributors and their audience if there is to be translation into knowledge application. Clearly, research and practice have been separated by a gulf that needs to be bridged. Whatever the loss to researcher and clinician in this process and there is loss to both - the most significant loss ultimately is to the clients in need and the public of which they are a part.

Different Drummers and No Conductor

The problem of multiple musicians is easily solved by anointing someone as conductor such that while solo performances can be encouraged, individuals can also be aided to make music together. It can be argued that the National Institute on Drug Abuse (NIDA) as originally organized had such a capacity. That is, the federal contributions to both research and services were administered through a single organization. While there were unquestioned deficiencies in the process and success of translating research to practice, it is noteworthy that, based on a large part on national studies of treatment effectiveness, and reports of the significance of their findings for clinical activity, stand-alone methadone detoxification was dropped as a separate treatment modality and support was generated for both the Therapeutic Community and methadone maintenance treatments. Indeed, even preceding the formation of NIDA, the awareness of relevant officials of evidence of the effectiveness of community-based (and multi-modality) programming in New York, Chicago, and Washington, DC, resulted in support for the creation of a national communitybased treatment system and ultimately led to the formation of NIDA itself. Whatever the shortcomings in the work of NIDA to promote knowledge application, the difficulties can be seen as having been exacerbated by the separation of research and practice demanded by Congress through the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992, housing each function in its own federal agency without developing crosswalks or demands for integrated activities. Even under those circumstances some significant efforts at knowledge application (i.e. of effecting clinical change based on research findings) have gone forward such that various iterations of diversion from Criminal Justice systems have been implemented (e.g. Treatment Alternatives for Safe Communities - TASC; Drug Courts, etc.), long-term (6 months) methadone detoxification was legislated, and HIV outreach programming was initiated in a vast number of communities as well as being written into law.

EFFECTING THE TRANSITION FROM DISSEMINATION TO APPLICATION – THE FEDERAL ROLE

In recent years, there has been the adoption by NIDA and the drug abuse field of implementation science, and the elevation of that area of study from having been of modest interest – when it was of any interest at all – to becoming a significant research concern. Implementation science, as embraced by NIDA, involves the development and testing of strategies designed to foster the transfer of evidence-based treatments into practice. In placing an emphasis on the implementation of evidence-based treatment, the Institute and field acknowledge the distinction between dissemination and application. As defined by the National Institutes of Health (NIH), dissemination involves the distribution of information about empirically supported treatments. Indeed, dissemination of information through journals, books, and monographs is a long-standing staple of the research community and, while it has not been a first priority for NIDA, the sharing of information with the service community has nonetheless been viewed as appropriate to its mission and has occupied a corner of its activities since the Institute's creation (see, e.g. the NIDA Notes initiated as the Services Research Branch (SRB) Notes in the 1970s). Application, with its focus on increasing the rate and likelihood of adopting new treatment practice, has never been seen as an obligation by the research community whose responsibilities have been limited to knowledge development and dissemination of findings to peers and to the funding agency. Both dissemination and application can be seen as having the potential to improve the quality and effectiveness of existing treatment services. However, as described above, dissemination is most often a peer-to-peer communication and embraces a language, style of reporting, and set of concerns that make it largely inaccessible to service providers. In addition, and in large part, because of the projected audience for disseminated materials, there is as great or greater emphasis on the use of findings to spur additional research as there is to stimulate treatment program change. Knowledge application, on the other hand, is concerned with changing process (or providing support to existing process) and therefore has a typically different audience, and thereby a different means of communication and set of strategies for achieving its objectives.

Given NIDA's historic mission and concern with knowledge development, and with its emphasis on using the research media for sharing information, caution can be raised as to how NIDA plans on making findings with regard to strategies for knowledge application available. It would strain the bounds of irony for NIDA to support the reporting of findings in the area of knowledge application in the research literature alone or even primarily. In that regard either NIDA or another agency with a dedication to knowledge application, and with actors and a structure in place to foster knowledge application, is essential to the task. As will be described below, an agency and structure do exist, but its effective use will require the joint activity of independently functioning federal organizations. To date there is reason for optimism in that the organizations in question – NIDA, and its sister Institutes, and the Substance Abuse and Mental Health Services Administration (SAMHSA)-are working together on several initiatives. These include the NIDA and SAMHSA Blending Initiative to accelerate the translation of research into practice; the SAMHSA/ Center for Substance Abuse Treatment (CSAT) Practice Improvement Collaboratives to improve treatment through the adoption of evidence-based practices; and the National Institute on Alcoholism and Alcohol Abuse (NIAAA/SAMHSA/CSAT) Research in Residence Program to encourage the adoption of research-based improvements.

Two critically important initiatives speak to actions by an agency, SAMHSA, to assume responsibility for the application of research findings to clinical practice through an identification of transferable treatment strategies, on the one hand, and the development of a structure and actors to carry out knowledge application, on the other. The National Registry of Evidence-based Programs and Practices (NREPP) provides the basis for selection of treatment components that can be seen as

supported by a body of research. It would be difficult to overstate the importance of having available a dispassionate and respected body of researchers to conduct such peer review. As has been noted earlier, research is an extraordinarily deliberative activity and the results produced by researchers are rarely sufficiently definitive to rule out the investigator's mantra: "Further study is warranted." In truth, further study is always warranted in relation to effectiveness with additional populations and/or in additional settings. However, as has already been described, research is of necessity always late to the show. At some point, some equally deliberative body has to be empowered to say whether a treatment component can be seen as effective even if caveats need to be stated with regard to the population and/or settings and/or providers on which findings are based. NREPP permits a structure to accomplish that and thereby has performed a major role in moving the knowledge application process significantly forward.

The second initiative undertaken by SAMHSA involves the development of a structure and actors for the conduct of knowledge application, namely the regional Addiction Technology Transfer Centers (ATTCs). As has been described, the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) Reorganization Act of 1992 effectively put substance abuse and mental health research and substance abuse and mental health services in separate boxes, creating a SAMHSA with its component agencies and dispatched NIDA and its sister institutes to the NIH with a request that people communicate across agency, but without incentive for them to do so or penalty if they did not. This left no organizational presence to unite research and practice with particular regard to taking treatment components capable of being described as evidencebased, introducing those to the service community, and brokering their adoption by that community. While SAMHSA has assumed large responsibility for the selection of research-based initiatives for transfer, it appears appropriate for the organizations that originate and monitor the development and testing of those initiatives to play a role in suggesting and evaluating them. More importantly, in large measure, NREPP provides little more than a list of available strategies. While manuals and other materials may be solicited from those who were involved with the intervention in question, there is need for more than even these printed materials to achieve knowledge application. The ATTCs represent an important presence in that regard, but have received only modest funding even as that funding has come jointly from differing federal agencies (SAMHSA and NIDA) over time and has been accorded little if any responsibility for undertaking the interpersonal activities with treatment programs, which has been found critical to effective knowledge application.

ACHIEVING PROGRAM CHANGE

The adoption of new clinical initiatives by a program can be seen as having two interrelated components. The first involves preparing the organization to accept the need for change and the second involves preparing the organization to adopt and maintain the specific change proposed.

Preparing the Organization to Accept Change

Program staff must be willing to accept a need for change before we can expect any new initiative to be embraced and adopted by the organization. Change is discomfiting and the status quo provides the security of the known and the routine. To move beyond the status quo and embrace a period of unease, members of an organization must come to have a view that (1) change is needed and/or desirable to increase program and/ or personal effectiveness; (2) the proposed new initiative will have the effect of increasing program and/or personal effectiveness; and (3) the adoption and implementation of the proposed new initiative are feasible. Thus, clinical administrators and their line staff must be of one accord that current program functioning is ineffective or inadequate in some significant part. This allows for a willingness to explore new clinical initiatives. Next, the new clinical initiative proposed must be seen as capable of meeting the challenge of increasing program and/or personal functioning and promoting greater effectiveness (i.e. must be seen as responsive to the need identified). In that regard, it becomes important to be able to cite a body of research indicating the proven ability of the proposed initiative to promote greater effectiveness with clients, and in settings comparable to those in which the new initiative is being introduced. To embrace it, the staff must be convinced of the greater utility of the new initiative for their organization and themselves. Finally, program staff must view the new initiatives as capable of being adopted by themselves and their program. That is, the new initiative must not be seen as demanding human or material resources that exceed program or individual capacity, and the initiative suggested for adoption must appear capable of being learned and incorporated into daily routine. An individual, or individuals, seen by the organization as having expertise (i.e. credibility) in the area in which change is being advanced, is typically seen as essential to the change process.

It is essential, then, to prepare the organization to accept a need for greater effectiveness in a given area, on the one hand, and to accept the utility of the proposed new clinical intervention for meeting that need, on the other. Nonetheless, preparing the organization for change is an area that has received far less attention

than it merits from both the research and service communities. As suggested above, research has concentrated far more on knowledge development and the identification of effective treatment initiatives than in understanding strategies essential for their acceptance and adoption. At the program level, to the extent new initiatives are introduced, they are often mandated with the expectation of acceptance and adoption, and without use of a process designed to gain staff understanding and support. Without preparation for change, there is the danger that the organization and its staff will be slow and unenthusiastic in adopting new procedures, and lack appreciation for the need to implement new procedures with fidelity to the selected model and/or lack concern for the long-term maintenance of those procedures.

Preparing the Organization to Adopt the New Initiative

With acceptance of a need for change to achieve greater clinical effectiveness, and of the utility of the proposed initiative to accomplish that, the next task becomes one acquisition of skills. Staff must be given the capacity to implement the new initiative with fidelity to the model found effective in other settings. That is, there must be administrative support for the tasks necessary to achieve adoption and implementation, training to permit the acquisition of new skills, and supervision to guarantee the continuing application of those skills with appropriate fidelity. Administrative support translates to making both time and resources available for training and supervision as well as providing visible continuing commitment to the new initiative as significant to program functioning. In contrast to the limited attention and literature devoted to other aspects of the change process, a great amount of attention has been paid to the training needed to achieve acquisition of the skills necessary to implementation with less attention paid to the supervisory strategies that can be seen as essential to implementation with continuing fidelity. In the latter regard, the risk of "drift" from the program model found to be effective has been well documented in earlier work.

Because training to achieve acquisition of skills is of unquestioned importance and has received the greatest attention in the field's literature, a particular attention will be paid to training by us as well. A first step in promoting training has been seen as the development of manuals detailing the step-by-step implementation of the proposed initiative. At the same time, it has become clear that dissemination of manuals alone is not sufficient to promote widespread adoption and implementation. Interpersonal contact has been found

indispensable to training with a particular emphasis on making use of trainers experienced with the initiative who can convey, thereby, an understanding and confidence in its capacity to be incorporated by program staff and to make a difference in program functioning. Training also involves the use of pre-training homework assignments, workbooks, role playing, and skills practice exercises, with an attention to the environment of learning such that the surroundings employed can be seen as being comfortable and nonthreatening. Increasingly, as well, there is a concern with getting away from the traditional single-shot training that ignores concerns about drift with the passage of time from the training event, a drift that is capable of reducing both fidelity and enthusiasm. Thus, there is an interest in incorporating booster sessions as a continuing education strategy as well as troubleshooting, or coaching, as a strategy for dealing with any issues or problems that emerge as trainees make effort to apply what they have learned in the real-world experience of clinical programming. It is noteworthy that both booster sessions and troubleshooting call for a commitment to the training process of greater duration and expense than that which is typically made by organizations. Finally, one has to acknowledge the high rates of counselor turnover common to many treatment settings. This creates a need to have a system in place for developing the skills of new staff for the implementation of the initiative in question (i.e. that create a need to make ongoing training and support available to assure the organization's capacity to sustain the initiative adopted).

Clinical supervision plays an additional and critical role in the change process. Supervision can serve as a primary source of support and monitoring to assure fidelity, and can provide a mechanism for continuous quality improvement as well. A challenge lies in the fact that training and supervision will typically be the responsibilities of different people. Trainers, as noted above, can be seen as most authentic and knowledgeable when drawn from the ranks of those who have themselves seen and employed the proposed initiative. They constitute the outside experts whose credibility rests, in part, on their having had experiences different from those of program staff. Clinical supervisors are part of the ongoing organization staff. It is essential that they be so if they are to provide continuing monitoring and support. This means that for some period of time supervisors will require continuing access to those outside experts to assure that they have the continuing support they will need to play their roles properly in implementing and sustaining change.

Knowing that change can be a painful and/or a difficult process, some have employed incentives, particularly financial inducements, to support the adoption of new initiatives. Single State Agencies and third party payers have made effort to increase motivation for use of science-based treatments through the availability of purchasing levers such as regulations requiring treatment standardization, contractual requirements to employ empirically supported treatments, and the imposition of performance standards for reimbursement purposes. These material inducements for change still need to be accompanied by the strategies described above in preparing the organization to accept a need for change and developing activities for the adoption of change. Moreover, it is well to remember that while material incentives can have unquestioned utility, we work with people who are in the helping business, and if the proposed change provides promise of benefitting their clientele while making realistic demands on themselves and their organizations, counselors are likely to be ready allies in acquiring those skills that will permit them to perform their helping roles with greater effectiveness. Regardless, the promise of increased competence, and the work that will be demanded to make good on that promise, suggest that one incentive to be uniformly made available is continuing education credit units as those may contribute to licensure or certification.

A further aid efforts to promote the adoption of new initiatives and to training in particular, has been the rise of the Internet putting us within a keystroke of information that can be provided in an appealing medium, often making use of interactive programming that can simulate the action of interpersonal programming. With the advent of computer-based training and online learning, a significant barrier has been removed for those wishing to continue their learning, but finding it difficult to do so due to responsibilities associated with their full-time employment. The Internet is accessible during and beyond the normal work-day, vastly increasing the availability of training opportunities. Online teaching, which can occur 24 h a day with an available Internet connection, offers a low-cost option for training, booster sessions, and an alternative for reaching new hires in the addictions field which is significant in light of the field's high turnover. Moreover, the new technology holds the potential for individualized instruction to help maintain and increases the knowledge and skills. To an increasing degree, new materials will be capable of being disseminated through different online, multi-media formats (e.g. video, webinars, podcasts, simulations, virtual tours, real case studies, demonstrations designed to stimulate and capture attention, etc.) with a capacity to meet the needs of different learning styles (e.g. visual or auditory learners) and schedules. While the Internet is certain to become increasingly important to knowledge application efforts, a single caution needs to be raised regarding that use. To date, interpersonal, as compared to impersonal, change strategies have been found to be the more effective. Impersonal strategies investigated have made use of print media. It remains to be seen to what extent interactive programming through the Internet can reduce the distance between audience and change agent (i.e. can simulate interpersonal strategies and achieve the adoption and implementation of new treatment).

CONCEPTUALIZING THE CHANGE PROCESS

Clearly, the successful incorporation of any new clinical initiative demands a process of organizational change. If the comfort of the status quo is to be overcome and knowledge application achieved, there will need to be a plan for allowing members of an organization to understand, accept, adopt, manage, and preserve that change. Leaders and managers within the organization play a special role in having a greater capacity than others to support or frustrate change by virtue of their greater control over resources and the administrative machinery of an organization, but everyone whose roles and functioning will be impacted by the change should be, and should feel themselves to be, a part of the process if they are to adopt and sustain change. Conceptual frameworks and models of change have been described in the literature and we offer a brief synthesis and integration of their common elements.

In general, there are only a few brief steps described as characterizing the change process. Across most conceptual models there is a planning phase, an action or implementation phase (carrying out what was planned), and an evaluation phase. In action steps, this translates to (1) introduction of the rationale for change with particular attention to the reasons for believing the intervention under consideration can enable the organization and individual to function more effectively; (2) adoption with specific regard to understanding and accepting the incorporation of the intervention into organizational functioning; (3) implementation with specific regard to making use of and testing the fit of the intervention into clinical practice; (4) sustainability with regard to setting up structures to permit the routine use of the intervention with an attention to fidelity to the model adopted; and (5) assessment of the utility of the intervention for the organization with an implied capacity for modification to the change process based on the results of the evaluation. The major differences between conceptual models typically lie in the number of detailed steps to the action plan or the elaboration of principles explaining the process. In all instances, organizational change is viewed as dynamic and participatory where those expected to implement change are not passive recipients of information and direction, but are active in assessing, questioning, and understanding the demands to be placed on them and the larger organization, and the benefits and difficulties associated with the adoption of change.

Since the process of change involves an active exchange between change agents and change adopters/ implementers, there is an implication that the initiative targeted for adoption may be modified to fit the organization's circumstances. Earlier, we described the phenomenon of "drift" as a negative activity in which there was the risk that, overtime, the initiative as practiced could become increasingly dissimilar to the initiative as adopted. Thereby, the initiative would become different from the model whose research base makes it appear worthy of being adopted by the organization. While drift from the model adopted can be seen as undesirable, there is another kind of modification that can be seen as inevitable even as it demands caution in its use.

Organizations differ in the nature and characteristics of clients served, staff, resources, and the physical structure in which services are offered. Those differences can be significant for the expression of a strategy to be adopted by an organization. An aftercare strategy found effective with a client population having limited responsibility for childcare may need to include elements responsive to the needs of a population with a greater number of dependent children. That same model developed in association with a largely voluntary population may need to be adopted for use by any organization whose clientele make it necessary for staff to work with significant numbers of parole and probation agents, and so on. The key here is that the intervention, in its basic structure and strategy, is found appropriate to the needs of the organization and its clientele, but in terms of selected elements may need to be tweaked to fit the organization's circumstances. Arguably, the process of adaptation is very nearly inevitable, but the adaptation demanded can be so extreme as to make necessary a model so different from its research-based original that it must be regarded as an essentially new, or at least, drastically altered intervention demanding its own evaluation. There are, unfortunately, no hard and fast rules for making the determination of when adaptation has crossed over to innovation, but it is a determination that needs to be made as best as the change agent and organization can. Where the intervention has lost critical association to the research-based model in structure and strategy, it risks failure frustrating clinical staff at the treatment setting, and defeating any opportunity to encourage adoption of the research-based model by others aware of its failed effort.

Just as organizations differ in their similarity to the organizations on which an intervention's effectiveness was established, organizations differ from one another in readiness to adopt innovation. Organizations differ in receptivity to new information and change based on past experience, individual staff characteristics, leadership, external pressures, and so on. The extent to which some organizations will be early adopters and others will lag behind or reject change altogether is well-known and has been widely reported. While an awareness of these differences is useful to any effort to induce or encourage change in practices in any one organization, it can be of great importance and utility in efforts to encourage changed practices over a large number of organizations. Thus, with the identification of organizations more and less accepting of change, effort can be made to first encourage an adoption of new practice in those organizations most likely to be early adopters for purposes of demonstrating to others that change is possible, need not be painful, and can reap benefits for the individual and the organization. There is also a capacity for change agents to work through issues related to encouraging adoption of the specific intervention with organizations most likely to act cooperatively with them. Significantly as well, change agents have opportunity to build confidence in their own capacities to achieve goals of adoption of new practices by working initially with organizations likely to support success.

A consistent message throughout this discussion is that organizational change processes are complex and involve many factors in terms of the organization's history, staffing, current functioning, and external pressures. Given that complexity, and the state of knowledge regarding organizational change strategies, the capacity to orchestrate change is both art and science. As will be explored below, we have need to expand the science even as we recognize our efforts are likely to continue to involve some degree of art in their elaboration.

DEVELOPING A SCIENCE OF IMPLEMENTATION

Even as we describe efforts to achieve the adoption and implementation of research-based clinical initiatives as an urgent issue, we find ourselves with only a modest knowledge base available to guide those efforts. It is more than a decade since the Institute of Medicine (IOM) alerted the field to the gap between research and practice, and to the need to develop a research base to guide the development of evidence-based approaches for effecting knowledge application. The IOM report stimulated a research focus on organization change (i.e. on the process of gaining the adoption and implementation of new initiatives by a treatment program). Without the findings from such research, we find ourselves in the embarrassing position of seeking the application of research-based clinical initiatives

through the use of untested application efforts. In fact, primarily because of work outside the substance abuse field, the situation is not nearly that bleak as we have the capacity to adapt findings from work undertaken with organizations in related health and service fields even as we have begun testing additional strategies specific to our field and its workforce. It is safe to say we are now, however belatedly, earnestly engaged in developing the science base necessary to the effective diffusion of innovations. As we develop that science base, four issues appear worthy of consideration.

Focus on the Practical

In considering strategies of organization change for study – just as should be the case in selecting researchbased treatment initiatives to be transferred - there is a need to be aware of the capacity of each organization to marshal the resources needed to participate in a program of adoption and implementation. If the knowledge application strategy demands resources in terms of computer capability that an organization doesn't have and can't acquire, or includes a training regimen demanding either time or dollars (as for off-site activity) that an organization cannot generate, the organization change strategy will need to be modified or abandoned. Arguably, any knowledge application strategy (i.e. organization change strategy) adapted from other fields, or developed for use with substance abuse programs, should make realistic demands on the resources of its most modestly endowed programs. That is, we should be concerned with developing knowledge application strategies that have the broadest possible potential for use. As we will discuss below, there is one possible exception to this general principle. For now, however, we are sufficiently familiar with the development and testing of clinical innovations having a life span confined to the length of the federal grant under which they have been implemented, to make effort to avoid recapitulating that situation in the study of knowledge application. We cannot afford the testing and development of instantly irrelevant strategies of knowledge application and should not tolerate such activity in clinical research.

In that regard we might add a word specific to the selection of clinical initiatives for adoption and implementation. Researchers, involved with university-supported treatment programs, and/or allying themselves with treatment agencies, to which they bring substantial resources, may find themselves exploring the effectiveness of treatment initiatives with limited capacity for adoption by other, typical, organizations. Any of several factors may put a clinical initiative out of reach of the typical program: a treatment model may make unrealistic demands on a program's physical structure (e.g. specialized individual and group counseling rooms,

facilities specific to the needs of particular populations such as mothers and their children); may conflict with immutable organizational policies and procedures (e.g. hours and days open for business); or may require staff and/or technology to which an organization lacks access. Before an increased interest was developed in securing the adoption and implementation of clinical initiatives, it was of less consequence whether or not an initiative could meet the needs of the typical treatment organization. As knowledge application has become a significant concern, the degree to which a clinical initiative meets a program's resource availability comes to have increased importance. Noticeably absent throughout the knowledge development process is the lack of attention to costs. Price tags have not been attached to the initiatives offered for purchase (i.e. adoption, implementation, and sustainability) by service providers. The clinical initiative that demands inaccessible resources is quite simply irrelevant to the process of knowledge transfer. This begs a question for the agency that funds clinical research: to what extent should it restrict funding to those clinical initiatives that appear to make realistic demands on available resources.

An Eye to the Possible

While we would argue for clear bias in favor of funding those studies of both clinical initiatives and knowledge transfer strategies that make realistic demand on available resources, we acknowledge the need for a modest investment in those initiatives and strategies that demand greater than typical resources. Such targeted investment can be made to satisfy two needs of the field. First, if we are to convince those providing governance to our field of a need for change in policy and/or financing, we will need evidence to support the change. A clinical case in point lies with a growing enthusiasm among some clinicians and clinical investigators for adoption of a recovery model of behavior change such that substance abuse treatment, as currently delivered, is viewed as a part of the process of effecting long-term behavior change rather than as the totality of that process. The recovery model can then be seen as demanding a period of continuing care posttreatment involving long-term monitoring and support. The recovery model would appear to demand a reconfiguration of treatment and the inclusion of services and a time frame well beyond current procedures. It will be essential to marshal evidence of the program effectiveness of service delivery strategies based on the recovery model paradigm if we can expect to see its adoption as treatment policy and the funding that a new and expanded service delivery system would require. Similarly, in terms of knowledge transfer, one can anticipate that continuing breakthroughs in distance learning, as highlighted above, make it essential that we conduct study allowing us to plan for the use of the electronic media and of electronic equipment that is not now available across all programs, but that almost certainly will become broadly available over the next several years.

Practice to Research

To this point in our discussion and in the field, knowledge application has focused on the transfer of clinical information and strategies from research to clinical practice. That is, we deal with a one-sided discussion such that new information flows in one direction only. Research is employed to influence practice, but practice is given no – or at best limited – opportunity to influence research. However, it is apparent that the more relevant the clinical research undertaken, the greater its likelihood of adoption. Research conducted on clinical issues volunteered by providers as being significant to them would appear to possess obvious clinical relevance.

Policy Change Research

A final area of concern involves an issue even less likely to be addressed than capturing the research concerns of clinicians. Again, knowledge application efforts have targeted treatment organizations, while as suggested above – policy makers may be the appropriate audience for the translation of research findings into new regulation, and changed levels and targets for financing. As obviously critical as it would seem to be to develop a knowledge base to inform policy change, there is little evidence of enthusiasm for any such effort. In part, work with policy makers is seen as foreign to the task of research and far beyond researchers' area of expertise or comfort. As noted, the research community has only come recently to accept a responsibility for changing practice. Influencing policy is more than another step: it is a leap. Moreover, study to understand strategies for effecting change in policy will require methodology far removed from the clinical trials paradigm of which funding agencies are so enamored. However, if policy change is the intended outcome of some portion of our research it behooves us to understand how to accomplish that objective. That will require knowledge application strategies appropriate a specialized audience and particular set of issues.

SUMMARY AND CONCLUSIONS

The substance abuse field has, understandably, concentrated its attention on a first task of knowledge development while assuming modest responsibility for sharing that knowledge through means other than the scientific journals. Thus, the emphasis has been on

knowledge dissemination and, in that effort, the written word has taken precedence over all other means of information sharing. More recently, there has developed a concern with knowledge application, that is the adoption and implementation of new practice, and the recognition that knowledge application demands a greater - and different - kind of activity, one that necessitates organizational change. That is, in accommodating new clinical initiatives the organization is, in some measure, transformed. Consequently, the process of bringing about knowledge application (i.e. of achieving the adoption and implementation of new initiative) is an organizational change process. That process has been found best accomplished through interpersonal contacts, making use of an external change agent and involving a staged sequence of events beginning with engaging organization staff in appreciating a need for the new initiative to allow themselves and the organization to function more effectively, and leading ultimately to the development of a strategy for the maintenance of the new initiative after initial adoption and implementation, and for evaluating its utility to the organization. There is, too, need to make knowledge application the subject of study, in terms of strategies with immediate potential, and with an eye to the future and particularly to the strides being taken in the development of strategies of distance learning.

While we find ourselves in the position of playing catch-up in acquiring knowledge application strategies appropriate to our field, there is good reason to believe that continuing progress is possible. Although the congressional action separating research activities from services support at the federal level has, in our judgment, complicated the task of transferring research to practice, the two organizations created - NIDA and SAMHSA – have nonetheless taken steps to increase our capacity to conduct knowledge application. The CSAT within SAMHSA has committed itself to the constant updating and maintenance of a registry of research-based interventions for adoption and implementation by treatment programs (NREPP), and has developed as well a regional organization of ATTCs with specific responsibility for knowledge transfer. While modestly funded, and functionally separated from NREPP, the creation of a regional system of organizations with responsibility for encouraging knowledge application provides the essential mechanism for making available the interpersonal contacts to date found necessary to the effective adoption and implementation of new initiatives. At the same time NIDA has, in the last few years, accepted responsibility for developing and testing strategies of knowledge application specific to drug abuse treatment organizations.

It remains to be seen whether these encouraging developments will be maintained and expanded in difficult economic times and with pressures to invest scarce resources elsewhere. To date, the primary strategy for knowledge sharing still appears to be one of knowledge dissemination rather than knowledge application and, however laudable the publication of Treatment Improvement Protocols (TIPs), NIDA Notes, and so on, publications provide information not organization change. Ideally, NIDA, NIAAA, and SAMHSA would join forces (as suggested to them in the legislation dividing them) to work together in (1) the selection of research-based initiatives ready for transfer such that the Institutes, with their oversight of substance abuse treatment research, play a role in extending the great strides undertaken through NREPP, (2) the conduct of knowledge application strategies expanding the institutional resource created by SAMHSA such that the ATTCs are empowered to contract with appropriate change agents (depending on the clinical change sought) to employ interpersonal strategies of knowledge application with evaluation of those efforts jointly by SAMHSA and the Institutes, and (3) a program of knowledge application research by the Institutes involving the development and testing of strategies suggested in significant part by the experiences and judgment of SAMHSA and the service providers ultimately responsible for adopting and implementing change.

SEE ALSO

Improving the Quality of Addiction Treatment, Evidence-Based Treatment

List of Abbreviations

CSAT Center for Substance Abuse Treatment

IOM Institute of Medicine

NIAAA National Institute on Alcoholism and Alcohol Abuse

NIH National Institutes of Health NIDA National Institute on Drug Abuse

SAMHSA Substance Abuse and Mental Health Services

Administration

Glossary

Adoption the process of selecting and employing a new and innovative technology for at least a limited period of time.

ATTC the Addiction Technology Transfer Center is a network of 14 Regional Centers and National Office designed to develop and strengthen the addictions treatment workforce by increasing the knowledge and skills of addictions professionals, and fostering regional and national alliances among practitioners, researchers, policy makers, funders, and the recovery community.

Knowledge application the adoption and implementation of evidence-based practices and associated organizational change.

Knowledge development the conduct of studies and generation of findings having potential for increasing the effectiveness of clinical practice.

Knowledge dissemination the distribution of information about empirically supported treatments.

Knowledge implementation the use of strategies to foster the transfer of evidence-based interventions into practice.

NREPP the National Registry of Evidence-based Programs and Practices is a searchable online database that includes substance abuse prevention, and mental health and substance abuse treatments based on research and available for use.

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Improving Medication Use in Addictions Treatment

Amanda J. Abraham

University of South Carolina, Columbia, SC, USA

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INTRODUCTION

A majority of substance use disorder (SUD) treatment in the United States is delivered in specialty substance abuse treatment settings. There are currently over 13 000 specialty treatment programs in the United States, including community-based programs, opioid treatment programs (OTPs), programs in the Veteran's Administration (VA) system, and treatment facilities located within the corrections system. These programs vary in terms of ownership, funding, treatment modality and services (e.g. outpatient, residential, detoxification, aftercare), and patients served. For example, programs may be owned by private corporations, local or state governments, or the federal government. Treatment programs operate as both for-profit and nonprofit entities and

may receive funding from private insurance, health maintenance organizations (HMOs) and preferred provider organizations (PPOs), government block grants, Medicaid, Medicare, self-payment, and the criminal justice system. Further, programs are located in both hospital and nonhospital-based settings. Substance abuse programs offer treatment for any combination of alcohol use disorders (AUDs), drug abuse and dependence (e.g. opiates, cocaine, methamphetamine), and tobacco dependence. Many programs also treat patients with co-occurring mental health disorders. SUD treatment may also be delivered in general medical settings such as primary care; however, the prevalence of SUD treatment in these settings is unknown.

Substance abuse treatment is typically delivered in individual counseling and/or group counseling sessions.

Available evidence-based treatments for SUDs include behavioral and pharmacologic therapies. Behavioral therapies used in substance abuse treatment include 12-step facilitation therapy, cognitive behavioral therapy, motivational incentives/contingency management, motivational interviewing/motivational enhancement therapy, community reinforcement approach, matrix model, brief strategic family therapy, and dual focus schema therapy. A majority of treatment programs in the United States include a 12-step component that may help explain low rates of medication adoption since 12-step approaches have not traditionally supported the use of medications in SUD treatment.

Medications for the treatment of SUDs are intended for use as an adjunctive treatment to behavioral therapies. In other words, medications are not recommended as stand-alone treatments; rather they are intended for use in conjunction with behavioral therapy. There are currently six medications approved by Food and Drug Administration (FDA) for the treatment of SUDs. These medications can generally be classified into two categories: (1) medications for the treatment of AUDs and (2) medications for the treatment of opiate abuse and dependence. There are four medications FDA approved for the treatment of AUDs: disulfiram, naltrexone, acamprosate, and extended-release injectable naltrexone. There are two medications FDA approved solely for the treatment of opiate abuse and dependence: (1) methadone and (2) buprenorphine. Oral naltrexone and injectable naltrexone are also FDA approved for opiate treatment.

This chapter will (1) describe the pharmacologic properties of each medication and provide a brief summary of clinical trial findings, (2) summarize the literature on the use of each medication in SUD treatment and identify key barriers to the use of each medication, and (3) offer overall strategies for improving the use of SUD medications. (Note that Levo-Alpha Acetyl Methadol (LAAM) is not discussed in this article. For a discussion of LAAM see Treatment Improvement Protocol (TIP) 43. In addition, smoking cessation medications are not discussed here.)

PHARMACOLOGIC PROPERTIES AND CLINICAL TRIAL FINDINGS

AUD Pharmacotherapies

Disulfiram (Antabuse®)

Disulfiram was the first medication FDA approved for the treatment of AUDs in 1951. Disulfiram is an alcohol-aversive medication that causes a severe physical reaction when mixed with alcohol. If a patient consumes disulfiram and then ingests alcohol, a disulfiram–alcohol reaction is produced. The reaction begins 10–30 min after the alcohol is ingested and the adverse effects may include nausea, vomiting, headache, chest pain, weakness, blurred vision, mental confusion, sweating, and difficulty breathing. However, effects vary by individual patient. Disulfiram is available in tablet form and the recommended dosage ranges from 250 to 500 mg day⁻¹.

Findings from clinical trials on the efficacy of disulfiram therapy are mixed. Results emphasize the importance of treatment setting and ongoing supervision of patients. The National Institute on Alcohol Abuse and Alcoholism TIP 49 states that both the level and the quality of supervision received by a patient are important elements in the success of disulfiram therapy and optimum response to the medication requires its use in specialty SUD treatment settings.

Oral Naltrexone (ReVia®)

Oral naltrexone was the second medication FDA approved for the treatment of AUDs in December 1994, nearly 50 years after disulfiram. In contrast to disulfiram, naltrexone is a mu-opioid antagonist medication that blocks the effects of heroin and most other opiates. Naltrexone has been shown to reduce the rewarding effects of alcohol, reduce craving for alcohol, and decrease the likelihood of alcohol relapse. It achieves effectiveness rapidly following the initiation of an oral dose. Naltrexone does not have addictive properties or produce physician dependence, and tolerance does not develop. The oral formulation of naltrexone is taken once daily by patients and is available in 25, 50, or 100 mg tablets.

Naltrexone was found to be effective in clinical trials in the United States but the effect size was small to medium over placebo. Results also indicated problems with patient compliance. A recent Cochrane Review found that naltrexone was associated with reductions in the risk of heavy drinking, number of drinking days, number of heavy drinking days, and amount of alcohol consumed per drinking day.

Acamprosate (Campral®)

Acamprosate was FDA approved for the treatment of AUDs in 2004. Acamprosate's mechanism of action is not clearly understood. However, acamprosate helps modulate and normalize alcohol-related changes in brain activity and reduces symptoms of post-acute (protracted) withdrawal. In contrast to naltrexone, acamprosate is not metabolized by the liver. Acamprosate must be taken three times daily and is available in 333 mg tablets.

While results from European clinical trials of acamprosate support the medication's efficacy, findings from US clinical trials are mixed. European trials found that acamprosate was associated with reduction in drinking days, increased complete abstinence, and increased time to relapse. However, the Combining Medications and Behavioral Interventions (COMBINE) study showed no evidence of efficacy with or without combined behavioral intervention.

Extended-Release Injectable Naltrexone (Vivitrol®)

Extended-release injectable naltrexone was approved by the FDA for the treatment of AUDs in 2006. Injectable naltrexone is microspheric formulation of naltrexone that is administered via monthly intramuscular gluteal injection. The medication has the same mechanism of action as the oral form of naltrexone. It is an opioid antagonist that binds to the opiate receptors in the brain and blocks the action of opioid medication and opiate neurotransmitters. Injectable naltrexone uses a lower dosage of naltrexone than the oral form, so it does not undergo first-pass metabolism in the liver and does not carry the same risk of hepatotoxicity as the oral form.

Clinical trial results showed efficacy in decreasing drinking days compared to placebo and decreasing the event rate of heavy drinking days compared to placebo. Injectable naltrexone also demonstrated efficacy in prolonging abstinence and reducing the number of drinking days and number of heavy drinking days in patients who were abstinent for as few as 4 days before beginning treatment.

Opiate Pharmacotherapies

Oral Naltrexone (Revia®)

Oral naltrexone was FDA approved for the treatment of opiates in 1984. Again, naltrexone is an opioid antagonist that blocks the effects of heroin and most other opiates. Naltrexone cannot be used in combination with methadone or buprenorphine and is less widely utilized in opiate treatment than methadone or buprenorphine. In contrast to methadone and buprenorphine, oral naltrexone is not a scheduled narcotic and is therefore not highly regulated by the federal government.

Patients addicted to opiates must be fully withdrawn for up to 2 weeks from all opiates before beginning naltrexone treatment. During this withdrawal period, many patients relapse to use of opiates. After beginning naltrexone therapy, the risk of overdose death may increase if the patient relapses. The FDA-approved oral naltrexone for opiate maintenance therapy without requiring proof of efficacy in clinical trials.

Extended-Release Injectable Naltrexone (Vivitrol®)

In October 2010, the FDA approved the injectable formulation of naltrexone for prevention of relapse to opiates. A randomized clinical trial showed a lower rate of relapse to opiates over a period of 6 months for

patients receiving injectable naltrexone compared to placebo.

Methadone (Dolophine®, Methadose®)

Methadone was never FDA approved for the treatment of opiate addiction in the United States; however, it has been used since the 1960s to treat opiate dependence. Methadone is a full mu-opioid agonist that works by suppressing opioid withdrawal for 24 h or more. Methadone suppresses opioid withdrawal, blocks the effects of other opiates, and decreases craving for opioids. Methadone is available in several formulations including diskettes, tablets, oral solution, liquid concentrated powder, and intramuscular injection (for patients that cannot take oral medications). Methadone can be used for detoxification, maintenance, and pain management. Patients taking methadone for maintenance are administered the medication daily.

Methadone is a Schedule II narcotic and is highly regulated by the federal government. The medication's production, distribution, and dispensing are subject to the requirements applied to Schedule II controlled substances by the Drug Enforcement Administration (DEA) to prevent diversion and illicit use. There is currently a three-tier system of federal regulation which includes the FDA, DEA, and most recently the Substance Abuse and Mental Health Services Administration (SAMHSA). In May 2001, the regulation and monitoring of methadone maintenance treatment (MMT) shifted from the FDA to SAMHSAs Center for Substance Abuse Treatment (CSAT). OTPs must be accredited by SAMHSA (42 CRF Part 8) and programs must be recertified every 3 years.

The distribution and use of methadone for opiate treatment is restricted to hospital pharmacies and physicians registered to both the FDA and the DEA who were authorized to dispense the medication in licensed OTPs only. Licenses are obtained through CSAT. In some states, methadone treatment is further restricted by state governments and agencies at the county and municipal level.

Patients receiving methadone must go to a methadone clinic daily to receive their dosage of the medication. After a period of time, some patients may be given take-home privileges. However, this varies based on state and local regulations.

Buprenorphine (Suboxone®, Subutex®)

Buprenorphine was FDA approved for the treatment of opiates in 2002. Before buprenorphine was FDA approved for opiate treatment it was used for pain management. FDA approval of buprenorphine for treatment of opiate dependence was intended to increase access for opiate addiction by allowing physicians in office-based settings to prescribe the medication.

Buprenorphine is a partial opioid agonist compared to methadone and heroin which are full opioid agonists. Buprenorphine has a lower risk of abuse, addiction, and side effects compared to full agonists. Buprenorphine can be used for detoxification, maintenance, and pain management.

There are currently two buprenorphine products FDA approved for the treatment of opioid addiction: Subutex and Suboxone. Subutex is comprised of only buprenorphine and is a partial mu-opioid agonist. Suboxone combines buprenorphine with naloxone and is both a partial mu-opioid agonist and a mu antagonist. The buprenorphine/naloxone combination appears to reduce abuse potential as compared to buprenorphine alone. Naloxone is added to buprenorphine to decrease the likelihood of diversion and abuse. Both Suboxone and Subutex are sublingual tablets that are available in two dosages.

In contrast to methadone, which can be administered only by OTPs, buprenorphine can be administered by waivered office-based physicians. In fact, one of the reasons for the FDA approval of buprenorphine was to facilitate greater access to treatment for opiate dependence, especially in areas of the county that do not have OTPs.

Buprenorphine is a controlled substance (Schedule III drug) that is monitored and regulated by the federal government (i.e. DEA and CSAT). Buprenorphine may be prescribed only by a waivered physician. To qualify for a waiver, physicians must complete 8 h of training; waivers are granted by CSAT. During the first year, physicians can treat only 30 patients at a time. After the first year, physicians may apply to CSAT to treat up to 100 patients.

Prior to 2003, OTPs were not allowed to dispense buprenorphine. However, in 2003, SAMHSA began allowing OTPs to also get certified to prescribe Subutex and Suboxone for maintenance or detox (not pain management). OTPs providing buprenorphine must conform to 42 CRF 8.12 which requires that OTPs provide medical, counseling, drug abuse testing, and other services to patients admitted to treatment. OTPs must also modify their registration with the DEA to add Schedule III narcotics to their registration certificates.

Clinical trials indicate that buprenorphine is more effective than placebo and equally effective to moderate doses of methadone and LAAM in opiate maintenance therapy. Results also show that buprenorphine is unlikely to be as effective as more optimal-dose methadone and, therefore, may not be the treatment of choice for patients with higher levels of physical dependence. Buprenorphine has been shown to be effective in short-term detox as well and may be used with pregnant women and adolescents.

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Research shows that medications are underutilized in the treatment of SUDs. Data from studies of specialty substance abuse treatment providers and prescription/ insurance claims data confirm the low utilization of SUD medications. Despite the availability of four medications for the treatment of AUDs and three medications for the treatment of opiate use disorders, less than 45% of specialty substance abuse treatment programs in the United States prescribe at least one of these medications. Not only are there low rates of adoption of substance abuse medications, but treatment programs have also been very slow to implement medications into routine clinical practice, that is, the diffusion of medications has been slow. Although the extent of use of medications in other health care settings (i.e. settings outside the specialty system) is understudied, data from prescription and health insurance claims reveal low use of medications for SUDs, especially, when compared to the number of prescriptions for medications to treat mental health disorders (e.g. SSRIs).

Use of Medications in Substance Abuse Treatment Settings

There are several sources of data on the use of medications for the treatment of SUDs in SUD treatment settings. A publicly available data source is the National Survey of Substance Abuse Treatment Services (N-SSATS), a self-report mail-based survey conducted by CSAT. This annual survey of substance abuse treatment providers provides a cross-sectional snapshot of substance abuse treatment services delivered by 13 000+ substance abuse treatment programs in the United States. N-SSATS data provide an annual report of the percentage of programs prescribing SUD medications. Table 69.1 shows that the use of buprenorphine (Subutex/Suboxone) increased since FDA approval in 2002 and acamprosate increased since FDA approval in 2004. However, the use of the other SUD medications remains consistently low with no more than 17% of programs reporting use in any given year. Note that N-SSATS data do not distinguish between the oral and injectable form of naltrexone, so it is not possible to determine the percentage of programs prescribing injectable naltrexone from 2006 to 2009. Since N-SSATS data are cross-sectional, it is not possible to examine longitudinal trends in use of medications. (For more information on N-SSATS, see Further Reading.)

In addition to the N-SSATS, there are several research studies that examine use of SUD medications in samples drawn from subsets of the specialty substance abuse treatment system. The samples include programs in the VA, the National Institute on Drug Abuse Clinical USE OF SUD MEDICATIONS 679

TABLE 69.1 Percentage of Substance Abuse Treatment Programs
Using SUD Medications by year

	2002	2003	2004	2005	2006	2007	2008	2009
Disulfiram	17.0	17.0	16.0	16.0	15.9	16.5	16.0	16.2
Naltrexone	13.0	12.0	11.0	12.0	12.8	15.2	15.4	15.8
Acamprosate	*	*	*	8.0	13.3	17.0	18.5	17.2
Methadone	*	*	9.0	10.0	10.1	10.7	8.3	11.3
Buprenorphine (Subutex and Suboxone)	*	5.0	7.0	*	*	14.3	15.0	16.9
Subutex	*	*	*	5.0	6.1	7.5	7.8	7.9
Suboxone	*	*	*	8.0	10.1	13.5	14.4	16.5

^{*}Data not reported.

Data from the National Survey of Substance Abuse Treatment Services (N-SSATS)

Trials Network (NIDACTN), outpatient only programs, and regional samples of treatment programs. Data from these studies examine organizational characteristics associated with SUD medication adoption and implementation and clinician (e.g. physicians, substance abuse treatment counselors) attitudes toward the use of medications for the treatment of SUDs. The theoretical framework guiding a majority of this research is Everett Roger's classic diffusion theory. (For more information on diffusion theory, see Further Reading.)

One major source of data on the use of SUD medications in specialty treatment is the National Treatment Center Study (NTCS) conducted by researchers at the University of Georgia's Institute for Behavioral Research. This family of research studies includes nationally representative samples of privately funded treatment programs, publicly funded treatment programs, specialty AUD treatment programs, and treatment programs participating in the NIDACTN.

Disulfiram

Although the medication has been FDA approved since 1951, there are relatively few research studies that examine the adoption of disulfiram in substance abuse treatment programs. A 2005 NTCS study showed that consistent with diffusion theory, programs were more likely to use the medication if they were based in a hospital setting and had a more professionalized staff (i.e. percentage of master's level or higher counselors). Treatment culture (i.e. emphasis on a medical treatment model) was also a significant predictor of disulfiram adoption. Another NTCS study revealed that the use of disulfiram decreased significantly from 1995 to 2004 from 51.6 to 35.7% in a nationally representative sample of privately funded treatment programs. The same study showed that government-owned programs, programs with a physician on staff, and programs

with greater revenues from private insurance were more likely to adopt disulfiram.

A study of counselor attitudes toward the use of disulfiram in publicly funded treatment programs showed that only 28.2% of counselors were unable to rate the effectiveness of disulfiram, indicating that the medication was widely diffused among counselors. Counselors in recovery and counselors with strong 12-step orientations held less favorable attitudes toward disulfiram. Counselors who received disulfiram specific training and worked in programs that currently used the medication also viewed the medication as more effective.

In summary, a number of organizational factors facilitate the use of disulfiram including medical infrastructure, access to prescribing staff, government ownership, and revenues from private insurance. Exposure to disulfiram via medication-specific training and use in the treatment programs were associated with more positive views of the medication by counselors. Barriers to the adoption of disulfiram include treatment culture at both the organizational and the clinician level.

Oral Naltrexone

A majority of research on the use of AUD medications in specialty treatment programs focuses on oral naltrexone. For example, in a study of treatment programs in New England, researchers found that agency mission, program size, counselor educational level, involvement with managed care, and use of selective serotonin reuptake inhibitors (SSRIs) were associated with oral naltrexone adoption. A set of studies using data from the NTCS revealed that program size, accreditation, staff professionalism, access to a prescribing physician, and percentage of patients paying with private insurance were positive predictors of oral naltrexone adoption. Treatment culture (e.g. 12step orientation) and percentage of referrals from the criminal justice system were negatively associated with use of oral naltrexone.

A pair of studies examining oral naltrexone prescribing patterns in a sample of physicians found that patient insurance coverage, physicians' perceptions of effectiveness, and exposure to information about oral naltrexone were associated with prescribing behavior. Barriers included concerns about patient compliance and the cost of the medication. A study of both physician and nonphysician clinicians (i.e. counselors) found that only 15% of clinicians prescribed or recommended oral naltrexone often. Both sets of clinicians were more likely to prescribe or recommend the medication if they worked in an organization that supported use of the medication. Clinicians cited lack of information about the medication, perceptions of clinical effectiveness,

treatment ideology, and concerns about the cost of the medication as barriers to adoption. Other studies cite lack of knowledge and confidence in the value of adjunctive AUD medications as barriers to use of oral naltrexone.

A 2009 NTCS study of counselor attitudes toward oral naltrexone found that 58.1% of counselors were unable to rate the effectiveness of the medication, indicating a moderate to low level of diffusion. Counselors receiving medication-specific training, counselors working in programs that currently used oral naltrexone, and those holding more favorable attitudes toward SUD medication adoption held more favorable attitudes toward the medication.

Key facilitators of oral naltrexone adoption include staff professionalism, use of SSRIs, program size, accreditation, and patient payer source. Organizational barriers to the adoption of oral naltrexone include ideological barriers (i.e. medications are not consistent with the program's treatment ideology), lack of knowledge about the medication, resource constraints, and lack of access to prescribing staff. Exposure to oral naltrexone via training and use in employer organization are associated with more favorable attitudes among counselors. Studies of clinician attitudes identify patient noncompliance, cost, ideological barriers, lack of information, and perceptions of clinical effectiveness as prominent barriers.

Patient Compliance with Oral Naltrexone and Disulfiram

Several research studies have investigated patient compliance with oral AUD medications since this has been identified as a critical barrier to wider utilization. Specifically, prescription and insurance claim data confirm low rates of patient compliance with the medication. A study in the New England VA using pharmacy data showed that less than 50% of patients received oral naltrexone prescriptions for more than 2 months and approximately 20% of patients received their prescription for 6 months or more. The same was true of disulfiram prescriptions. More specifically, 38.8% of patients received disulfiram for 1 month or less and 36.5% of oral naltrexone users received the medication for 1 month or less. Two additional research studies show low rates of patient compliance with oral naltrexone. First, a study using paid health insurance claims data revealed that less than 20% of patients in this population were supplied oral naltrexone for more than 1 month. Second, a study of oral naltrexone prescription persistence for AUDs (2000–2004) using data from Marketscan commercial claims and encounters database (50 large US employers) revealed that more than 85% of patients failed to fill their prescription for 80% or more of a 6-month treatment period.

Acamprosate

Two organizational-level studies examine the adoption of acamprosate in specialty treatment programs. A 2006 NTCS study used bivariate analyses to identify predictors of early acamprosate adoption (adoption in the first year of FDA approval) and found that early adopters of acamprosate were more likely to be hospital based, accredited, have access to a prescribing physician, have fewer referrals from the criminal justice system, and to use SSRIs. A 2010 NTCS study found that adoption of acamprosate was associated with participation in research, staff professionalism, and access to a prescribing physician.

A 2009 study of counselor attitudes toward acamprosate showed that 76.1% of counselors were unable to rate the effectiveness of the medication, indicating a low rate of diffusion. The study also showed that counselors with a strong 12-step orientation rated the medication as less effective and counselors with positive attitudes toward general SUD medication use rated the medication as more effective. Counselors working in programs that currently used acamprosate viewed the medication as more acceptable for use in AUD treatment.

In summary, facilitators of acamprosate adoption in treatment organizations include medical infrastructure (hospital based), accreditation, staff professionalism, access to a prescribing physician, and use of SSRIs. Exposure to acamprosate via medication-specific training and use in the treatment program were associated with more positive attitudes toward acamprosate among counselors. Key barriers to adoption are treatment culture and referrals from the criminal justice system.

Extended-Release Injectable Naltrexone

A 2010 NTCS study of early adoption of injectable naltrexone for alcohol dependence in privately funded treatment programs revealed that program size, percentage of patients paying with private insurance, and programs using other alcohol pharmacotherapies (i.e. either disulfiram, oral naltrexone, or acamprosate) were more likely to be early adopters of injectable naltrexone. The study also identified barriers to the adoption of injectable naltrexone including the cost of the medication, lack of knowledge, treatment culture, and access to a prescribing physician. Patient compliance was not identified as a barrier to use the medication.

Methadone

Since methadone treatment is restricted to licensed OTPs (currently numbering roughly 1230), this section outlines key barriers associated with methadone treatment, focusing specifically on MMT. A major barrier to the treatment of opiate dependence is related to access. First, the number of patients in need of opiate treatment in the United States exceeds the number of available

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slots in methadone clinics. Since the number of methadone clinics and the location of clinics are limited, many persons in need of opiate treatment do not have access to a methadone clinic. For example, some states do not have methadone clinics. Second, opiate abusers have been reluctant to seek treatment in methadone clinics due to the stigma associated with MMT and the inconvenience of required daily visits for dosing. In fact, it is estimated that only 20% of those in need of opiate treatment seek treatment in methadone clinics.

The stigma surrounding opiate abuse and opiate treatment is significant. Historically, opiate abuse has been considered a moral weakness rather than a medication condition or disease. MMT has been viewed as a 'substitute therapy' that replaces one addiction with another addiction. This stigma affects the patients, the treatment programs and their staff members, the general public, the criminal justice system, and the wider medical community. Further, the media has perpetuated negative views of methadone patients and methadone clinics.

Some of the negative consequences of this stigma include isolation of opiate treatment from mainstream medicine, community resistance to OTPs due to patient loitering, drug sales, diversion, and lack of funding for methadone treatment (e.g. Medicaid does not cover methadone treatment in all states). To reduce the potential for diversion, methadone clinics have employed a number of strategies including closely monitored take-home dosing. However, research shows that methadone is more likely to be diverted to opiate-dependent persons who cannot afford methadone treatment rather than recreational use.

In order to improve use of MMT, efforts are needed to address the high levels of stigma surrounding methadone clinics and methadone patients. Strategies for reducing stigma include national educational campaigns to the general public and medical community, increased training and education for substance abuse treatment professionals, and prohibition of loitering and strategies to reduce and prevent diversion on the part of methadone programs.

Research actually demonstrates a number of positive outcomes associated with MMT including a decrease in opioid use and related crime, increase in employment, decrease in transmission of HIV, decrease in needle sharing, improvement in physical and mental health, and decreases in overall mortality from opiate use disorders. However, these positive outcomes are not widely disseminated to the general public or medical community.

Buprenorphine

Several studies examine the early adoption of buprenorphine in substance abuse treatment programs. An NTCS study of early buprenorphine adoption (2002–2005) found that adoption of buprenorphine increased from 6.4 to 14.1% over a 1-year period. Privately funded programs were significantly more likely to adopt the medication than public sector programs. Multivariate analyses showed that adoption was greater in accredited centers, for-profit facilities, organizations offering detoxification services, and programs using oral naltrexone. A study of VA treatment programs also showed increases in the use of buprenorphine from 2003 to 2005. Another study that examined early adoption of buprenorphine using 2003 N-SSATS found that use of buprenorphine was greater in OTPs, naltrexone-using centers, and programs offering medically supervised withdrawal.

Several studies examine clinician attitudes toward buprenorphine. A 2005 NTCS study examined diffusion of buprenorphine among substance abuse treatment counselors in a national sample of private and publicly funded treatment programs. This study found that a majority (66.5%) of counselors were unable to rate the effectiveness of buprenorphine (i.e. buprenorphine was not widely diffused among treatment counselor). Exposure to buprenorphine via specific training and use in the treatment program were associated with more favorable attitudes toward the medication. Counselors with a stronger 12-step orientation held more negative attitudes toward buprenorphine.

A 2007 study of counselor and client attitudes toward buprenorphine in three different treatment settings (i.e. methadone, outpatient, and residential settings) found that intentions to use buprenorphine were neutral in methadone and outpatient settings and negative in residential settings. Clients were less informed about buprenorphine compared to other opiate medications. Overall, perceptions of buprenorphine were neutral, with the most positive views of the medication being found in outpatient treatment settings.

A more recent study of physician attitudes toward buprenorphine found that willingness to prescribe buprenorphine varied based on the physicians level of experience with the medication (i.e. experienced, novice, nonprescribers). The study indicated that evidence of clinical effectiveness and preferences for alternative treatments for opiate dependence did not influence physician willingness to prescribe buprenorphine. However, training of clinical staff on buprenorphine, access to behavioral health services (counseling, mental health services, supportive services), an effective referral system for alternative drug treatment, adequate time per patient visit, and concerns about chronic pain medications strongly affected their willingness to prescribe buprenorphine. More experienced buprenorphine prescribers rated reimbursement as significantly more important than novice or nonprescribers.

Buprenorphine addresses a number of the limitations of methadone, namely access to treatment, daily attendance requirements, and diversion. However, there are barriers to the use of buprenorphine. Key barriers include lack of information, lack of clinician training in the use of buprenorphine, lack of access to waivered physicians in specialty SUD treatment settings, the cost of the medication, clinician and patient attitudes toward buprenorphine, and state-level barriers such as funding and policy (e.g. support from the Single State Authority (SSA)).

Comparing the Use of SUD Medications

While a majority of research focuses on the use of a single SUD medication, three studies compare overall utilization of SUD medications. First, a 2008 study examined availability of SUD medications in private health plans, that is, whether the medications were included on formularies and placement of the medications on co-pay tiers. The study showed differences in access to AUD and opiate medications. In general, AUD medications were most accessible. Approximately 6% of health plans excluded naltrexone and only 1.3% excluded disulfiram products. However, 31% of insurance products excluded buprenorphine from their formulary and more than 80% of insurance products placed buprenorphine on the highest cost-sharing tier.

Second, data from the IMS National Prescription Audit (NPA) Plus (TM) database of retail pharmacy transactions were used to evaluate trends in US retail sales and prescriptions of SUD medications. National data showed that the overall prescriptions for AUD medications increased from 2003 to 2007, growing from \$30 million in sales to \$78 million in sales. According to the researchers this growth was largely attributed to the introduction of acamprosate to the market in 2004. Prescription of buprenorphine (i.e. Subutex and Suboxone) increased over the study period as well, growing from \$5 million in sales to \$327 million in sales. While the sales of SUD medications have increased, they are still extremely low when compared to sales of antidepressants, estimated at \$15 billion in 2006.

Third, a 2010 NTCS study compared use of SUD medication in privately funded treatment programs. Programs reported greater use of buprenorphine for detoxification (32.8% of programs) compared to the use of buprenorphine for maintenance (20.9% of programs). Roughly 22% of programs reported using oral naltrexone for the treatment of opiate dependence. Turning to AUD medications, approximately 32% of programs reported using oral naltrexone for AUDs and acamprosate while only 24% reported using disulfiram. The study also examined the percentage of eligible patients receiving each SUD medication. Results

showed that a greater percentage of opiate patients received medications than AUD patients, indicating the opiate medications are more widely utilized than AUD medications.

STRATEGIES FOR IMPROVING USE OF SUD MEDICATIONS

As described throughout this chapter, medications are underutilized for substance abuse treatment. Researchers have identified a variety of barriers to the use of SUD medications including stigma, state policy and funding, public and private insurance coverage and reimbursement, treatment culture, clinician attitudes, and patient-related barriers. To improve the use of SUD medications, these barriers must be addressed. Given this wide range of barriers, improving the use of SUD medications will require a number of strategies. This section outlines potential strategies for improving the use of medications for the treatment of SUDs.

Stigma associated with SUD treatment among the American public and wider medical community must be addressed. While endorsement of the medical view of SUDs (i.e. SUDs are a disease similar to diabetes and hypertension) has increased over the past two decades, many Americans continue to view SUDs as moral weakness. An effective strategy for reducing stigma is more effective educational campaigns and information dissemination about substance abuse treatment and the use of SUD medications to the American public (e.g. through media campaigns sponsored by federal health care agencies). If Americans are more informed about SUD treatment, perhaps there will be more acceptance of the medical view of SUDs, leading to greater support for treating SUDs on par with other medical conditions. To increase knowledge about SUDs in the wider medical community, medical schools should incorporate training about SUDs into the curriculum. As of 2010, there are only a few medical schools that offer specialty training for SUDs and this training is optional.

Improving the use of SUD medications will require major changes in state policy and funding. A majority of SUD treatment is funded by federal block grant funds allocated to states and administered by the Single State Authority (SSA). Medicaid, administered through the state system, also plays a role in the funding of substance abuse treatment services. Therefore, the delivery of substance abuse treatment services, including SUD medications, varies by state. Each SSA, for example, decides whether block grant funds will be allocated for SUD medications and whether the state will actively support the use of SUD medications in substance abuse treatment programs. Further, each state

system decides which SUD treatment services are included in the Medicaid benefit and how much money will be allocated for the selected treatment services.

Policy barriers could be addressed through reallocation of portions of existing state budgets to cover SUD medications and related services. Another strategy is to create more uniform state policy regarding the delivery of substance abuse treatment. Policy could also be altered to include incentives for treatment programs to provide medications for the treatment of SUDs.

Improving the use of SUD medications will also require expanding both public and private insurance coverage and reimbursement for SUD medications. Data show that many states do not include medications in the Medicaid benefit or have limitations on Medicaid benefits for SUD treatment (e.g. low reimbursement rates for SUD medication, no reimbursement for physician time associated with prescribing SUD medications). In fact, a recent study of barriers to SUD medication adoption in public treatment programs revealed that the programs' primary funder would not pay for costs associated with medications, including the medications themselves, physician time, and lab costs associated with medications.

Many private insurance plans also exclude SUD medications from their formulary. For example, a 2008 study showed that 31% of private insurance products excluded buprenorphine from formularies and 55% placed it on the highest cost-sharing tier. Many states also control substance abuse treatment services through contracts with managed care organizations which often limit benefits for SUD treatment services.

These barriers could be addressed through the creation of new billing codes for SUD medication related services, changes in reimbursement for medication related services on the part of Medicaid and private insurers, and reallocating portions of existing substance abuse treatment budgets to cover medications.

The recent parity and health care reform legislation promises to address state policy and funding issues. Specifically, parity legislation, enacted in January 2010, ensures equal coverage for SUDs among private insurers (with 50 or more employees) that choose to cover mental health/substance abuse treatment services. For Americans with such private insurance coverage, access to SUD medications should increase. Health care reform legislation seeks to increase public insurance coverage for SUDs, largely through Medicare and Medicaid. Since health care reform is in the early stages of implementation, it is not yet clear how health care reform will impact the delivery of substance abuse treatment services. However, since Medicaid and Medicare will remain under state control, benefits for SUD medications will continue to vary by state.

Barriers within substance abuse treatment programs must also be addressed, beginning with treatment culture (i.e. ideological resistance to the use of medications). Many treatment programs in the United States are based on 12-step models that traditionally have not been supportive of the use of SUD medications. The 12-step approach views treating SUDs with medications as substituting one drug for another drug. In fact, research shows that programs with a strong 12-step ideology are less likely to use SUD medications. The development of more effective dissemination strategies to address lack of knowledge and perceptions of ineffectiveness of SUD medications may be a viable strategy to address ideological resistance to the use of medications in treatment programs.

Resistance to the use of SUD medications extends beyond treatment programs to community-based self-help groups (e.g. Alcoholics Anonymous (AA)) that are part of the recovery process for a majority of patients. Many AA groups and other self-help groups will not accept members who use SUD medications as part of their treatment regimen. In response, new self-help groups that are amenable to the use of medications have emerged in various parts of the United States. Efforts to disseminate information about SUD medications should be targeted to self-help and other community service agencies who interact with SUD patients to address this barrier.

Another critical barrier to improving the use of SUD medications in treatment programs is access to physicians. This barrier can be addressed by increasing funding to cover the costs of employing physicians and nurses in treatment programs through federal block grant dollars and other state funds. This would likely require a change in state policy. Research also shows that a large percentage of treatment programs with access to a physician do not prescribe any SUD medications, suggesting that SUD-specific training for physicians and nurses already embedded in the treatment system is necessary. This could be facilitated through increased funding and incentives for physicians and nurses to obtain specialty SUD training from state and federal funding agencies. Since turnover is a major issue in the substance abuse treatment field, the treatment system must also develop mechanisms to attract and keep physicians and nurses with specialty SUD training.

Another strategy to increase access to prescribing staff is to integrate SUD treatment services with primary care and other general medical settings such as emergency rooms and dental clinics. The federal government and related health agencies are strongly promoting this strategy. However, since a minority of primary care physicians do not have specialty substance abuse training, SUD training and other incentives will likely be necessary to facilitate integration. Each of these strategies will require additional funding and incentives for medical staff to obtain specialty SUD training.

Research consistently finds barriers to the use of SUDs among clinicians, including both counselors and physicians. These barriers include lack of information about medications, perceptions of clinical effectiveness, lack of knowledge about how to implement SUD medications within their treatment settings, lack of training, and general treatment ideology. Educational interventions and SUD specialty training for clinicians, as well as greater dissemination efforts (through written and web-based materials), will be necessary to address clinician willingness to prescribe and recommend SUD medications.

Finally, to improve use of medications in SUD treatment, patient-level barriers must be addressed. For example, research shows that patients lack knowledge of SUD medications as a treatment option. Patient willingness to take SUD medications may also be affected by stigma. To increase patient awareness and knowledge of SUD medications, educational interventions and information dissemination should be targeted at SUD patients. Patients ability to pay for SUD medications is also a key barrier. Since many SUD patients have no insurance, public or private, they are not likely to receive SUD medications. Again, increased insurance coverage and reimbursement for SUD treatment would facilitate greater access to medications.

CONCLUSION

Although there are promising medications available for the treatment of SUDs, these medications are not widely used in the US substance abuse treatment programs or in general medical care settings. In fact, less than 45% of specialty treatment programs prescribe any single medication for the treatment of SUDs. Strategies to improve adoption and implementation of SUD medications include changes in state policy and funding, increased access to physicians through partnering with local primary care physicians and other general medical care settings, increased clinician training in the use of SUD medications, increased dissemination of information about SUD medications to patients, and changes in insurance coverage of SUD medications.

SEE ALSO

Improving the Quality of Addiction Treatment, Evidence-Based Treatment, Dissemination of Evidence-Based Treatment into Practice, Twelve-Step Facilitation Therapy, Methadone Maintenance, Antagonists for the Treatment of Opioid Dependence, Buprenorphine for Opioid Dependence, Naltrexone and Opioid Antagonists for Alcohol Dependence, Acamprosate for Alcohol Dependence, Disulfiram for Alcohol and Other Drug Use

List of Abbreviations

AA Alcoholics Anonymous AUDs alcohol use disorders

CSAT Center for Substance Abuse Treatment
DEA Drug Enforcement Administration
LAAM Levo-Alpha Acetyl Methadol
MMT methadone maintenance treatment

NIDACTN National Institute on Drug Abuse Clinical Trials Network

NTCS National Treatment Center Study OTPs opioid treatment programs

SAMHSA Substance Abuse and Mental Health Services

Administration

SUDs substance use disorders

TIP Treatment Improvement Protocol

VA Veteran's Administration

Glossary

Acamprosate was FDA approved for the treatment of alcohol dependence in 2004. Acamprosate helps modulate and normalize alcohol-related changes in brain activity and reduces symptoms of post-acute withdrawal from alcohol dependence.

Buprenorphine is a Schedule III narcotic that was FDA approved for the treatment of opiate dependence in 2002. There are two buprenorphine products available for opiate treatment, Subutex and Suboxone. Buprenorphine is a partial mu-opioid agonist in contrast to methadone, which is a full mu-opioid agonist. Buprenorphine has a lower risk of abuse, addiction, and side effects compared to full agonists.

Disulfiram was FDA approved for the treatment of alcohol dependence in 1951. It is an alcohol-aversive medication that causes a severe physical reaction when mixed with alcohol.

Methadone is a Schedule II narcotic that has been used for the treatment of opiate dependence in the United States since the 1960s. Methadone is a full mu-opioid agonist that works by suppressing opioid withdrawal for 24 h or more.

Naltrexone there are two formulations of naltrexone FDA approved for the treatment of substance use disorders. The oral formulation of naltrexone was FDA approved for the treatment of opiate dependence in 1984 and alcohol dependence in 1994. The injectable formulation of naltrexone was FDA approved for alcohol dependence in 2006 and prevention of relapse to opiates in 2010. Naltrexone is a mu-opioid antagonist medication that blocks the effects of heroin and most other opiates. Naltrexone has been shown to reduce the rewarding effects of alcohol, reduce craving for alcohol, and decrease the likelihood of alcohol relapse.

Substance use disorders (SUDs) it refers to abuse or dependence of a substance (e.g. alcohol, heroin, prescription opiates, cocaine, marijuana) as defined by the Diagnostic and Statistical Manual of Mental Disorder IV (DSM-IV).

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Drug Decriminalization and Legalization

Wayne Hall, Jayne Lucke

University of Queensland, UQ Centre for Clinical Research, St Lucia, QLD, Australia

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INTRODUCTION

In many developed countries, policies that prohibit adults from using drugs like cannabis, cocaine, and heroin are criticized as ineffective and counter-productive. Critics of these policies argue that it would be a better policy to decriminalize or legalize the adult use of all currently illicit drugs. In this chapter, we consider these arguments with a primary focus on developed countries because these are the settings where such proposals are most often made and where drug use has been most extensively researched.

If we define a rational social policy as one that uses the most efficient means to pursue a society's goals, then there can be no unique rational drug policy unless there is societal agreement on what the goals of the policy should be. Such policy goals, however, depend upon deeper beliefs about the priority that should be given to competing ethical values such as individual freedom and the protection of human health and well-being. These turn on questions about what role, if any, the state should have in restricting adult behavior that primarily harms the

individual. There are major differences of opinion about these issues in most liberal democracies.

According to libertarians, adults should have the liberty to pursue their own choices so long as they do not harm anyone else. Harms arising from drug use that affect the user are solely the user's concern; harms that a user may cause to third parties (such as, car crashes if users drive while intoxicated) or social nuisances (e.g. being kept awake by noisy drunks) are matters for criminal and tort law, respectively. A rational drug policy for a libertarian would therefore be one that allowed any adult to use the drug if they wished. The only restrictions would be limiting this use to those over the age of adult autonomy (18 or 21) and banning use by adults in situations that put others at risk, for example driving a car while intoxicated.

Legal moralists, by contrast, believe that (at least some types of) drug use is inherently wrong, for example, because drugs are intoxicating or undermine autonomy, and argue that such wrongful behavior should be criminalized. For legal moralists, a rational drug policy would be one that prohibited the use of the drug and imposed

criminal sanctions on those who used it. Any societal costs in enforcing the law are irrelevant from this perspective because legal moralists would argue that laws against drug use, like laws against murder and theft, are morally right, and hence should not be evaluated by considering the costs incurred in enforcing them.

Many people reject both the libertarian and legal moralists' views. They are at least conditionally prepared to accept that the state may have the right to restrict adult choices if there is good evidence that these choices cause serious harm to individuals and society. Anyone who takes this implicitly utilitarian approach would want to know whether prohibiting drug use prevented these harms, and if so whether this outcome was achieved at an acceptable social and economic cost. This approach to policy formulation requires some form of social accounting that examines the costs and benefits of drug use and the enforcement of the prohibition on such use. There are two major problems in undertaking any such accounting: advocates of both liberalization and of a continuation of criminal penalties often have very different views on what these costs and benefits are; and disagree on how these costs and benefits should be weighed against each other.

ILLICIT DRUG USE AND PROBLEMS IN DEVELOPED COUNTRIES

Cannabis is the most commonly used illicit drug in most developed societies, such as Australia, Europe, and North America. The next most commonly used drugs are the so-called party drugs, MDMA and amphetamine-type stimulants (ATS). Cocaine and heroin and other opioids have the lowest rates of use among the illicit drugs.

Illicit drug use can adversely affect the health of those who use the drugs and the health and safety of nonusers. Heroin and other opioids are the illicit drugs that are least likely to be used, but they cause the most harm to users and to public health. They produce opioid dependence that can be difficult to overcome; premature deaths from drug overdoses; and increased rates of accidents, injuries, and suicides. They can also contribute to violence, blood-borne viruses (BBV) infection (HBV, HCV, HIV) leading to AIDS, hepatitis, chronic liver disease, and some cancers.

The ATS can also produce dependence which can be difficult to treat. When these drugs are used regularly in large doses they can cause heart disease and stroke, psychosis, severe depression, and violence. These drugs are often favored by criminal offenders because they fit well with life in the "night-time economy" by increasing wakefulness and energy, improving mood and self-confidence, and facilitating the use of violence.

Cannabis is a drug of dependence but its dependence risk is less than that of opioids and cocaine. In Australia in 2007–2008, cannabis was the principal drug problem in 22% of 154 000 drug treatment episodes and was a drug of concern in 44% of these episodes. It is a popular drug among disaffected young men who are at high risk of criminal careers: poor school performers, sexually precocious, and anti-socially oriented. Heavy cannabis use probably contributes to failures of social role in much the same way as alcohol does: increasing the likelihood of early school leaving; depression; poor mental health, including psychoses; poor employment performance, increased likelihood of welfare dependence, and unstable relationships; and poor life satisfaction in young adulthood.

DRUG CRIMES

Possession and use of most controlled substances is a crime by definition in all developed countries that are signatories to international drug control treaties. In many countries, cannabis use and possession has comprised the majority of drug offenses for several decades. The police do not specifically target cannabis offenses, so the high rate of these arrests reflects a number of factors. Firstly, there are many more users of cannabis than there are of other illicit drugs. Secondly, around half of all persons arrested for any offense are regular cannabis users. This makes cannabis possession an easy charge for police to lay when they lack evidence to support a more serious offense. Very few cannabis users end up serving prison sentences for possession and use, but police and judicial processing of such cases requires a substantial amount of scarce resources.

Property crime and drug dealing to finance use are probably most often engaged in by regular users of opioids and ATS. Heavy cannabis users may also engage in low-level dealing (buying in bulk to reduce their costs and selling the surplus to other users). These patterns are reflected in the prevalence of different types of illicit drug use among arrestees in Australia and other countries. They are also supported by studies showing that enrollment in methadone maintenance treatment (MMT) reduces crime among dependent opioid users and by evidence that property crime in New South Wales declined after the onset of a heroin shortage at the beginning of 2001.

DECRIMINALIZATION OPTIONS

In the remainder of the chapter, we focus on decriminalization policy options for cannabis and heroin. Cannabis is the drug for which decriminalization and

legalization have been most often advocated. This is for several understandable reasons. It is the most widely used illicit drug among young people. Cannabis users are not as involved in drug-related and property crime as are heavy users of opioids, cocaine, and ATS. Cannabis does produce adverse health effects in heavy users (such as dependence) and such use is associated with a variety of adverse health effects. Nonetheless, cannabis does not cause fatal overdose, as the opioids do, and its other adverse health effects are much less severe than those that can arise from the heavy use of stimulant drugs.

Heroin and other opioids present the largest public health and order problem arising from illicit drugs in many but not all developed countries. The decriminalization policies advocated for heroin are not as radical as those advocated for cannabis. They typically involve measures designed to encourage heroin-dependent people to reduce the risks of their drug use and engage with addiction treatment. These include decriminalization of personal possession and use and injecting equipment; decriminalization of opioid and other drug use in medically supervised injecting rooms; the medical prescription of oral opioids such as methadone and buprenorphine for therapeutic purposes; and the medical prescription of injectable heroin to treat refractory heroin-dependent persons.

HOW CAN WE TELL WHAT WORKS?

In evaluating drug policies, we can only randomly assign persons with illicit drug problems to one or more treatments and compare the effects of the different treatment on drug use and crime. Randomization (e.g. by a coin toss) ensures equivalence between the groups in relevant characteristics and thereby makes treatment the most plausible explanation of any differences observed in drug use and crime after treatment. This approach to evaluation can be used to assess the effectiveness of treatments for drug dependence (e.g. methadone and heroin maintenance treatment) and schoolbased drug prevention. Its use in the criminal justice system has been largely restricted to drug courts.

In the absence of randomized controlled trials, the next best type of evidence comes from quasi-experimental studies that attempt to simulate the characteristics of controlled experiments. These involve conducting statistical analyses of the effects of policy interventions on health or other outcomes over time (e.g. drug-related deaths or arrests); assessing the effects that "natural experiments," such as the Australian heroin shortage, have on drug use and crime; and comparing the effects of different policies in different states of countries with a Federal system (e.g. Australia and the

United States); and much less certainly, comparing the effects of different policies in different countries.

A major problem in evaluating proposals to legalize currently illicit drugs is the lack of any experience with legal markets for these drugs in the past century. This is because international drug control treaties severely constrain the policy options that can be trialed in all countries that have signed them.

IS PROHIBITION A FAILURE?

A popular argument for decriminalization is that drug prohibition has failed, just as it is asserted alcohol prohibition failed in the United States in 1920–1932. Evidence cited in support includes the fact that during the 1990s cocaine and heroin prices fell while purity increased in the United States, despite steep increases in funding for law enforcement; and rates of illicit drug use rose among young adults in many developed countries during the 1990s, despite increased drug-related arrests in these countries over this period.

What outcomes should we reasonably expect from any drug policy, including prohibition? Some advocates of prohibition do set the implausible goal of a "drug-free society." Indeed, the UN General Assembly resolved in 1998 to eliminate illicit opiate and cocaine production by 2008. When judged against its own goals, drug prohibition has failed.

But requiring the elimination of all drug use is arguably an unreasonably high standard against which all social policies would be adjudged failures. It is not a standard used to evaluate public health programs where we ask instead: Does the policy improve public health overall? Is this achieved at an acceptable social and economic cost? Are there other ways of achieving the same benefits at a smaller cost?

A similar approach to evaluating drug policy would ask: Does the criminalization of drug use reduce drug use and drug-related harm? If so, is this achieved at an acceptable social cost (in terms of the creation of a black market, violation of the law, police corruption, etc.)? Are there other ways of reducing drug related-harm while minimizing the adverse effects of criminalization?

DECRIMINALIZATION POLICIES FOR CANNABIS

Decriminalization of Possession and Use

Under this policy it remains illegal to produce or supply cannabis, but fines or other noncriminal penalties would be imposed on persons who possessed and/or used quantities of cannabis up to a specified maximum. Persons possessing larger quantities of cannabis may face criminal charges. The main argument in favor of this policy is that it reduces some societal costs of cannabis prohibition while retaining most of its benefits. For example, since the mid-1980s, three Australian territories have legislated to replace criminal penalties for cannabis use with fines (referred to as expiation). South Australia adopted the Cannabis Expiation Notice (CEN) system in 1987. Under the CEN, possession of up to 100 g of cannabis was punished by a \$50–\$150 fine. If the fine was paid within 60 days, there were no criminal proceedings and no offense was recorded. Failure to pay the fine could lead to criminal proceedings and imprisonment.

Most evaluations of cannabis decriminalization have compared lifetime and past year cannabis use in household surveys in states or countries where criminal penalties have been retained and those in which they have been removed. These studies found that cannabis use increased during the 1990s at the same rate in South Australia and other states. More recently, rates of past year cannabis use decreased at the same rate in states that had decriminalized use as in states that retained criminal penalties. The Australian experience largely replicates analyses of survey data in the United States in the 1970s and 1980s. There is less data on the impact of similar policy experiments in Italy, Portugal, and England in the 1990s and 2000s, although rates of use do not appear to have increased after decriminalization in any of these countries.

These evaluations have a number of limitations. First, the small sample sizes in these surveys can rule out large increases in recent use, but it is more difficult to exclude the possibility that use is heavier or more persistent among existing users. More recent studies using large nationally representative samples and more sophisticated statistical models suggest that criminal penalties may discourage some people from using cannabis but they do not appear to influence the quantity that is used by those who do use.

Second, the differences in penalties imposed between jurisdictions that have nominally decriminalized and those who retained criminal penalties may be small. States that nominally retain criminal penalties rarely impose them and residents of states that have decriminalized cannabis are often unaware of the change in penalties. States also vary in the rigor with which they enforce these laws. Third, jurisdictions with different cannabis policies also differ in other ways that may affect rates of cannabis use.

Overall, even with these caveats, reducing penalties for cannabis use has had minimal impacts on rates of cannabis use. This is probably for two reasons: there is little difference in practice between states that do and do not enforce criminal penalties; and the risk of arrest for cannabis use is so low (typically only 2% of persons who used cannabis in the past year) that the criminal penalties do little to deter use.

Decriminalization can have the unintended, counterproductive effect of increasing the number of cannabis users who are penalized by the police and appear in court. This happened, for example, after the cannabis infringement notice system was introduced in South Australia. There was more than a doubling in the number of people who were issued CEN notices between 1987/88 and 1993/94. Because only 45% of those charged paid their fines, decriminalization increased the numbers of cannabis users who received criminal sanctions because those who failed to pay fines ended up in court and could be gaoled for nonpayment of fines.

De Facto Legal Cannabis Markets

A legal cannabis market would legally allow the cultivation, production, distribution, wholesale and retail sale, promotion, and advertising of cannabis to adults. There are no legal cannabis markets anywhere in the world because UN treaties preclude them. A number of countries have nonetheless tolerated limited de facto retail cannabis markets.

In the Netherlands, since 1976 a policy of nonenforcement has made it de facto legal to possess and sell up to 30 g of cannabis while the country officially retains a prohibitionist policy against cannabis. Prosecutors and police refrained from enforcing the law when the quantity possessed or sold did not exceed 30 g and when sales occurred in licensed coffee shops. Over the next decade, a series of guidelines regulated the de facto retail cannabis market by preventing coffee shops from advertising, selling hard drugs, cannabis to minors, or more than the legally specified maximum quantity to each customer, or allowing public disturbances. In the 1990s, the Dutch government limited the number and location of coffee shops and in 1995 it reduced the amount of cannabis that could be sold to 5 g.

Policy analysts disagree about whether the coffee shop system affected cannabis use in the Netherlands. MacCoun and Reuter compared survey data on cannabis use in the Netherlands, the United States, Denmark, and Germany. They concluded that while removing criminal penalties for use had little effect on rates of use until 1992, increasing access to cannabis via coffee shops between 1992 and 1996 was followed by increased rates of cannabis use by young people. Their critics argued that trends in cannabis use in the Netherlands, other European countries, and the United States simply mirrored changes in youth culture in all these countries.

Why Not a Legal Cannabis Market?

The major problem with Dutch cannabis policy is the "back door problem," namely that retail cannabis sales are legal in coffee shops but the supply of cannabis through the coffee shops' back door remains illegal. The solution, according to critics of prohibition, is the legalization of the cultivation and sale of cannabis. There are a number of major social and political obstacles to doing so in developed countries that have signed the Single Convention on Narcotic Drugs.

First, the international drug control treaties prohibit the legalization of cannabis for nonmedical use. These treaties have strong support in the international community (most especially by the United States). Any country that legalized cannabis would have to renounce these international treaties and bear the strong international and public disapproval that would follow.

Second, a minority of the public support cannabis law reform even in the Netherlands. Support had declined during the early 2000s, probably because of strengthening evidence that cannabis use can harm some users. In many other developed countries, the cannabis policy debate has often been simplified to a choice between two policy options: (1) we should legalize cannabis, or at the very least decriminalize its use, because its use is harmless; or (2) we should continue to prohibit its use because it harms some users. Given this policy framing, evidence that cannabis use harms some users has seemingly strengthened the case for prohibition, as was evidenced by the decision of the UK government in 2009 to reinstate criminal penalties for cannabis use citing evidence that cannabis use caused psychosis.

Medical Marijuana in California

A different route to legalizing cannabis has been adopted in California. In 1996, a citizen-initiated referendum, Proposition 215, was passed by 44 to 56%. This allowed the medical use of marijuana for a set of indications that included not only nausea, weight loss, pain, and muscle spasm (for which there was some evidence of efficacy), but any serious medical condition that a doctor believed could be relieved by using cannabis.

Proposition 215 (and similar referenda later passed in other US states) created a number of problems. First, these State laws conflicted with US Federal law that banned the use and the sale or supply of cannabis for any purpose. Second, securing a legal supply of cannabis was solved in California by Cannabis Buyers' Clubs that sold cannabis to patients who had a doctor's prescription and sourced their cannabis from the illicit market. The US Supreme Court ruled in 2001 that persons who sold or supplied cannabis for medical use

were not protected from Federal criminal prosecution by State laws. The Bush administration attempted to enforce Federal laws, but the Obama administration decided not to do so in states that allowed the medical use of cannabis.

There have been no evaluations of Californian marijuana policy, but studies of medical marijuana patients in the San Francisco Bay area in 2001–2007 suggested that compassion clubs largely function as marijuana maintenance programs. Most (77%) of the patients were males with an average age of 32 years; 89% had used cannabis since the age 19; and 90% were daily smokers. The patients' age and sex suggest that they are unlikely to have had cancer or neurological diseases. Indeed, one study reported that a substantial proportion of these users used cannabis as a substitute for alcohol and other illicit drugs.

In November 2010, a citizen-initiated referendum in California that proposed to legalize marijuana production for sale to any adult over the age of 21 years was narrowly defeated (46-54%). Advocates of the referendum argued that California would save up to \$1 billion from no longer having to enforce cannabis prohibition and that a \$50/oz tax would generate \$1.4 billion in revenue. There was a great deal of uncertainty about these claims because of a lack of detail on the regulatory regimes that would be adopted if production, distribution, and sale of marijuana were made legal, and the lack of any similar policy changes anywhere in the world from which to predict the effects on state revenue, law enforcement costs, marijuana use, and harms related to such use. Proponents of legalization have indicated that they intend to reintroduce the referendum proposal.

DECRIMINALIZATION POLICIES FOR HEROIN USE

Possession of Heroin and Injecting Equipment

Possession of small quantities of illegal drugs that are injected remains a criminal offense in most developed countries, but the possession of injecting equipment has been de facto decriminalized. While it is still technically a criminal offense, many governments distribute clean needles and syringes as a public health measure to prevent HIV and other BBV. The fact that possession remains a criminal offense allows the police discretion in enforcing the law; it may also deter injectors from disposing of used injection equipment in a socially irresponsible way. But politicians have often been unwilling to change these laws to reflect actual practice for fear of being seen to be soft on drugs.

Medically Supervised Injecting Rooms

Supervised injecting facilities (SIFs) are legally sanctioned places, usually located near illicit drug markets, in which injecting drug users can inject drugs under medical supervision. They have primarily been introduced to reduce injecting in public and discarded needles while reducing injecting drug users' exposure to BBV, treating drug overdoses, and engaging drug users in medical, drug treatment, and social welfare services.

Opponents of SIFs argue that they facilitate injecting drug use, attract drug users into the local area, and send the wrong signal about the social acceptability of injecting drug use. Rigorous evaluations of SIFs have not proven easy to do for a number of reasons.

Firstly, randomized controlled trials cannot be done. SIFs are usually established in areas where public injecting is a problem and they aim to attract as many injectors as possible. Injectors cannot therefore be randomly assigned to use an SIF or not.

Secondly, evaluations usually compare risk behavior, drug use, and drug-related harm in samples of injectors who do and do not use SIFs. The interpretation of these studies is complicated by pre-existing differences in risk behavior between injectors who do and do not use SIFs. Critics are unconvinced by reductions in self-reported risk behavior but it has proven difficult to use HIV or hepatitis C infections, fatal and nonfatal drug overdoses as indicators, because the rate of these events can be affected by many other factors.

Thirdly, the conditions under which governments have allowed SIFs make it unlikely that they will have a large impact on the harms caused by injecting drug use. Governments typically impose age limits on SIF clients, exclude intoxicated and pregnant injectors, and restrict the number of facilities (e.g. only one each in Sydney; Australia; and Vancouver, Canada). These restrictions limit the impact that SIFs can have on population-level drug-related harm. When multiple SIFs have been allowed, as in some German cities, overdose deaths appear to have been reduced at a community level.

Research suggests that SIFs can operate safely and to the benefit of the health and well-being of the socially marginalized injecting drug users that use them. They do not increase crime or public nuisance and they reduce the public visibility of injecting drug use, the most probable reason for public tolerance of SIFs in Europe.

Opioid Substitution Treatment

Opioid substitution treatment (OST) involves substituting a long-acting, usually orally administered, opioid for the shorter-acting injected heroin. MMT is the most common form of opioid substitution worldwide. When taken daily in high doses, methadone

blocks the effects of heroin, allowing individuals to take advantage of rehabilitative services. Its effectiveness is supported by randomized controlled trials and observational studies that show it decreases heroin use, criminal activity, and HIV transmission while users remain in treatment.

Buprenorphine is a mixed agonist-antagonist that has similar effects to those of morphine and blocks the euphoric effects of heroin. When given in high doses, its effects can last for up to 3 days enabling dosing every 2–3 days (rather than daily with methadone). It is marginally less effective in retaining patients in treatment than methadone but approximately equivalent in reducing heroin use. Because of its antagonist effects, buprenorphine has a substantially lower risk of overdose and it is easier to withdraw from than methadone.

Heroin maintenance treatment (HMT) maintains dependent heroin users on daily injectable heroin. The safety and effectiveness of HMT in treatment refractory patients have been evaluated in a series of randomized controlled trials in Switzerland, the Netherlands, Spain, Germany, Canada, and the UK. It has been shown to be more effective than MMT in reducing illicit heroin use and crime in these patients. The participants in these trials were more criminally involved than standard MMT patients and they had to have failed at MMT to enter HMT. These were also well-staffed programs that probably provide optimistic estimates of the effectiveness of HMT in routine clinical practice. HMT is much more expensive than MMT because of the need to supervise the more frequent injection of heroin. It is only more cost effective than MMT if its effects on crime are included. This makes HMT harder to sell politically because critics can argue that it rewards the most criminally involved heroin users by giving them their drug of choice. The higher costs of providing HMT mean that it will remain a second-line treatment of modest scale and with limited demand, as indicated by the difficulty in attracting patients into clinical trials. Its impact on public health and drug-related crimes is therefore likely to be modest.

CONCLUSIONS

Options for decriminalizing currently illicit drugs are severely limited by international drug treaties which prohibit legal markets in these drugs for all except medical and research purposes. Public opinion in most developed countries strongly supports this policy.

In most developed countries, marginal changes in penalties for personal possession and use of cannabis have been the most radical policy changes that public opinion has allowed. These changes do not appear to have had any large effects on rates of cannabis use. The Netherlands is one country that has de facto FURTHER READING 695

legalized small-scale retail cannabis sales. The US State of California has liberalized access to cannabis by allowing its use for medical uses very broadly defined.

In the case of heroin, publicly funded needle and syringe programs have de facto decriminalized the possession of needles and syringes in many countries. Many developed countries have expanded access to oral methadone and buprenorphine substitution treatment for opioid-dependent persons. In a small number of countries, injectable heroin maintenance has been offered as a second-line treatment for patients who have failed at other forms of OST. Given the modest scale of use, the impact of HMT on heroin use as a public health and order problem is likely to be modest.

SEE ALSO

International Policies to Reduce Illicit Drug-Related Harm and Illicit Drug Use, Methadone Maintenance

List of Abbreviations

ATS amphetamine-type stimulants

BBV blood-borne virus

CEN Cannabis Expiation Notice

HBV hepatitis B virus

HMT heroin maintenance treatment

HVS hepatitis C virus

MDMA 3,4-methylenedioxy-N-methylamphetamine ("Ecstasy")

MMT methadone maintenance treatment OST opioid substitution treatment SIF supervised injecting facilities

Glossary

- Amphetamine-type stimulants are drugs that produce effects that are similar to those of amphetamines, namely activating the sympathetic nervous system, increasing wakefulness, lifting mood, and increasing endurance. These include dexamphetamine, methamphetamine, methylphenidate, and MDMA.
- **Cannabis** includes any drug derived from the *Cannabis sativa* plant that contains tetrahydrocannabinol, such as marijuana (flowering leaves and heads) and hashish (resin from the flowering tops of the plant).
- **Cocaine** is a drug with stimulant properties that is derived from the coca plant grown widely throughout South America. It can be used orally or intranasally, smoked, or injected.
- **Decriminalization** is an umbrella term for policies that remove criminal penalties for (1) personal possession and use, (2) drugs used under medical supervision, and (3) drugs manufactured for personal use.
- **Drug-related crimes** include the simple possession and use of illicit drugs and the importation, manufacture, and distribution of these drugs. Drug-related crimes also include property crimes (such as shop-lifting and house-breaking) and drug dealing engaged in to finance personal drug use; and violent crimes committed to resolve disputes between participants in illegal drug markets to fund drug use.
- **Heroin** is an illicit opioid drug derived from the opium poppy. It has limited medical use in a small number of countries and is primarily used illicitly, often by injection.

Illicit drugs are drugs whose use by adults is prohibited for all except medical and scientific purposes under international drug control treaties, such as the UN Single Convention of 1961. They include cannabis; heroin and other opioids; amphetamine-type stimulants (such as methamphetamines); cocaine; "party drugs" (such as MDMA, ketamine, etc.); and benzodiazepines.

- **Legalization** is more often used to describe policies that would make it legal to manufacture, distribute, and sell any of the currently illicit drugs, and thereby allow these drugs to be sold in regulated legal markets like those for tobacco and alcohol.
- **Legal moralists** believe that at least some types of drug use are morally wrong (e.g. because they are intoxicating or undermine autonomy) and argue that morally wrong behavior should be criminalized.
- **Libertarians** adopt a moral and political philosophy which argues that the only permissible reason for restricting adults' rights to use drugs is if that drug use harms others. They advocate for removing laws that prohibit adults from using drugs because they may harm themselves.
- **Net widening** is an unintended effect of decriminalizing drug use that results in more users being prosecuted and appearing before the courts than occurs when drug use remains illegal.
- **Opioid substitution treatment** involves substituting a long-acting, usually orally administered, opioid as a therapeutic substitute for the shorter-acting, injected heroin. The substitute drug (most often methadone or buprenorphine) is taken in doses that block or reduce the effects of heroin and allow individuals to take advantage of rehabilitative services.
- **Single Convention on Narcotic Drugs, 1961** is a United Nations treaty that commits states who sign it to criminalizing the use of cannabis, cocaine, and heroin for all but medical or scientific purposes.
- Supervised injecting facilities (SIFs) are legally sanctioned places, usually near illicit drug markets, in which drug users can inject drugs under medical supervision. These aim to reduce injecting in public and reduce injecting drug users' exposure to blood-borne viruses (BBV), treat drug overdoses, and engage drug users in medical, drug treatment, and social welfare services.
- **Utilitarians** support a moral theory that the major aim of public policy and ethics should be to select policies that maximize the good (e.g. the happiness) and minimize the costs of all those affected by them. In its simplest form, the aim is to ensure the greatest happiness for the greatest number.

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- http://www3.interscience.wiley.com Addiction: leading journal in the addictions field that publishes articles on drug policy.
- http://www.beckleyfoundation.org Beckley Foundation: a charitable foundation that publishes analyses of drug policy.

- http://www.drugpolicy.org Drug Policy Alliance: a leading US group advocating for the liberalisation of illicit drug policies.
- http://www.emcdda.europa.eu European Monitoring Centre on Drugs and Drug Addiction (EMCCDA): a leading European agency that publishes research on patterns of drug use and related barms.
- http://www.bepress.com Journal of Drug Policy Analysis: a journal emphasising informed and practical multidisciplinary approaches and problem solving.
- http://www.unodc.org United Nations Organization on Drugs and Crime: leading UN agency on illicit drugs that publishes an annual World Drug Report.
- http://www.who.int World Health Organization (WHO): leading UN health agency on substance abuse.

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The Impact of Drink Driving Laws

Barry C. Watson, Nerida L. Leal, David W. Soole Queensland University of Technology, Brisbane, QLD, Australia

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THE IMPACT OF DRINK DRIVING LAWS

The purpose of this chapter is to provide an overview of the role of alcohol in road traffic crashes and to review the historical and current state of practice for addressing alcohol-impaired driving behavior. The evidence regarding the effectiveness of various approaches to the prevention of alcohol-impaired driving and the management of offenders is critically evaluated. Specifically, this chapter discusses the evidence in relation to the three primary components of traffic law enforcement, legislation, policing, and sanctions, with specific reference to the problem of alcohol-impaired driving. The chapter concludes by providing evidence-based best practice principles for preventing and reducing impaired driving behavior and recommendations for future research.

While a variety of terms are used around the world to describe alcohol-impaired driving, the term "drink driving" is preferred for use throughout this chapter rather than "drunk driving." This acknowledges that

a driver's crash risk can be significantly increased even at low levels of impairment.

THE ROLE OF ALCOHOL IN ROAD TRAFFIC CRASHES

Road traffic crashes are a major public health problem and a leading cause of death and injury around the world. According to the World Health Organization (WHO), nearly 1.2 million people die in road traffic crashes each year, with millions more injured or disabled. Most of these deaths and injuries occur in low- and middle-income countries. As well as creating enormous social costs for individuals, families, and communities, traffic crashes represent a significant burden on health services and economies. Indeed, WHO estimates that traffic crashes cost countries approximately 1–2% of their gross national product. As motorization increases, so too do road traffic crashes, particularly in developing countries.

Evaluations indicate that a range of road safety countermeasures have proven successful in reducing road trauma. For example, the use of seatbelts, helmets, and child restraints has saved thousands of lives by reducing the severity of injuries. Moreover, safe road infrastructure, the enforcement of blood alcohol concentration (BAC) limits, and the management of vehicle speeds and improvements in vehicle safety have also been shown to be effective in reducing both the incidence and severity of road traffic injuries.

Alcohol and Crash Risk

Alcohol represents a risk factor in two ways. Firstly, it increases the risk of crash involvement by impairing driver performance. Secondly, alcohol is commonly associated with other high-risk road user behaviors that may also increase crash risk and/or the severity of injury in the event of a crash. Research has consistently shown that the consumption of alcohol, even in small amounts, increases the risk of being involved in a crash for motorists and pedestrians. For example, a survey of studies conducted in low- and middle-income countries found that alcohol was present in the blood between 4 and 69% of injured drivers, 18–90% of injured pedestrians, and 10-28% of injured motorcyclists. In highincome countries throughout the world, as many as half of all fatally injured drivers have been reported to have excess alcohol in their blood (e.g. BAC in excess of the legally prescribed limit).

Alcohol impairment increases the likelihood of a crash given that it causes poor judgment, increased reaction time, lower vigilance, and decreased visual acuity. Alcohol-related impairments in judgment can increase crash risk even at relatively low BAC levels; however, the effects become progressively worse as the BAC increases. Indeed, case-control studies suggest that a driver is twice as likely to be involved in a crash when driving with a BAC of 0.05 g per 100 ml, and that crash risk increases dramatically with a BAC beyond 0.05. For example, it is estimated that the risk of crashing is 25 times higher for a driver with a BAC of 0.150 g per 100 ml, compared to a driver who has not consumed any alcohol.

There are a number of common characteristics of alcohol-related crashes. For example, alcohol-related crashes are more likely to occur during high alcohol consumption times, such as at night, on weekends, or other periods of high leisure activity. Alcohol-related crashes also often involve single vehicle crashes (e.g. driver loses control of vehicle and collides with a fixed roadside object) and/or excessive speeds. Finally, alcohol-related crashes tend to be associated with increased severity of injury, partly as a function of the

impact of alcohol on the human body, which can interfere with recovery, as well as the co-occurrence of other high-risk behaviors, as discussed below.

Alcohol and Other High-Risk Road User Behaviors

In addition to directly increasing the likelihood of crash involvement, alcohol consumption also has a negative impact on other aspects of driver safety (such as seat belt wearing, helmet use, and speed choice), which have the potential to increase the risk and severity of crashes. Furthermore, the consumption of alcohol, due partly to its tendency to reduce inhibition, is sometimes associated with the use of other drugs, which can also impact upon driving performance.

Factors Associated with Drink Driving

While the profile of drink drivers differs somewhat between regions of the world, there are a number of factors that have consistently emerged as being associated with increased involvement in alcohol-related crashes. Specifically, research has found that drink-driving offenders are more likely to be male, younger (e.g. under 30 or 35), single, from low socio-economic backgrounds and have low self-esteem. In addition, drink driving offenders are more likely to have engaged in drink driving in the past, have prior criminal offenses, and also engage in other high risk-driving behaviors including speeding and seat belt offenses. Research has also shown that other high-risk groups, such as unlicensed drivers, are more likely to drink and drive.

TRAFFIC LAW ENFORCEMENT

Given the aforementioned association between alcohol consumption and increased risk of traffic crash involvement and severity of injuries sustained, there is a fundamental need to develop and implement effective countermeasures to reduce and prevent drink driving. Arguably, traffic law enforcement approaches represent the most commonly used countermeasures in many countries. Traffic law enforcement consists of three components:

- 1. Traffic rules, regulations, and laws;
- 2. Policing practices; and
- 3. Penalties and sanctions.

Countries with more specific drink driving laws and accompanying traffic law enforcement have observed a decreasing trend in alcohol-related crashes, and such reductions are commonly attributed to the effectiveness of interventions at all three levels. Moreover, the effectiveness of such approaches is found to be optimized when preceded and/or complemented by public education and awareness campaigns.

The remainder of this chapter will examine the different types of drink driving laws in use internationally and the functions of these laws from a preventative perspective. In addition, this chapter addresses drink driving laws and enforcement from a deterrence theory perspective, given that this doctrine has guided the development and implementation of drink driving policies and practices in many countries.

Briefly, deterrence theory proposes that the ability for enforcement practices to deter drink driving, or any proscribed behavior for that matter, is a function of the perceived risk of detection, as well as the perceived certainty, severity, and swiftness of punishment. Deterrence is argued to be achieved via two processes. Firstly, through the process of general deterrence, the motoring public is discouraged from offending through practices and policies aimed at increasing the perceived risk of detection and punishment. Secondly, specific deterrence refers to the process whereby actual offenders are deterred from reoffending through experiences of the consequences of detection and punishment.

The classical approach to deterrence theory has more recently been expanded to include the concepts of punishment avoidance (e.g. the absence of punishment in association with offending) and vicarious learning (e.g. experiences of punishment and punishment avoidance among significant others). Indeed, it has been argued that punishment avoidance experiences often do more to reinforce behavior than experiences of punishment do to discourage behavior. This is particularly the case for behaviors like drink driving, where the chances of detection remain relatively low despite improvements in policing practices.

General Prevention/Deterrence of Drink Driving

A number of traffic law enforcement and related public education countermeasures designed to prevent or deter the general driving population from drink driving are in use internationally. Such approaches include

- prescribed alcohol limits;
- per se legislation (also known as the Scandinavian model);
- policing provisions, such as RBT and sobriety checkpoints; and
- public education campaigns.

The prescribed alcohol limit in grams per 100 ml of blood, known as BAC, differs between and within jurisdictions. A number of countries, including Sweden and Norway, have adopted a 0 or 0.02 BAC limit for all drivers, which effectively allows no alcohol to be consumed prior to driving. Conversely, other countries have limits ranging from 0.03 to as high as 0.15. Moreover, in many countries, particular high-risk groups of drivers have lower prescribed alcohol limits. For example, in the various Australian jurisdictions, the prescribed alcohol limit for general drivers is 0.05, but a limit of 0.02 or 0 exists for novice and professional drivers. Many jurisdictions use the BAC reading of the driver, when detected, to impose different levels of sanctions, with more severe penalties applied for high alcohol readings, and/or repeat drink driving offenses.

Evaluations have confirmed the road safety benefits associated with lower proscribed alcohol limits, particularly lowering limits to 0.05 for all drivers and to 0 for young drivers. While there is also recent evidence suggesting that reducing such levels below 0.05 for all drivers can produce further benefits, the extent to which these can be attributed to the BAC limit alone, rather than to other associated enforcement and media activity, is not yet conclusive.

Per se legislation means that a driver can be charged with drink driving on the basis of the alcohol reading alone, and that evidence of impaired driving is not required. This type of legislation has benefits for law enforcement, in that the decision about whether a drink driving offense has occurred is objective, making the detection and punishment process more straightforward.

Traffic policing methods that have been used to effectively modify drink driving behavior include random alcohol screening and targeted enforcement based on intelligence. Random alcohol screening predominately serves a general deterrent function, while targeted enforcement serves to facilitate prosecution of drivers who refuse to stop drinking and driving. To maximize effectiveness, a mix of both randomized and targeted enforcement activities should be utilized, such that enforcement activities are unpredictable.

Some countries, such as Australia, allow for random alcohol screening (e.g. RBT) of any driver at any time. For example, Australian jurisdictions use "booze buses" to stop drivers and conduct roadside and evidentiary alcohol screening tests (see Figs 71.1 and 71.2). Other countries, such as the United States, require "probable cause" before a driver can be screened for alcohol consumption, referred to as selective breath testing.

Based on the available evidence, drink driving enforcement operations are most effective when conducted in a random, highly visible and unavoidable



FIGURE 71.1 Random breath testing operations conducted in Australia at night. Image courtesy of Queensland Police Service.



FIGURE 71.2 Random breath testing operations conducted in Australia during the day. Image courtesy of Queensland Police Service.

manner, sustained over a period of time and are well-publicized. Indeed, visible and frequent enforcement is critical to deterring the general public from drink driving and not simply catch those who break the laws.

Combining enforcement activities with public education has been found to increase the general deterrent impact of drink driving enforcement programs and serve a number of additional functions. Such campaigns are useful both prior to and following the implementation of drink driving laws and associated enforcement programs. Public education can facilitate awareness about drink driving as a road safety issue, inform the

motoring public regarding increases in enforcement intensity or the severity of sanctions (and in turn increase the perceived likelihood of detection), and highlight the personal risks associated with alcoholimpaired driving. These factors can subsequently facilitate greater community acceptance of enforcement efforts.

Managing Drink Driving Offenders

A variety of legal sanctions are applied to drink drivers throughout the world, in order to control and

reduce their offending behavior. Major differences exist in the way these sanctions are administered, depending on whether the primary objective is to punish, restrain, or reform offenders. Nevertheless, the more common sanctions tend to fall into one of the following categories:

- Monetary fines;
- License actions (e.g. demerit point schemes, license suspension/disqualification, restricted licenses);
- Remedial programs (e.g. assessment, treatment, or rehabilitation);
- Vehicle sanctions (e.g. alcohol ignition interlocks, vehicle impoundment/immobilization); and
- Confinement (e.g. jail, home detention, community service orders).

These sanctions have a number of functions including retribution, incapacitation or constraint, reform (e.g. rehabilitation, specific deterrence), and general deterrence. The first function, retribution, refers to balancing the crime committed by an offender with a commensurate punishment. The retributive effectiveness of drink driving sanctions is often difficult to quantify given that it requires an estimate of the culpability of offenders. In addition, given that many drink driving episodes do not result in a crash (and hence any harm to the community), it has been argued that sanctions should be designed to match the *potential* harm, or *objective probability*, of drink driving.

A second function of drink driving sanctions relates to their capacity to constrain or incapacitate offenders from committing further offenses, such as license and/or vehicle sanctions. A more extreme form of incapacitation involves confinement in jail or some form of supervised detention. In effect, opportunities for re-offending during the term of the sentence are removed, thus acting as an exposure-control measure.

A third function of criminal sanctions is to reform offenders, in order to reduce the rate of re-offending. Reform can operate through two processes: rehabilitation and specific deterrence. The goal of rehabilitation is to resolve the underlying medical or psychosocial factors contributing to criminal behavior. In the case of drink driving, this may involve treatment for alcohol misuse or dependence. In contrast, the goal of specific deterrence is to deter offenders from re-offending due to the fear of further punishment. In the latter case, it is the threat of punishment that motivates behavior change.

Finally, drink driving sanctions can perform a general deterrent function, such that behavior is influenced through the *threat* of punishment rather than via direct experience. As such, general deterrence effects can influence the behavior of the community in general, not just those who are caught and punished.

Impact of Drink Driving Penalties and Sanctions on Drink Driving Behavior

This section will focus on the impact of specific penalties and sanctions for drink driving on preventing or reducing subsequent impaired driving among drink driving offenders. In addition, attention will be given to whether the penalties have any impact on the general driving population.

License Actions

License actions include a range of restrictions that deprive offenders from the use of their driver's license. In many countries, the primary license actions are suspension and disqualification (or revocation). Although these terms tend to be used interchangeably, suspension generally refers to situations where licenses are reinstated automatically after the period of suspension, while disqualification refers to situations where a driver must reapply at the end of the period to have it reinstated. License actions vary in the degree to which they restrict driving. While license suspension or disqualification typically prohibits offenders from using their license under all circumstances, restricted licenses can also be applied, which permit driving for specific purposes, such as for employment or treatment.

Another major difference relates to whether license actions are administered judicially or administratively. Traditionally, license suspension has been applied through judicial processes in most countries, with suspension contingent upon conviction and subject to criminal standards of proof and plea bargaining. Over the last three decades, however, there has been a substantial growth in the use of administrative license suspension, particularly in North America. This process requires less stringent standards of proof, often involves mandatory license disqualification periods, and operates from the time a drink driver is arrested, thus increasing the swiftness and certainty of the sanction. As this process tends to be less costly, administrative suspension appears to improve the overall cost-effectiveness of license loss. In addition, immediate license suspension is increasingly being utilized as a sanction for high-range offenders; however, some have raised concerns about the loss of deterrence associated with non-attendance at court.

For some time, the evidence has indicated that license suspension is a very effective countermeasure, compared with other sanctions commonly applied to drink drivers. In North America, the most compelling evidence has emerged from the use of administrative license suspension laws. Evaluations have suggested that these laws can act as a general deterrent by contributing to a reduction in the level of alcohol-related crashes in the community. This is illustrated by the fact

that license actions reduce non-alcohol-related offenses and crashes among offenders, as well as alcohol-specific incidents. In other words, license actions are effective exposure-control measures that produce road safety benefits well beyond their impact on drink driving. Although the evidence suggests that these effects can persist well after the end of the suspension period, this may, in part, be due to offenders choosing not to become relicensed.

Australian experience indicates that court imposed license disqualification can also be an effective sanction for drink driving offenders. Research conducted in the 1990s examined the records of over 25 000 disqualified drink drivers and found that crash and offense rates during the disqualification period were about one third of the rates incurred during legal driving. More recent research has suggested that offenses during periods of disqualification are suppressed by up to 15% of the level incurred during periods of legal driving among the same offenders. However, evidence relating to the optimum length of license disqualification is inconclusive suggesting that further research is required to identify the most efficacious approach.

In terms of the retributive effect of license actions, there are concerns regarding the impact on an offender's capacity to earn a living. A British study found that while most disqualified drivers considered the sanction justified, some reported that they had lost their job as a direct consequence of the disqualification. However, research in the United States suggests that only a small minority of suspended drivers experience employment or income losses. Some researchers have compared the impact of administrative license suspension on the employment levels of drink driving offenders with the impact of alcohol-related crashes on the employment of "innocent" people involved in these crashes. They found that while there was no pronounced impact on the jobs or incomes of offenders, a substantial effect was experienced by the seriously injured victims. They argued that this justified the continued use of administrative license loss.

The administration of restricted licenses to offenders who can demonstrate that they and/or their family would experience significant hardship associated with the loss of their license is a common approach adopted in some jurisdictions to overcome such problems. However, such practices have been criticized, such that providing restricted licenses for employment purposes only is argued to be discriminatory and fails to acknowledge the importance of educational and domestic functions. In addition, it has been argued that the widespread use of restricted licenses may undermine both specific deterrence (by failing to break an offender's reliance on driving) and general deterrence (by reducing the perceived certainty of license loss).

Interestingly, an Australian study reported no statistical differences between the recidivism rates of drink driving offenders granted restricted licenses with those receiving full license disqualifications, at least during the term of the sanction. However, it was noted that magistrates are typically selective about granting restricted licenses, tending to favor older drivers with better driving records. Therefore, the results do not necessarily countenance the wider use of restricted licenses, since they may not be as effective with more recalcitrant offenders. Moreover, the authors noted that further research was required to determine whether restricted licenses undermine the general deterrent effect of license loss for drink driving.

From another perspective, the effectiveness of license loss may be undermined if offenders continue to drive during the suspension/disqualification period. In effect, these offenders are not experiencing the full impact of their punishment. In this regard, the level of illegal driving by suspended/disqualified drivers has been reported to be relatively high in most jurisdictions. Surveys in the United Kingdom, United States, and Australia have found self-reported levels of disqualified/suspended driving ranging from 25% to almost 70%, and the self-report nature of these studies suggests that these findings may represent underestimates of the extent of the problem. In addition, there is evidence that disqualified drivers who continue to drive have up to three to four times the crash risk of licensed drivers, confirming that they are a high-risk group.

It is likely that many offenders who choose not to reobtain a license after the expiry of their disqualification/ revocation period continue to drive unlicensed. This practice further undermines the integrity of the licensing system by reducing the impact of other sanctions, which manages the driver's behavior, such as demerit points. Therefore, in terms of incapacitation, while license loss is an effective measure it is far from perfect. Indeed, from a compliance standpoint, license disqualification/ suspension is a relatively inefficient measure. The likely outcome of this low compliance is that the full impact of the suspension is compromised and the long-term effectiveness of the system potentially eroded.

In addition to targeting offenders, license actions are also intended to perform a general deterrent function. A number of North American studies have suggested that license suspension can act as a general deterrent by reducing the overall rate of crashes likely to involve alcohol. However, some qualifications need to be placed on these studies. Firstly, they almost exclusively relate to the use of administrative license suspension, and it has been suggested that the success of administrative suspension is linked to the greater certainty and swiftness delivered by this process, compared with judicially imposed license suspension. Secondly, in many cases the

studies evaluated the impact of a package of drink driving countermeasures, often featuring a range of sanctions implemented in conjunction with administrative license suspension, creating difficulties in quantifying the specific effect of license actions. Nonetheless, it is worth noting that community surveys in the United States generally indicate that license suspension is the most well-understood and feared drink driving sanction.

Remedial Programs

Unlike most other drink driving sanctions, remedial programs are not generally designed to be retributive or to incapacitate offenders. Rather, they are intended to reform offenders and thereby reduce the likelihood of further drink driving incidents. Despite this common objective, major differences exist in the focus, content, and delivery of remedial programs. At the broadest level, remedial programs fall into two categories: assessment and rehabilitation.

Assessment programs are generally designed to screen and identify drink driving offenders with a high risk of re-offending. These programs use a variety of biological, medical, and psychosocial criteria and can be used to assess whether an offender is suitable to be relicensed or to direct them to appropriate rehabilitation. However, there has been considerable debate about the validity of certain assessment criteria, particularly the use of an offender's BAC.

Similarly, rehabilitation programs also vary in their content and format, ranging from short educational courses through to therapeutic interventions involving medical treatment, psychotherapy, counseling, or a combination of these modalities. In addition, there is substantial variation in the manner in which remedial programs are delivered, ranging from mandatory programs, whereby relicensing is contingent upon completion through to programs where attendance is voluntary or at the discretion of the court. Remedial programs are most commonly used to complement other sanctions, particularly license actions, and may be reinforced by probation.

Traditionally, there have been difficulties in establishing the effectiveness of drink driving remedial programs. During the 1980s, research tended to suggest that the effectiveness of remedial programs was at worst negligible and best limited to reducing subsequent drink driving offenses rather than crashes. Indeed, researchers concluded that the behavioral impact of education and treatment programs are typically small, inconsistent, and limited to first offenders and/or persons diagnosed as non-problem drinkers.

However, from the early 1990s more optimistic findings began to emerge regarding the impact of assessment and rehabilitation programs on drink driving recidivism in both the United States and Europe. The evidence suggested that remedial programs added to the effectiveness of license actions in reducing alcohol-specific offenses and crashes, compared to when license sanctions were used in isolation. These results suggest that license actions are primarily an exposure-control measure, while remedial programs are more sensitive to the factors contributing to drink driving recidivism.

Perhaps the most compelling evidence in favor of remedial programs was obtained from a meta-analysis of 215 independent programs. This study confirmed an average reduction of 7-9% in drink driving offenses and alcohol-related crashes. The review suggested that multifaceted programs were most effective, particularly those involving education, psychotherapy, counseling, and follow-up contact or probation. It was noted that treatment effects have traditionally been underestimated due to the strong emphasis placed on educational interventions for dealing with all offenders. These findings are consistent with other evidence that problem drink drivers are not a homogenous group and that many remedial programs had traditionally adopted too narrow a focus. While the meta-analysis confirmed the potential effectiveness of rehabilitation, research since this time has focused on identifying the optimum types of approaches with different offenders and in different contexts.

Vehicle Sanctions: Alcohol Ignition Interlocks

Since the late 1980s, a number of jurisdictions in the United States and Canada have implemented alcohol ignition interlock programs for drink driving offenders, while a number of other countries have also introduced such programs in recent years, including Sweden and Australia. Essentially, interlock devices are connected to vehicle ignitions and prevent the vehicle from being started until a breath test has been passed (e.g. at a preset BAC level). Interlocks are administered either judicially or administratively and are generally a condition of license renewal. While research has suggested that the take-up rate for alcohol ignition interlocks is very low unless mandatory, interlocks have been strongly supported in many jurisdictions throughout the world.

Evaluations have produced promising results, suggesting that interlock programs can produce large reductions in drink driving recidivism over and above more traditional approaches. Indeed, evaluations involving electronic data loggers suggest that the devices are an effective tool to prevent alcohol-impaired drivers from operating their vehicles. However, the literature has indicated that recidivism rates typically revert to levels consistent with control group offenders upon removal of the devices. Far fewer studies have evaluated the effectiveness of interlock devices to produce crash reductions. From the limited available evidence, it

appears that there is some potential for the devices to reduce alcohol-related crash involvement while interlocks are fitted to vehicles.

The finding that the impact of interlock devices on recidivism rates is contingent upon ongoing installation of the devices suggests that interlock programs must be implemented as part of a broader approach to reduce alcohol abuse and dependency problems. That is, the device, used in isolation of other approaches, is unlikely to produce long-term behavioral impacts. However, more sustained impacts on recidivism may be achieved when interlock programs require appropriate levels of monitoring (e.g. data logging) and reporting to properly evaluate an offender's readiness to receive full license reinstatement. In addition, there appears to be a need for authorities and courts to apply criterion-based, rather than time-based, principles regarding the removal of the device. Such criteria could include data obtained from the interlocks and objective behavioral assessments of the relative risk of offenders.

While typically utilized for the purposes of secondary prevention, interlock programs can also serve a primary prevention function through implementation in fleet vehicles (e.g. trucks, taxis, and commercial fleets). Such interventions would be the most effective in industries where there are notable problems associated with impaired driving. There have also been propositions in a number of countries to move toward mandated fitting of interlock devices in all new vehicles. Such suggestions represent a long-term proactive countermeasure to impaired driving; however, they have received opposition from vehicle manufacturers and civil rights groups.

Criticisms of interlock programs have typically focused on the potential inconvenience the devices pose for offenders and their families. To some degree, these concerns have been mitigated by the tendency for jurisdictions to utilize interlocks only with high-range and/or repeat drink driving offenders. While anecdotal evidence suggests many offenders may originally resent the imposition of the devices, high levels of acceptance are later reported largely as a function of the educational and motivational effect the device provides as an extra incentive to refrain from drinking.

Another criticism relates to the tendency for evaluations to involve only motivated offenders involved in volunteer programs, whereby installation of an interlock device is associated with a reduction in license suspension or other penalties. Further research is required to explore the effects of alcohol ignition interlocks on these more motivated offenders compared with court-ordered offenders.

Early literature criticized the efficacy of interlock programs based on the potentiality for the offenders to circumvent or tamper with the device, thereby reducing their incapacitation effect. However, research has suggested that such practices do not appear to be widespread. In addition, in recent years, ongoing development has made interlock devices increasingly robust to circumvention and tampering. Specifically, many devices can detect breath signatures, require a learned breath delivery technique (e.g. hum-blow), require additional "rolling-retests" after the initial sample, include data logs and are regularly inspected and calibrated. Creating an offense category related to attempted or successful circumvention of the devices may also reduce such actions further.

Finally, it is often not feasible to install an interlock device on every vehicle used by an offender. As such, additional license sanctions should be utilized that clearly identify the interlock provisions for driving on an offender's license, as well as approaches that address alcohol abuse and dependence.

Vehicle Sanctions: Vehicle Impoundment and Forfeiture Programs

Vehicle impoundment programs give police and/or other authorities the power to seize and impound vehicles for specific periods of time for engaging in any number of offenses including high-range or repeat drink driving offenses. The specific period of impoundment typically increases as a function of the severity of offenses or the recidivist nature of offending, with forfeiture generally reserved for only the most persistent offenders. Impoundment programs are typically implemented to complement more traditional license actions.

Evidence has suggested that vehicle impoundment programs can produce substantial reductions in drink driving recidivism, as well as reductions in other traffic offenses, particularly unlicensed driving. Such impacts are largely attributed to the specific deterrent effect associated with hardship experienced by individuals close to the offender. Indeed, the potential impact on innocent third parties (e.g. spouses, children, family members, friends, work colleagues), who may also use the sanctioned vehicle, has been cited as a major criticism of vehicle impoundment and forfeiture. Thus, further research is required to determine whether such sanctions are overly punitive in their effect on non-offenders and identify provisions in legislation to mitigate such effects.

Long-term effects of vehicle impoundment have also been evidenced, albeit to a lesser extent when compared to the period of impoundment, suggesting some level of habituation among offenders to not having their vehicle. However, it is unclear whether the cost and inconvenience of the sanction motivates the offender to avoid being detected again (e.g. specific deterrence) or if access to sanctioned vehicles is restricted/denied in instances where an offense resulted in the impoundment of an employer's or spouse's vehicle (e.g. incapacitation).

While there is evidence of the specific deterrent effects associated with vehicle impoundment and forfeiture, there appears to be limited evidence to suggest such vehicle sanctions have a broader general deterrent impact on either offense rates or traffic crashes.

A question that naturally arises is whether or not progression to vehicle forfeiture has an incremental effect beyond impoundment. While the available evaluative literature is limited, there is evidence to suggest positive impacts of vehicle forfeiture on alcohol-related traffic crashes and offending. However, this research has typically only assessed the short-term impact of such sanctions and further research is required to identify the long-term effectiveness of vehicle forfeiture programs. In addition, future evaluations should aim to disentangle the unique and combined general and specific deterrent effects of vehicle-based sanctions and concurrent interventions and sanctions, such as administrative license suspension.

Other Vehicle Sanctions

A number of other vehicle-based sanctions have been implemented or trialled as a countermeasure to unlicensed driving including license plate tagging, license plate impoundment or confiscation, and electronic licenses. While these measures are designed to reduce unlicensed driving in general, they are of particular relevance to drink driving. Firstly, drivers with a history of unlicensed driving have also often been detected for drink driving. Secondly, these sanctions offer the potential to strengthen the effectiveness of license actions imposed for drink driving offenses and further deter the general public from drinking and driving.

A number of studies have provided evidence of the potential effectiveness associated with license plate tagging and impoundment laws. These findings are likely to be a product of specific deterrence, such that offenders are discouraged from driving due to their higher visibility and the ease in which police can identify them as suspended drivers. However, the evidence is typically less compelling than that regarding vehicle impoundment, arguably a function of the relatively low administration of such sanctions, the general lack of publicity given to such laws, and the concurrence of vehicle impoundment laws.

DRINK DRIVING LAWS IN AUSTRALIA: A CASE STUDY

Australia embarked on a sustained program to reduce alcohol-related crashes from the mid-1970s onward. As a result of increasing community concerns about the impairment effects of alcohol, support was obtained for legislation setting a maximum BAC level

for drivers. Given that traffic laws in Australia are enforced at a provincial level by state police services, operating under the federal system of government, the legal BAC level adopted was not initially uniform across all states. Over time, legal limits were reduced, again in a nonuniform manner. However, since the late 1980s these limits have been uniform, with all states enforcing a BAC of 0.05 for general drivers and 0.02 or 0 for novice and professional drivers.

Following the adoption of legal limits, large-scale police enforcement of these limits was undertaken from the 1980s. This was supported by a range of other interventions including publicity campaigns, community announcements, community activity programs, variations in alcohol licensing laws, and distribution arrangements for alcohol. There was also ongoing monitoring of performance involving blood tests on drivers involved in crashes, with particularly high levels of testing for serious crashes.

Over the last 40 years, the role of alcohol in fatal road traffic crashes in Australia has halved. Moreover, there have been notable shifts in community attitudes toward drink driving, with recent surveys suggesting a strong community view that such behavior is socially irresponsible. The success of Australia's drink driving laws can be attributed to a number of factors including:

- Strong political commitment to prevent drink driving, with legislation targeting drink driving receiving strong support from the highest levels of government and subsequently sending a clear message to society that drink driving and traffic safety are vital national issues;
- Legislation that clearly defines illegal BAC levels associated with operation of a motor vehicle and penalties for drink driving offenses including lower BAC limits for younger drivers as part of graduated driver licensing programs;
- Strong and well-publicized enforcement campaigns involving random and targeted breath testing regimes;
- Public education aimed at modifying attitudes toward drinking and driving and informing the community about enforcement practices;
- Prevention programs in licensed venues;
- Strict and swiftly enforced penalties for those caught breaking the law including immediate mandatory license loss for some offenders and increased penalties for repeat offenders; and
- The use of other sanctions to constrain offenders, such as alcohol ignition interlocks and vehicle impoundment, as well as drink driver rehabilitation programs (see above for more information regarding these sanctions).

In summary, for drink driving laws to be successful, the public must: know *why* driving while impaired by alcohol is both unsafe and antisocial, be *aware* of the laws that govern drink driving, *perceive a high risk* of being caught if they break the law, and know that if caught, the *consequences will be severe*.

CONCLUSIONS

Current State of Knowledge

Alcohol, through its impairment of the behavioral and cognitive functions required to operate a motor vehicle, contributes to a substantial degree of road trauma, including fatalities and injuries, as well as producing significant implications for society at large. In addition, alcohol-impaired driving has been found to be highly correlated with a number of other illegal, high-risk driving behaviors. Traffic law enforcement approaches aimed at reducing and preventing impaired driving involve three components: legislation, policing, and sanctions. The literature has suggested positive effects associated with each of these approaches; however, the degree to which recidivism and alcohol-related traffic crashes is reduced differs depending on the approach in question.

Policy Recommendations

Overall, a multifaceted approach to the problem of drink driving is required. As a starting point, the need for appropriate per se legislation and prescribed alcohol limits is clear. There is also scope to consider reduced limits for high-risk groups. Policing approaches should involve highly visible and sustained programs, involving a mix of stationary and mobile, as well as random and targeted operations. There is general consensus that greater effectiveness of testing procedures is achieved when such operations are conducted in a randomized and widespread, rather than selective, manner.

It is likely that the optimal mix of approaches will differ by context. For example, static approaches operated overtly, and augmented with concentrated and highly intensive activities conducted periodically, will predominantly serve a general deterrent function and be most effective in urban areas with high traffic flows. Conversely, mobile operations tend to serve a specific deterrent function and reduce experiences of punishment avoidance among offenders and are likely to be more effective in rural areas. While targeted operations at peak times and locations are important, random operations at non-peak times and locations also increase the unpredictability of enforcement efforts. In either

instance, adopting intelligence-led approaches improves the overall efficacy of enforcement.

Finally, with regard to sanctions, the objective should be to increase the perceived and actual certainty and swiftness of punishment. While penalties must be appropriately severe, there is evidence to suggest overly punitive sanctions can produce diminished returns or even be counterproductive. Moreover, different types of sanctions should not be conceptualized in isolation of one another, given that they can serve separate and complementary functions, such as behavior modification and addressing factors associated with alcohol abuse and dependency.

Future Research Directions

Ongoing research is required to further develop the evidence-base regarding best practice in the prevention of drink driving behavior and offender management. Future research should continue to evaluate specific aspects of policing approaches with the objective of identifying the optimal mix of stationary, highly visible operations and more targeted, mobile approaches. In addition, the impact of sanctions on recidivism, particularly in the long-term, should be fully explored, with findings utilized to further develop and enhance sanctions. From a legislative perspective, further research is needed to investigate the likely benefits of reducing prescribed alcohol limits for high-risk groups or for the driving community at large. Moreover, research should assess the impact of broader alcohol policies, such as those implemented in licensed venues, on drink driving behavior.

SEE ALSO

Driving While Impaired (Treatments), Criminal Iustice Interventions

List of Abbreviations

BAC blood alcohol concentration
DUI Driving under the influence
DWI Driving while impaired
RBT random breath testing
WHO World Health Organization

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- http://www.cdc.gov/injury Injury Center, Centers for Disease Control and Prevention (CDC).
- http://www.icadts.org International Council on Alcohol, Drugs and Traffic Safety (ICADTS).
- http://www.nhtsa.gov National Highway Traffic Safety Administration (NHTSA).
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Effects of Licensing and Supply Practices

Jordy F. Gosselt, Joris J. van Hoof, Menno D.T. de Jong Institute for Behavioral Research, University of Twente, Enschede, The Netherlands

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INTRODUCTION

Some products in modern life are associated with risks. The potentially negative effects of drinking alcohol, smoking tobacco, using drugs, gambling, and exposure to violent or otherwise detrimental movies or games are widely acknowledged. Risks may involve people's mental or physical health and/or their social well-being. Risks may be especially valid for specific groups in society. Societies generally aim to protect children and adolescents from risky products.

In this chapter, we will focus on availability as an important predictor of the use of risky products. We distinguish four types of availability: physical, economic,

legal, and social availability. Governmental legislation is an important instrument to reduce these types of availability and, as a consequence, curb people's use of risky products. A crucial factor that affects the effectiveness of such legislation is compliance.

RISKY PRODUCTS: CONSUMPTION AND CONSEQUENCES

Many risky products have in common that the risks involved are not associated with moderate and incidental use, but rather with prolonged and/or excessive use. Three general tendencies, however, are relevant in this

respect. First, habituation and addiction are important risk factors in most risky products. Consumers may get used to the products or even become physically or mentally dependent on them. Second, research has shown that early use of risky products is a strong predictor of problematic use during adulthood. Third, the so-called "gateway theory of drug use" predicts that the use of entry drugs (e.g. alcohol or cigarettes; sometimes marijuana is also included as an entry drug) may eventually result in more severe and illicit drug use (e.g. marijuana, ecstasy, or cocaine).

Below we distinguish between five types of risky products: alcohol, tobacco, illicit drugs, gambling products, and detrimental media. We discuss the products and explain briefly why they must be regarded as problematic.

Alcohol

Alcohol is the number one recreational drug in the world. It is embedded in social events in many countries, and positive health effects of alcohol have been reported when used in moderation. However, there are several risks associated with alcohol consumption. In the short term, alcohol use may lead to risky behaviors, including violence, traffic accidents, or unprotected sex. In the long term, excessive alcohol consumption is known to harm physical health, mental health, and social relations. Often addiction is involved. Alcohol use during pregnancy may cause birth defects. Adolescent alcohol use is associated with an important additional risk: Alcohol use at young ages leads to permanent damage to the brain, which is still developing during adolescence.

Tobacco

Despite governmental attempts to reduce tobacco consumption, tobacco products are still very popular worldwide. It is generally recognized that tobacco products are addictive and have detrimental effects on smokers and their immediate environment (passive smoking). In the short term, smoking may lead to allergic reactions and respiratory problems. In the long term, tobacco use may cause heart problems, lung cancer, emphysema, and strokes. Fifty percent of lifetime smokers will eventually die from their habit, and half of these deaths will occur in middle age. Smoking during pregnancy may cause birth defects.

Illicit Drugs

Apart from alcohol and tobacco, which are legal in most countries, many illicit drugs are available. The main types of drugs are opiates (e.g. heroin), cocaine, cannabis, and amphetamine-type stimulants (e.g. amphetamines, methamphetamine, and ecstasy). Cannabis is the most widely

cultivated, trafficked, and abused illicit drug. Research has confirmed the potentially detrimental health effects of all illicit drugs. The degree to which illicit drugs are addictive appears to vary per substance. An extra complication of illicit drug use is that it is closely connected to illegal and criminal environments.

Gambling

Gambling is practiced as a leisure activity, for instance in casinos, in lotteries, online, or private settings. Depending on the national context, some of the gambling opportunities are legal and others are illegal. Research has shown that gambling can be an addictive activity. The addiction urges gamblers to continue playing, even if they cannot afford it. Obsessive or irresponsible gambling may cause severe financial and social problems. Problem gambling is usually defined by the harm that is caused to the gambler or the gambler's environment, rather than by the gambler's behaviors.

Detrimental Media

Media products can also be considered to be risky products, as movies, television programs, and video games often contain potentially harmful elements. The harmfulness of media products is usually defined in relation to the media user's age. In particular, sexually explicit and violent media contents are considered to have detrimental effects on children and adolescents. Several studies found negative effects of harmful media content attitudes and behaviors in the users. Other studies, however, did not find such effects, or only found small effects. Many governments as well as parents agree that children and adolescents should be protected from detrimental media. There is no proof that detrimental media are addictive, but habituation and cultivation effects have been found.

AVAILABILITY AS A PREDICTOR OF CONSUMPTION

Availability can be seen as an important predictor of the consumption of risky products. Based on epidemiological research in the domain of alcohol, the "availability theory" was introduced. The theory assumes a causal relationship between the availability of alcohol and the alcohol consumption levels in a region, and between the alcohol consumption levels and the prevalence of problem drinking and its consequences.

Consumption patterns are more than just personal choices; they are also co-determined by the environment in which people live. If products are easily available, consumption will generally be higher than when

people's access to the products is limited. This applies not only to formal types of availability (e.g. the price of a product, the opening hours of outlets, the location of outlets, or the attractiveness and diversity of the assortment in a store) but also to informal and social types of availability (e.g. the presence of products in people's social network, or the standards and values of peers concerning the use of the product). Below, we distinguish between four types of availability: (1) physical, (2) economic, (3) legal, and (4) social.

Physical Availability

Research into the physical factors of availability, especially in the fields of alcohol and tobacco, focuses mainly on outlet density and opening hours. Several studies show that outlet density correlates positively with consumption: Higher outlet density corresponds with higher alcohol consumption in a region. Other studies, however, have not found such relations, or have even shown contradictory results. The local or national context might play a relevant role here and should therefore be considered when interpreting results. Research on opening hours led to consistent results: restrictions on opening hours are related to a decrease in consumption, whereas longer opening hours lead to higher consumption levels. Physical availability is closely related to the issue of licensing. Governments may decide whether or not risky products can be legally sold in their country and may also decide on the kinds and number of outlets that are entitled to sell them and the conditions for those outlets.

Economic Availability

Research generally shows that the price of risky products is negatively correlated to the consumption of these products. Higher prices lead to lower consumption of risky products and lower prices (e.g. in the case of special promotions) increase consumption. The most used governmental tool to curb the consumption of risky products is by taxes. Not only do prices affect usage behavior, but research has also shown that increasing prices or taxes reduces product-related problems (e.g. drinking and driving) and product-related crime. Research with a broader perspective on health care costs and health consequences also shows that a tax increase is a cost-effective policy.

Legal Availability

In addition to the physical and economic availability, governments or other parties may also focus on the legal availability of risky products. This implies that all outlets have to adhere to certain rules when they sell

risky products to customers. A widespread example of measures to decrease the legal availability of risky products is the use of age restrictions, meant to protect children and adolescents from the harmful effects of risky products. In general, higher legal ages correspond to a decrease in consumption. In the context of alcohol sales, the introduction of higher age restrictions was even found to decrease alcohol-related car crashes and other injuries. In the case of age restrictions, adolescents may look for other ways to obtain the product. Adolescents may use fake IDs, or ask older friends or even strangers to purchase the risky products for them. The latter is called "shoulder-tapping." Another example of measures to decrease the legal availability involves the phenomenon of over-serving: In some countries legislation does not allow the serving of alcohol to apparently intoxicated customers.

Social Availability

The last, and least formal, type of availability is social availability – the norms and values that are prevalent in people's social environment regarding the use of the risky products. It includes parents' styles of upbringing, their own role behaviors, the agreements they make regarding the risky products, as well as peers' behaviors in terms of social pressure, social norms, and role behaviors. With respect to the environment of adolescents, research has shown that underage individuals have easy access to risky products in their homes and that easy access leads to higher consumption rates. In the context of alcohol, adolescents not only have easy access to alcohol at home, but some parents appear to actively supply alcohol to their underage children, or facilitate their children's alcohol use in informal drinking places.

REDUCING AVAILABILITY: LEGISLATION, SELF-REGULATION, AND CO-REGULATION

To control and influence availability (in particular physical, economic, and legal availability), three types of regulations may be used, depending on the role of the parties involved (i.e. government versus industry): legislation, self-regulation, and co-regulation. The last-named can be seen as a combination of the first two.

Legislation

The first type of regulation is governmental legislation. In this case, a law is promulgated or enacted by a legislative or governing body. In addition, there is the responsibility to maintain the law and punish violators. Such legislation is as follows.

Legislation Reducing Physical Availability

Governmental legislation may be aimed at reducing the physical availability of risky products. These policies include limitations on the number of outlets, opening hours, and/or geographical location of outlets. Such regulations are mainly executed by licensing. For some risky products (e.g. alcohol, marijuana), sales within a certain distance from schools are prohibited. Restrictions on physical availability might reach the level that a substance is absent, which means it cannot be obtained legally.

A controversial example of the opposite is the Dutch drug policy, which can be characterized as liberal. Dutch drug policy has received much attention worldwide, and many have judged it to be too liberal and too tolerant. The Netherlands' drug policy distinguishes between "soft" and "hard" drugs, and aims at separating the markets and the social contexts of soft and hard drugs. Law-enforcement efforts are focused on the higher levels of the supply system. Retail trade in cannabis is tolerated in the Netherlands' numerous so-called coffee shops. The aim of this policy is to avoid situations in which consumers of cannabis suffer more damage from criminal proceedings than from use of the drug itself (Engelsman 1989). The use of hard drugs is considered to be the Netherlands' major public health problem. Policy components concerning hard-drug use include easily accessible social assistance programs, methadone supply, other drug treatment facilities, and needle exchange. Officially, cannabis remains a controlled substance in the Netherlands, and both possession and production for personal use are still misdemeanors, punishable by fine. However, in practice the possession of soft and/or other illegal drugs for one's own use is rarely punished. The Dutch alternative is a pragmatic compromise between two extreme options: An intensified war on drugs and legalization. By contrast, most other countries view recreational drug use as detrimental to society and as a practice that must therefore be outlawed. Recently, the Dutch had the effects of their drug policy examined. For all narcotics, with the exception of ecstasy, the prevalence of the use in the general population in the Netherlands is below the European average and lower than in the United States.

Legislation may also focus on the visibility of risky products. There is increasing evidence that exposure to alcohol and tobacco marketing practices is one of the environmental factors that has significant influence on juvenile consumption. Many countries therefore have introduced advertising restrictions on risky products. These restrictions include matters such as place (e.g. not near schools), contents (not aimed at youth), channel (not on youth media), or time (no broadcasting before a certain time).

Legislation Reducing Economic Availability

To reduce economic availability, the sales prices of risky products must be raised. When these risky products are sold legally, taxes are levied on most of them (alcohol, tobacco, drugs, gambling products). Legislation may be aimed at minimum levels of taxing and/or pricing. In many countries, for instance, taxes on tobacco are more than half of the final sales prices. Governmental legislation regarding economic availability may also involve limitations of price discounts and advertising at the retail level. Despite legislation affecting pricing and taxes, risky products may still be available at low prices in various ways. People may smuggle cheaper items across the border. To obtain, for example, cheap alcoholic drinks, beverages are sometimes home-brewed or home-distilled. Such illegal production creates even higher risks for people's health, inasmuch as the products are often of questionable quality.

Legislation Reducing Legal Availability

In many countries, age restrictions on the sale of risky products have been introduced to protect children and adolescents. Worldwide, many different age restrictions and age restriction systems exist, also depending on the specific type of risky product. In many countries, the legal age for buying alcohol is 18 years. In the United States, however, the buyer has to be at least 21; in contrast, in some European countries alcohol can be obtained at the age of 16. Some countries have different starting ages for drinking and purchasing alcohol. For example, in Great Britain, one has to be at least 5 years of age to consume in private (Children under 5 must not be given alcohol unless under medical supervision or in an emergency), 16 years to consume in public with a meal and accompanied by an adult, and 18 otherwise, whereas there is only one legal buying age (18 years). For tobacco, the starting ages for buying and consuming sometimes also differ. In general, most countries use either 16 or 18 years as an age restriction.

For media products, many different age-rating systems exist. Media rating systems (also known as age classification systems, warning label systems, or restrictive ratings) can serve as an effective tool in restricting access and exposure to harmful media. Such systems, which at this time are used in at least 52 countries worldwide, are designed to inform parents about and protect children from violent or otherwise harmful media content. Age pictograms (also known as evaluative ratings) show whether a media product's content is harmful for minors below a given age. Furthermore, in various systems, the actual content is specified with additional warning pictograms (descriptive ratings). Both the age classification labels and the warning labels can be placed on covers, packing materials, posters, and

other advertising materials, and they can be shown at the start of a movie or television program. Just as there are different ages for drinking alcohol or smoking tobacco, worldwide, many countries have their own rating systems with their own pictograms and their own regulations. Especially in the ratings of television programs, many differences can be found, for example, regarding whether classifications are compulsory, the types of television networks involved, when the classification is shown, and restrictions regarding the time of broadcasting. Furthermore, most countries have their own system of coding media products, which may result in very different classifications per country for the same media product.

Self-Regulation

Self-regulation involves the regulation of an industry that is intended to achieve shared goals that are deemed important (Dorbeck-Jung et al. 2010). In the private sector self-regulation has a long tradition. The party's own interest is prominently present but goes beyond just making profit. Self-regulation may prevent governmental regulations from being introduced or contribute to the industry's reputation, which is in line with a growing interest in corporate social responsibility. Self-regulation may increase customer confidence and create customer loyalty. The rise of self-regulation may also be explained by unsuccessful enforcement activities by governmental bodies, and the divide between the traditional hierarchical government and new developments in the "civil society." Self-regulation activities play a significant role in Europe, the United States, Australia, and Canada. Often self-regulation is established as a result of governmental initiatives. Pure selfregulation where the initiative comes solely from the industry itself is rather rare.

Co-Regulation

When the government is explicitly involved in self-regulation activities we speak of co-regulation. This means that the industry and government cooperate, and together they formulate the conditions that apply. For example, legal rules prohibiting the exposure of minors to certain media are said to be extremely difficult to enforce. For this reason most countries entrust the protection of minors from harmful media to a regulatory system that combines private and public regulation at various regulatory levels (including international, regional, and national legislation, self-regulation, funding, and distribution of information). In Europe's regulatory systems, all forms of hybrid regulation can be found (i.e. co-regulation, enforced self-regulation, meta-regulation,

and multilevel regulation). In many European countries, different regulatory systems are used for television, movies, DVDs/videos, and games. The regulations on games are based on harmonized self-regulation at the European level, while the other media (DVDs, movies, and TV programs) are controlled by combining governmental and nongovernmental regulatory activities at the national level. Often these kinds of regulations are controversial because of the multiple interests that are at stake. The industry strives for maximum profits, customers may prefer easy access and affordable prices, while governments and health organizations are concerned about the health risks associated with consumption (Heather and Stockwel 2004).

COMPLIANCE WITH LEGISLATION

Rule compliance – the idea that the regulated parties obey established rules – depends on whether those parties are able and willing to comply. The regulated parties must know and understand the rules. Their willingness to comply depends partly on their attitudes toward the regulations (intrinsic motivation) and on their estimations of the consequences of violations (extrinsic motivation). Research into shop-floor compliance with the age restrictions for media products, for instance, showed that three factors were important predictors of compliance: (1) salespersons' personal acceptance of the media rating system, (2) the perceived legal basis for the age restrictions, and (3) the perceived degree of (external) surveillance.

In regulations that combine public and private regulation, rule compliance depends on several conditions, including sufficient overlap of private interests with public interests; the existence of specific pressures to comply; a small number of actors in a highly organized and homogeneous sector; and a high degree of social responsibility within the sector. Public and private interests may overlap when public and private regulators purport to have similar objectives, when private regulators acknowledge reputational advantages, and when they have an interest in forestalling legislation. Compliance with private regulations depends on the pressures on companies to comply. A relatively small number of actors and a relatively high degree of homogeneity and organizational capacity in a given sector are required for the establishment and maintenance of self-regulation. Social responsibility is indicated by the activities of the trade association and by a strong business community with a generalized concern for taking private regulation seriously. The involvement of organizations in societal issues like responsible sales is also referred to as corporate social responsibility. It can be

a natural result of the ideological beliefs of the organization, but can also – through media – be compelled by the public and actually manifest itself in behavior or actions that seem to be inconsistent with an organization's core activities. Today, corporate social responsibility is no longer conceived solely as a moral responsibility of an organization for greater social good, but also as a strategic resource to be used to improve performance.

MONITORING AND IMPROVING COMPLIANCE WITH LEGISLATION

After setting the rules, it is important to monitor whether all regulated parties actually comply with them. Worldwide, the results of many studies indicate that compliance with regulations aimed at restricting people's access to risky products is problematic. In many cases customers are still able to obtain the desired products, despite the regulations. The success rates fluctuate and appear to be related to the specific product concerned and the degree of enforcement involved in the region (e.g. the use of fines or license suspensions). Because compliance is important in reducing the consumption of riskassociated products, and given the fact that compliance levels are generally low, it is important to look for approaches to improve compliance. Four general approaches may be distinguished: governmental instruments, (2) industrial instruments, (3) societal instruments, and (4) research.

Governmental Instruments on Legislation and Co-Regulation

Low compliance rates indicate that incentives to continue sales seem to outweigh the incentives to comply. Two types of instruments may complement each other. First, it is important to raise awareness of the importance of the regulations and make all parties involved aware of their (legal and/or contractual) status. This strategy is aimed at reducing ambiguities and convincing people. Second, it is important to connect possible violations of the regulations to negative consequences. The parties involved must be aware of substantial and effective surveillance activities of their compliance and must recognize that the sanctions for violations are severe (either high fines or suspension). Several compliance studies show that more severe interventions, such as increased enforcement levels and police interventions, cause higher compliance rates. Various kinds of enforcement are fruitful ways of reducing sales of risky products, especially if they not only include warnings and penalties in the case of violations, but also focus on the actual and perceived chance of being caught. Recent discussions on enforcement strategies include the possibility of punishing not only the seller of products but also the buyer.

Industrial Instruments on Self-Regulation and Co-Regulation

In the case of self-regulation and co-regulation, compliance performance has to be assessed by the own industry. In cases of noncompliance, the industry has to impose sanctions on its own members. As a result, compliance and control activities within the own industry are hard to execute. The industry may choose to focus on informing and educating its members, for example, by campaign materials or training programs for personnel. However, several studies show that an exclusive focus on information will not suffice to ensure compliance with rules.

Societal Instruments

Other parties in society may play its role in increasing compliance. When a vendor violates certain rules, many regulatory systems offer customers the opportunity to file a complaint. Complaint boards may then impose fines when the obligations laid down in the statutes are violated. If it is possible for members of the general public to complain, it is crucial that this possibility be made public and that the complaint procedure be easy and transparent.

Research

Research may also contribute to compliance by making policymakers, industry representatives, vendors, and/or the general public aware of problems with compliance. Due to issues of social desirability and the problem of making correct judgments about people's own behavior in ambiguous situations, survey research is not a valid research option. For instance, despite the fact that compliance levels with age restrictions to sell alcohol are consistently very low in the Netherlands (10–20%), more than 90% of the store managers reported in surveys that no single violation of age restrictions would happen in their stores.

Instead, mystery shopping (also called decoy operations) has proved to be a far more valid way of investigating actual compliance levels. Selling points are then visited by trained research assistants, who pretend to be "regular" customers, but who act according to a script. Immediately after the visit, a detailed form is completed about the mystery shopper's experiences. Mystery shopping is frequently used to investigate the service quality of stores and the quality of medical care. In more and

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more countries and regions, this type of undercover research has also been used to investigate retailers' compliance with age restrictions or other kinds of legislation.

Legal and Ethical Considerations

Conducting mystery visits at outlets that are not aware of the fact that they are being investigated raises some legal and ethical issues. For example, in most countries, stores that sell age-restricted products to underage purchasers commit an offense and are therefore liable to penalty. Also, regarding the stores involved, an important issue is whether it is justifiable to include them in a study without their prior consent. Four important criteria may be found in the literature to judge the appropriateness of undercover research approaches (Gosselt et al. 2007): (1) societal relevance of the research topic, (2) inadequacy of the more conventional research methods, (3) public nature of the events observed, and (4) avoidance of negative consequences for the research participants. In principle, all four criteria can be met. First, age restrictions are designed and implemented for specific reasons, namely, the protection of specific (mostly underage) consumers. It is generally deemed important to protect children and adolescents from the dangers of risky products, and noncompliance with the regulations is the most important potential leak in the system. Second, the inadequacy of more conventional research methods like surveys has been demonstrated in earlier research. Third, the interactions between customers and store personnel are normally not private: Other people may enter the store whenever they want and are able to observe the transaction. Fourth, negative consequences for stores and vendors can be avoided if (1) the mystery shoppers behave like normal customers and do not demand too much time of the store personnel and (2) the anonymity of all stores and vendors in the study is safeguarded. Regarding the minors who may participate in studies like these, two ethical considerations are relevant. First, to avoid unwanted effects on the mystery shoppers' attitudes and behaviors regarding the risky product at hand, it is important to select just those adolescents who have prior experience in buying and consuming the product at hand, to ask their parents for informed consent, and to debrief them personally about the dangers of the product. Second, to prevent adolescents from being confronted with awkward situations, vendor aggression, or police interrogations during the mystery visits, the minor must be given an official letter explaining the research purpose of the buying attempt, and research assistants are required to stand by to intervene.

Research Findings

Recently, compliance checks on legislation have been executed in many countries. Despite the large number of

studies, specific predictors of compliance on legislation are not clear. Literature on compliance states that compliance levels depend on knowledge of the regulation, the cost-benefit ratio, the degree of acceptance of the regulations, the loyalty and obedience of the regulated parties, informal monitoring, informal report probability, monitoring probability, detection probability, selectivity of the inspector, chance of sanctions, and severity of sanctions. Initiatives in the Netherlands issued by the industry and local projects (mainly on alcohol) only achieved a (temporary) increase in compliance of 0–20%. The highest level on compliance in the Netherlands appears to be 50%, but in other countries compliance sometimes reaches about 100%. A crucial factor in the system is that age verification still depends on individual cashiers on the shop floor.

A rather drastic but very promising intervention designed to increase compliance can be remote age verification. Recently, a remote age verification system was developed, aimed specifically at age-restricted products. When customers want to purchase risky products, a live video connection is made with a remote control center, and the cashier can only finish the payment after receiving an authorization from trained judges at the remote center. A compliance study (Van Hoof et al. 2010) found that the compliance rate differed considerably between the remote age verification and the traditional purchase situations. Results showed that the adoption of a remote age verification system led to a drastic improvement in shop floor compliance with age restrictions. The effects may be attributed to three mechanisms. First, the remote age verification system has a priming effect, as is underlined by an increased number of ID requests. Cashiers have many different tasks, such as scanning products, counting money, and interacting with customers, so that age verification becomes an extra activity for them. The remote verification system automatically signals when age verification is required, and the remote age verification employees only have one task. Second, remote age verification employees may be expected to have more expertise and practice in judging the age of adolescents and reading and interpreting IDs (e.g. determining someone's age using a date of birth). Third, remote age verification removes the social pressure from the decision of whether to sell. It may be difficult for cashiers to refuse to sell cigarettes to customers, especially when they are close in age.

CONCLUSIONS

The availability of risky products is a strong predictor of the consumption of these products. To decrease consumption, it seems important to decrease physical, economic, legal, and social availability. To control and influence availability, three types of regulations may be used, depending on the role of the parties involved: legislation, self-regulation, and co-regulation. After setting the rules, it is important to monitor whether all parties actually comply with the rules. Rule compliance depends on whether those parties are able and willing to comply. The regulated parties must know and understand the rules. Their willingness to comply partly depends on their attitudes toward the regulations (intrinsic motivation) and on their estimations of the consequences of violations (extrinsic motivation). Results of many studies indicate that compliance with regulations aimed at restricting people's access to risky products is problematic. In this chapter, we discussed four approaches that can be used to improve compliance with regulations: (1) governmental instruments, (2) industrial instruments, (3) societal instruments, and (4) research. Interventions all boil down to a combination of enforcement strategies and communication. Communication will only be effective if sellers wholeheartedly endorse the necessity to comply. Enforcement checks will only be effective when store managers are aware of them and are periodically informed about their results and consequences. On the level of stores or store chains, managers inform and train employees, supply aid in facilitating age verification, or create special counters for risky products. Technological innovations include the introduction of cashier systems that beep whenever risky products are scanned. On the national level, public information campaigns inform people about the requirement to show identification when buying risky products. The effects of these interventions, however, are limited.

SEE ALSO

Marketing and Advertising Control, International Policies to Reduce Alcohol Consumption and Related Harms

Further Reading

Dorbeck-Jung, B.R., Oude Vrielink, M.J., Gosselt, J.F., Van Hoof, J.J., De Jong, M.D.T., 2010. Contested hybridization of regulation: failure of the Dutch regulatory system to protect minors from harmful media. Regulation & Governance 4, 154–174.

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73

Marketing and Advertising Control

Peter Anderson

Apartat de Correus, Girona, Spain

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WHAT IS THIS CHAPTER ABOUT?

This chapter is about commercial communications (marketing) and the use of alcohol and tobacco, and how commercial communications should best be regulated. Commercial communications play a key role in shaping alcohol and tobacco-related knowledge, opinions, attitudes, and behaviors among individuals and within communities. Media communications include brand-specific advertising and promotion, news coverage, depictions of drinking and smoking and alcohol and tobacco products in entertainment media, public relations, corporate sponsorship, corporate advertising, political advertising for ballot initiatives and referenda, and media campaigns for alcohol and tobacco control (see Fig. 73.1).

Commercial communications on alcohol and tobacco are big business. For example, the total annual advertising expenditure in the United Kingdom across all sectors in 2007 – from car insurance to soft drinks – was just below £9bn, of which some £200m was spent on alcoholic drinks advertising on television, the radio, in the press, outdoors, and in cinemas. In comparison, the expenditure on carbonated soft drinks and hot

drinks was some £100m and £40m respectively, and on all food products (excluding sweeteners, jams and spreads, confectionary and beverages), some £400m. Television was the key medium for alcoholic drinks advertising, accounting for 49% of expenditure compared with 43% of total UK advertising spent on television, the radio, in the press, outdoors, and in cinemas. There were some 440 000 alcoholic drinks advertising spots on television in 2007. Including other marketing activities such as sponsorship, competitions, special promotions, and online and mobile phone advertising increased the UK alcohol industry's £200m annual spend to £800m for marketing communications as a whole. Alcoholic drink companies were the second largest source of sport sponsorship funding behind the financial services sector.

Cigarettes are one of the most heavily marketed products in the United States. Between 1940 and 2005, US cigarette manufacturers spent about \$250 billion (in 2006 dollars) on cigarette advertising and promotion. In 2005, the industry spent \$13.5 billion (in 2006 dollars) on cigarette advertising and promotion (\$37 million per day on average). Currently, most of the cigarette industry's marketing budget is allocated to promotional

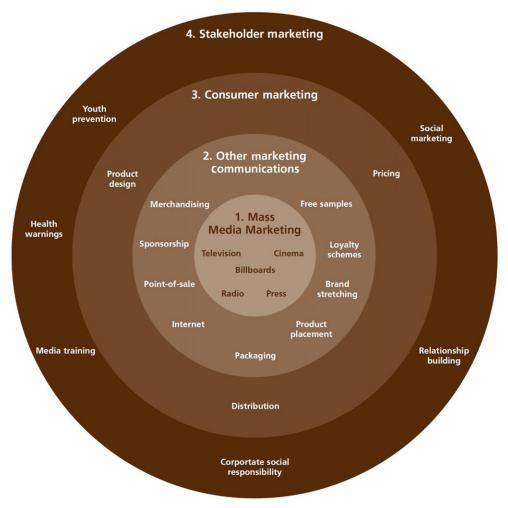


FIGURE 73.1 The four layers of marketing. Adapted from: National Cancer Institute (NCI). Davis, R.M., Gilpin, E.A., Loken, B., Viswanath K, Wakefield, M.A. (Eds.), 2008. The Role of the Media in Promoting and Reducing Tobacco Use. NCI Tobacco Control Monograph Series No. 19. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute. NIH Pub. No. 07-6242, June.

activities, especially for price discounts. Price discounts accounted for 75% of total marketing expenditures in 2005 (\$10.1 billion in 2006 dollars). Less than 1% of cigarette marketing expenditures are now used for advertising in traditional print media. Tobacco advertising is dominated by three themes: providing satisfaction (taste, freshness, mildness, etc.), relieving anxieties about the dangers of smoking, and creating associations between smoking and desirable outcomes (independence, social success, sexual attraction, thinness, etc.).

ADDICTIONS AND BRAIN FUNCTION

The pharmacological effects of addictive drugs on behavioral decision-making show that they have a predictable unfair advantage over other products, as also seems to be the case with other consumer products, such as high energy foods, food with high fat and sugar content. All addictive drugs disrupt calculations made by the brain's reward circuitry. To determine the value of naturally rewarding substances, the brain conducts an in-depth calculation of the impact of consumption of the substance on the consumer within the current and historical environment. Addictive drugs shortcircuit this assessment by pharmacologically augmenting a signal thus indicating the difference between the predicted value of the reward and the observed reward, such that the circuit mistakenly overestimates the value of consuming the drug, regardless of whether the consumer was helped or hurt as a result of drug use. This leads the consumer to favor working harder to obtain it, even if it provides no objective or subjective benefit to the user. Thus, addictive drugs, such as alcohol, include a chemical that directly distorts the brains' decisions about how much work to devote to consume them, ensuring that people will pay more to get the drug than it is worth. Adolescents aged 14-17 EXPERIMENTAL STUDIES 719

years with alcohol use disorders showed substantially greater brain activation to alcoholic beverage pictures than control youths, predominantly in brain areas linked to reward, desire, and positive affect. The degree of brain response and the desire to drink increased linearly with the number of drinks consumed per month. This evidence shows that addictive drugs (as well as some high energy dense foods) have an unfair competitive advantage over other consumer products and thus should be regulated accordingly.

ADVERTISING AND EXPECTANCIES

Advertising is one of the many factors that have the potential to encourage young people to drink and smoke. The expectancies (the action or fact of expecting, in this context expecting the use of alcohol or tobacco) of young people who have not started to drink or smoke are influenced by normative assumptions about teenage drinking and smoking as well as through observation of drinking and smoking by parents, peers, and models in the mass media. Research has linked exposure to portrayals of alcohol and cigarette use in the mass media with the development of positive expectancies by children and adolescents. Young people with more positive affective responses to advertising hold more favorable drinking and smoking expectancies, perceive greater social approval for drinking and smoking, believe drinking and smoking are more common among peers and adults, and intend to drink and smoke as adults. Fourteen-year-olds who are more exposed to advertisements in magazines, at sporting and music events, and on television are more aware of them than those with less exposure, as are teenagers who watch more television, pay attention to advertisements and know adults who drink and smoke. Among 10-17-yearolds, the perceived likeability of advertisements is a function of the positive affective responses evoked by the specific elements featured in the advertisements. The liking of specific elements featured in advertisements, such as humor, animation, and popular music, significantly contribute to the overall likeability of these advertisements and subsequently to the effectiveness of advertising indicated by intent to purchase the product and brand promoted by the advertisements.

Theoretical models of the impact of advertising on young people go beyond a simple view that advertising primarily works by changing consumer attitudes to a product or by increasing brand salience before changes in behavioral patterns occur. Studies in neuroscience, psychology, and marketing conclude that adolescents may be especially attracted to risky branded products that, in their view, provide immediate gratification,

thrills, and/or social status. According to the Message Interpretation Process model, individuals progressively internalize messages using a combination of logically and emotionally dominated processing strategies. The model, supported by decision-making theory, social cognitive theory, and dual-process theories of persuasion, proposes that certain responses to messages interrelate in ways that progressively lead to behavioral decisions. If a portrayal corresponds closely to personally relevant reference groups, for example, children will be more likely to wish to emulate the portrayal. If children admire a mediated reference group such as models in an advertisement, they will tend to expect that imitating the models' behaviors will bring positive results.

Although such studies find positive relations between expectancies and drug use, expectancy studies, by themselves, do not establish whether advertising actually influences young people's behavior. Further, there is increasing evidence that such prebehavior cognitions, for example, expectancies and attitudes, are related to consumption in a more complex way. For example, for adolescent smoking, it has been shown that, over time, behavior can predict attitudes more strongly than attitudes can predict behavior.

CROSS-SECTIONAL STUDIES

Because they cannot show whether exposure preceded drinking or smoking uptake, cross-sectional studies, which take a snapshot of exposure to advertising (awareness and/or appreciation) and levels of drinking and smoking, leave open the possibility that any correlation is as likely to reflect drinking and smoking encouraging young people to take an interest in advertising as vice versa. Paying attention to advertising presupposes that the viewer is getting some benefit or reward from it - most fundamentally that they are doing the right thing by consuming the product advertised - and advertisers deliberately design their work to provide such rewards. Thus, cross-sectional data can shed a useful light on the role advertising plays in young people's drinking and smoking; and such studies have consistently reported correlations between increased exposure and greater likelihood of current drinking and smoking.

EXPERIMENTAL STUDIES

Some of the most powerful evidence for the impact of advertising has come from experimental studies and the use of alcohol. An experimental study has found that the portrayal of alcohol on television influences actual drinking behavior. In a naturalistic setting (a bar laboratory), 40 young adult male pairs (80 participants) watched a film clip with two commercial breaks for 1 h and were allowed to drink nonalcoholic and alcoholic beverages. The films American Pie 2 (2001) and 40 Days and 40 Nights (2002) were selected because they were comparable concerning genre and Motion Picture Association of America rating. In American Pie 2, characters drank alcohol 18 times and alcoholic beverages were portrayed an additional 23 times. In 40 Days and 40 Nights, characters consumed alcohol three times and alcoholic beverages were portrayed an additional 15 times. After 14 and 33 min the clips were interrupted by a commercial break for 3.5 min, containing either exclusively neutral advertisements (e.g. promoting a car or a video camera) or neutral advertisements combined with alcohol advertisements. Each of the combined breaks contained two alcohol commercials. The participants were randomly assigned to one of four conditions varying on type of film (many versus few alcohol portrayals) and commercials (alcohol commercials present or not). The results indicated that, independently, participants assigned to the conditions with substantial alcohol exposure in either the film or commercials consumed more alcohol than other participants, controlling for the participant's weekly alcohol consumption. Those in the condition with higher alcohol portrayal in the film and commercials drank on average three glasses within a period of 1 h, compared to one and a half glasses drunk by those in the condition with little or no alcohol portrayal. Thus as little as 1 h of exposure doubled the student's alcohol consumption in real time.

In another experiment, 184 young adults were invited to watch a movie (Watchmen) in a real service cinema where people can order drinks and snacks during the movie. On one Wednesday, four alcohol commercials and six nonalcohol commercials were shown and on the other Wednesday, six nonalcohol commercials were shown. For the young adults who normally drank more than seven drinks a week, those who were exposed to the alcohol commercials drank over twice as much alcohol during the 2.5 h movie than those who were not exposed to the alcohol commercials. For the lighter drinkers (those who normally had seven or less drinks a week), the exposure to the movie commercials did not change the amount they drunk whilst watching the movie.

LONGITUDINAL STUDIES

Strong and consistent evidence from longitudinal studies indicate that exposure to cigarette advertising influences nonsmoking adolescents to initiate smoking and to move toward regular smoking.

Similar findings have been shown for alcohol, but, since they are more recent, the results are discussed in more detail. At least 13 longitudinal studies have been identified from at least two systematic reviews that have investigated the impact of marketing communications on young people beginning to drink and continuing to do so. The 13 studies, which followed up a total of over 38 000 young people, were drawn from the United States (9 studies), Belgium (1 study), Germany (1 study), and New Zealand (1 study). Three studies reported on the impact of overall alcohol advertising, one study on brand recall and receptivity, three studies on television advertisements, two studies on media exposure, three studies on alcohol use in films, one study on radio exposure, two studies on magazine exposure, two studies on beer concession stands, two studies on in-store displays, three studies on ownership of alcohol-branded merchandise (ABM), and one study on outdoor advertisements.

Twelve of the thirteen studies concluded that exposure did have an impact on subsequent alcohol use, including starting to drink and heavier drinking among existing drinkers, with a dose–response relationship in all studies that reported such exposure and analysis. There were variations in the strength of association and the degree to which potential confounders were controlled for. The 13th study, which tested the impact of outdoor advertising placed near schools, failed to detect an impact on actual alcohol use but found an impact on intention to use.

There was no consistent evidence that the size of the impact varied across the countries. When controlling for exposure to all forms of advertising, the size of the impact appeared greater for television and media exposure, including exposure to alcohol use in films, and for ownership of ABM than for exposure to radio, magazines, beer concession stands, and in-store displays. The impact applied to overall advertising (3/3 studies), and, when controlling for exposure to other types of marketing, brand recall and receptivity (1/1 study), TV advertisements (2/3 studies), TV and video exposure (3/3 studies), alcohol use in motion pictures (3/3 studies), beer concession stands (1/2 studies), and ABM (3/3 studies), but not for radio (1/1 study), magazines (2/2 studies), or in-store displays (2/2 studies).

One of the few studies that allowed an estimate of the absolute size of impact was one of 11–12-year-olds. At 1-year follow-up, 17% had reported drinking beer during the past year. Twenty per cent of those in the highest quartile of advertising exposure (including exposure to television advertisements, magazine reading, radio listening, beer concessions, in-store beer displays, and ownership of beer promotional items),

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had used beer during the previous year, compared with 13% in the lowest quartile, a 50% increase.

Seven of the eight studies that measured the impact of exposure on initiation of drinking included an interval or continuous level exposure measure, and all seven studies found a dose-response relationship. One study on multiple measurement points at 8-month intervals found that movie alcohol exposure at baseline predicted alcohol use at 8 months, while movie alcohol exposure between baseline and 8 months did not predict alcohol use at 8 months, but did predict alcohol problems at 16 months, and movie alcohol exposure between 8 and 16 months predicted alcohol use at 16 months. At all times, alcohol use predicted alcohol problems and there were significant indirect and independent effects of movie exposure at baseline, 8 and 16 months on alcohol problems at 24 months. In the same study, when investigating the influence of ownership of ABM, this ownership at baseline had a significant direct impact on initiation of binge drinking at 8 months, but not initiation of binge drinking between 8 and 16 months, whereas new ownership of ABM at 8 months had a significant direct impact on initiation of binge drinking at 16 months.

ECONOMETRIC STUDIES

Although potentially very important, econometric studies, which look for correlations between the amount of alcohol and tobacco advertising and the amount of smoking and drinking taking place in a particular jurisdiction, run into a number of methodological difficulties. First, measures of the amount of advertising, which typically use expenditure on advertising, vary in accuracy and inclusiveness. Second, analysis depends on the construction of a complex model that ascribes values for all the different variables – including price, drinking and smoking restrictions, and disposable income – as well as any advertising that might be implicated. Third, variations in the amount of advertising tend to be minor (few comprehensive bans have been introduced). So researchers are looking for potentially small changes in drinking and smoking patterns. Fourth, measures of the overall amount of advertising do not necessarily give an accurate picture of exposure by young people.

Not surprisingly, only modest effects have been found in some studies, while others have found no effects. For example, looking at alcohol advertising expenditure data across states in the United States, it has been found that, when controlling for alcohol price, income, and a number of sociodemographic variables, advertising expenditure had a modest and independent effect on adolescent monthly alcohol use and binge

drinking. It could be estimated that a 28% reduction in alcohol advertising would reduce adolescent monthly alcohol use from 25% to between 24 and 21%, and binge drinking from 12% to between 11 and 8%. In a meta-analysis of 132 studies which provided 322 estimated advertising elasticities, a positive impact of advertising was found on consumption which, in a meta-regression procedure controlling for alcohol price and income, was significantly larger for spirits than for beer. On the other hand, controlling for price, income, and minimum legal drinking age across US states, another study found total alcohol consumption rose after bans on price advertising, but fell after bans on billboard advertising.

The studies of tobacco advertising bans in various countries show that comprehensive bans reduce tobacco consumption. Noncomprehensive restrictions generally induce an increase in expenditures for advertising in "nonbanned" media and for other marketing activities, which offset the effect of the partial ban so that any net change in consumption is minimal or undetectable.

SELF-REGULATION

In some jurisdictions, marketing relies on selfregulation by economic operators including advertising, the media, and producers. To be effective, however, selfregulation needs a clear legislative framework. Furthermore, a self-regulatory system needs sufficient incentive to be effective. There is no reason to believe that the industry will participate for selfless reasons just to improve public health. A threat of government adjudication can be a strong incentive. In general, a selfregulatory system works best when pressure from government and civil society and lawsuits are the greatest and least well where there is little advocacy. Also, regulations should cover the entire range of marketing activities to which young people are exposed in order to avoid advertisers simply using the new media to avoid the regulations. Interpretations by the general public, and especially by vulnerable groups such as young people, should be included in evaluation of the advertisements, since evidence from a number of studies shows that these voluntary systems do not prevent the kind of marketing that has an impact on younger people. Self-regulation can only be effective as long as there is provision for third-party review of complaints concerning breaches. Otherwise, the interested persons who create and agree to abide by a code are the same ones who monitor its application. Sanctions and the threat of sanctions are needed to ensure compliance. An independent body or a government agency should be responsible for monitoring alcohol-marketing practices and should carry it out systematically and routinely.

There are many studies that show that self-regulation does not work. An independent review for the UK government in 2008 of the voluntary social responsibility standards in the production and sale of alcoholic drinks identified many areas of poor practice frequently used in clubs and bars for young people including people who appear to be under 18 years frequently being admitted to age-restricted venues in which they cannot purchase alcohol legally, the promotion of alcohol through low price offers, inducements by DJs to consume greater quantities, and glamorization through links with sexual imagery, encouragement to drink more and faster through shots and shooters being "downed in one," sales to blatantly intoxicated people, several health and safety issues inside bars and clubs – for example, overcrowding, broken glass, and spilled alcohol, poor dispersal practices, and several instances of antisocial behavior and low level crime (fights and assaults, urinating and vomiting in public places, criminal damage). The review concluded that the trading climate led to a commercial imperative that overrides adherence to self-regulation standards. The standards were considered as having negligible impact in either reducing bad practice or promoting good practice on the ground; they lacked focus and they were a confusing mix of provisions, and there was no evidence to suggest any direct causal link between the impact of self-regulation standards and a reduction in alcohol-related harm.

Another example comes from the United States, where, historically, the alcohol and tobacco industries have been the biggest users of outdoor advertising. However, the 1999 Master Settlement Agreement (MSA) outlawed tobacco billboards and transit furniture (e.g. bus, bench) advertisements, and the Outdoor Advertising Association of America pledged to voluntarily eliminate advertisements for alcohol and tobacco within 500 feet of schools, playgrounds, and churches. However, observational studies in preKatrina southern Louisiana and in Los Angeles County during the years 2004-2005 found that more than one in four tobacco advertisements in Louisiana failed to comply with the MSA. In Los Angeles, 37% of alcohol advertisements and 25% of tobacco advertisements were located within 500 feet of a school, playground, or church; in Louisiana, roughly one in five advertisements promoting alcohol or tobacco fell within this distance.

An analysis from the Center on Alcohol Marketing and Youth found that exposure to alcohol advertising on US television increased 71% between 2001 and 2009. Driving this increase was the rise of distilled spirits advertising on cable television. Youth exposure to all distilled spirits TV advertising was 30 times greater in 2009 than in 2001. By 2009, the majority of youth exposure to advertising for all alcoholic beverages on cable

was occurring during programming that youth ages 12–20 years were more likely to be watching than adults 21 and above. Under pressure from the Federal Trade Commission to reduce youth exposure to alcohol marketing, in 2003 trade associations representing beer and distilled spirits companies joined wine marketers in committing to advertise only when the underage audience composition is less than 30%. This threshold has been ineffective in reducing youth exposure on television, either in absolute or in relative terms. Using as the comparison to 2004 (the first full calendar year after beer and distilled spirits adopted the 30% threshold), data show that by 2009 youth exposure to alcohol advertising on television had grown by a greater percentage than that of young adults ages 21-34 or adults ages 21 and above. Moreover, industry compliance with the 30% threshold remained uneven. In 2009, 7.5% of all alcohol product advertisement placements (23 718 ads) and 9% of all alcohol product ad placements on cable (16 283 ads) were on programming with underage audiences greater than 30%.

Although in magazines, alcohol companies have almost universally met the self-regulatory standard they set in 2003 for maximum youth audience composition of media in which they would place their advertising, these standards precluded advertising in only nine of the 160 magazines used by alcohol companies between 2001 and 2008. Compliance with the 30% standard left 25 magazines with youth audience compositions above 15%. Advertisements placed in these 25 magazines accounted for 78% of youth exposure to alcohol advertising in magazines in 2008. Sixteen, mostly major, alcohol brands (5% of the 325 alcohol brands advertising in magazines in 2008) generated more than half of the youth exposure in these 25 magazines. Thus, while total youth exposure to alcohol advertising in magazines has declined, overexposure is still common, and overexposing ad placements account for the majority of youth exposure to alcohol advertising.

An overview of what internal tobacco company documents have to say about tobacco advertising in the UK highlights three things. First, it confirms the key conclusions that tobacco advertising can increase consumption as well as brand share, where young people are a key potential target who are particularly susceptible to psychosocial appeals, that sponsorship works in exactly the same way as advertising (only with greater subtlety), and that advertising is only a small fragment of marketing. The internal documents show that, despite public pronouncements to the contrary, the industry has clearly been working on the assumption that all these findings are correct. Furthermore, it is exploiting the opportunities that result: Market growth is a goal, brand images secure the young, the subliminal qualities of sponsorship are welcomed, and the pack (a marketing FURTHER READING 723

tool often overlooked by regulators) is exploited to the full. Secondly, and perhaps more worrying than these specific practices is the overall picture that emerges of an industry that is doing everything it can to encourage smoking. The commercial imperative is all, and the enthusiasm and competitive drive to meet its demands are palpable. Ethical doubts are not acknowledged, and health consequences barely get a mention.

Thus, a range of experiences demonstrates the unworkability of self-regulation. The only solution is statutory regulation, with the overt aim of removing all tobacco and alcohol marketing. This regulation has to be powerful, comprehensive, and flexible: Powerful to ensure that, in a profitable market, transgression does not pay; comprehensive to ensure that all facets of marketing are controlled, and flexible to ensure that innovations are identified and stopped.

SEE ALSO

International Policies to Reduce Alcohol Consumption and Related Harms, International Policies to Reduce Tobacco Use

List of Abbreviations

ABM alcohol-branded merchandise **MSA** Master Settlement Agreement

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Relevant Websites

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http://www.stap.nl/en/eucam/ – EU-Central Asia Monitoring. http://www.niaaa.nih.gov/Pages/default.aspx – National Institute on Alcoholism and Alcohol Abuse.

http://camy.org/ - The Center on Alcohol Marketing and Youth.

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International Policies to Reduce Alcohol Consumption and Related Harms

Tim Stockwell

Centre for Addictions Research of British Columbia, University of Victoria, BC, Canada

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INTRODUCTION

Alcohol is the psychoactive drug of choice in most contemporary societies, and its consumption is responsible for substantially greater harm overall than are all the normally illegal substances such as cannabis, heroin, cocaine, and ecstasy. A group of drug experts in the United Kingdom recently published a report in the prestigious medical journal, *The Lancet*, which ranked the potential hazards from different psychoactive substances against different health and social harm criteria. They concluded that alcohol ranked first as the most harmful, followed by heroin and crack cocaine at some distance.

The consumption of alcohol in most modern societies is so commonplace and the act of pleasurable and apparently harm-free drinking is so familiar that scientific evidence of harm is often greeted with disbelief both by the public and their elected decision makers. Nonetheless, a substantial body of evidence has accumulated around the world demonstrating the relative effectiveness of different policies designed to reduce consumption and related harms. This chapter provides an overview as well as a discussion of the difficulties in communicating the scientific evidence about alcoholrelated dangers and the potential effectiveness of alternative policy responses.

By the way of a small local illustration, a report was released in British Columbia, Canada, in 2009, which linked increasing alcohol consumption and deaths in the province to a dramatic increase in the number of liquor outlets between 2001 and 2008. The report outlined several evidence-based policy responses to reverse this trend involving pricing alcoholic drinks to reflect

their alcohol content, linking prices to inflation and increasing minimum prices. The local media caricatured these policies as a "price hike"; talk radio stations received angry calls pouring scorn on the idea that raising prices would influence the behavior of "alcoholics"; and newspapers published editorials sympathetic to the manufacturers of locally produced high-alcohol content "craft" beers. Members of the government of British Columbia (BC) were skeptical about the need for and effectiveness of such policies, especially when they were given personal briefings offering such objections as the following: "no one else seems to be saying this is a problem; surely alcohol does not cause cancer; people can make their own alcohol and there are always ways to get round increased prices." In the end, however, the BC government did arrive at some improved public health policies on alcohol, including scrapping a planned reduction in the price of alcohol. This decision may have been influenced by the report, and also the public debate generated - but the overall response still fell well short of an optimal and comprehensive set of evidence-based policies.

The field of alcohol policy can sometimes be characterized as a dialogue of the deaf between well-meaning scientists and educators on the one hand and a mass of skeptical consumers and their elected representatives on the other. Decision makers in democratic societies rarely act on issues like alcohol policy purely in the interest of public health and safety unless they believe a majority of the voting public will be in support. This is despite the fact that the global evidence for the enormous burden of serious alcohol-related harm has never been stronger. Studies sponsored by the World Health Organization have estimated that annually, 2.26 million deaths can be attributed to alcohol. The evidence for what constitutes effective alcohol policy that would reduce this harm has also never been more clearly demonstrated and communicated. However, before political leaders are willing to listen to this evidence, they perhaps need to hear it from their voters rather than earnest scientists. The size of this challenge is well illustrated by studies of public opinion that find significant and negative relationships between public support for alcohol policies and regional per-capita alcohol consumption. In other words, the "wetter" a culture is, the more resistant it is to the introduction of effective policies to reduce consumption and its consequent harm. Similarly, studies of drinking behavior and public opinion have found that heavier drinkers tend to be more opposed to effective strategies such as raising the price of alcohol and reducing the hours of sale for liquor. By contrast, almost everyone is in favor of educational approaches, though evidence for the effectiveness of these approaches in isolation is usually extremely limited.

Public discourse about alcohol policy interventions is not for the fainthearted and requires strong counterarguments to dispel popular myths that seem to impede good policy. This chapter discusses drinking patterns and related harms in a way that directly addresses some of these widely held misconceptions. It then describes scientific evidence supporting a range of policies capable of substantially reducing the health, social, and economic costs associated with alcohol misuse. This description is accompanied by a discussion of some common sources of skepticism that have emerged when such policies are discussed publicly.

THE BURDEN OF ALCOHOL-RELATED HARM TO SOCIETY AND THE PREVENTION PARADOX

A common perception of alcohol-related problems is that they are essentially restricted to (1) drinking and driving, (2) liver disease, and (3) a small number of people who become "alcoholic." The scientific evidence, on the other hand, is that in most countries these three particular issues collectively account for less than a third of all alcohol-related harm. In fact, alcohol-related harm is distributed broadly across the whole drinking population and includes nondrinkers who are often affected by the drinking behavior of other people. Alcohol-related road trauma tends to be the leading cause of "acute" alcohol-related harm, but there are many other effects associated not only with injury (intentional and unintentional) but also some acute illnesses such as poisoning, overdose, and pancreatitis. Alcoholic liver disease is among the most common causes of death and hospitalization attributable to alcohol, but collectively there is more serious harm from cancer, gastrointestinal, and cardiovascular illnesses (all of which are at least partially attributable to alcohol consumption). In 2007, the International Agency for Research on Cancer classified the ethanol contained in alcoholic beverages as a carcinogen, with the evidence strongest in relation to cancers of the mouth, throat, esophagus, liver, bowel, and female breast. Total numbers of deaths in developing countries attributable to alcohol vary depending on the precise methodology used in studies, but they are in excess of those limited to alcohol-related road trauma and liver disease. The World Health Organization methodology for estimating the global burden of disease from alcohol includes in excess 60 separate diagnostic categories of injury or illness at least partly caused by alcohol.

From the perspective of public policy, a grave concern is that the risk of these potentially fatal conditions appears to have no threshold effect, with the risk mostly increasing from an average of one drink per day,

increasing in some cases exponentially as consumption increases. At low levels of consumption (up to roughly two drinks per day for women and three for men), these concerns can be alleviated somewhat by evidence of protection against one of the most common causes of premature death: coronary heart disease. However, the extent of these benefits is probably quite limited for a number of reasons: A pattern of occasional heavy drinking eliminates the health benefits from otherwise "moderate" consumption; the superior health status of moderate drinkers compared with that of abstainers is likely due mostly to a range of other differences in risk behavior such as less obesity, better nutrition, and more exercise. In addition, there are other unresolved methodological problems with many of the studies suggesting health benefits from moderate consumption.

Even if one takes the optimistic view that at low levels of alcohol consumption the health benefits in relation to coronary heart disease compensate for the increased risk of many other serious illnesses, there is worrying evidence that most alcohol consumption in contemporary developed countries falls outside such low levels of consumption. Analyses of national drinking surveys from different countries indicate that the top 10% of drinkers by volume consume at least 50% of all the alcohol – and these are all underestimates due to serious underreporting biases in self-report surveys. Furthermore, when examining the amount consumed per day or per week, as much as 73% of all alcohol consumed in Canada and 64% of alcohol consumed in Australia fall outside of the low-risk drinking levels defined within these countries.

In relation to a number of health and social problems, a "Prevention Paradox" has been identified whereby most alcohol-related problems identified through national survey data are reported by people who, on average, are classified as moderate drinkers. It follows that to prevent these problems measures are required, which impact broadly on the drinking of many people and not just a small number of "problem drinkers" or "alcoholics." Subsequent analyses of national survey data have shown that many of these numerous and apparently moderate drinkers can be classified as occasional "binge drinkers" (usually defined as anyone drinking five or more drinks per day), a pattern of drinking that is common in many contemporary societies.

In summary, the threat to public health and safety posed by the widespread use of alcohol is not limited to road trauma, liver disease, and alcohol dependence but is broadly distributed throughout the population, among both drinkers and the people who are affected by the drinking of others. Because of the widely held popular perception to the contrary, it maybe an important first step to embark on a program of community

education regarding the harms associated with alcohol so that efforts to introduce effective public policies will be better received. For this reason, there have been increasing calls for a reorientation of public education and persuasion strategies regarding alcohol away from a goal of changing behavior toward one of preparing the ground for the more effective public health and safety measures.

EDUCATION AND PERSUASION STRATEGIES

Public debates about what can be done to reduce problems of alcohol frequently canvas the proposition that in a free and democratic society there should be no heavy-handed restrictions on access to alcohol; instead, the thinking is that people should be simply educated on the risks and be encouraged to regulate their own behavior. While this viewpoint is appealing from many perspectives, a series of comprehensive reviews of the international research literature have come to the conclusion that the great majority of public education campaigns have had no discernible effect on drinking behavior. A small number of well-designed studies have demonstrated modest progress toward reduced drinking and risk from others who drink in some school-based programs. There have also been some potential benefits from community education programs that support other regulatory and policy measures, for example, drink driving and liquor law enforcement. However, overall it would appear that public education and persuasion in isolation can have only very limited impacts on hazardous drinking patterns and related harms. In addition, efforts to increase alcohol consumption through advertising, sponsorship, and other forms of promotion appear to be effective and in many societies, by comparison with public health campaigns, are ubiquitous. This does not mean that education about alcohol and health should cease, but rather that its objectives need to be reconsidered.

The case of alcohol warning labels is an interesting case in point. There is only limited evidence of behavior change triggered by the introduction of warning labels. Most of the relevant research on warning labels has been conducted in the United States where a series of hard-to-read black-and-white labels were introduced in 1988 advising of the risks from alcohol for pregnant mothers and drivers, as well as the potential for dependence and some serious diseases. There was some evidence that after their introduction in the United States the labels increased conversations about the health risks of alcohol and were associated with a slightly reduced likelihood of drinking and driving. The research also

showed quite clearly that warning labels have the unique virtue of reaching those who arguably are most in need of understanding the messages: heavier drinkers. Also, compared with other public policies on alcohol, such as increasing prices for reducing hours of sale of liquor stores, introducing warning labels has been consistently found to be highly popular in surveys of public opinion in North America and elsewhere. In the United States, they actually became more popular after their introduction. In discussions of whether to introduce warning labels on alcohol containers in countries such as the United Kingdom, Canada, and Australia - and quite possibly many European countries as well – the failure of the US warning labels to convincingly change behavior has been used as an argument against their introduction elsewhere. This was certainly the case when the Canadian Standing Committee on Health considered a Private Members Bill to introduce alcohol warning labels in 2005, a committee whose final deliberations were witnessed by this author. It is hard to imagine another substance or product with proven carcinogenic and/or addictive properties for which potential population-wide behavior changes have to be proven before health warnings are required by lawmakers.

Among the many risks posed by alcohol consumption, cancer is perhaps the least well known, and there is a strong argument that the public has a right to be informed of this risk. A comprehensive public education strategy might usefully include the introduction of a series of highly visible, readable, and colorful health messages on all alcohol containers. Given the evidence that warning labels are read most and remembered best by people who drink most, this could be one effective way to communicate the health and safety risks of alcohol consumption within the context of national low-risk drinking guidelines - that is, advice on "how much is too much." One focus of such a campaign might be to raise awareness of health risks from drinking for the more prevalent forms of cancer – breast cancer and cancer of the esophagus.

A growing body of research also strongly supports the idea that exposure to alcohol promotions during adolescence increases the likelihood of both drinking and drinking heavily as young adults. Analyses of the wide array of media to which adolescents are exposed to in contemporary societies indicate whether through print media, social networking sites, sponsored sporting events, television, or radio, young people are exposed to a higher level than ever before to messages that variously normalize, glamorize, and promote alcohol use. There is also a small literature examining the effects of restricting alcohol promotions, which in the main suggests that restrictions on advertising result in reductions in alcohol consumption. In other words, another place to start with educational and persuasion strategies

is to develop policies that effectively reduce the exposure of young people in the general population to messages promoting the use of alcohol.

PRICING AND TAXATION APPROACHES

In stark contrast to the status of educational strategies, evidence for the effectiveness of increasing and/or maintaining alcohol prices is the strongest of any single intervention that has been evaluated. This has been the conclusion of multiple comprehensive reviews and has recently been confirmed by a series of meta-analyses as well as focused studies of natural experiments in public policy. Dr Alex Wagenaar, a renowned epidemiologist at the University of Florida, identified high-quality studies from many countries across the globe employing data collected across a period of more than 200 years and generating more than 1000 estimates of the relationship between alcohol prices on the one hand and the levels of consumption on the other. The conclusion was that a 10% increase in price led to an average 4.4% reduction in consumption across the entire drinking population. For studies of problem drinkers, there was a slightly smaller but still significant effect size of 2.8% reported. However, it is important to note that very different types of studies focus on individual level drinkers, which typically produce lower estimates of effect sizes than do aggregate studies. It is likely that problem drinkers are just as responsive to price changes as light or moderate drinkers. In fact, some studies suggest they are more responsive. Wagenaar and colleagues also conducted meta-analyses to estimate the relationship between alcohol price changes and changes in the levels of different types of alcohol-related mortality reporting that doubling the US alcohol excise tax would reduce alcohol-related mortality by an average of 35%, traffic deaths by 11%, sexually transmitted diseases by 6%, violence by 2%, and crime by 1.4%. Many country- or jurisdiction-specific studies evaluating the impact of sudden changes in the price or taxation of alcohol show clear reverse effects on alcohol-related harm.

Significant and substantial impacts on rates of death caused by alcohol were also demonstrated for Alaska immediately following two large increases in tax rates over the past 20 years. Similarly, when a special tax was introduced in the Northern Territory of Australia of five cents per drink in the early 1990s, significant and substantial reductions in alcohol consumption, alcohol-caused deaths, road trauma, alcohol-related hospitalization, and economic costs were demonstrated. When the policy was reversed, these gains were lost when a comparison was made with regions in neighboring states with similar population profiles.

Again, in stark contrast to education and persuasion strategies, pricing and tax increases are consistently found to be highly unpopular approaches. There is also evidence that many people simply do not believe that raising the price would impact levels of drinking by people who are harming themselves from their alcohol consumption.

Another difficulty with the proposal that we simply "increase the price of alcoholic drinks" is that in any market there are typically many thousand varieties of alcoholic beverages with different prices and strengths that allow people to choose cheaper alcohol when prices increase. In response to these perceived difficulties in selling the idea of price increases to the public and political leaders, recommendations for effective alcohol price policies have started to become more specific to both better target hazardous drinking and, hopefully, be less rejected in popular opinion. Examples of more targeted alcohol pricing policies include the following:

Inflation Proofing Alcohol Prices

In many countries, alcohol taxes are not linked to the cost of living and so in real terms they have become cheaper, thus placing downward pressure on alcohol prices and increasing the risk of more consumption and related harm. One response from governments has been to use the mechanism of a sales tax that automatically adds a fixed percentage to the retail price of alcoholic beverages and so is automatically linked to inflation. Unfortunately, this strategy also favors cheaper products with low production costs that can deliver highalcohol content at a very low price. In the United States, there are jurisdictions that have not increased beer taxes in more than 50 years. In Canada, the consent of Parliament is required to raise alcohol excise, and this has been done only twice in 25 years. By contrast, in Australia alcohol excise taxes on beer and spirits are raised every three months with the cost of living so that their real values are maintained. Thailand has developed an interesting twin method of taxing alcoholic beverages both on their alcohol content (i.e. the more alcohol in a product the higher the tax) and on their final retail price (i.e. a sales tax). Their policy has the virtue of selecting that form of taxation that results in a higher price so that prices are automatically indexed to inflation without encouraging a market for cheap high-strength products.

Enforcing Minimum Prices per Standard Drink

Econometric models have suggested that raising minimum prices in the United Kingdom would significantly reduce alcohol-caused deaths and health care costs. Canadian jurisdiction in common with some Scandinavian countries and a few US states retain government alcohol monopolies on the distribution of alcohol, including the power to set and enforce minimum retail prices. Typically, these prices are set independently of alcoholic strength and are not linked to the cost of living, which guarantees that at least a small number of very cheap high-strength products remain – for example, 8% malt beer, 23% fortified wine, and 75% rum. US research has estimated that the top 10% of heaviest drinkers on average spend less than a dollar per standard drink compared with nearly 5 dollars per drink for the bottom 50% of lightest drinkers. Canadian research has confirmed that raising minimum prices is not only an effective way of targeting heavy drinkers: It is also a highly effective means of reducing overall consumption. Nonetheless, defining a minimum price for a standard unit of ethanol and regularly raising this price in line with inflation would be an even more effective public health strategy.

Linking Price to Both Alcohol Content and Percentage Strength

It is ethanol that causes harm from alcohol, whether this be through dose-response toxic effects on the body over the long term or through levels of intoxication in the short term. Typically, drink prices bear little relationship to the level of alcohol content and hence to potential harm. Health authorities and academics are increasingly calling for ethanol-based pricing within each main category of alcoholic beverage. This is not to be confused with a simple strategy of requiring higher rates of taxation for spirits as opposed to wine and beer. There are many hundred, even thousands of varieties of beverage strengths in each of these broad beverage categories, so that a crude differentiation based on beverage type would be insufficient. Instead, such a policy would mean that lower-strength beers would always be cheaper than beers with higher alcohol content and similarly for wines and spirits. It would be possible to have one unified set of taxation rates based entirely on ethanol content. This approach could replace the complex tangle of literally hundreds of different rates of tax that are often applied to alcoholic drinks in many countries, for example, depending on how they are made, where they are manufactured, and where they are bought. This would not mean that a standard drink of beer would cost exactly the same as a standard drink of wine or spirits, but that the rate of taxation would be tiered according to both the volume of ethanol and the percentage alcohol content of the beverage; that is, 500 ml of 8% beer would cost more than 1 l of 4% beer, even though both contain exactly the same ethanol. Australia has long implemented a policy of encouraging consumption of beers with lower alcohol content through lower rates of taxation, which created a vibrant market for lower-strength products and effected an overall reduction in the amount of ethanol consumed in the form of beer. This kind of reform could still be beneficial even if introduced in a "revenue-neutral" manner – that is, without necessarily increasing the overall amount of taxes raised from alcoholic drinks (though that would be more effective still).

Introducing Harm-Reduction Levies on Alcohol

There is some evidence that the unpopularity of hiking the price of alcohol to reduce problems can be offset if the rationale provided involves raising revenue to pay for treatment and prevention programs. Such earmarked or "hypothecated" taxes have been introduced in a number of countries variously for alcohol, tobacco, and gambling. As mentioned previously, there is both general and specific evidence that such special taxes reduce harm while generating extra revenues. Not only do increased alcohol taxes result in increases in the price of alcohol, and hence lower consumption and rates of harm, but they also would almost invariably result in increased revenues for government - because reductions in consumption are almost invariably less than the tax increases. Many effective forms of prevention and treatment strategies could be funded from such increased revenue - for example, increased roadside breath testing, violence prevention programs, brief early intervention programs delivered by health professionals, and a more substantial infrastructure of detoxification and rehabilitation programs for people suffering from alcohol dependence.

However well presented and evidence based the above set of strategies maybe, anyone proposing them in the public domain will be subjected to a strong backlash from consumers and commercial vested interest groups. Having said that, this author has observed more favorable public and media comment on the idea of pricing drinks according to their alcohol content without necessarily raising overall revenue and also on the idea of a "harm-reduction levy" to fund muchneeded treatment programs.

The two most common counterarguments to such proposals are that (1) they do not impact on the people who drink the most who would drink regardless of price, and (2) their families will consequently suffer and the individuals may turn to more dangerous forms of nonbeverage alcohol. The first argument has already been refuted in this chapter, while the second argument needs further consideration. It would be fairly unique for an increase in price to have absolutely no effect on the consumption of a product, however "addicted" a consumer might be. It is also not clear what strategies alcohol-dependent individuals actually use when they cannot afford to purchase alcohol. Do they wait until

payday or the next welfare check before they go drinking? Do they work harder through legitimate means to raise extra money? Or do they resort to crime and neglect of family members? In a small-scale qualitative study of homeless problem drinkers in Victoria, British Columbia, hardly anyone resorted to drinking nonbeverage alcohol when they last experienced this circumstance, while almost all participants reported instead waiting for the next welfare check and/or "working harder" to earn money by collecting recyclable products left on the street. It maybe that this apparently deep-seated fear of how vulnerable problem drinkers would be affected by price alcohol rises is not based on reality. In addition, certain strategies can be adopted to compensate for the possibility of unintended consequences, such as increased consumption of nonbeverage alcohol: "wet shelters." Some housing options for people who continue to use alcohol and other drugs have evidence of effectiveness, including programs that actually provide free alcohol to residents. One published evaluation of the latter reported that individuals on the program in fact reduced their alcohol consumption as well as their visits to emergency rooms and problems with the police. Such programs are only offered in a well-structured institutional setting for people who have repeatedly failed with traditional abstinence-based treatments and who would otherwise be putting their lives at immediate risk by drinking nonbeverage alcohol.

Pricing and taxation strategies need to be the first priority of any comprehensive response to alcohol-related problems. Any society that allows unfettered access to very cheap alcohol would make it harder for all other prevention and treatment strategies to be effective. It is important to be aware of counterarguments to the valid case for maintaining drink prices with the cost of living, adjusting them according to alcohol content, ensuring minimum prices are not too low, and taking advantage of the opportunity to raise revenue for those most affected by alcohol-related harm. It is also important to continue to conduct research that carefully examines the validity of the many prevalent arguments against pricing policies.

REDUCING THE AVAILABILITY OF ALCOHOL

Limits on the Number of Liquor Outlets

A substantial body of evidence links the "density" of different kinds of liquor outlets with rates of both alcohol consumption and alcohol-related harm. In addition, there is evidence for changes in the density of liquor outlets (whether measured in terms of number per head of population or per square mile), resulting in corresponding changes in consumption and harm. For example, increased density of liquor stores has been shown to predict later increases in consumption and to increase per capita consumption as well as rates of alcohol-related mortality at the local area level; changes in the density of liquor stores over time have been related directly and significantly to crime rates.

Limits on the Hours of Sale of Liquor Outlets

There is strong evidence that large changes (e.g. adding or subtracting a whole day) in the trading hours of bars and liquor stores can influence the rates of consumption and harm. At first sight, the wider literature on the effects of adding or subtracting an hour or two to the trading times of bars suggests the following: (1) most studies have evaluated the effects of increasing trading hours reflecting deregulatory trends in the last half of the twentieth century; (2) results are conflicting, with many finding no effect. However, a more careful analysis of the better-designed studies finds that the great majority support the hypothesis that increased hours result in increased problems, including violence and road-safety issues. One study also reported increased blood alcohol levels associated with later trading hours, which provides a plausible causal mechanism for the increases observed in problems. More recently, well-designed studies have also begun to emerge that have demonstrated reductions in violent incidents following reduced trading hours.

Restricting the Legal Age of Purchase

There is strong historical evidence that increases and decreases in the legal drinking age such as that happened in the United States over the past three decades have significantly predicted corresponding decreases and increases, respectively, in road trauma involving young people. There is also a small literature regarding the effectiveness of various enforcement strategies designed to limit access to underage drinkers to alcohol purchases. Both the legal age of purchase and the extent to which this is enforced would limit access to underage drinkers and potentially reduce harm to this specific group who are at very high risk for a range of alcohol-related problems.

Responding to Counterarguments

It can be challenging to debate whether or not to implement such controls in the public domain. Because by their very nature these restrictions can be seen as restrictions on the freedom and liberty of individual citizens, it is important to stress that these issues must be resolved through democratic means with public debate

informed by scientific evidence. Interestingly, there is good evidence of strong public support for strategies that limit the trading hours of bars and restaurants, with levels of support as high as 70% not being unusual. However, this finding has not stopped trends in many countries toward more liberal opening hours over the past few decades. Those who doubt the effect of an hour or two of extra trading after midnight might be persuaded if they consider that at these times on-premise outlets, especially on weekends and holidays, are at their busiest and also when people are intoxicated they are more likely to spend freely. A common counterargument often mounted is that restricting hours would force people to hurry their consumption and they will leave more intoxicated. The empirical evidence suggests otherwise, however: Patrons from premises with longer trading hours picked up by random breath-testing patrols have been found to have significantly higher blood alcohol levels. It is also often argued that bar closing hours should be "staggered" to avoid having drunken patrons all competing for space on the pavement, the roads, and public transit at the same time. Alcohol industry advocates often use this claim as a basis for arguing for all-night or at least much longer trading. The evidence from a number of countries is that all-night trading might lead to a more orderly progression of violent and dramatic incidents associated with alcohol, which might be more readily dealt with by emergency personnel. However, when all the incidents are added up at the end of the night, there are many more when the bars stay open all night. It is also possible to "stagger" closing hours without creating an overall increase in hours. Being allowed to stay open later could be used as a privilege and rather than a right so that, for example, only premises with low rates of violent incidents could be permitted to stay open later.

Public debate regarding restrictions on the sheer number of liquor outlets can also trigger disbelief. Some of this skepticism maybe assuaged with discussions of how: (1) physical convenience in terms of distance to the nearest store and (2) the ability of entrepreneurs to adapt their products to local niche markets can maximize sales and how (3) the proximity of many liquor outlets can lead to greater competition, thereby driving down prices and increasing managers' preparedness to serve underage and intoxicated customers. Ultimately, however, it is never easy to persuade communities where the majority of people consume alcohol at least occasionally that access to this popular drug should be made more difficult.

Other Effective Alcohol Policy Strategies

One of the difficulties associated with each of the more effective population-wide strategies that involve reducing physical and or economic availability is that they are perceived as inconveniencing or even punishing the great majority of moderate drinkers. While it is possible to argue that those who drink the most are most inconvenienced and light or moderate drinkers are hardly inconvenienced at all, strategies that are seen to directly target harms or high-risk drinkers are generally better received. Some of these strategies show strong evidence of effectiveness as well. In particular, there has been an increase in knowledge worldwide on how best to deter drink-driving and hence reduce alcohol-related deaths. Deterrence theory requires that penalties need to be immediate and certain, though not necessarily severe to achieve maximum effectiveness. A combination of a low legal blood alcohol limit for driving and highly visible and frequent random breath testing would make the most effective contribution to reducing the road toll. Brief interventions for early-stage problem drinkers delivered by health practitioners show very strong evidence of effectiveness. These interventions involve screening all patients attending primary or secondary health care facilities for a range of health-related risk behaviors and then providing brief advice and followup to those identified as having early-stage problems. While only a minority of early-stage problem drinkers tend to reduce their consumption when receiving these interventions, it has been estimated that if this approach was employed routinely in a majority of health care facilities, then there would be substantial impacts on the levels of problem drinking and related harm.

There are also a number of strategies with a strong rationale, low implementation costs, but only limited evidence of effectiveness. Some of these strategies can be described as being "harm reducing" in that they modify the environment to reduce risk to the drinker without necessarily requiring reduced alcohol consumption. One example is the thiamine fortification of alcoholic beverages or as an ingredient in food consumed even by heavy drinkers. Thiamine deficiency caused by prolonged and heavy alcohol can generate a serious form of brain damage known as Wernicke-Korsakoff Syndrome. In the late 1980s, the Australian government required that all breadmaking flour be fortified with thiamine, a policy that resulted in a measurable decline of this serious condition. Another example involves requiring the use of plastic or shatterproof glassware at events or venues where there is a high risk of alcohol-related violence. There is evidence that many barroom brawls result in injuries caused by using broken glasses or bottles.

REGULATING THE LICENSED DRINKING ENVIRONMENT

In addition to pricing policies and restrictions on the location and hours of operation of licensed premises, there are a number of policing and environmental strategies that can be effective in reducing problems such as violence and public nuisance issues in bars and clubs.

Some highly predictable aspects of late-night drinking environments are associated with increased risk of problems. In most countries, a relatively small number of bars and clubs contribute to the bulk of incidents of violence and public disturbance – for example, as few as 10% may contribute to more than 60% of disturbances. This means there is a special role for police and licensing authorities being involved in identifying and targeting higher risk venues. Studies of the latenight drinking environment have identified risk factors that are easy to identify and modify - for example, permitting overcrowding, selling discounted alcohol, badly arranged physical spaces in which there is much jostling and bumping between patrons, lax "anything goes" management, and aggressive security staff who escalate rather than defuse potentially violent situations.

The overall regulatory environment in which licensed premises operate is critical to mitigating and reducing some of these risk factors. The density of bars and nightclubs in a particular area will influence the amount of crowding and competition for space on the one hand and degree of competition on the other. Pricing policies will determine how easy it is for patrons to overconsume. The extent to which licensing authorities check whether effective responsible management policies are in place is also key. In many jurisdictions, data on violent incidents and violations of liquor laws are not shared in any effective way between police and licensing authorities so that high-risk premises continue to operate while perhaps only suffering occasional fines. Regular audits of drinking venues in terms of risk for alcohol-related harm have been shown to be an effective way for police to monitor and control problems with the late-night drinking environment. Some studies also support an active community policing role visiting late-night drinking establishments in a way that supports and encourages the management to operate responsibly. In some instances, this has taken the form of a local "accord" between civic authorities, police, and licensees that lays out an agreed code of conduct. Evidence suggests that this approach is effective only if there is some significant deterrence against breaches of the code - that is, owners, management, and staff realize that noncompliance could have serious consequences.

Some studies have used "pseudo-patrons" or "mystery shoppers" to check whether bars permit obviously drunk patrons or whether potentially underage patrons are served. The recommended practice with these approaches is to first deliver warnings that these audits will be happening, then to give a warning for first offenses followed by graded fines, and, ultimately, license suspensions or termination. In general, the research on licensed

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drinking environments and violence prevention suggests that effective regulation and enforcement of liquor laws are critical for community-based policing approaches to be effective.

CONCLUSIONS

Public education campaigns in isolation are inadequate and are often wrongly targeted. However, an alternative form of public education aimed toward (1) prompting informed debate on the extent of harms caused by alcohol and on optimal policy responses, and (2) restricting alcohol promotions maybe warranted. Such a campaign might usefully be built on a foundation of nationally accepted low-risk drinking guidelines endorsed by a broad range of public health and medical agencies and promoted through multiple media, including the Internet and messages on alcohol containers. Targeted strategies that are easy to understand as being focused on hazardous drinking and directly reducing harms are most readily supported in public discourse, and some of these have a degree of effectiveness. However, the most effective strategies for managing and improving public health and safety outcomes from alcohol consumption involve imposing restrictions on the economic and physical availability of alcohol to all potential consumers. These are much harder to sell and explain, but the evidence for their widespread benefit is growing. It is suggested that effective national alcohol policies need to start with ensuring that the voting public is fully aware of a causal relationship between particular drinking patterns and a range of serious health and social problems. In addition, pricing and taxation of alcoholic beverages need to be established so that access to very cheap alcohol is minimized. One of the most cost-effective strategies of all (and because it is revenue positive) involves enforcing minimum prices per standard drink which are regularly updated with the cost of living, with prices otherwise geared toward encouraging consumption of drinks with lower alcohol content. Once such fundamental strategies are in place, it maybe easier to implement a raft of other evidencebased strategies, including measures to reduce drinkdriving, public violence, problem drinking, cognitive impairment, and alcohol dependence.

SEE ALSO

Effects of Licensing and Supply Practices, Marketing and Advertising Control

Further Reading

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International Policies to Reduce Illicit Drug-Related Harm and Illicit Drug Use

Max Hopwood, Carla Treloar

The University of New South Wales, Sydney, NSW, Australia

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INTRODUCTION

Harm reduction is a social and health-related movement that emerged during the twentieth century in response to the risks associated with the burgeoning nonmedical injection of drugs. Today, harm reduction interventions like needle and syringe program (NSP) and opioid substitution treatment (OST) are the international gold standards in human immunodeficiency virus (HIV) prevention among people who inject illicit drugs. In 2010, Harm Reduction International, a nongovernmental organization and global leader in harm reduction and drug policy reform, reported that there were almost 16 million people who inject illicit drugs in 158 countries around the world, with China, the US and Russia having the largest injecting populations. Ninety-three countries and territories explicitly support a harm reduction approach and this number is growing annually. Nevertheless, only 8% of all people who inject illicit drugs currently have access to an NSP and an OST. High-income regions like Western Europe and North America have the majority of harm reduction services. The adoption of harm reduction policies in many low-and middle-income countries remains slow and patchy despite escalating injecting-related HIV epidemics. There is an urgent need to expand harm reduction services globally given the conclusive evidence of their effectiveness in preventing HIV transmission among people who inject illicit drugs.

Harm reduction is a contentious model of risk management. Controversy arises because a harm reduction sensibility is the antithesis of the punitive ethos of global prohibition, which has been the policy response to illicit drug use for the past century. In contrast to prohibition, harm reduction views an individual's illicit drug use as a health issue that benefits from education

and medical intervention rather than a criminal behavior deserving punishment. Whereas prohibition seeks to criminalize, demonize, and marginalize people who use illicit drugs, harm reduction values the dignity and human rights of illicit drug users and views them as integral parts of communities with partners, friends, and other loved ones who may also be adversely affected by drug-related harm. Underpinning its substantial achievements in HIV prevention is a professed nonideological and amoral stance on illicit drug use, which is augmented by pragmatic evidence-based risk-reduction interventions. Although there are divisions within the movement itself, harm reduction in the early twenty-first century continues to build momentum.

HARM REDUCTION DEFINITION AND OVERVIEW

Harm reduction refers to policies, programs, and practices that aim to decrease the adverse social, health, and economic harms associated with the use of illicit drugs. Harm reduction aims to assist people who feel unable to, or do not want to, cease illicit drug use. Instead of preventing illicit drug use, the emphasis is on reducing its potential harms through the application of individual and community-focused interventions.

Cessation of drug use is supported by harm reduction programs if abstinence is the goal of an individual. However, a focus on drug abstention per se is not harm reduction. Harm reduction policies, programs, and practices ideally are outcomes of collaboration between people who use illicit drugs, health professionals, community service providers, and policymakers. Their central aim is to make illicit drug use less risky. Proponents of harm reduction accept that drug use is a part of life and that ways to minimize the potential negative consequences of illicit drug use should be based on scientific evidence. Harm reductionists evaluate current and proposed social, public health, and legal policies related to illicit drugs in terms of their capacity for producing, exacerbating, or ameliorating harm. For example, harm reductionists do not advocate for the decriminalization or legalization of illicit drugs, unless decriminalization or legalization is proved effective in reducing harm to individual illicit drug users and the community. In theory, the principal measure of successful harm reduction is improvement in the health, well-being, and quality of life of people who continue to use illicit drugs. In reality, however, political, economic, and social dynamics have limited harm reduction's core business to mainly HIV prevention among people who inject illicit drugs.

From Human Rights to HIV Prevention

Over the past 30 years, harm reduction has evolved from a peer-based human rights movement to a medical model, which has fixed its focus firmly on efforts to contain and reduce HIV transmission among people who inject illicit drugs. Indeed, the HIV epidemic was the catalyst for the development of the modern harm reduction movement and HIV prevention remains the international priority of harm reduction, as it has immense social, health, and economic benefits for individuals and communities in undeveloped, transitioning, and developed societies. Commentators including harm reduction activists have criticized this successful medical model of harm reduction for being overly preoccupied with the use of medical interventions to prevent HIV infection. They argue that harm reduction must broaden its scope beyond HIV prevention to engage with the myriad risks associated with illicit drug use, while continuing the excellent work in HIV. Critics of the medical model of harm reduction view social and economic issues like poverty and the stigmatization of people who use illicit drugs as neglected areas that generate the majority of the world's drugrelated harms. The past decade has seen a renewed interest in harm reduction activism. Human rights groups have called upon the United Nations (UN) to remove the limitations imposed on the expansion of harm reduction programs because of international adherence to the 1961 Single Convention of the global illicit drug control regime. Indeed, some UN bodies like the Commission on Narcotic Drugs as recently as 2010 refused to include the term harm reduction in its Political Declaration on Drugs. On the other hand, the UN Member States of the Economic and Social Council in 2009 included the term in a resolution on the work of UNAIDS. In 2011, most UN bodies supported a harm reduction approach to HIV prevention; however, the ongoing controversy in international drug policy forums highlights an ongoing need for activism. One example of this occurring is The Vienna Declaration of 2010. This is a seminal statement drafted and supported by leading international experts and activists in public health, public policy, and medicine, and which seeks to improve community health and safety by incorporating scientific evidence into illicit drug policies. This declaration calls upon all UN bodies to support a global harm reduction approach.

A HISTORY OF HARM REDUCTION

The origin of harm reduction principles is found in the nineteenth century tenets of preventive medicine. The foundations of the modern harm reduction movement were laid with the emergence of the disease model of addiction during the early twentieth century. By the late nineteenth century in Europe, the injection of opiates had become increasingly common within some social circles. In response to evidence of increasing addiction among the population of the UK and the poor treatment of people dependent on drugs by some medical practitioners, the Rolleston Committee was formed to investigate possible strategies to limit the health impacts of drug use. At this time in the UK, drug addiction was understood to be a middle-class phenomenon that did not attract criminal sanctions. Accordingly, the Rolleston Committee of 1924 made credible the idea of minimizing health risks to individuals who were dependent on opiates through the medical supply of morphine and heroin. The Committee's recommendations are the first evidence of a modern harm reduction sensibility emerging within medicine.

From the time of the Rolleston Committee until the 1960s, there was little practical or theoretical development in harm reduction. Global prohibition had become entrenched as the response to illicit drug use well before the 1961 UN Single Convention, which drew together all previous drug prohibition conventions under one umbrella. Prohibition is a system devised by the US and implemented by the UN and comprises a series of international agreements, which are underpinned by the political and economic interests of the US. Today, three UN Conventions limit proscribed drugs to scientific and medical purposes. International adherence to this regulatory system has been impressive, albeit driven by nations' fears of political and economic consequences via US pressure through the UN. This system of global illicit drug control remains remarkably resilient and even today is largely invisible to the world outside of academics, policy-makers, and harm reductionists.

Following an escalation of experimental, recreational, and dependent illicit drug use during the 1960s, some Dutch health professionals, social and political activists, and policy makers began to oppose and openly criticize prohibitive policies. Instead, they advocated for pragmatic strategies to address the problems they saw arising from significantly increased levels of illicit drug use. By the 1970s, the Dutch Parliament began to promote the "balance-of-harms" approach, which encouraged the police and the courts to assess whether prosecution for minor drug offenses would be in the best interests of individuals and society, or whether prosecution itself might lead to more harm for people than their drug use. This was an enlightened idea for the time because it positioned prohibitive drug laws as potentially harmful and ineffective at managing the burgeoning rate of illicit drug use in society. Prohibition had criminalized the production, manufacture, export, and import of an ever-expanding list of drug classes, and

demonized people who possessed and/or used them. On the other hand, a balance-of-harms approach privileged the health and well-being of individuals over the supposed deterrent effect of criminalization.

Harm reduction continued to develop in the Netherlands and by the early 1980s networks of injecting drug users in the city of Rotterdam had formed junkiebonden. These were drug users' advocacy groups that lobbied government officials to observe the human rights of illicit drug users. Members of junkiebonden also began distributing sterile injecting equipment in an attempt to ameliorate the impact of a hepatitis B epidemic among people who inject. Similar advocacy and harm reduction activities began shortly after in UK cities like Liverpool in response to the newly identified HIV epidemic. Within a few short years, the riskreduction strategies implemented by these peer-based social and political movements were informing the development of government-funded harm reduction interventions, like programs for distributing sterile needles and syringes. By the late 1980s for example, the Australian and Canadian Governments had implemented NSP and increased funding for OST to curb HIV transmission rates. The evidence has subsequently shown that harm reduction strategies based on these medical interventions do successfully reduce morbidity and mortality through a reduction of HIV transmission.

HARM REDUCTION TODAY: PRIMARY SERVICES

The following section provides an overview of harm reduction interventions that employ medical and public health strategies to minimize the risk of blood-borne viral (BBV) infections like HIV and hepatitis C among people who inject illicit drugs.

Needle and Syringe (Exchange) Program

The reuse of equipment for injecting illicit drugs is the main risk practice for transmission of HIV among people who inject. In regions like the Netherlands, Spain, the UK and Australia, government-funded NSPs have successfully limited the transmission of HIV among people who inject. Sterile needles, syringes, and ancillary injecting equipment can be accessed at no cost from primary NSPs, which are often shop-front services designed exclusively for the provision of injecting equipment, safer injecting information, and in some cases BBV testing, counseling, and referral to OST. In some countries, injecting equipment is also available through secondary outlets like hospitals and community-health centers. Pharmacies often sell sterile

injecting equipment or provide new equipment at no cost if used equipment is returned. Vending machines another source of purchasable injecting equipment and these are often located on the grounds of hospitals and community-health centers. In 2010, 82 countries and territories had programs to deliver needles and syringes. A large volume of data has been collected over the past 25 years to demonstrate the cost-effectiveness of an NSP. For example, an analysis of 103 cities from around the world show that in cities that ever had an NSP, there has been an average annual decrease in HIV prevalence of 18.6%. In cities that have not had an NSP, there has been an average annual increase in HIV prevalence of 8.1%. The cost-benefit of an NSP is substantial. In Australia between 2000 and 2009, the NSP is estimated to have prevented more than 32 000 HIV infections with savings to healthcare estimated at \$AUD1.28 billion.

The reuse of equipment for the injection of illicit drugs is the main driver of HIV and viral hepatitis epidemics in regions like Eastern Europe and South-East Asia. Yet, the provision of sterile injecting equipment is either nonexistent or inconsistent across developing, transitioning, and developed nations. In countries that adopted an NSP early in the HIV epidemic, current rates of infection among people who inject are extremely low. For example, Australia has around 1% prevalence of HIV infection in the injecting population. However, in many low-middle-income countries in Europe, Asia, the Middle East, and Latin America, injecting drug use accounts for the highest proportion of HIV infection in the general population, with rates often above 20% and higher than 80% among people who inject in some regions. HIV infection rates are high in some countries or regions because an NSP is nonexistent, or is slow to be implemented, or the demand for equipment cannot be met. The cost of providing HIV antiretroviral treatment to one person is many times greater than the cost of providing them with sterile needles and syringes to prevent HIV infection.

A common criticism leveled at harm reduction is that services like NSP send a wrong message about illicit drug use; that they implicitly condone and materially facilitate illicit drug use. Yet, among the myriad studies of the effectiveness, safety, and cost-effectiveness of NSP, there is no evidence to support such a contention. Key measurable factors such as age of initiation to injecting, the frequency of injecting, and the duration of injecting have not changed since the introduction of NSP and other harm reduction services. When harm reduction programs are introduced, the evidence strongly indicates that they either prevent a HIV epidemic from occurring, or they stabilize or reduce the rate of HIV infection among the injecting population.

Substitution Treatments

Another primary harm reduction strategy is the medical provision of substitution treatments to people who are dependent on illicit drugs. There are a variety of drugs used in substitution programs to reduce craving and withdrawal symptoms and block the euphoric effects of illicit opiates and opioids. Methadone, a semisynthetic opiate, is currently the most widely prescribed OST. Methadone is usually administered from special clinics in the form of syrup that is ingested once daily by registered attendees. Similarly, the drug buprenorphine, usually taken in tablet form, effectively reduces cravings and withdrawals in people dependent on opioids. Compared to methadone, which is addictive, buprenorphine is less likely to lead to dependency, is harder to inject, is less likely to cause overdose, and has less of a euphoric effect. In 2010, 70 countries and territories around the world had OST programs for people dependent on opioids.

Treatment with semisynthetic opiates like methadone and buprenorphine can significantly improve drugdependent people's quality of life. Treatment increases health and psychosocial stability, which leads to increased employment opportunities and social integration. It also reduces the risk of infection with HIV and hepatitis C because OST drugs replace the need for multiple daily injections of illicit drugs. People usually only require one oral dose of methadone or buprenorphine per day to prevent the onset of withdrawal symptoms. The provision of OST is strongly associated with a reduction in HIV prevalence among people who inject. Also, drug overdose deaths are reduced when people have good access to OST. Opioid substitution drugs are regulated, noncontaminated substances that cost significantly less than, for example, heroin bought off the street.

In some countries like Switzerland, the Netherlands, the UK and Spain, evaluations of heroin prescription for opioid dependence have shown good outcomes. In the UK, heroin has been prescribed to a relatively small number of people for over 40 years, and evaluations show that this pharmacological intervention is cost-effective. Regulated heroin is extended to people when OST drugs do not stabilize their health to a point where they can function satisfactorily.

Finally, the recreational and dependent use of illicit amphetamine and methamphetamine (e.g. ecstasy) has increased substantially over the past two decades. While there are long-standing substitution treatments for opioid dependence, and alternatives are emerging, there is no well-evidenced substitution treatment for dependence on amphetamine-type substances. A number of substitution drugs have been used for this purpose, but research on their efficacy is very limited. The lack

of a well-evidenced substitution treatment limits the options available to those experiencing dependence on amphetamine-type substances.

Drug Consumption Rooms

A drug consumption room (DCR) – sometimes referred to as a medically supervised injecting center is a supervised clinical environment where people can inject illicit drugs without the fear of police prosecution or harassment and disapproval by noninjectors. They are usually located in inner-urban areas known for their high rates of dependent injectors, and they are staffed by medical practitioners and allied health professionals who can immediately respond to injecting-related emergencies such as overdose. In 2010, there were 92 DCRs operating in 60 cities, mostly in Western European countries like the Netherlands, Switzerland, Spain, and Germany, and also in Canada and Australia. DCRs reduce the health and publicorder problems associated with the street-based injection of illicit drugs. These facilities do not provide illicit drugs; however, people can attend a DCR to inject drugs procured elsewhere. While the interior designs vary, DCRs are often clinical in appearance and comprise an admission area, tiled and stainless steel booths for injecting, and a space for clients to recuperate prior to leaving the premises.

Like all harm reduction services, DCRs are politically contentious despite overwhelming evidence for their effectiveness. DCRs prevent overdose deaths and injecting-related injury, and they educate people about the risks associated with injecting. Evidence shows that these facilities reduce the number of risky street-based injecting episodes and improve the safety of local neighborhoods by removing activities associated with injecting away from the surrounding streets. DCRs reduce ambulance callouts and they provide an opportunity to engage some of societies' most marginalized people with harm reduction information, health services, and counseling. Evaluations reveal that clients of DCRs are more likely to seek referrals for OST, and they are more likely to access general health services than people who inject and do not attend DCRs.

Illicit Drug User Organizations

Government and nongovernment-funded illicit drug user organizations provide a range of health information-related services for people who use illicit drugs. These organizations are usually staffed by people who use illicit drugs, or former users, for the purpose of providing peer-education to prevent BBV transmission,

overdose, and other illicit drug-related health problems. As previously noted, peer-based initiatives are the foundation of the modern harm reduction movement. Peers are perceived as trustworthy and having specific expertise and contextual knowledge of the practice of injecting and living as a person who uses illicit drugs. In Canada, Australia, the Netherlands, and the UK, illicit drug user organizations have played a pivotal role in encouraging people to change their injecting practice by teaching safer methods of injecting. The work of professionalized peer-based illicit drug user organizations and the willingness of people to change their injecting behavior continue to be at the core of the successful response in HIV prevention around the world. These organizations also publish health promotion materials and magazines that provide the latest harm reduction information. Peer-workers in these organizations report that harm reduction is more effective when programs, strategies, and interventions are developed in cooperation with affected populations.

Finally, there are a variety of independent (i.e. nongovernment)-funded organizations, which aim to effect change in global illicit drug policy by ensuring that the voice and expertise of people who use illicit drugs inform the development of drug policy and harm reduction strategies. For example, The Vancouver Declaration 2009 is a statement by an international network of activists reclaiming the right to self-representation and self-empowerment through collective action. The Declaration outlines activists' aim to replace global prohibition with policy informed by a harm reduction sensibility, which respects the human rights and dignity of people who use illicit drugs.

Information, Education, and Communication

The provision of information and education is a tenet of HIV prevention, which is endorsed by the World Health Organization. Despite this endorsement, the role of information, education, and communication (IEC) within the medical harm reduction model and its acceptance in political and popular spheres are tenuous. The evidence base for IEC is limited, with little specificity regarding what messages or communication strategies and in what settings (e.g. school, point of purchase of consumption, online) work for which parts of the target group (e.g. novice or experienced users, people using drugs with sexual partners or social networks). Also, providing information on safer drug use poses challenges for conservative groups, like political parties and media outlets, which can effectively silence or dilute crucial aspects of harm reduction IEC and other programs. IEC is are more effective, including effects beyond raising knowledge, awareness, and understanding,

when it is employed with other harm reduction services within a supportive social environment.

Interventions for Non-Injecting Drug Use – Pill Testing

Illicit drug supply is subject to unknowable processes in manufacture and distribution that sometimes have fatal consequences for users of illicit drugs. To better inform consumers of what precisely is in a pill marketed as ecstasy (and related drugs), pill-testing programs have been devised where an analysis of the content of pills is offered at the site of consumption (e.g. raves, festivals, or nightclubs), or via the Internet. The goal of pill-testing programs is to prevent people from ingesting pills contaminated with harmful substances. Other programs use pill testing in combination with information provision, sometimes as a draw-card. Implementation of pill testing is not widespread and there are significant limitations to the tests that exist. Pill test results usually inform consumers of the presence of a limited range of toxic substances, without indicating exactly what other ingredients the pill contains. Further, there is lack of adequate research to demonstrate the effectiveness of pill testing as a harm reduction strategy. The legal status of pill testing is uncertain in most countries and the strategy is typically absent or not integrated within drug policies.

Harm Reduction Programs that Address Broader Social and Economic Harms

The literature that has emerged since the late 1990s on the social determinants of health highlights the largely disproportionate burden of harm related to alcohol, tobacco, and illicit drugs experienced by people within lower socioeconomic bands. Since then, a related literature and response to social exclusion has been developed, which recognizes the multiple and interrelated ways in which disadvantage can compound and be expressed within individuals' lives including poorer educational, employment, and income indicators, poorer health and mental health outcomes, and intergenerational patterns of disadvantage and poor outcome. Responses to social exclusion include whole-of-government promoting joined-up approaches in which social inclusion measures are used as performance indicators for all government portfolios. Harm reduction has had little formal connection to these more sophisticated and integrated initiatives in social policy. This may be because of the focus of medical harm reduction on HIV prevention at the expense of broader social and economic harms experienced by individuals and communities.

A SOCIOLOGICAL ANALYSIS OF MEDICAL HARM REDUCTION

The medicalization of harm reduction is a product of the times; medical harm reduction is a movement in step with globalization, a phenomenon that has led to significant developments in the functioning of capitalism. The emergence of the medical harm reduction movement is part of an overall shift away from addressing social problems through the coercive power of the state (i.e. via law enforcement and military) toward the role of individuals' governance of self and others. Neoliberal values of individualism and self-regulation are salient in the language and interventions of medical harm reduction. Today, harm reduction is a regime of (self) governance, which is predicated upon a scientific calculation of risk based on epidemiological analysis. Epidemiological evidence informs statistical models of risk practice and risk communities with an aim of developing harm reduction interventions that encourage and normalize self-regulation. An example of this is the "injecting drug use community," a geographically and demographically unbounded collective that share a statistically determined susceptibility at a population level to poor health outcomes like HIV infection. The medical harmreduction movement has become critically important for public health through teaching "community" self-management risk-reduction interventions, like using sterile equipment for every injection.

Within a neoliberal framework, the onus is on illicit drug-using individuals to negotiate risk, much of which is generated by the state via prohibitive drug laws and the operations of police. People from lower socioeconomic circumstances are disproportionately affected by drug-related harm relative to those from the middle classes. This is partly due to having less access to healthier but more expensive options and poorer uptake and compliance with modes of self-regulation. Medical harm reduction ignores the constraints against "choosing" healthy practices and lifestyles that many people experience. Individualism and the ideology of personal responsibility can undermine the social effort to improve health for example via community-based capacity building programs that use the arts, sporting, cultural, education, and similar programs to build resilience and "protect" people and communities from anomie, alienation, boredom, and dislocation, which often lead to problematic drug use. An overemphasis on personal responsibility also increases the likelihood of emerging health-related stigma. Individuals or groups of people whose lifestyle practices are deemed to be a personal or community health risk, like people with HIV or viral hepatitis, are held responsible for their own health problems and often viewed as a drain on resources and a threat to others.

Medical harm reduction is also criticized for lacking a coherent theoretical framework, which among other problems makes it difficult to accurately define. Commentators claim that to become a unified paradigm, harm reduction must: (1) maintain its successful programs in injecting-related HIV prevention and (2) foreground human rights to challenge entrenched power, double standards around drug use, and abuses against all people who use any illicit drug. This will be challenging as the value of harm reduction has long been measured by its capacity to prevent transmission of HIV infection, and social and political analyses highlight how the cost-benefit analysis of HIV prevention for governments and wider societies underpins harm reduction's growing international acceptance. By focusing attention on interventions that halt the spread of HIV, harm reduction programs are acceptable enough to politicians, religious leaders, and members of the wider community. On the other hand, advocating for illicit drug users' human rights and drug law reform leaves harm reduction politically vulnerable to opposition from powerful conservative groups and a public that has been socialized to see illicit drug users as criminal deviants.

A reluctance to engage with broader social issues has led some commentators to characterize medical harm reduction as a conservative movement that is dominated by health professionals, academics, and bureaucrats. For the most part, medical harm reductionists are comfortable attending to a set of health risks for people who inject that are largely created by the systems under which we all live and work. In this way, the medical model of harm reduction enables states to continue harming illicit drug users without taking responsibility for state inaction on prohibition, poverty, stigma, and social marginalization. The voice of illicit drug users is silenced by biomedical imperatives regarding population health. Indeed, the success of HIV prevention strategies has reduced the incentive to address more socially and politically difficult dynamics like economic marginalization and punitive illicit drug policies, which continue to damage large numbers of people who use illicit drugs.

The transition in harm reduction over the past 30 years from an activist movement to a medical model has prompted renewed interest in advocacy in the new millennium. Prior to the HIV epidemic, harm reduction was imbued with a strong communitarian ethos. It was a movement that represented the interests of people who used any illicit drugs, not just those who injected opioids at risk of HIV infection. Harm reduction had an expansive agenda to advocate for drug law reform, to protect the dignity and human rights of people who use illicit drugs, to tackle poverty, and to work toward finding long-term solutions to the world's illicit drug problems. Against this background, the medical model of harm

reduction represents a compromise; a band-aid solution that very effectively addresses the immediate risks associated with injecting drug use but has nothing to offer in the way of effecting significant improvements beyond the prevention of physical disorders, as important as that is. People involved in harm reduction advocacy today demand wider social and political change and believe that medical harm reduction must become engaged with ethics in order to optimize health-related outcomes. A reinvigoration of political activism within harm reduction is drawing attention to the impacts of poverty and marginalization on health-related decision-making, and it is encouraging to note that protection of illicit drug users' human rights has begun to emerge in the discourse of medical harm reduction. Harm Reduction International recently highlighted issues such as the systemic torture of people who were forced to attend drug detention centers in countries like China and Cambodia. This is seen as a welcome development, but a small step on a long path ahead.

ILLICIT DRUG USE REDUCTION

This section moves from a discussion of policy, which aims to reduce drug-related harm to a discussion of policy and approaches, which aim to reduce illicit drug use. Beginning in the twentieth century and continuing today, a global prohibition of specific classes of drugs criminalized users of classified substances in an effort to deter their use. The era of global prohibition peaked following the introduction of the "War on Drugs" by the US President Richard Nixon in 1970. Nonetheless, like alcohol prohibition of the 1920s, the prohibition of illicit drugs has been an abject failure in the US and elsewhere. After decades of failed attempts of reducing supply, of criminalizing specific drug classes, and demonizing and targeting the people who use them, prohibition did not result in a reduction of illicit drug use. Conversely, in most illicit drug markets around the world each year, drugs become more accessible, cheaper, and generally of a higher quality.

Below is a review of health-related policies and methods employed to reduce the use of illicit drugs. These approaches are used by people who wish to stop their own illicit drug use, or who provide services to people who want to stop using illicit drugs.

Naltrexone

Naltrexone is a drug used to treat the physical dependence on opioids. It first gained media attention when it was touted as a means of rapid detoxification leading to a "cure" for opioid dependence. However, throughout

the intervening years its usefulness in long-term management of opioid dependence has been questioned because it carries considerable risk for dependent people. Naltrexone decreases tolerance to heroin, thereby increasing the risk of overdose if an individual returns to heroin use after being treated with naltrexone. In addition, it is significantly more expensive to prescribe than other substitution drugs. Naltrexone does not produce physical dependence or euphoric effects, but works by blocking the action of opioid receptors. This means that people taking naltrexone cannot experience the pleasurable high of opiate intoxication. On the other hand, the prescription of naltrexone requires confirmed abstinence from opioids for 7-10 days prior to starting treatment with naltrexone. This period of abstinence can be a significant barrier to those living with opioid dependence. The current state of evidence indicates that people show better outcomes with substitution treatments.

Other Methods of Reducing Illicit Drug Use

A range of other options to address drug dependence exists. For example, professional counseling (e.g. motivational interviewing), peer-to-peer support (see section on Narcotics Anonymous below), detoxification (i.e. medicated or not), and residential rehabilitation (i.e. highly structured programs requiring 6- or 12-month stay within a therapeutic community setting). These treatments are generally considered as a package or provided simultaneously for optimal effect. For example, detoxification is not considered an endpoint of treatment, and those who undertake only detoxification without supporting or ongoing treatment are likely to return to prior drug use levels. The goals of individuals entering treatment may vary. Some people may seek abstinence as a goal of treatment, while others may be seeking assistance in lowering the frequency or level of drug use. Relapse to former patterns of illicit drug use after a period of lower drug use or abstinence places individuals at a higher risk of fatal overdose, particularly in the context of relapsing to opiate use.

There are also a number of methods, sites, and structures in which these services may be provided or facilitated. These include court diversion programs (rather than imposition of a period of incarceration) or online counseling and support services as developed, for example, for people concerned about their level of cannabis use. As with any therapeutic intervention, the motivation and goals of the client underpin the success of the treatment program. However, in all models of treatment, relapse is a common occurrence. Given the chronic, relapsing course of drug dependence, multiple treatment episodes are better understood as parts of a cyclical process of recovery and remission rather than

as failed efforts. While clinicians, researchers, and government policy-makers have long recognized the value in conceiving treatment in terms of episodes, episodes of treatment have received little attention in the literature of research/evaluation treatment outcomes.

Throughout the world, global prohibition has inculcated a widespread belief that people who use illicit drugs are inherently disordered. In some regions, there is evidence that the philosophy of drug treatment has been misused by governments to control and punish people who use illicit drugs. For example, forced treatment in China has been likened to labor camp conditions. Other mechanisms employed to control or punish people who use illicit drugs, such as violence, being placed under arrest, being placed on a drug-user registry, capital punishment, and summary execution, are violations of human rights agreements that serve to drive people away from opportunities for drug treatment.

Peer-to-Peer Support and Other Self-Management Strategies

Narcotics Anonymous (NA) is a not-for-profit, nonsectarian, peer-to-peer support network. NA operates on a disease model of addiction and is premised on the goal of achieving and maintaining abstinence using the 12-step framework. Originally developed in the US, NA groups operate in most countries. Meetings of members are informal, no membership list is held, and anonymity is a key to ensuring that members can participate without fear of legal or social consequences.

The self-management and recovery training (SMART) program is similarly a voluntary self-help group that is focused on assisting people to recover from addictive behaviors. The SMART program is based on cognitive behavioral therapy and advocates for the appropriate use of medications. It is not based on a disease model of addiction and trained, professional staff coordinate the meetings.

Most people who are dependent on drugs will have tried a number of strategies, such as those mentioned above, to manage, reduce, or stop illicit drug use. Other approaches, which are commonly used by individuals to reduce illicit drug use, include removing oneself from networks of people who use drugs (i.e. a "geographical" or a "health-trip"), going "cold turkey" (i.e. nonmedicated withdrawal), or self-medication using benzodiazepines, alcohol and/or cannabis. Many people will have tried these strategies without any professional or peer support. Finally, "maturing-out" of drug use has also been described. In this case, individuals become abstinent when they tire of the undesirable aspects of an illicit drug-using lifestyle and simultaneously aspire to attain the "rewards" from leading a conventional life.

FURTHER READING 743

SEE ALSO

Health Care Reforms and Treatment for Substance Use Disorders, Improving the Quality of Addiction Treatment, Evaluating Treatment Efficacy, Economic Analysis of Addiction Treatment Programs, Ethical Issues in the Treatment of Drug Dependence, Evidence-Based Treatment, Harm Reduction Approaches, Therapeutic Communities®, Drug Decriminalization and Legalization, Disparities in Health Services for the Treatment of Substance Use Disorders, Policies and Interventions to Reduce HIV Risk, HIV/AIDS and Substance Abuse

List of Abbreviations

BBV blood-borne virus

DCR drug consumption room

HIV human immunodeficiency virus

IEC information, education, and communication

NA Narcotics Anonymous NSP needle and syringe program OST opioid substitution treatment

SMART self-management and recovery training

UN United Nations

Glossary

Blood-borne virus a virus that can be transmitted via blood-to-blood contact e.g. HIV, hepatitis C.

Epidemiology the study of patterns of disease within communities; used to inform public health policy including harm reduction strategies and interventions.

Initiation to injecting the circumstances surrounding the first time an individual self-injects or is first injected by another person in a nonmedical setting.

Injecting equipment includes needles and syringes, tourniquets, spoons, water vials, swabs, winged-infusion sets, and any other equipment used to inject a drug.

Medicalization a process whereby human behavior, conditions, and problems become defined as medical issues to be treated by medical professionals.

Medical harm reduction harm reduction programs, strategies, and interventions based on medical and public health technologies, like epidemiological surveillance, and needles and syringes and substitution drugs, to reduce the risk of transmission of blood-borne viruses, especially HIV, among people who inject illicit drugs.

Neoliberalism a set of market-driven economic policies underpinned by a social and moral philosophy that privileges individualism and self-regulation, and moves responsibility for risk from governments and corporations onto individuals.

Rave a type of dance party associated with the use of amphetamine and methamphetamine.

Social determinants of health the social and economic conditions into which people are born, raised, and aged, and the relationship of these variables with health outcomes.

Stigmatization characterizing individuals, social groups, health conditions, and practices as highly undesirable and a threat to society.

Further Reading

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http://www.viennadeclaration.com/the-declaration/ - The Vienna Declaration.

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76

International Policies to Reduce Tobacco Use

Luke Clancy

TobaccoFree Research Institute Ireland (TFRI), The Digital Depot, Dublin, Ireland

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INTRODUCTION

The World Health Organization (WHO) estimates that there are approximately 6 million tobacco-related deaths per year at present and that this will rise to 10 million in the next 20 years. Currently, these deaths are equally distributed between the developed and the developing world, but in future, the deaths will be predominantly in the developing world because smoking is decreasing in the developed world. The mortality in the past century from smoking has been in the order of 100 million people, but it is expected that this century it could go up to 1 billion deaths; this is because of the rapid spread of cigarette smoking to highly populated countries such as China and India and other eastern countries. While smoking is declining markedly in the West and in so-called developed countries, it is continuing to increase in these highly populated countries. Since it is known that some 50% of people who smoke die because of it and on average lose 10–15 years of life, the appalling loss of life is likely to increase enormously in countries with very high prevalence of smoking, such as China. In addition to the loss of life, there is the reality that disease from smoking such as chronic heart disease, heart failure, chronic bronchitis, and other chronic noncommunicable diseases often manifest some 10–20 years before death, and therefore in addition to premature death, there is the prospect of many years of ill health, with consequent loss of quality of life and employment possibilities, and heavy usage of resources, particularly in health care.

TOBACCO INDUSTRY

The tobacco industry is active worldwide and is a highly profitable transnational industry. This industry is well aware that its product is addictive and causes death and disability on a massive scale. Rather than

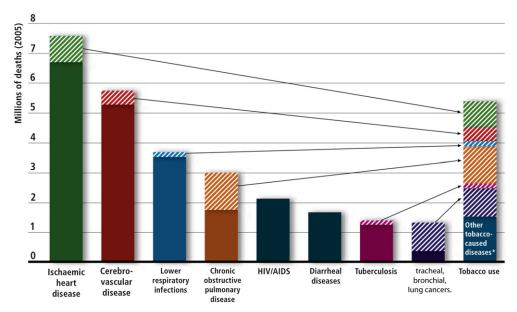


FIGURE 76.1 Tobacco use is a risk factor for six of the eight leading causes of death in the world. WHO 2008b. Global Tobacco Epidemic 2008, The MPOWER Package. Switzerland.

alleviating the problems caused by tobacco products, the tobacco industry undermines policies aimed at reducing tobacco smoking and its associated harms. Nicotine makes cigarettes addictive, and smoking cigarettes causes cancer, heart disease, chronic respiratory disease, and a myriad of other illnesses. Therefore, it seems incumbent on the tobacco industry to do more to alleviate this very serious health problem. However, at present, efforts by the industry to produce safer cigarettes appear inadequate and leave their product in its present harmful, deadly state while continuing to maximize profits.

Some countries have implemented measures to limit the supply of tobacco products. These mainly consist of efforts to reduce access by children and to regulate the distribution of the product in the society. Marketing bans, advertising bans, sponsorship bans, and efforts aimed at reducing access to this lethal product are met by the tobacco industry with opposition. The industry tends to respond not with adoption of these bans but with adaptations such that effects of these interventions on the industry are minimized. While current effort to control the supply of tobacco is weak, it seems unlikely that the society will continue to tolerate the tobacco industry profiteering from a product that kills half its consumers (Fig. 76.1).

In the United States, litigation has been used to try to make the industry pay for the damage caused by its products, and although there have been successful cases imposing heavy fines – amounting to US \$216 billion – this does not seem to have alleviated the problem.

FRAMEWORK CONVENTION ON TOBACCO CONTROL

The WHO's Framework Convention on Tobacco Control (FCTC) is an evidence-based international treaty and the first legal instrument designed to reduce tobacco-related morbidity and mortality worldwide. As the most widely accepted treaty in United Nation's history with at present 172 parties to date having signed up to its principles, the FCTC has provisions and sets international standards and guidelines for tobacco control (TC), which those who ratify have a legal obligation to meet. It consists of 11 parts and contains 38 articles, which have a wide-ranging remit aimed at mainly controlling demand for tobacco products and, to a lesser extent, some measures to regulate supply.

Price and TC

It is a firmly held tenet of TC that tobacco taxation is the most effective TC intervention available. Governments can reduce the demand for cigarettes and tobacco through taxation, with its effect related to the price elasticity of demand. Price elasticity of demand for tobacco is the proportional change in consumption of tobacco relative to a change in its price. Since tobacco is addictive, demand for tobacco in response to a price increase is relatively inelastic, meaning that the proportional change in consumption is less than the change in price. Various econometric estimates of the price elasticity for tobacco products have been made in many countries

under many different circumstances; however, robust estimates suggest that for a 1% rise in price, there is on average 0.3–0.5% reduction in consumption. Young people and those in lower socioeconomic groups of the population tend to be more responsive to price increases.

Tobacco taxation helps prevent young people from starting to smoke, encourages smokers to quit, and reduces consumption among those who continue to smoke. The tax structure to achieve this varies and is to some degree regulated, especially in the European Union (EU), which sets limits on what proportion of the retail price of tobacco products should be taxed. For instance, the minimum total tax as a percentage of the retail price is set at 57%, with a minimum rate of €64/1000 cigarettes. This does not preclude Member State governments from having higher taxes but sets the lower limit of tax. The tax structure may consist of specific taxes, which are expressed in monetary terms per unit of tobacco (e.g. 1000 cigarettes or per 1000 kg of tobacco) and ad valorem taxes, which are a percentage of prices. There are also value-added taxes, and these vary from country to country. The tobacco industry usually responds by trying to lower the price by various interventions depending on the tax structure being used by the government. Determining the optimal structure and rates of taxation is very complex and depends on a number of factors. Whatever structure is used, it seems that for every price rise, there will be a reduction in smoking and an increase in revenue. However, there are several concerns about using price as an instrument of TC. First, it can be considered regressive, which means that poorer people pay a greater proportion of their income than the wealthy. Second, increased taxation may have a deleterious effect on illicit trade, smuggling, and counterfeit manufacture of cigarettes. All of these problems are real but surmountable, where there is a will in government to achieve the desired result of better public health. The tobacco industry invariably tries to deter governments from raising the price and will vary their tactics. Often they will argue that government revenue will decrease, smuggling will increase, and public health benefits will be negligible in comparison. Governments seem to be susceptible to these arguments despite counterarguments, which show that despite the realities of these occurrences when the only intervention is a price rise, then revenue increases and consumption falls. There is a theoretical point where so many people will stop smoking that revenue will also fall, but this has not been achieved in any country to date.

The approach to illicit trade varies. TC advocates insist that it is a matter of law and order. Several studies show that while there is a relationship between price and smuggling, it is small and that most illicit trade

and smuggling are related to other factors, including availability of cheap cigarettes, a distribution network and criminal involvement, corruption at many levels, poor enforcement, and lack of political and legal will. This is evidenced by the generally low level of fines imposed. However, these arguments do not seem to hold sway at all times. In the EU, the free movement of goods and the huge differential in the price of cigarettes between countries provide incentives for tax avoidance. Tax avoidance involves the legal purchase of cigarettes in a lower price country for consumption in a higher price country. The price of a package of 20 cigarettes in the most popular price category ranges from €2.50 in some northern European countries to €8.50 in Ireland. As such, there are great incentives for consumption of non-domestic duty-paid cigarettes in high-priced countries especially with the greatly increased cheap air travel between member nations.

The regressivity of tax is a worry, and if taxation is to be used as a principle instrument of TC, then its effects on the poorest in society need to be addressed. While the hope is that more people will stop smoking as a result of this effective intervention, there are many smokers who are not able to reduce their cigarette consumption unaided and wealth redistribution may be needed so that they are not impoverished further by tax rises. The TC approach to this is to increase and improve the treatment of tobacco dependence and improve the access to these services available to the population and in particular to people who are most disadvantaged. It is well known that the smoking rates are higher among lower socioeconomic groups and also that other interventions have less effect among this group, particularly the impact of public health messages. Therefore, targeted services for smoking cessation treatment and targeted media campaigns should be provided to this segment of the population. Revenue earned through tobacco taxation could be directed toward these activities, or other attempts to improve the economic situation of this segment of the population such as better access to transportation, childcare, and social welfare benefits, so that increased tax would not be a further cause of inequality.

As previously stated, young people are particularly responsive to price increases, which discourage them from starting to smoke and encourage them to stop. Also, young people are likely to have less disposable income and may be less addicted and therefore may be more susceptible to price at this stage. Another consideration in using taxation for TC is the range of compensatory behaviors that smokers engage in to minimize the impact of a tax increase. In response to a price increase, smokers may switch to other lower-taxed smoking materials or cheaper cigarettes where these are available. Some countries have a wide price range

for different "qualities of cigarette" but high prices create a greater incentive to seek out illicit or smuggled cigarettes. As mentioned earlier, smuggling and illicit trade need to be tackled in their own right, and if there is any worry about increased price having a further increase on this, then some of the resources becoming available from the higher tax could be used to combat this crime. Intuitively, a measured price rise on already expensive cigarette is unlikely to have a significant influence on smuggling.

The use of tax as a TC measure is unevenly distributed throughout the world, with high-income countries more inclined to avail of this intervention (Fig. 76.2).

Non-Price-Based Articles in the FCTC

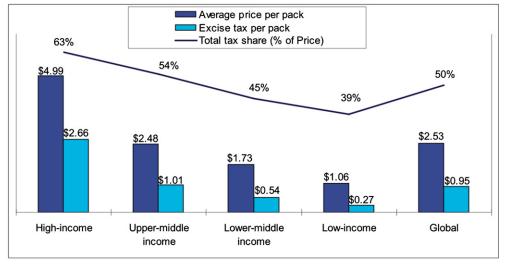
In addition to price and tax measures of TC, the FCTC supports non-price measures, such as smokefree legislation, treatment of tobacco dependence, tobacco product regulation health warnings, advertising, promotion and sponsorship, and youth access to tobacco.

Smokefree

The harm caused by exposure to environmental tobacco smoke, passive smoking, or, as it is better known, secondhand smoke (SHS) is also serious. It causes many of the same diseases as direct smoking. These include carcinoma of the lung, heart attacks, strokes, exacerbations of asthma, sudden infant death syndrome, birth abnormalities, and a variety of irritant symptoms, such as watering of the eyes, sneezing, scratchiness of the throat, and hoarseness. It has taken a long time and very painstaking research to establish

SHS as a cause of these diseases because it is difficult to separate the effects of SHS in active smokers. Nevertheless, there are now more than 30 reliable studies showing these effects.

SHS exposure has become an increasingly contentious issue in the society. Smokers and their allies in the tobacco industry state that smoking is legal and therefore they should be allowed do it where they like. On the other hand, the TC community and environmentalists claim that people have the right to breathe clean air, and since the diseases caused by SHS are well known and very serious, smoking should be prohibited in public. The smokefree movement began in North America, with early leaders such as California, Massachusetts, and New York introducing smokefree laws, and spread to jurisdictions within Canada, Australia, and New Zealand. However, Ireland was the first country to introduce comprehensive national legislation extending to workplaces and including bars, discos, clubs, casinos, and restaurants. Since then, the movement has accelerated, with many European countries introducing comprehensive smokefree laws that do not allow any smoking areas indoors including Norway, Scotland, and then the rest of the United Kingdom, France, Slovenia, Turkey, Greece, and Spain. Although others such as Italy and Sweden technically allow some indoor-smoking areas, in practice, the regulations are so strict that effectively they are equivalent to comprehensive laws. Many of these countries had earlier implemented partial bans and restrictions in certain areas, with varying success, but it is now agreed that a comprehensive law is the most likely to be successful if implemented and monitored correctly. The benefits from comprehensive smokefree laws are



Source: WHO GTCR, 2009

FIGURE 76.2 Simple average price of the most sold brand, excise tax per pack, and total tax share by Income Group, 2008. WHO 2010. WHO Technical Manual on Tobacco Tax administration. In: WHO (ed.). Malta.

immediate. After the introduction of a properly implemented comprehensive smokefree law, dramatic reductions in exposure can be shown in particle measurements, such as PM 2.5, which acts as a surrogate for cigarette smoke, in ambient nicotine, and in cotinine in biological samples such as saliva, urine, or hair.

The health benefits of smokefree laws are dramatic and in many cases occur very early. For instance, most studies show that irritant symptoms of SHS exposure are dramatically improved immediately after a smokefree law is implemented. There is also significant improvement in pulmonary function as measured by spirometry and in measurements of other parameters, such as oxygen diffusion into the blood through the lung. However, the most significant health benefit is the immediate reduction in admissions to hospital of patients suffering from myocardial infarction. This effect varies, but most studies show effects in the order of a 10% drop in admissions within the first year. Most of the studies are open to criticism, but the direction and to a lesser degree the magnitude of the effect favor a very positive outcome for smokefree. Clearly, the possible benefits as regards cancer are of a much slower time course. The lag time between exposure and disease in malignancy related to smoking can be very long and is often in the order of 20–30 years. Therefore, it is unlikely that big changes in the incidence of these diseases will be seen in the short term and will require very careful and complex study (Fig. 76.3).

With the known risks of exposure to SHS and the benefits of protecting people from such exposure, it is

Support for comprehensive smoking bans in bars and restaurants after implementation

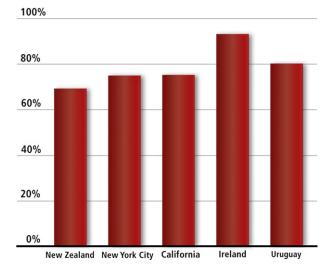


FIGURE 76.3 Smokefree areas are popular. WHO 2008a. A Policy package to reverse The Tobacco Epideminic. In: WHO (ed.). Switzerland.

surprising that despite this and the undoubted popularity of such legislation, all countries have not adopted smokefree legislation. Arguments concerning civil liberties and infringement of rights do not seem to hold credence when the dangers are so obvious and clearcut. An analogy is often drawn between SHS and asbestos dust exposure. Both substances have a known and definite risk of causing cancer; however, the former is only regulated in some instances, while the latter is forbidden for use by workers and as a building material. This difference in approach is difficult to understand but may partially be explained by the fact that malignant mesothelioma, although a remote risk, is almost exclusively caused by asbestos exposure, while smoking is a much greater cause of lung cancer than SHS. Whatever the explanation, it is hard to understand why many would still argue that exposure to SHS, which is known to be so harmful, should be allowed because smoking is legal when a workable alternative strategy of smokefree legislation has been shown to be effective where it has been introduced.

Another potential benefit of smokefree legislation is its potential to influence attitudes toward smoking. Legally allowing smoking in the presence of nonsmokers weakens the acceptance of the fact that SHS is harmful or may even reduce the confidence in the fact that smoking is so harmful. People may be reluctant to accept the pervasive risk of SHS exposure if they are legally exposed to it in their daily lives. Comprehensive bans on smoking send a clear message that SHS exposure is dangerous and that people should be protected from exposure. In addition to the aforementioned health benefits of smokefree laws, strong laws are likely to contribute to the process of denormalizing smoking the gradual shift in social norms away from the social acceptability of smoking. If smokefree legislation does in fact make smoking less acceptable in the society, then these laws could reduce smoking by encouraging smokers to stop smoking and preventing children from starting to smoke. Recent prevalence studies in the Western world have shown a reduction in smoking among children in countries with smokefree laws. However, many other types of intervention are occurring simultaneously, so attributing this reduction to smokefree alone is not proven, although it should at least be helpful in this regard. The FCTC has laid down protocols for implementing smokefree laws; the application of these protocols should facilitate the spread of smokefree environments in all FCTC countries.

Treatment of Tobacco Dependence

Approximately half of all smokers die as a result of their smoking and on average lose 10–15 years of life; however, regular smokers who quit at the age of 60, 50,

40, or 30 can gain 3, 6, 9, or almost 10 years of life expectancy in comparison with those who continue to smoke. However, smoking is an addiction and people find it very difficult to stop. Nevertheless, most people who stop smoking do so unaided. This shows that it is possible to stop if smokers are fully motivated and make the effort. It is imperative, therefore, that smokers are encouraged and enabled to quit by the use of all available evidence-based, cost-effective methods. Interventions that increase motivation such as mass media campaigns and advice from doctors and other health care professionals have important and proven roles in this regard.

The main reason that people continue to smoke is nicotine addiction; the release of the reward-linked neurotransmitter dopamine is thought to be important in maintaining this addiction and seems to be accompanied by a reduction in cortical control mechanisms. The localization of this release in the brain is reasonably well understood, and the related activity in the nucleus accumbens and amygdala has been mapped in various studies including the use of functional magnetic resonance imaging. The cortical localization of control, including areas such as the dorsolateral prefrontal cortex, anterior cingulate cortex, and insula, is known, but the relationship between bottom-up/top-down neural responses to smoking needs further investigation. However, efforts to block the site of addiction have been only partially successful (Fig. 76.4).

The most successful approaches to cessation seem to be cognitive therapy and pharmacotherapy, either alone or together. The success rates achieved seem to be similar but variable and in the order of 10–20%; in some clinics, success rates as high as 50% have been achieved. The degree of addiction varies and scores such as the Fagerstrom Scale have been designed to estimate the level of addiction. These scales consist of questions to establish how soon people smoke first thing in the morning after waking, when they smoke, and the total number of cigarettes they smoke per day. While these scales offer a measure of the degree of addiction, they are not always closely allied with success in stopping. In general, the higher the level of addiction, the more difficult it is to stop.

The scientifically proven, cost-effective pharmacological agents at present available for treatment of nicotine addiction include nicotine replacement therapy, bupropion, and varenicline. All of these pharmaceutical agents seem to greatly increase the chance of successful quitting, at least doubling the success rate, and when combined with counseling can yield higher success rates. Access to and appropriate use of these scientifically proven treatments are important health initiatives encouraged by a recent protocol for Article 14 of the FCTC. Nevertheless, it is obvious that better therapeutic agents are urgently needed, and an increase in research in this field is to be encouraged.

Despite the availability of successful treatments, few smokers seem to access such services for many reasons. In many countries, services are not available, and where they are available, they can be difficult to access. The

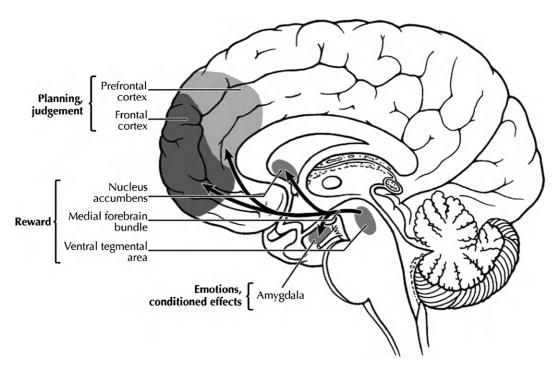


FIGURE 76.4 Effects of nicotine on the brain. Tomkins, D.M., Sellers, E.M., 2001. Addiction and the brain: the role of neurotransmitters in the cause and treatment of drug dependence. CMAJ 164 (6), 817–821.

reasons for this are complex. Although nicotine dependence is a WHO-recognized disease with its own International Classification of Diseases code, it is not regarded as a disease by many of those who have the condition or indeed by some in the medical profession who might be expected to offer treatment for this disease. Furthermore, there is often limited awareness of available services, as they are not always well advertised. The reasons health care workers do not offer such treatment are equally varied. Treatment of tobacco dependence is often not a significant feature of health care training for doctors, nurses, pharmacists, psychologists, or any other health care professional. As such, lack of knowledge may be a barrier to providing cessation treatment. Responsibility for providing these services is not always clearly assigned; the health profession providing these services varies within and between countries and seems to be a function of the individual health professional's interest. Current services are generally poorly developed, poorly accessed, and limited in their success. It is obvious that a standardized approach to the treatment of tobacco dependence is badly needed. The recent protocol for Article 14 of the FCTC is an appropriate step in this direction. Guidelines are urgently needed. With the implementation of FCTC protocols and subsequent guidelines, it is hoped that matters will improve in the future and this underutilized intervention for TC will achieve reductions in smoking prevalence and related mortality. The importance of the treatment of tobacco dependence is crucial to the reduction in smoking-related mortality over the next 25-50 years and so should become a priority in preventive health care.

Tobacco Product Regulation and Labeling

The FCTC has tobacco product content regulations that set standards for contents and emissions and require parties to have guidelines for testing and measuring contents and emissions. Product regulation can be expensive and difficult to undertake and should be managed through regional or international mechanisms, rather than consuming scarce TC resources at the country level. This approach has some merits in achieving a safer cigarette, but the costs involved should be borne by the tobacco industry. It is recognized that tobacco and smoking have disastrous health consequences and various analyses have shown the agents that are likely to be responsible. Also, it is clear that the tobacco industry changes constituents on an ongoing basis, and it is, therefore, important that there is a mechanism in place to get information on the contents and emissions of tobacco products. This should be a simple, legislative matter. On grounds of commercial confidentiality, the industry often refuses to disclose additives that

can have an effect on addictiveness and attractiveness of cigarettes for defined identified targets such as children or women or specific ethnic origin groups. Therefore, the requirement that the industry reveal the contents of its products is important and should be legislated. The United States, which is not as yet a party to the FCTC, enacted The Family Smoking Prevention and Tobacco Control Act in 2009 and is expected to address these issues in the frame of the Act.

The importance of tobacco product regulations and labeling has been studied and is clearly of great importance in initiating or perpetuating the use of these products. Since the overall aim of the treaty is to reduce or eliminate the use of tobacco, it is important that the packaging and labeling of tobacco products are controlled and enforced. Consequently, misleading and erroneous impressions created by labeling such as low tar, light, ultra light, or mild have been restricted and increasingly outlawed, and laws to make this possible are recognized by the international community as important. Tobacco product packaging provides an important vehicle for the industry to attract consumers and thereby encourage initiation and usage; likewise, the package could instead be used to dissuade children from starting to smoke and make it less attractive for adult tobacco users. With this in mind, the treaty urges the use of rotating health messages and pictorial warnings, taking up at least 50% of the main display area of the package and no less than 30% of the other main surface. A further development that has occurred since the FCTC was introduced is that many TC professionals now advocate for plain packaging. This would further deprive the tobacco industry of space on the packs to advertise their products and perhaps mislead the public. These plain packages could continue to have health messages and graphic images of smoking-related diseases without the concomitant damage done by allowing the industry to market its products on the packages. This would also make it logical to ban the advertising of tobacco products at the point of sale, as has already been done in Iceland, Ireland, and a number of other countries. In most countries, however, at present where there are strong advertising bans, point of sale has often been exempted. This exemption is clearly not in the interest of TC. The extension of the ban on point of sale advertising is desirable and will probably proceed, especially when other possibilities of advertising have been eliminated (Fig. 76.5).

Tobacco Advertising Promotion and Sponsorship

There has been much debate about the appropriateness of banning tobacco advertising, promotion, and sponsorship. The contra-arguments are usually based



FIGURE 76.5 WHO graphic image/pictorial warning. Adapted from 2011. European library of graphic pictorial warnings [Online]. Available: http://www.tobaccolabels.ca/gallery/european/eu200~3 [Accessed 01.05.2012 2012].

on the fact that tobacco is a legal product and it is legitimate to advertise goods that are legal. Therefore, the advertising of this legal product should be allowed in fairness to the tobacco manufacturers. However, it could be argued that enticing people to buy goods that they may or may not need, on promises that may or may not be true, is probably wrong in itself. Furthermore, tobacco is not a normal good and the normal rules should not apply. Normal goods do not cause medical disease, death, and disability in nearly half of their users when used exactly as intended. Thus, the society can decide that it is an undesirable product and its advertising and promotion should be regulated. Most countries now accept that advertising, promotion, and sponsorship by tobacco companies are wrong and are now required by the FCTC to introduce laws to make these activities illegal within 5 years of signing up to the treaty. It can be assumed that tobacco advertising, promotion, and sponsorship will soon become illegal worldwide as it is now in many countries.

The industry will continue to innovate and find new ways to attract consumers. Therefore, attention should be paid to the industry reports on both its advertising and marketing strategies and budget. TC experts are conscious of the diverse efforts made by the industry to circumvent legislation in this area and should continue to study the marketing tactics and techniques. Such monitoring of the industry is embedded as a requirement in the treaty. In general, advertising bans have been very successful, with restriction on advertising and promotions sponsored on radio, television, print media, and other media such as the Internet. The potential threat to successful implementation of such laws that is posed by social media and advances

in new media such as Near Field Communications is considerable.

The importance of education and communication as well as training and public awareness about the harms of tobacco use is well understood by the TC community. Parties to the FCTC are bound to bring in legislative and other measures to ensure access to educational and public awareness programs about the health effects and the addictiveness of tobacco consumption and the dangers of exposure to tobacco smoke. The methods of doing this and usefulness of it are well known. Nevertheless, it is clear that the message quite often does not get out to the target audience. There seems to be more success in spreading the message about the harmful effects of tobacco but a lot less about the benefits of discontinuing tobacco use in terms of health, economic well-being, and protection of the planet and the promotion of a better quality of life. It is only with access to good and sustained information that awareness can be increased and attitudes changed. Any such information campaigns should include commentary on the tobacco industry and its activities.

The target for such education needs to be focused. There needs to be special training for health care workers, educators, and decision-makers so that they are aware of the most cost-effective and beneficial methods of communication and education. In this way, it is likely that they would be able to communicate the message more effectively and health care workers would be able to deliver more appropriate treatments.

MEASURES TO REGULATE THE SUPPLY OF TOBACCO PRODUCTS

Illicit Trade

The FCTC is at its strongest in advocating measures to reduce demand. In its preamble, it attests to the fact that it concentrates on demand rather than supply-side measures, unlike other efforts targeted at addictive products. While demand-side measures are perhaps more important, it would appear that in strengthening demand-side reductions, the treaty may have diminished the supply-side efforts, by comparison with approaches to other addictions. Failing to strengthen and enforce supply control could prove to be a mistake in terms of TC. Within the treaty, the main efforts to regulate supply are targeted at reduction of illicit trade in tobacco products. This is important as smuggling, illicit manufacturing, and counterfeiting are likely to make available cheap and potentially even more harmful cigarettes. Furthermore, illicit trade complicates the monitoring of tobacco use and the collection of revenues, thereby increasing the burden of associated health FUNDING 753

costs. From the society's point of view, this is an important law and order issue but may not be the strongest method of supply control. There needs to be national and international collaboration in this effort and further development of tracking and tracing methods, which will make control better and easier. In this regard, attention to packaging of tobacco products is also necessary. The tobacco industry is arguing that plain packaging, for instance, would make smuggling and illicit trade easier. If appropriate tracking and tracing methods are implemented, which can be just as readily applied to plain packaging, the industry argument need not be a reality. There is no doubt that the control of smuggling and illicit trade is very difficult; it will only be successful if there is international cooperation and further development of methods of control.

Youth Access Restrictions

Another supply reduction measure is the control of sales of tobacco to and by minors. This measure has its basis in the fact that children may not be fully competent to make decisions about the use of tobacco. While there is some truth in this, especially for the very young, it is less obvious in late teenage years when many young people do start. The logic is that restriction of sale to everyone would be justified if a method could be found. It is therefore surprising from a TC's point of view to see that nowhere in the present approach to TC is it envisaged that there will be no access to tobacco in the long term. Most TC specialists are of the opinion that the total banning of tobacco and tobacco products at present would not be feasible and would not lead to better control. However, this does not seem to be a logical reason for the absence of a long-term goal to see the elimination of all use of tobacco products. The support for ban of sales to minors seems entirely justified, but it may be somewhat illogical not to aim to extend this ban to all age groups when this becomes feasible.

Support for Alternative Livelihoods

Also within the supply-side control is the concept of support for alternative economic activities for tobacco growers. It is conceded that this is a difficult problem. Many growers are maintained just above the poverty line by involvement in this industry, with great insecurity and the dangerous health effects that managing this crop entails. This concern also leads to a concept of environmental protection and need for the protection of tobacco growers' health and well-being independent of smoking. It is likely that this aspect of tobacco production will have increasing prominence in the future as it becomes more fully understood as how harmful to the

environment this product is both in its growing and on the health of its growers and in its use in the society when it is processed by a profit-orientated transnational industry.

Litigation

In some countries and in particular in the United States, the use of litigation to enforce liability for the death and destruction caused by tobacco and the liability for this that the industry has because of its knowledge of the harmful effects and its hiding and lying about such effects over a long period made litigation a powerful weapon of TC in that country. Litigation has not been pursued to the same extent in any other country or continent. It is difficult to understand fully why, but in some countries, it seems that such litigation would have difficulties in being successfully prosecuted. There have been some successful cases but they are few, and the legal structures are such that individuals challenging a powerful and rich industry such as the tobacco industry often do not have the resource to get their legitimate claims satisfied. On that basis, it is obvious that joint actions at national and international levels are a more logical approach and would pit the industry against states and communities such as the EU with better access to the necessary resource to mount appropriate legal challenges. If such litigation were undertaken by states, it would certainly help toward TC, particularly if successful but even if not, the gathering of information to show the damage and to show the activities of the industry would certainly be beneficial.

FUNDING

The FCTC provides a model and roadmap on the way to the elimination of tobacco smoking as a norm in the society. However, its aims cannot be attained without planning, effort, and appropriate resourcing. The disparity between resources allocated to other scourges such as tuberculosis, malaria, and HIV/AIDS is striking, considering their relative contribution to the global burden of disease (Fig. 76.6). There is no suggestion that these resources are not needed for those other diseases, but TC is seriously underfunded by comparison and needs much more attention. The paucity of resources is all the more surprising, considering that tobacco taxation amounts to \$162 billion and that only a tiny fraction of this is made available for TC. This needs to be changed if TC is to be successful.

Modeling of interventions individually and as part of a comprehensive strategy suggests that stronger policies would have powerful effects on smoking and related mortality. However, these models have not considered

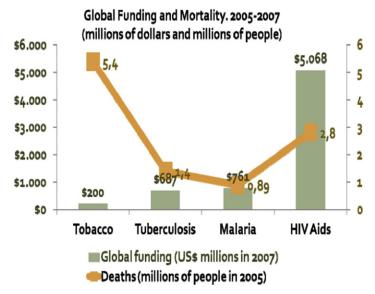


FIGURE 76.6 Investment in tobacco control compared to other diseases. Adapted from Cynthia Callard and Neil Collishaw (Physicians for a Smoke-Free Canada). The Global Tobacco Economy: A snapshot of the economies of multinational tobacco companies and of international tobacco control efforts in 2008. September 2009.

the possibility of eliminating tobacco use in the short to medium term. While the WHO treaty is a great step forward, it does not go far enough to prevent the continued spread of the smoking epidemic and its calamitous health effects. The treaty acknowledges its limitations in articles calling for continued research, surveillance, and information exchange, so that the treaty itself can evolve and be strengthened by TC research developments. Despite the considerable challenge to health posed by tobacco, at present, TC research is not prioritized and poorly funded, with only a tiny fraction of the revenue from tobacco taxes made available in most countries. The FCTC encourages the provision of an organization, training, and support systems to enable TC research to be performed and translated into activities, which are implemented and evaluated. It greatly encourages cooperation in this regard, both nationally and internationally. A health problem of such high importance should by these means achieve a level of priority commensurate with the seriousness of the problem it addresses. At present, however, although the tools to control tobacco use are known, less than 5% of the world's population benefits from effective use of these tools. It is clear that unless there is a strong and successful research into the best methods to introduce effective control of tobacco, the ravages of the tobacco epidemic will continue.

List of Abbreviations

EU European Union

FCTC Framework Convention on Tobacco Control

SHS Secondhand smoke TC Tobacco control

WHO World Health Organization

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www.tri.ie - TobaccoFree Research Institute Ireland.

www.fctc.org - The Framework Convention Alliance.

www.fda.gov/NewsEvents/PublicHealthFocus – US Food and Drug Administration.

www.who.int/fctc - World Health Organization.

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Policies and Interventions to Reduce HIV Risk

Bradley Mathers

The Kirby Institute, University of New South Wales, Sydney, NSW, Australia

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THE ASSOCIATION BETWEEN DRUG USE AND HIV RISK

People who use drugs are at elevated risk of HIV infection compared to people who do not. This elevated risk is largely related to injecting drug use (IDU); there is also, however, significant risk associated with drug use via other routes of administration. Typically research, policy development, and programmatic responses to drug use in relation to HIV focus primarily on IDU. This discussion will similarly focus on IDU, but 'noninjecting drug use' will also be considered.

Internationally there is a lack of strong data on the prevalence of IDU and of HIV among injecting drug users (IDUs). As a result, there is limited understanding of the exact scale of the potential burden on health posed by the risk of HIV transmission through IDU. It is clear, however, that IDU occurs across the globe, and that the nature and extent of IDU can differ both between and within countries. Further, by the end of the 2000s, IDU had emerged as the primary mode of HIV transmission in many countries within Asia and Eastern Europe.

A range of substances are injected, the most common include opioids, both naturally occurring opiates, such

as heroin, and pharmaceutical opioids; amphetaminetype stimulants, most commonly methamphetamine and amphetamine; cocaine, including 'crack' cocaine; and various other depressants such as benzodiazepines. Different drug types are more commonly used and injected in different geographic regions and between countries. 'Poly-drug use' among IDUs is also common.

Just as there is considerable heterogeneity across countries and settings in which IDU occurs, there also exists significant diversity within IDU populations with respect to demography, social economic status, vulnerability, and need. There is also very often overlap between IDU populations and other groups identified as being at increased risk of HIV, including in particular men who have sex with men and people who engage in sex work.

HIV Transmission Through IDU

HIV can pass from an infected to a noninfected person during the process of drug injection via the use of a piece of injecting equipment that has been contaminated with blood containing HIV. Typically, this is a needle or syringe that has been used previously by an HIV-infected person, but it is also possible, though less likely, to occur via the use of other pieces of contaminated injecting paraphernalia such as spoons or other vessels used to prepare drugs for injection; water for mixing drugs into an aqueous solution; cotton wool or other material used as a filter when drawing up the drug solution into a syringe; or a shared tourniquet.

Reuse or shared use of injecting equipment may occur when sterile equipment is unavailable or when people are unaware of the potential risks of doing so.

Risk of transmission from injecting using a contaminated syringe is estimated to be many times greater than sexual exposure for a female in penile–vaginal intercourse where her male partner is HIV seropositive. Exposure through receptive anal intercourse may confer similar infection risk to the use of a contaminated syringe.

If sharing of injecting equipment occurs, people who inject most frequently are potentially most at risk through repeated exposure. A person who is dependent on a drug will typically inject more frequently than a nondependent person. When there are more people within a network of drug users who are HIV positive, there is a greater likelihood that a used syringe may be contaminated with HIV.

Sexual Transmission of HIV among People Who Use Drugs

Drug use is associated with increased HIV risk through sexual transmission, independent of the risk associated with injecting as a route of administration. The proportion of incident HIV infections among IDUs attributable to sexual transmission is uncertain, but may be considerable. The sexual transmission of HIV between IDUs and people who do not inject drugs is a significant pathway for the spread of HIV from a concentrated epidemic among this at-risk group to the wider population, the sexual partners of IDUs acting as a 'bridging population.'

Elevated risk of sexual transmission is associated with the use of a variety of substances, including both illicit drugs and alcohol (*see* Alcohol, Sexual Risk Taking, and Sexually Transmitted Infections). The level of risk differs between drug types and is related to drug effects such as disinhibition and enhancement of sexual arousal or pleasure. The association between high-risk sex behaviors and drug use is strongest for cocaine and amphetamine-type stimulant use. Risk behaviors observed among stimulant users include having multiple sexual partners, high rates of unprotected sex, and engagement in sex work.

While drug use, and stimulant use in particular, is strongly associated with elevated sexual risk, whether or not drug use can be said to cause this elevated risk is not clear. People who choose to take drugs may, in general, be more inclined to engage in risk-taking behaviors; having a tendency toward risk taking is itself a risk factor for drug use (*see* Impulsivity, Disinhibition, and Risk Taking in Addiction). Some people may also choose to use a drug in order to become sexually disinhibited or to increase sexual arousal. As such it may be more useful to regard drug use as a marker for high-risk sexual behaviors, rather than drug use necessarily causing sexual risk behaviors.

Sexual transmission of HIV has biologically increased in the presence of many sexually transmitted infections (STIs) such as syphilis and herpes simplex virus. The prevalence of STIs is commonly high in drug-using populations and increases HIV risk in this group.

Other Factors That Can Shape HIV Risk Associated with Drug Use

As outlined above, the primary mechanisms of HIV transmission associated with drug use are the use of contaminated injecting equipment and sexual transmission. While these mechanisms are present across drugusing populations, the risk of acquiring HIV differs in different locations and contexts and between IDUs. Numerous so-called 'structural' factors that are external to the individual have been identified or proposed as having the potential to increase or reduce HIV risk. Structural factors may impact an individual's capacity to avoid HIV risk, the likelihood of being exposed to HIV, or the accessibility or effectiveness of various

interventions that aim to address HIV and drug use. These influential factors overlap and interact, impacting in multiple ways drug users and the broader communities in which they live, and in doing so shape HIV risk.

Drug Availability

Drug availability is influenced by numerous factors including conditions of drug production and distribution, market forces, and law enforcement efforts to limit the availability of drugs. Proximity to locations where drugs are produced and drug trafficking routes impact drug availability, drug use, and the development of drug markets.

Greater drug availability and increased drug use result in more injecting episodes and potential HIV exposure as a consequence. Conversely, however, if drugs become more scarce or more expensive, injecting may increase as this may be considered a more efficient and economical means of deriving enhanced level of effect from a smaller amount of the drug as would be experienced through other routes of administration that result in lower bioavailability. Some forms of a drug may be more easily, or more commonly, injected than others; different forms of a drug may be available in different locations and may influence the prevalence of use by injection and hence HIV exposure.

Social Networks

Drug use commonly occurs in a social context and drug users are socially connected to one another. Social networks that exist between drug uses and their peers can exert influence over drug-using behaviors as well the spread of HIV and other contagions.

Because it is through these network connections that HIV is spread between drug users via the sharing of contaminated injecting equipment, the structure and dynamics of these networks, and an individual's proximity within the network to the epicenter of HIV, will determine the likelihood of being exposed to the virus. Population mobility, proximity to trade routes, and migration also contribute to the mixing of networks and populations.

The behavioral norms that exist and evolve within peer groups can perpetuate or modify risky behaviors such as syringe sharing, and patterns of drug use; as people join networks they may be introduced to different behaviors.

Physical Environment

PUBLIC SPACE

When using drugs in public spaces, where there is the chance of being apprehended, riskier drug-using may occur: People may inject more hurriedly to avoid detection and may be more likely to share injecting equipment; used injecting equipment may also be discarded and pose a risk to other community members.

CLOSED SETTINGS

Commonly, a significant proportion of people incarcerated in prisons are drug users. Many of those imprisoned have been incarcerated for reasons related to their drug use, having broken criminal laws relating to drug use, possession or trade, or for undertaking activities that may be illegal such as theft or sex work (which is illegal in some jurisdictions) to fund drug use.

Despite the presence of security measures, drug use commonly occurs within prisons and other closed settings and takes place covertly, generally with limited access to sterile injecting equipment. Because drugs are typically difficult to acquire, drug users may be more inclined to inject drugs in an effort to maximize the effect of smaller amounts of a drug; people may even initiate IDU while in prison. In these environments, sharing of needles and syringes is common with scarce, often improvized, injecting equipment reused many times and shared among large numbers of people.

Similarly, consensual and nonconsensual sex commonly occurs within prisons and HIV risk is elevated if condoms are unavailable. Risk of bloodborne virus transmission through improvized tattooing and other body modification practices also exists in prison environments.

Socioeconomic Factors

Poorer socioeconomic status (poverty, homelessness, low level of education) is associated with elevated HIV risk, increased vulnerability, and poorer health outcomes more generally. Socioeconomic inequalities may vary spatially (i.e. in different geographic locations), across ethnic and language groups, and may be determined by economic activity, access to welfare and social services, and employment and educational opportunities. Each of these factors can have a bearing on drug use, the likelihood of risky injecting and sexual behavior, as well as access to drug treatment and HIV prevention, treatment, and care services.

Stability of accommodation is also important in terms of HIV risk. People who are homeless typically have worse health than those with stable accommodation and have poorer access to healthcare services including treatment for drug dependence and HIV. Homeless IDUs are also more likely to inject in public environments (see above).

Unstable economic conditions can also encourage the growth of informal economies including the development of the drug trade, which in turn influences levels of drug use and associated HIV risk.

Access to Health and Welfare Services

Drug users typically have low rates of utilization of mainstream healthcare services, contributing to poorer health status, with medical conditions going untreated or presenting in a later stage of disease progression. People who use drugs may be reluctant to access health services for fear of discrimination because of their drug use; they may prioritize other matters such as obtaining and using drugs, shelter, and food over attending to healthcare needs; or they may have difficulty accessing a service due to its location or hours of operation. Some drug users who may have more chaotic lifestyles or those with other mental health or behavioral issues may have difficulty successfully engaging with service providers, particularly those that are not equipped or experienced in dealing with people who use drugs. Specialized drug user services may also be unattractive to people who use drugs if they fear arrest or harassment from police targeting the clients of these services. Further, in some locations mainstream HIV programs may have restrictions excluding drug users from accessing services.

POLICIES AND INTERVENTIONS ADDRESSING HIV AND DRUG USE

There is a clear imperative to reduce HIV risk and prevent HIV transmission associated with drug use. To do so effectively, multiple interventions and policies are required to address the different mechanisms of transmission and influential structural factors that shape this risk.

Responses to drug use and HIV differ between countries, with national strategies having differing focus on health-based approaches to address drug use and related harms (including HIV), or law enforcement approaches aimed at reducing drug use. In those countries where IDU is acknowledged to occur, national HIV strategies typically include specific programs to address it.

Interventions intended to reduce HIV risk associated with drug use aim to interrupt the mechanisms of transmission, address factors that shape HIV risk, or reduce drug use itself. Ultimately, these interventions seek to prevent the individuals from becoming infected with HIV.

'Harm reduction' is a term frequently used to describe approaches that focus principally on preventing and reducing harms associated with drug use, including HIV, rather than seeking exclusively to prevent drug use itself (see Harm Reduction Approaches). Harm reduction approaches have been incorporated into national HIV strategies in many countries. The World Health Organization (WHO), the United Nations Joint Programme on HIV/AIDS, and the United Nations Office on Drugs and Crime (UNODC) have endorsed a core set of harm reduction interventions to address IDU and HIV, these are needle and syringe programs (NSPs); opioid substitution therapy (OST) and other drug-depentreatment; HIV testing dence and counseling; antiretroviral therapy (ART); prevention and treatment of STIs; condom programs for IDUs and their sexual partners; targeted information, education, and communication for IDUs and their sexual partners; vaccination, diagnosis, and treatment of viral hepatitis; prevention, diagnosis, and treatment of tuberculosis.

Determining the effectiveness of interventions in reducing HIV incidence among IDUs presents methodological challenges. Recruitment and retention of IDUs in intervention research can be difficult. For most interventions, existing evidence is largely comprised of observational data from ecological, cross-sectional, case—control, and cohort studies. Measuring changes in HIV incidence attributable to an intervention or policy strategy is difficult and much of the existing evidence on HIV risk among drug users is based on observations in changes in self-reported risk behavior attributable to exposure to an intervention.

Reducing Drug Use to Reduce HIV Risk

A range of interventions and policies seek to reduce HIV risk and other harms by both reducing the prevalence of drug use within a population (see International Policies to Reduce Illicit Drug-Related Harm and Illicit Drug Use) and reducing the frequency of drug use at the level of the individual. It is intended that achieving reductions in drug use will result in reducing the number of injecting episodes where HIV exposure might occur, as well as reducing the risk of sexual transmission of HIV associated with drug use. Further, management of drug dependence improves treatment adherence and outcomes for co-occurring conditions including HIV, other infections, and mental health disorders; these enhanced treatment outcomes can also contribute to reducing HIV risk.

Treatment of Drug Dependence to Reduce HIV Risk

Treatment for drug dependence is discussed in detail elsewhere in this book (see section on Treatment). Treatment that achieves abstinence or a reduction in the frequency of drug use and injection episodes reduces HIV risk. Improvement in general health and social functioning brought about by treatment for drug dependence can also contribute to a reduction in HIV risk.

Drug dependence is typically chronic and recurrent in nature. Following, and often during, treatment people may resume drug use. In addition, for many people abstinence may not be the goal of treatment and they may continue to engage in some level of drug use. Treatment for drug dependence, therefore, may not eliminate HIV risk entirely, and in order to prevent HIV transmission it is important that other HIV prevention strategies are also available to people receiving treatment for drug dependence; for example, by ensuring ready access to sterile injecting equipment for people undergoing or

having completed treatment, and providing follow-up aftercare.

OPIOID SUBSTITUTION THERAPY

Methadone (an opioid agonist) and buprenorphine (partial opioid agonist) are both listed as essential medicines by the WHO, as substitution therapy, for the treatment of opioid dependence. Other opioid preparations are also, but less commonly, used as substitution therapy. Prescribed heroin has been used as substitution therapy in a number of countries and appears to be effective in reducing drug use including among people for whom other forms of OST have proven unsuccessful. (*See* also Methadone Maintenance, Buprenorphine for Opioid Dependence).

OST is well established in many countries but absent, or not widely available, in some where opioid injection and dependence are common; legislation restricts the use of OST to treat opioid dependence in many of these countries.

The evidence of the effectiveness of OST in treating opioid dependence and in preventing HIV transmission is strong: OST has been shown to reduce drug use and drug injecting; to reduce unsafe, risky injecting behaviors (i.e. sharing of used injecting equipment); and to improve health and social functioning. OST also improves adherence to HIV treatment among opioid-dependent people. Improved treatment outcomes, including reductions in HIV risk, are observed with higher doses, longer duration of treatment, and adjunctive psychosocial support and counseling. Findings from economic modeling suggest that OST is a cost-effective means of reducing HIV incidence and thereby avoiding the much greater costs of treatment for HIV.

OPIOID ANTAGONISTS

The opioid antagonist naltrexone, in oral or implantable preparations, is available in some countries for the treatment of opioid dependence (*see* Antagonists for the Treatment of Opioid Dependence). Poor patient retention in treatment and the risk of overdose for those who resume drug use posttreatment are significant limitations to the effectiveness of naltrexone. In contrast to agonist pharmacotherapy for opioid dependence, there is insufficient evidence to suggest that naltrexone might be effective in reducing HIV risk and preventing HIV transmission.

PHARMACOTHERAPY FOR STIMULANT DEPENDENCE

Various stimulant drugs, including oral amphetamines, have been investigated to determine if they might be suitable as maintenance therapy for stimulant dependence in the same manner that methadone and buprenorphine are used in the treatment of opioid dependence. Other drugs, such as the alerting agent modafinil, have also been trialed for the treatment of cocaine and amphetamine dependence. (*see* Pharmacotherapy of Cocaine Dependence, Medication Development for Amphetamine Dependence. Medications for Cocaine Dependence).

While findings from some trials have suggested that increases in treatment retention, reductions in stimulant use and injection, and improvements in health and social functioning might be gained from these proposed medications, evidence has not been strong enough to support the clinical introduction of pharmacotherapies for stimulant dependence, and hence their role in reducing HIV currently remains limited.

MEDICALLY SUPERVISED DETOXIFICATION

Detoxification is frequently an important first step to drug treatment for many drug-dependent people. Providing support and medication to manage the symptoms of drug withdrawal increase the likelihood that a drug-dependent patient will complete detoxification. While an important part of a comprehensive approach to drug dependence, detoxification is not effective as a standalone treatment in bringing about long-term behavioral change and reductions in drug use; accordingly, reductions in HIV risk have not been observed.

PSYCHOSOCIAL INTERVENTIONS FOR THE TREATMENT OF DRUG DEPENDENCE

Various evidence-based, nonpharmacological, psychosocial interventions are available for the treatment of drug dependence and hence also have a role in reducing associated HIV risk. These include therapeutic communities (see Therapeutic Communities®), cognitive behavioral therapy, (see Cognitive Behavioral Therapies) and other psychotherapeutic approaches, delivered in either outpatient or residential settings, in groups, couples, or one-on-one (see Individual and Group Counseling for Substance Use Disorders). Psychosocial approaches delivered in concert with pharmacotherapies can improve treatment outcome compared to these treatment modalities delivered alone.

Psychosocial interventions are particularly important in the management of stimulant dependence where pharmacotherapies are currently not available; with evidence suggesting that cognitive behavioral therapy and contingency management approaches may be of most benefit in reducing stimulant use.

Residential rehabilitation programs are commonly abstinence focused; successful models have been developed, however, incorporating OST as well as providing HIV prevention measures such as the provision of sterile injecting equipment.

Legislation and Punishment to Deter Drug Use

Laws regarding drug use and possession differ between countries, but share the aim of deterring the people from using drugs, other than for authorized medical and scientific purposes. With the exception of a small number of countries, possession or use of any drugs that are listed as controlled substances are considered either criminal or civil offenses. The severity of penalties imposed is generally determined in consideration of the type and amount of the drug involved and may range from incarceration or even physical punishment to lesser administrative penalties such as a fine.

The effectiveness of these approaches in reducing drug use is contested, as is their cost-effectiveness in comparison to other drug use reduction strategies (*see* Drug Decriminalization and Legalization).

While such legislation is not always considered explicitly as part of a country's HIV strategy in response to drug use, in many countries the resources allocated to address drug use via these law enforcement approaches greatly exceed that for other interventions that aim to reduce drug use, including evidence-based approaches such as the drug-dependence treatment modalities discussed in the preceding sections. Punishment for drug use in these countries represents the predominant policy approach to reducing drug use and consequent harms including HIV transmission.

Legislation that criminalizes drug use has a number of important consequences in relation to HIV risk. Imposing custodial sentences as punishment for drug use or possession contributes to a greater number of people incarcerated who may be drug dependent or IDUs; drug use and elevated HIV risk in prisons are significant (see above).

Compulsory Detention Aiming to Achieve Abstinence from Drug Use

Drug detention centers operate in a number of countries with the aim of preventing ongoing drug use by removing drug users from the community and compelling them to participate in activities that are intended to promote abstinence from drug use. In many of these countries, compulsory detention represents the predominant drug demand reduction strategy, both in terms of resource allocation and numbers of drug users participating in these programs.

These compulsory detention centers differ from prisons in a number of ways, notably that they operate outside of the judicial system, and lack a process by which an appeal against detention can be made. Typically medical assessment of drug dependence is not made, programs within these centers are not medically supervised, and detoxification is not medically assisted. Programs may involve participation in forced labor, military style drills, or in

some cases punishment. Release from detention is arbitrarily or administratively determined and is not related to demonstrated treatment outcomes.

Rates of relapse to drug use following detention are high, and reentry into these centers is common. There is no evidence that compulsory detention is effective in producing sustained reductions in HIV risk.

Interventions to Reduce Risky Sex and Injecting Behavior

In order to prevent the use of contaminated injecting equipment and to increase condom use by people who use drugs, it is necessary for sterile injecting equipment and condoms to be accessible and for people to have both the knowledge and motivation to practice safer sex and safer injecting.

Access to Sterile Injecting Equipment

Programs for the distribution of sterile needles and syringes have been introduced in the majority of countries around the world where IDU is known to occur; the scale to which these programs have been implemented, however, varies substantially between countries. These NSPs are intended to increase IDUs' access to clean injecting equipment and to decrease the number of used needles and syringes in circulation, thereby reducing the number of injections for which contaminated equipment is used.

Various service delivery models for NSPs have been developed: Some require that used needles and syringes be returned in exchange for new equipment, while others place no such restrictions on the provision of clean needles and syringes, but still encourage the return and safe disposal of used equipment. Distribution may take place from a range of delivery points including from fixed locations, at facilities where other health or welfare services are provided, from vending machines, from mobile distribution services, or through outreach programs, including through peer to peer distribution among IDUs. The presence of multiple distribution options increases the accessibility of injecting equipment.

In many countries, needles and syringes are available for purchase, without prescription, commonly from pharmacies or similar outlets. These are also important access points to sterile injecting equipment, particularly in the absence of NSPs or in circumstances where an IDU prefers not to access an NSP.

NSPs have been studied in multiple settings, in both high- and low-income countries. There is strong evidence that these programs reduce the frequency of injecting with used equipment. Correlations between NSP provision and decreasing HIV prevalence and incidence have been observed in multiple ecological, cross-sectional, and prospective cohort studies. Empirical

evidence that NSPs might increase or encourage injecting has not been produced.

Evidence from observational studies, and supported by mathematical modeling, suggests that the impact of NSPs is proportional to the number of needles and syringes distributed within IDU networks, and accordingly the proportion of IDUs receiving sufficient needles and syringes to enable them not to reuse equipment that has been previously used by another injector.

In some countries where IDU is reported to occur, legislation prohibits the distribution or possession of injecting equipment, thereby preventing the operation of NSPs. As discussed in further detail above, in some countries where NSPs have been introduced other barriers limiting access to NSPs exist including, for example, police activity targeting people who utilize NSPs.

In addition to (or in some cases instead of) providing new, sterile needles and syringes, HIV prevention services may promote the cleaning of used injecting equipment by distributing bleach along with information on how to disinfect injecting equipment. If done correctly, disinfecting used injecting equipment can substantially reduce the risk of reusing injecting equipment and can contribute to reduction in HIV transmission. However, the effectiveness of such strategies is limited by how well the equipment is cleaned; it may be difficult for IDUs to thoroughly clean equipment as required.

Access to Condoms

Consistent condom use has been shown to make a significant impact in reducing HIV transmission in the general population, and condoms are available for purchase in most countries. Because of the elevated HIV risk through sexual exposure among drug users, 'low-threshold' condom distribution programs targeting these groups are often established in an effort to increase condom access and use amongst this group. Programs that provide services to drug users such as drug treatment programs and NSPs are thus common sites for condom distribution.

Behavioral Interventions and Education to Reduce Unsafe Sex and Injecting Behavior

It is important for people who use drugs to have an understanding of how HIV is transmitted as well as other risks associated with drug use and how these can be avoided or minimized.

Risk reduction information conveyed through brief education interventions has been shown to reduce the frequency of unsafe injecting and unprotected sex. Repeated exposure to these interventions over time may be required to maintain positive behavior change.

These interventions appear to be most effective when delivered by drug users. So-called 'peer-led' interventions involve drug users receiving training to be peer-educators to disseminate risk reduction information, promoting safer injecting and sexual behaviors, through their social networks. Such methods are particularly valuable in being able to reach people at risk who may not otherwise access HIV prevention services. Peerled interventions make use of the influence behavioral norms and practices have within drug user networks to modify HIV risk.

Discouraging Initiation into IDU

Initiation to IDU is commonly a peer-driven or socially influenced process. Typically, the first time a person injects, he or she will receive assistance from a more experienced injecting drug user to do so. In recognition of this, some interventions that seek to prevent initiation to injecting focus on encouraging existing IDUs to not initiate others.

Drug dependence is also recognized as a risk factor for initiation to IDU among noninjectors. Drug dependence treatment for noninjectors is also therefore important for reducing HIV risk by reducing the risk of initiating IDU.

It has been proposed that drug users may be less likely to move to IDU if the means of consumption by other routes of administration providing similar immediate onset of action and bioavailability are available. Accordingly, some HIV prevention programs distribute equipment for smoking of drugs such as heroin or methamphetamine.

Addressing structural factors that influence the development of drug dependence and initiation to IDU may also contribute to reducing HIV risk (see below).

Interventions to Reduce the Likelihood of HIV Transmission

Antiretroviral Therapy as HIV Prevention

ART for the treatment of HIV reduces viral load in blood and semen. This reduction in viral load has been demonstrated to reduce the risk of sexual transmission of HIV between serodiscordant partners. It has been proposed that a similar reduction in the risk of transmission may occur in the context of exposure to HIV through shared injecting equipment. ART may therefore have a role in the prevention of HIV transmission among IDUs.

Typically, IDUs have poorer access to ART than non-IDUs. This may be due to guidelines that restrict ART to people who are not active drug users, or in some circumstances may be because clinicians are reluctant to provide drug users with ART out of concern that adherence to treatment will be poor. Treatment of IDUs has been shown, however, to achieve positive treatment outcomes, equivalent to that of nondrug users.

Adherence and treatment outcomes among drug users can be improved by the management of co-occurring drug dependence.

Post-exposure prophylaxis (PEP) involving a short course of ART (usually 4 weeks duration) is administered immediately following known or suspected exposure to HIV to prevent infection. While there may be some role for PEP in preventing HIV infection among IDUs, access is generally limited.

Prevention and Treatment of STIs

Given the high prevalence of STIs among drug-using populations, and the potential for STIs to biologically increase sexual transmission of HIV, the prevention and treatment of STIs has important implications for reducing HIV risk among drug users.

Strategies to increase STI screening and treatment access for people who use drugs include integrated models of care where drug treatment, HIV prevention, or other services that provide care for drug users also offer sexual health services, or where there are solid referral pathways to other services able to provide this care.

Prevention of STIs among drug users through the promotion of safe-sex practices and by increasing the accessibility to condoms is also important (see above).

Addressing Structural Factors

Structural factors that shape HIV risk are influenced, or in some cases defined, by policy and legislation. How changes in various policy or legislative conditions might affect changes in HIV risk and incidence is largely untested. A number of policy approaches and interventions have been identified, however, as having some impact on different structural factors and from this in modifying HIV risk. These approaches may act to increase an individual's capacity to reduce HIV risk or the utilization or effectiveness of various HIV prevention strategies.

Legislation and Law Enforcement Supporting HIV Prevention Approaches

Legislation that allows for, and supports, the distribution of injecting equipment is necessary for the operation of NSPs. If legal restrictions are imposed limiting the availability and accessibility of injecting equipment, the prevalence of sharing of used injecting equipment is elevated. If possession of injecting equipment is illegal, or may be used as evidence of drug use and grounds for arrest or police intervention, IDUs may be reluctant to carry clean injecting equipment, and thus are more likely to share used equipment.

As pharmaceutical opioids are controlled substances, legislation is required in most jurisdictions to allow for the provision of OST; in some countries OST remains prohibited due to such legislative restrictions.

Legislation and policing practices that respect and protect the human rights of drug users contribute importantly to minimizing HIV risk.

Police surveillance of sites where drug treatment and HIV prevention services are provided, or the targeting of drug users using these programs, acts to discourage drug users from accessing services, thereby increasing HIV risk. In some settings, police may also target service providers themselves and thus disrupt the provision of these services. Policies to ensure that police activity does not negatively impact upon service provision or utilization can have a significant impact on HIV risk and prevention.

People may be reluctant to access drug treatment services if the names of those receiving treatment for drug dependence are added to registers that are shared with law enforcement agencies, or if doing so can result in undesirable consequences such as removal of child custody or denial of employment.

Reducing HIV Risk in Closed Settings

Both sexual- and injecting-related HIV risk behaviors occur in prison and other closed settings environments. HIV prevention interventions such as condom provision, NSPs, and evidence-based treatment for drug dependence, including OST, have been introduced in prisons in some countries and demonstrated as being effective in reducing the prevalence of HIV risk behaviors; they have not been shown to increase or encourage sex or drug use.

Supervised Injecting Facilities

Supervised injecting facilities (SIFs) have been established in a number of countries. These are sites where drug users are provided with clean equipment and may consume pre-obtained drugs in a hygienic environment under the supervision of professional staff who, in some centers, are medically trained. SIFs facilitate safer injecting episodes, provide an alternative to public injecting, and enable staff to intervene if drug overdose occurs. These are 'low threshold' services in terms of access and as such can function as a useful entry point to other health and welfare services including drug-dependence treatment and HIV prevention, treatment, and care services. While those SIFs currently in operation are able to reach only a small proportion of the total IDU population, evidence suggests that these services are able to attract those with greatest HIV risk.

Socioeconomic Status

Low socioeconomic status is associated with drug use and HIV risk. Policy approaches to address

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socioeconomic inequality and disadvantage are complex and well beyond the scope of this discussion. It is important to note, however, that initiatives and policy approaches that improve access to education, employment, stabile accommodation, and other factors may also have the potential to consequently reduce HIV risk associated with lower socioeconomic status.

Drug User Involvement in the Response to HIV Risk Associated with Drug Use

The role drug users themselves have in delivering peer-based interventions to effectively reduce HIV risk is described above. In addition to participation in service provision, drug users, particularly through organized drug user groups, have made important contributions to the development and planning of programs addressing drug use and HIV risk. The principle of meaningful involvement of people who use drugs (often articulated as 'nothing about us without us') recognizes the critical role drug users have in improving understanding of HIV risk and the needs of drug users, and in formulating, delivering, and evaluating HIV prevention programs. This principle is supported by international organizations involved in the response to HIV/AIDS and drug use.

SUMMARY

Drug use is associated with significant HIV risk, related to both IDU and sexual transmission of the virus. To reduce HIV risk, strategies are required that address the mechanisms of transmission and influential structural determinants. These strategies can be enhanced by the involvement of drug users themselves in the planning, delivery, and evaluation of HIV prevention programs.

Reducing the prevalence of drug use in a population and reducing the frequency of drug use at the level of the individual reduces HIV risk. Treatment for drug dependence resulting in abstinence or reduction in levels of drug use has been shown to reduce the frequency of HIV risk behaviors. In the treatment of opioid dependence, OST has been demonstrated to prevent incident HIV infections; similar reductions have not been observed for opioid antagonists in the treatment of opioid dependence. Psychosocial interventions for drug dependence can also contribute to reducing HIV risk, and are particularly important in the management of stimulant dependence where pharmcotherapies are currently unavailable for use clinically. Incarceration of drug users in detention centers for the purpose of reducing drug use has not been shown to produce sustained reductions in HIV risk.

Reducing the use of contaminated injecting equipment is critical to reduce HIV transmission among IDUs who are unable or unwilling to abstain from drug use. Distributing sterile injecting equipment through NSPs has been demonstrated to decrease the prevalence of injecting with used equipment, but has not been shown to increase the prevalence of IDU.

Similarly, condom distribution programs targeting drug users and their sexual partners have been developed to increase the availability of condoms and reduce sexual risk. Prevention and treatment of STIs among IDUs also has a role in reducing the risk of HIV transmission among sexually active drug users for whom the prevalence of STIs is commonly elevated.

To encourage safe injecting and sex risk behavior, it is important that drug users have an understanding of HIV risk and how this can be avoided or minimized; this information may be most effectively conveyed by trained peer-educators.

ART for people living with HIV reduces infectivity, thereby decreasing risk of HIV transmission. Provision of ART for both past and active drug users is able to achieve positive treatment outcomes and good levels of adherence that can be enhanced by the concomitant management of drug dependence and other significant co-occurring conditions.

Legislation and law enforcement practices can contribute to reductions in HIV risk through supporting the provision of evidence-based HIV prevention strategies. The existence of legislation prohibiting OST or the distribution of sterile injecting equipment is a critical barrier to effectively addressing HIV in settings where IDU is present.

Addressing various other structural factors that can shape HIV risk among drug users, such as the accessibility of health and welfare services or socioeconomic status and conditions, has also been proposed as having the potential to reduce HIV risk.

The most substantial reductions in HIV risk are observed where these multiple, evidence-based interventions and policy approaches are implemented in combination, both in the community as well as in prisons and other closed settings.

List of Abbreviations

AIDS acquired immunodeficiency syndrome ART antiretroviral therapy HIV human immunodeficiency virus **IDU** injecting drug use **IDUs** injecting drug users NSP needle and syringe program **OST** opioid substitution therapy PEP post-exposure prophylaxis SIF supervised injecting facility STI sexually transmitted infection

UNAIDS Joint United Nations Programme on HIV/AIDS **UNODC** United Nations Office on Drugs and Crime

WHO World Health Organization

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Relevant Websites

www.ihra.net – International Harm Reduction Association (IHRA). www.idurefgroup.com – Reference Group to the United Nations on HIV and Injecting Drug Use.

www.who.int - World Health Organisation: Evidence for action series - technical and policy briefs on HIV/AIDS and injecting drug users.

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Alcohol Misuse Prevention in the Military

Robert M. Bray, Janice M. Brown, Marian E. Lane RTI International, NC, USA

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Alcohol misuse or abuse prevention efforts are often synonymous with harm reduction approaches and are best characterized as efforts aimed at reducing the occurrence of serious harm associated with alcohol use, without necessarily requiring abstinence. Prevention efforts include implementing controls on the physical availability of alcohol, creating safer drinking environments, and using social marketing techniques to decrease alcohol misuse. The goal is to reduce the total alcohol consumption of a population as a means for reducing related problems. One of the most significant tools for limiting alcohol-related problems is the ability to control both the physical and economic availabilities of alcohol. Public health advocacy is vital to prevention strategies just as implementation of strategies is dependent on public awareness of the issues. The military provides a unique setting for examining alcohol misuse prevention contexts, strategies, and policies.

THE ALCOHOL MISUSE PROBLEM IN THE MILITARY

Overview

Excessive alcohol use and alcohol-related problems are well known in the military services. Over the years, heavy drinking has been widely accepted and to some extent has become a part of military culture. In earlier times, alcohol was thought to be necessary for subsistence and morale; it was provided as a daily ration to sailors and soldiers. Within the US military population, which is predominantly male, heavy drinking and being able to hold one's liquor have served as indicators of suitability for the demanding masculine military role. Indeed, a common stereotype has been to characterize hard-fighting soldiers as hard-drinking soldiers. In the United States, the availability of alcoholic beverages was seen by military authorities as good for the war

effort. Following the end of Prohibition, brewers were required to allocate 15% of total annual production of beer for use by the armed forces, and local draft boards were authorized to grant deferments to brewery workers who were highly skilled and considered irreplaceable. On one occasion, the Teamsters Union was ordered to end a strike against Minneapolis breweries to help ensure continued beer manufacturing during World War II. Alcohol's ease of availability has no doubt contributed to excessive drinking among many military personnel. Although the modern military has made some progress in changing perceptions and practices regarding alcohol use, heavy alcohol consumption still remains a concern. There is still evidence of norms, traditions, and cultural factors that encourage heavy drinking. For example, in today's US military, over one-third of heavy drinkers report that consuming alcohol is "part of being in the military."

Currently, the US Department of Defense (DoD) strongly discourages alcohol abuse within the armed forces because of its negative effects on the health and well-being of military personnel, its detrimental effects on military readiness, and the need to maintain high standards of performance and discipline. Considerable research indicates that personnel who drink heavily defined as five or more drinks per typical drinking occasion at least once per week - are likely to experience a variety of physical, social, and psychological problems. Those who consume five or more drinks at one time on a regular basis are more likely than those who drink at lighter levels to experience serious health consequences and injuries, to have poorer academic performance, to have social/family problems, to engage in unplanned or unsafe sex, and to be at higher risk for assault and aggressive behavior.

DoD Health-Related Behaviors Surveys: Alcohol Findings

To help monitor the extent of substance use, including alcohol use and abuse, and to define the need for increased prevention efforts, DoD initiated a series of comprehensive worldwide surveys of health-related behaviors (HRB) among active duty military personnel in the Army, Navy, Marine Corps, and Air Force (HRB surveys). Ten of these surveys have been conducted from 1980 to 2008, of which nine (all but the first) were by Robert Bray and his colleagues at RTI International. These surveys, which provide the most definitive information on alcohol use in the military, have all been carried out using similar methods. RTI researchers, working with DoD, first randomly selected a sample of approximately 60 military installations to represent the armed forces throughout the world and then randomly

selected men and women of all ranks at those installations to represent active duty personnel. Civilian research teams administered printed questionnaires anonymously to servicemembers in classroom settings on military bases or aboard ships. Personnel who were unable to attend the group sessions (e.g. those who were on leave, sick, or temporarily away from the base) were mailed the questionnaires and asked to complete and return them. These procedures yielded between 12 000 and 28 000 completed questionnaires for each survey.

It is important to realize that the military population has a considerably different demographic makeup than the general population of the United States. The armed forces comprise personnel who are predominantly male (85%), relatively young (47% aged 18–25 years), white non-Hispanic (64%), married (54%), and reasonably well educated (45% have some college education, 22% have a college degree or higher). Nearly 83% of personnel are enlisted members ranging from junior to more senior ranks, and the remaining 17% are officers spanning junior to senior ranks. This compares with the civilian population aged 18–64 years, which is about 51% male, and 15% aged 18–25 years.

Figure 78.1 presents HRB survey data showing trends from 1980 to 2008 of the percentages of active duty military personnel who were abstainers or infrequent/light drinkers and those who were heavy drinkers during the 30 days prior to each survey. As shown, there has been a substantial increase from 1980 (26%) to 2008 (38%) in servicemembers who were abstainers (drank once a year or less) or infrequent/light alcohol users (drank from one to four drinks per typical drinking occasion, one to three times per month). Heavy alcohol users (five or more drinks on the same occasion at least once a week) decreased between 1980 and 1988, showed some fluctuations between 1988 and 1998, and increased significantly from 1998 (15%) to 2008 (20%). Of interest, the heavy drinking rate in 2008 (20%) was not significantly different from the rate in 1980 (21%) when the survey series began. These findings indicate that over the years, the military has shown increases in those who are abstaining or drinking alcohol at light levels but that there has not been much change in the proportion of heavy drinkers.

Binge drinking is another term that has been used widely in recent years to indicate excessive alcohol use that is likely to lead to problems. For the military, binge drinking is defined as consuming five or more drinks on a single occasion at least once in the past 30 days. The definitions of binge and heavy drinking are related; heavy drinkers are also binge drinkers, but binge drinkers are not necessarily heavy drinkers. Data from the HRB surveys indicate that the rate of binge drinking

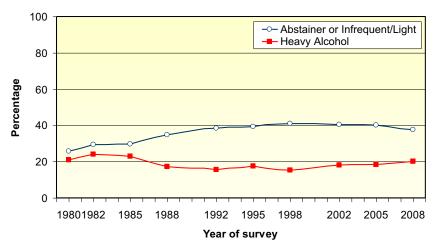


FIGURE 78.1 Alcohol use trends, DoD services, past 30 days, 1980–2008.

increased among active duty military personnel from 35% in 1998 to 47% in 2008.

Figure 78.2 shows the relationship between drinking levels and serious consequences among military personnel in the different military branches. Serious consequences were defined as one or more alcohol-related problems in the past 12 months and included such things as being passed over for promotion because of drinking, loss of 1 week or more from duty because of drinking-related illness, or arrest for driving under the influence (DUI) of alcohol. As shown, rates of serious consequences are higher among binge drinkers than among regular drinkers but are highest among heavy drinkers, more than double the rates of binge drinkers.

Because military binge drinkers and heavy drinkers are likely to experience negative outcomes from their drinking and because these binge and heavy rates have remained steady or increased over the years, the military needs effective alcohol abuse prevention programs.

Comparisons of Military and Civilian Heavy Drinking

To understand alcohol misuse prevention efforts in the military, it is useful to know how heavy drinking in the military compares to heavy drinking among civilians. To answer this question, Bray and colleagues compared military data from the HRB survey with civilian data from the National Survey on Drug Use and Health after equating the data for age and geographic location and adjusting the civilian data to resemble the demographic distribution of the military. Comparisons were made for four age groups: those aged 18-25, 26-35, 36-45, and 46-64 years. The analysis showed that military personnel had significantly higher rates of heavy drinking than civilians among persons aged 18-25 years (26 versus 16%) and 26-35 years (18 versus 11%), no significant difference in rates for those aged 36-45 years (10 versus 8%), and lower rates among those aged 46-64 years (4 versus 9%).

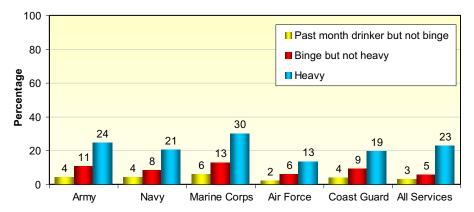


FIGURE 78.2 Serious consequences from alcohol use by Drinking Category and Service, 2008.

These findings indicate that heavy drinking patterns in the military do not mirror similar use among civilians. The higher rates of heavy drinking in the military among those aged 18–35 years suggest that certain aspects of military life may foster heavy drinking or that those military policies and programs directed toward reducing heavy drinking have not been as effective in the military as similar efforts among civilians.

Factors Influencing Alcohol Use in the Military

When addressing alcohol misuse prevention, it is important to consider a number of complex factors that may contribute to alcohol misuse and subsequent alcohol-related problems in the military. These include individual, social/cultural, and environmental factors. Individual factors include demographic and psychological components. Individual factors such as age and gender are possible risk factors for alcohol use: young adults and males are more likely to engage in alcohol misuse than their older or female counterparts. Psychological components include individuals' beliefs, attitudes, intentions, and values, some of which lead to higher risk for heavy alcohol use. In addition, some civilians who are heavy alcohol users may choose to join the military due to the perception that heavy alcohol use is accepted and thus bring their alcohol habits with them.

Social/cultural factors include family; friends; norms and perceptions about traditions and acceptable practices; and perceptions of acceptance, support, and tolerance for use. Peer pressure to fit in with friends (normative influence) or expectations about drinking after work may lead servicemembers to engage in the heavy drinking habits of their buddies. Customs and traditions about drinking rituals and celebrations, as well as high alcohol consumption in the countries where servicemembers are stationed, may also encourage excessive alcohol use.

Environmental factors include easy access to alcohol, advertising that encourages use, and lack of enforcement of policies to control use. With the exception of basic training, during which alcohol use is banned, alcohol is readily available to servicemembers and use is encouraged via advertising (e.g. alcohol advertisements in military news publications such as *Army Times* and *Navy Times*). These factors may contradict and interfere with some policies and programmatic efforts to reduce alcohol use in the military. Similarly, the finding that rates of heavy drinking among young adults in the military are higher than those in the civilian population indicates some level of acceptance, tolerance, and/or lack of enforcement of policies among some services, installations, or commanders.

PREVENTION AND POLICY APPROACH

Military Prevention Emphasis

The armed forces approach to alcohol misuse prevention combines education, training, slogans and campaigns, and intervention programs. DoD directives provide an overarching framework and objectives, and the military branches implement alcohol abuse prevention policies and programs aimed at the needs of their servicemembers. Training and education classes provide members with basic information on alcohol and alcohol abuse and emphasize early detection and early intervention as critical in the prevention of alcohol abuse. Onbase driving privileges are revoked if military members are convicted of driving while intoxicated (DWI) either on base or off base. Many commands offer safety stand-downs and red ribbon campaigns prior to holidays and the vacation season, reminding members of the dangers of drinking and driving. National Drunk and Drugged Driving Awareness Week is another opportunity that commands use to make members aware that "drinking and driving do not mix."

Commands encourage their personnel to use designated drivers for situations where alcohol will be available, and most bases provide server training for employees of on-base clubs and restaurants that serve alcohol. Designated drivers often receive free nonalcoholic beverages from various clubs and restaurants. It is common for bases to set up driving mazes at gates and other checkpoints to detect intoxicated drivers, especially on weekends. Alcohol deglamorization campaigns stress the importance of food and nonalcoholic beverages at command-sponsored social events. In addition, the armed forces emphasize personal responsibility and caring for your buddy. Supervisory personnel are expected to lead by example and be role models for junior personnel, both on and off duty.

Alcohol control policies and minimum age requirements are also part of the military's prevention efforts. However, alcohol control policies are inconsistent across service branches. In earlier times, anyone on active duty could consume alcohol on military installations, regardless of the legal drinking age off base. However, in the mid-1980s, advocacy groups, such as Mothers Against Drunk Driving (MADD), lobbied Congress to change this. Federal law now requires military installation commanders to adopt the same drinking age as the state in which the military base is located. There is one exception to this rule. If the base is located within 50 miles of Canada or Mexico, or of a state with a lower drinking age, the installation commander may adopt the lower drinking age for military personnel on base. Even with these restrictions, commanders of DoD installations may waive age requirements if they determine that the exemption is justified by special circumstances such as the conclusion of arduous military duty or the anniversary of the establishment of a military service or organization. However, the event must be held on a military installation and the commander must ensure that appropriate controls are in place to prevent endangering servicemembers or the surrounding community.

Development and Implementation of DoD Alcohol Policy

Serious substance abuse prevention efforts in the military began as a result of drug and alcohol abuse problems that became increasingly visible during the late 1960s and early 1970s. In response to the recognition of widespread reports of drug and alcohol abuse of military servicemembers, particularly during the Vietnam War, DoD convened a task force in 1967 to investigate drug and alcohol abuse in the military. In 1972, it implemented an alcohol abuse policy based on task force recommendations. The overall policy emphasized the prevention of alcohol abuse through education and law enforcement procedures focusing on detection and early intervention, with the goal of rehabilitating users with problems and returning them to service. This policy was issued as a DoD directive titled "Alcohol Abuse by Personnel of the Department of Defense."

In 1980, the directive on alcohol abuse was combined with a directive on drug abuse under a single comprehensive directive titled "Drug and Alcohol Abuse by DoD Personnel," which shifted the focus away from the rehabilitation of problem users to a broader emphasis on detection, treatment, rehabilitation, and prevention. This consolidated policy has been updated periodically (1985, 1997, 1999) but has remained largely unchanged since its 1980 origination. Alcohol abuse is defined under this directive as "the use of alcohol to an extent that it has an adverse effect on the user's health or behavior, family, community, or the DoD, or leads to unacceptable behavior as evidenced by one or more acts of alcohol-related misconduct." This policy defines prevention programs as "training, education, and public information activities designed to influence participants to avoid alcohol abuse."

Under these policy guidelines, specific tasks to be accomplished include the deterrence and identification of alcohol abuse and dependence that exist on installations and facilities under DoD control; periodic assessment of the extent of alcohol abuse in the armed services; the provision of education and training on DoD policies for alcohol abuse and/or dependency and on effective measures to alleviate problems associated with alcohol abuse and/or dependency; counseling and providing treatment and/or rehabilitation for

military personnel who abuse alcohol; and prohibition of DoD personnel from possessing, selling, or using alcohol other than in accordance with laws, regulations, and DoD directives.

DoD policies and programs typically encompass both alcohol and other drugs. Army alcohol misuse prevention falls under the umbrella of the Army Substance Abuse Program, which provides comprehensive alcohol and drug abuse prevention and control policies, procedures, and responsibilities for soldiers. Alcohol and other drug abuse prevention are conceived broadly as all measures taken to deter and reduce the abuse or misuse of alcohol and other drugs to the lowest possible level. The Navy Alcohol and Drug Abuse Prevention Program serves both Navy and Marine Corps personnel in providing support to individual and command alcohol abuse and drug use prevention efforts. Its mission is to support readiness by fighting alcohol abuse and drug use. The Air Force calls its program Alcohol and Drug Abuse Prevention and Treatment (ADAPT). The objectives of ADAPT are to promote readiness and health and wellness through the prevention and treatment of substance abuse; to minimize the negative consequences of substance abuse to the individual, family, and organization; to provide comprehensive education and treatment to individuals who experience problems attributed to substance abuse; and to return identified substance abusers to unrestricted duty status or to assist them in their transition to civilian life, as appropriate.

Pricing Discrepancies

While the DoD directive "Drug and Alcohol Abuse by DoD Personnel" seeks to prevent and eliminate alcohol abuse, it does not formally address approaches to responsible alcohol use within the military community. Another DoD directive titled "Armed Services Exchange Policy," issued in 2005, is related to the promotion of responsible alcohol use through regulation of the sale and pricing of alcohol in DoD facilities. These include military exchanges or convenience stores, commonly referred to as Class 6 stores or Shoppettes, which are located on the vast majority of US military installations worldwide. This policy stipulates that alcohol prices in DoD facilities may be discounted up to 10% less than the best local shelf price in states under Alcohol Beverage Control (ABC) regulation and in overseas facilities and up to 5% in states not under ABC regulation. Unfortunately, this policy may send a mixed message to servicemembers that the military is supportive of alcohol use because the government is making it available to them at somewhat discounted prices. Discounted alcohol prices on military facilities may encourage

increased rates of alcohol use, possibly evolving into abuse, if policies and programs do not define and teach tenets of responsible use.

MILITARY ALCOHOL MISUSE PREVENTION PROGRAMS

As part of their efforts to encourage alcohol abuse prevention, DoD and the armed services have developed or adopted several programs ranging from media campaigns to interventions. Their goal is to increase awareness about problems that can result from excessive drinking and to encourage persons to engage in responsible alcohol use. Six such programs are described below.

"That Guy" Campaign

"That Guy" is a DoD-funded, multifaceted campaign to increase awareness of the problems associated with binge drinking and to reduce excessive drinking behaviors. The campaign encourages young enlisted personnel to reject binge drinking because it detracts from the things they care about: family, friends, dating, sex, money, and reputation. The campaign uses a combination of humor, realistic imagery, and drinking facts to raise awareness of the impact of drinking too much during a social event or outing, and to deliver a serious message: "Don't Be That Guy!" (i.e. anyone who, because of excessive drinking, behaves in a manner that others do not want to emulate or be around). The campaign leverages its Web site as the key communication tool in its counter-marketing efforts to provide prevention education to servicemembers worldwide. The "That Guy" campaign also includes the distribution of its key message through the display of posters and flyers in various locations on military installations and other community-based media, including billboards, newspapers, and television and radio ads.

The Right Spirit

The Navy's Right Spirit campaign emphasizes promoting healthy lifestyles for all Navy members, with the primary focus of prevention education. With additional focus on deglamorization of alcohol use, alternatives to drinking, and clear and enforceable policy guidance, the campaign stresses responsibility at all levels: command, leadership, shipmate, and individual. The Right Spirit campaign calls for removing alcohol from traditional ceremonies, providing alternatives to drinking, recognizing the effects of alcohol use, and promoting personal responsibility concerning

alcohol use. The Right Spirit Web site provides information about available education and training materials, publications, and links to other relevant Web sites. The Navy credits the Right Spirit campaign with a sizable reduction in alcohol-related incidents and a decline in arrests for DUI.

Personal Responsibility and Values: Education and Training

The Navy's Personal Responsibility and Values: Education and Training (PREVENT) Program is designed primarily for young adult sailors aged 18-26 years. The program addresses four main areas, including alcohol misuse prevention and related substance abuse and mental health concerns. The 3-day, 24-h our preventive education course is designed to clarify individual values and to increase behaviors that enhance personal wellness and are consistent with established Navy organizational standards for military bearing and character. The program applies a stagesof-change approach to motivate young recruits to modify their behaviors toward a more healthy lifestyle. PREVENT is offered on a regular basis at Navy installations worldwide. Approximately 26 000 Navy men and women complete PREVENT education courses annually.

101 Days of Summer Campaign

The Marine Corps' 101 Days of Summer campaign encompasses both alcohol and illicit drug abuse prevention efforts, utilizing programs that share the mission of promoting responsible use of alcohol and eliminating illegal drug use. Aimed at prevention through education, the program includes a variety of activities between Memorial Day and Labor Day, an especially risky period for alcohol- and drug-related incidents. Through a variety of unit competitions, giveaways, entertainment, and educational opportunities, the campaign seeks to raise awareness of substance abuse; promotes responsible alcohol use; educates service-members regarding the dangers and consequences of illicit drug use; and offers fun, healthy activities as viable alternatives.

0-0-1-3 Campaign

In 2004, the commander of Francis E. Warren Air Force Base located near Cheyenne, Wyoming, recognized that heavy alcohol use was creating problems and developed a campaign called 0-0-1-3 to address this issue. At the time, a base-wide survey found that the average airman thought "unsafe" drinking began with eight drinks or more. Many seasoned servicemembers appeared to

have false perceptions on what constituted normal drinking, so it was decided to specifically define "responsible, periodic drinking" as a way to help set realistic expectations. The slogan 0-0-1-3 was an easy way for airmen to remember an approach to safe drinking: (0) zero drinks if you are under 21, (0) zero DUIs, (1) if of age, no more than one drink per hour, and (3) no more than three drinks per night. The campaign is based on research by the National Institute on Alcohol Abuse and Alcoholism and the National Academy of Sciences that underlines the importance of setting a clear standard. Although research found that people might not immediately follow the standard, they would at least start counting their drinks and comparing their habits to the standard. Francis E. Warren Air Force Base reported that the program was successful in reducing alcohol incidents, underage drinking, and drunk driving. Because of the success of 0-0-1-3 at this base, the Air Force subsequently implemented the program at all Air Force bases.

Program for Alcohol Training, Research, and Online Learning

Program for Alcohol Training, Research, and Online Learning (PATROL) is a Web-based alcohol program for military personnel adapted from two interventions that were originally designed for and tested on civilian populations. The first intervention, called Alcohol Savvy, is a universal prevention program aimed at adults in the workplace. It is a fully narrated, multimedia primary prevention program that incorporates rich video and audio elements as well as interactive components. Alcohol Savvy's primary goal is to encourage moderate drinking and to prevent escalation of alcohol use among mainstream populations. The second intervention, called the Drinker's Check-Up, is based on the principles of motivational interviewing and focuses on assessment of alcohol use, personalized feedback of alcohol use relative to peers, and exercises to encourage individuals to change their drinking behavior. The primary goal of Drinker's Check-Up is to reduce alcohol use among high-risk drinkers. PATROL integrated Alcohol Savvy and Drinker's Check-Up with the goal of providing low-risk drinkers with a primary prevention program (Alcohol Savvy) and high-risk drinkers with an alcohol reduction program (Drinker's Check-Up). Both programs were substantially modified for the military, including the use of military graphics and language and militaryspecific norms regarding alcohol use.

The interventions were evaluated in a scientific study using approximately 3000 active duty military personnel at eight military installations (two each from the Army, Navy, Marine Corps, and Air Force). Participants

completed an initial baseline survey and were assigned to one of three study conditions – (1) Alcohol Savvy, (2) Drinker's Check-Up, or (3) control – where they completed the intervention materials. Follow-up surveys were completed 1 and 6 months following baseline. Findings showed that at the 1-month follow-up, participants who completed the Drinker's Check-Up had significant reductions on several indicators of alcohol use compared to persons in the control condition. These 1-month reductions were maintained at the 6-month follow-up. Unfortunately, there were no statistically significant changes in alcohol use for participants who completed the Alcohol Savvy intervention. This study is important because it provided a scientific evaluation of two possible interventions and provided evidence that Web-based programs (Drinker's Check-Up in particular) can significantly decrease alcohol use in the military. The PATROL program has been made available to all the military services.

APPROACHES TO ENCOURAGE RESPONSIBLE DRINKING

To be effective, efforts to prevent alcohol misuse need to address the individual, social/cultural, and environmental factors noted earlier that may encourage irresponsible drinking. This section describes the efforts of DoD and the military branches to address these factors.

Individual Factors

A key effort in military campaigns to promote safer drinking among servicemembers gives large emphasis to individual factors, especially encouraging members to take personal responsibility for their own behavior and ensuring that behavior is in keeping with military and personal values. Each service calls special attention to this facet of the prevention and education cycle, citing personal responsibility as the most important factor in decisions regarding safe alcohol use. It should be noted that, in addition to targeting individual behavior, these campaigns recognize and endorse the collaborative efforts of individuals, fellow servicemembers, military leadership, and military organizational structure and values to form a comprehensive framework for responsible alcohol use and prevention of problem use. Nonetheless, the cornerstone of prevention is individual responsibility.

Service-level programs promote responsible drinking behaviors, which logically include discouraging drinking to intoxication. DoD's "That Guy" campaign graphically depicts a variety of the pitfalls of excessive drinking to the point of vomiting or blacking out, behaviors that are depicted as not only embarrassing but also directly counter to military values. In addition, zero tolerance for any drinking behaviors by servicemembers under the age of 21 bolsters the services' policies and campaigns for responsible, safer drinking within the military. Military installations located in close proximity to areas with lower drinking ages, such as overseas locations and locations along the US-Mexico border, may be at higher risk for problem drinking by servicemembers between the ages of 18 and 21; however, these installations often take precautionary measures to deter such behavior. Although penalties for alcohol-related problems (such as DWI) can be more severe for military members than for civilians (including reduction of rank and pay), these penalties are harsher still for underage members. The services also recognize that punitive actions alone are likely to fail. Therefore, service-level prevention and education programs seek to provide information to servicemembers in a way that allows them to obtain and evaluate necessary information prior to being confronted with difficult choices on their 21st birthday. In this way, the services not only discourage any drinking prior to age 21 but also equip members with the tools they will need to make good choices when they become of drinking age.

Social/Cultural Factors

The US military services have taken several steps in their alcohol misuse prevention efforts to incorporate social and cultural factors into their programs and campaigns, focusing particularly on the use of normative and peer influences. The "That Guy" campaign makes use of humor and entertainment to engage the young audience. It focuses on social disapproval and short-term negative consequences and pushes a peerto-peer approach as opposed to top-down influence through the chain of command. The Right Spirit campaign attempts to change social norms and cultural traditions and practices as a mechanism for changing alcohol use behavior. Specifically, the program attempts to develop norms of responsible use and a culture that does not rely on alcohol abuse to define success. PREVENT and the 101 Days of Summer campaign also make use of peer pressure and influence to modify behavior. Similarly, the 0-0-1-3 campaign encourages healthy, controlled alcohol use behavior and nonuse for those who are underage. The 0-0-1-3 campaign established safe normative behaviors that move DoD forward in addressing the health threats of alcohol. PATROL also uses normative influences to change expectations about acceptable levels of drinking. This is done by helping servicemembers realize that their peers are likely to be drinking less than they formerly believed and using this discrepancy as motivation to reduce their use.

In recent years, the military has placed an emphasis on deglamorizing alcohol use among servicemembers. The general approach has been to help change norms and perceptions about alcohol use by ensuring that nonalcoholic beverages are available at functions where alcohol is served and to make clear that alcohol use before or during work hours is unacceptable. Commanders are urged to emphasize that alcohol consumption should not be the main focus of any unit event. As noted above, deglamorization is a key element of the Right Spirit campaign. Data from the HRB surveys indicate that the practice of having alcohol alternatives is generally being implemented, but deglamorization is not yet having its full intended effect. In the 2008 HRB survey, over 60% of servicemembers agreed that nonalcoholic beverages are always available at parties. However, about 15% also indicated that personnel are encouraged to drink at parties and social events. A survey of Air Force officers attending Air Command and Staff College found that although the environment was supportive of alcohol deglamorization, students' attention was often focused on alcohol and emphasis was placed on bringing alcohol to social activities.

Environmental Factors

A number of approaches are available to address environmental factors, including licensing provisions, policy development, education, publicity campaigns, and working with the local community. The military's focus on safer drinking environments to prevent alcohol-related problems includes limiting access to establishments that are known to have violations, for serving underage patrons, being a location for the purchase of illegal drugs, having a large number of alcohol-related arrests, or some other violation. Lists of "off-limits" establishments are circulated to military members, and routine inspections of bars are conducted to ensure servicemembers' compliance.

Policy decisions are often made that are specific to installations. For example, US forces in Okinawa have been banned from patronizing off-base establishments that sell alcohol after midnight in response to a series of alcohol-related incidents and accidents. Servicemembers at installations located near the Mexican border are often drawn to the bars in Mexico by inexpensive alcohol and a minimum drinking age of 18. In response, commanders at Camp Pendleton, located in southern California 65 miles from Mexico, adopted a policy that required Marines to receive written permission to cross the border. After the policy was implemented, the

number of underage Marines returning across the Mexican border was reduced by 78% and the number returning with blood alcohol content of 0.08% (the legal limit for intoxication) or higher was reduced by 84%.

Two areas with somewhat inconsistent policy applications are the minimum drinking age and alcohol pricing. On most installations, the minimum drinking age is 21. However, the Marine Corps recently instituted a new policy to allow the consumption of alcohol by persons aged 18 years or older at unit-sponsored functions if the unit function is held on a US base. The new policy defines these circumstances as infrequent, non-routine military occasions when an entire unit, as a group, marks a uniquely military occasion at a military installation. Although the policy opens the door for Marine commanders to lower the drinking age temporarily on any service's birthday, as well as the day their unit was formed, commanders must ensure the safety of military servicemembers and the surrounding community. In addition, the minimum drinking age on a DoD installation located outside the United States is 18 years or older if specified by international treaties and agreements and based on the local situation as determined by the installation commander.

With respect to alcohol pricing, there is a wealth of data to support the idea that raising alcohol prices reduces use and alcohol-related problems. Unfortunately, the military has not used higher prices as an environmental mechanism to address alcohol misuse. Although the lower prices for alcohol products are set by military regulations and targeted to be within 5–10% of the lowest prices in the civilian community, it is not unusual to find that the prices on beverages can range from 9 to 27% less than prices in state-operated alcohol stores.

Thus, although the military is making efforts to address environmental contributors to the increasing rates of alcohol problems among its members, there is inconsistency in minimum age requirements and pricing policies that may encourage patterns of excessive alcohol use.

SUMMARY AND FUTURE DIRECTIONS

The military has a long tradition and culture of excessive alcohol use, which often creates problems for individual servicemembers and for the military as a whole. To address this issue, DoD and individual armed services have developed alcohol policies and alcohol misuse prevention programs that emphasize on education, training, slogans and campaigns, and interventions. These prevention programs target key individual, social/cultural, and environmental factors related to the highest risk of misuse.

There is evidence that the policies and prevention efforts of the military are having some positive effects in reducing some alcohol misuse, but additional efforts and continued vigilance are needed. The fact that the rates of heavy and binge alcohol use have been rising in recent years suggests that some of the policies and prevention programs are not reaching a key target group. Approximately 20% of personnel are heavy drinkers, the group most likely to experience negative outcomes. The fact that the programs are not fully effective should not be surprising. The military poses a challenging and complex environment in which to implement and monitor programs. There are several reasons for this. One is the relatively high rate of turnover in the military. Leaders must regularly and consistently review and emphasize the principles of safe drinking and resources available to personnel. Another may be a somewhat uneven emphasis and implementation of the programs by commanders and other leaders who bring their own personalities and potential biases to their jobs. Because military leaders face many demands, some of them are likely to give greater emphasis to the issues of alcohol misuse prevention and others are likely to give lesser emphasis. Finally, personnel undergo regular transfers to different installations, sometimes to unfamiliar overseas locations in different host nations that may have cultures that encourage high alcohol consumption.

Looking to the future, military alcohol misuse prevention efforts would benefit from two important actions. The first action is to give greater emphasis to more uniform implementation of existing prevention programs and policies across installations both within the United States and abroad. This relatively simple step should yield high dividends if all commands were to give alcohol misuse prevention high priority at their installation. The second is to invest in research to ensure that there is scientific evidence underlying the effectiveness of the current programs and that they are changing behaviors as expected. Although the military has adopted or developed a variety of alcohol misuse prevention programs, there has been little attempt to evaluate these programs with rigorous scientific studies to understand if they are having their desired effects. Having a solid evidence base for prevention programs will ensure the most effective use of resources to contain alcohol misuse in the military.

List of Abbreviations

ABC Alcohol Beverage Control

ADAPT Alcohol and Drug Abuse Prevention and Treatment

DoD Department of Defense
DUI driving under the influence
driving while intoxicated

HRB health-related behaviorsMADD Mothers Against Drunk Driving

PATROL Program for Alcohol Training, Research, and Online

Learning

PREVENT Personal Responsibility and Values: Education and

Training

Further Reading

- Air Force Alcohol and Drug Abuse Prevention and Treatment (http://usmilitary.about.com/cs/airforce/a/afdrugalcohol.htm) provides information about the Air Force Alcohol and Drug Abuse Prevention and Treatment program, the objectives of which are to promote readiness, health, and wellness through the prevention and treatment of substance abuse; minimize the negative consequences of substance abuse to the individual, family, and organization; provide comprehensive education and treatment to individuals who experience problems attributed to substance abuse; and return identified substance abusers to unrestricted duty status or assist them in their transition to civilian life.
- Army Substance Abuse Program (http://acsap.army.mil/sso/pages/index.jsp) provides information about this program's mission to strengthen the overall fitness and effectiveness of the Armýs workforce, to conserve manpower, and to enhance the combat readiness of soldiers.
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- Department of Defense "That Guy" Campaign (http://www.thatguy.com/): DoD-created website serving as part of a national effort to reduce excessive drinking among young servicemen of all branches of Service (Army, Navy, Air Force, Marine Corps).
- Navy Alcohol and Drug Abuse Prevention (NADAP) (http://www.npc.navy.mil/CommandSupport/NADAP/) provides information and assistance to support individual and command alcohol abuse and drug use prevention efforts. The mission of NADAP is to support fleet readiness by fighting alcohol abuse and drug use.

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Screening and Assessment of Substance Use Disorders in Youth and Young Adults

Joel R. Grossbard*, Briana A. Woods^{\$}, Nadine R. Mastroleo**

*University of Washington, Seattle, WA, USA *University of North Carolina, Chapel Hill, NC, USA

**Center for Alcohol and Addiction Studies, Brown University, Providence, RI, USA

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INTRODUCTION

Substance use by youth and young adults¹ is a significant public health problem due to its high prevalence and negative consequences. In 2000, the use of alcohol and illicit drugs was estimated to contribute to 10% of the total global burden of disease for people aged 15–29 years, particularly in economically developed countries, where approximately 23% of the global burden is attributable to alcohol (18%) and illicit drugs (5%). Results of the most recent 2010 Monitoring the Future survey given to 8th, 10th, and 12th grade students in the United States indicated that 27% of

students used an illicit drug in the past year and 16% reported illicit drug use in the past month. In terms of alcohol use, 26.8% reported consuming alcohol and 14.6% had gotten drunk in the past month. Moreover, recent national studies of US college student alcohol use in the past month indicate 70% of students have consumed alcohol and over 40% engaged in binge drinking, defined as five or more drinks in a row for males and four or more drinks for females.

It is well established that adolescents and young adults who use alcohol and other drugs (AOD) are at risk for a range of physical, psychological, social, and legal consequences, and heavy drinking is a leading

¹In this chapter, youth (i.e. adolescents) and young adults are defined as being 12–17 and 18–22 years of age, respectively. These age ranges have been defined in previous developmental research. The majority of instruments discussed in this chapter have been standardized across these age groups.

cause of morbidity and mortality in young people. In order to better identify individuals who are at risk for or are currently exhibiting AOD problems, the development and implementation of standardized screening and assessment tools have been at the forefront of prevention efforts. It is essential that screening, assessment, and treatment strategies for AOD for younger populations be specifically designed to the needs of adolescents and young adults, rather than simply modifying protocols established in adult populations. Given the developmental differences between adolescents and adults, using screening instruments that are developmentally appropriate is essential to appropriately identify potential AOD issues with this younger population. This chapter addresses strategies and tools that have been widely used for AOD screening and assessment in adolescents and young adults in nonmedical settings.² The specific goal of this chapter is to provide readers with a greater understanding of the following topics related to screening and assessment of AOD in adolescents and young adults: (1) developmental considerations in substance use patterns; (2) defining and differentiating the goals of screening and assessment; (3) commonly used screening and assessment tools and rationale for their use; and (4) clinical implications and future research directions.

DEVELOPMENTAL CONSIDERATIONS

Applicability of Diagnostic Criteria

The current diagnostic criteria for substance abuse and dependence in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR) specify the presence of substance use-related problems (1 symptom for abuse, 3 symptoms for dependence) within the previous 12 months. It is noteworthy that the diagnostic classification of substance use disorders was validated using adult samples, and it is questionable whether the current criteria are adequate when applied to adolescents. Adolescents exhibit different patterns of substance use than adults, have unique developmental and social issues, and show a higher prevalence of substance use and co-occurring disorders. Short-term use of substances such as alcohol and tobacco typically occur in a social context, which makes identifying those individuals at risk for developing long-term consequences challenging. Results of studies evaluating substance use patterns in adolescents suggest that adolescents are more likely to use alcohol in conjunction with other drugs (e.g. marijuana) rather than just using alcohol, and that adolescent substance use is typically more sporadic and involves experimenting with a number of different substances as opposed to heavy use of one substance. Due to their developmental stage, it is less likely that adolescents will report impairment in romantic or occupational functioning. Furthermore, dependence symptoms may look different in adolescents, with studies demonstrating that adolescents have a lower likelihood of experiencing physiological dependence (e.g. withdrawal, tolerance, medical complications) than adults. Alternatively, alcohol-dependent adolescents do report blackouts, cravings, risky sexual behavior, reduced activity level, and affective symptoms. Many researchers are investigating whether the criteria for substance use disorders accurately reflect the unique features of adolescents and if not, what modifications to adult criteria are needed.

Although adolescents are more likely than adults to meet diagnostic criteria for substance use disorders within a shorter time period after initial use, researchers note that this finding may reflect a limitation of the diagnostic criteria to adequately capture developmental patterns of substance use in adolescents. Studies also suggest a low occurrence of withdrawal symptoms and related medical problems in youth, as these problems typically occur after prolonged use of alcohol or drugs. Studies have shown that another symptom of substance dependence, tolerance, has low specificity in terms of poorly distinguishing adolescents with varying levels of substance use problems. Additionally, due to the one-symptom diagnostic threshold for substance abuse, there is a large amount of heterogeneity across adolescents who may endorse one of the four symptoms indicative of substance use-related problems. Perhaps most relevant to the topic of screening and assessment, many adolescents may not meet criteria for abuse and only endorse two symptoms of dependence. Thus, while these individuals may not receive a formal diagnosis for a substance use disorder, further assessment and followup treatment may still be needed.

Normative versus Clinical Patterns of Substance Use

Substance use is related to adolescent developmental transitions and goals. Adolescence in general is characterized by experimentation with a variety of behaviors and lifestyle choices as one develops their identity. This process typically involves separating from parents, connecting more with peers and gaining acceptance

²Given the impact of cultural factors on substance use, we acknowledge that we do not address language issues related to the instruments discussed in this chapter. Screening and assessment tools have not been validated specifically within minority populations, and any use of them with these individuals should be interpreted cautiously.

from them, and developing one's sense of autonomy, independence, and maturity. While some form of substance use in adolescence is considered normative, there is substantial heterogeneity in patterns of clinical and functional impairment in relation to substance use. Alcohol, tobacco, and marijuana are the most frequently used substances among adolescents, with other drugs being rarer but still problematic. During early adolescence, substance use typically occurs in a social context and involves substances that are easily available (e.g. alcohol, tobacco, inhalants). Many adolescents discontinue use after a short period of experimentation; however, other adolescents develop patterns of regular use, and some may progress to other substances such as marijuana, hallucinogens, and other illicit drugs. It appears that there are various steps or stages of adolescent substance use, progressing from experimentation to more problematic levels of use and disorder, where initial social motivations for substance use become more psychologically or pharmacologically driven.

No single factor predicts adolescent alcohol and substance use problems; rather, multiple factors influence risk at different levels (individual, interpersonal, contextual). Furthermore, there are numerous subtypes and trajectories of adolescent substance use disorders. Adolescent alcohol and drug use often co-occur with each other and other adolescent problem behaviors (e.g. delinquency and sexual risk behavior), and these relationships can be dynamic and complex. For example, illicit drug use is both a risk factor and a consequence of sexual risk behavior; early initiation of substance use is associated with later sexual risk behavior, and early sexual risk behavior predicts later drug use. Frequently, adolescent substance use disorders are also co-morbid with other disorders, including both internalizing (depression, anxiety) and externalizing (ADHD, conduct disorder) disorders. The heterogeneity and diversity of patterns, trajectories, consequences, and co-occurring disorders and risk behaviors support the need for psychometrically sound brief screening and comprehensive assessment tools.

SCREENING AND ASSESSMENT: DEFINITIONS AND GOALS

Screening

The first step to identifying the presence of a substance use problem is an initial screening, a process that involves asking questions carefully designed to determine whether a more thorough assessment for a particular problem or disorder is warranted. A screening instrument is used as an indicator, not as a diagnosis, and

evaluates the possible presence of a particular problem. This is typically assessed by a "yes" or "no" response to a brief set of specific questions. Screening can be differentiated from assessment in that the purpose of screening is to identify people at risk for or actually experiencing harm associated with their substance use. The purpose of assessment is to gather details about specific patterns of use and consequences to inform intervention. Although screening does not serve as a diagnostic tool, results may indicate that an individual demonstrates behaviors or possesses attributes shared by people who are at risk for substance abuse or dependence. Screening can serve as a brief and effective method for identifying at-risk populations and an effective use of limited resources. Adolescents and young adults who are not at risk for substance use problems are identified with little time and effort, and those who are at risk can have resources directed to their needs.

Assessment

Results of an initial screening for substance use problems indicate whether a more comprehensive biopsychosocial assessment is needed to gather more detailed information about an individual's substance use patterns and to determine whether treatment is indicated. The specific goals of the assessment are to (1) evaluate whether a substance use disorder exists based on formal diagnostic criteria, and if so, to determine its severity, (2) permit the evaluator to learn more about the nature, correlates, and consequences of the individual's substance use behavior, (3) ensure that additional related problems not noted in the screening process are identified, including medical and psychological status, social functioning, family relations, academic performance, and delinquent behavior, (4) examine the extent to which the adolescent's family can be involved, (5) identify specific strengths of the adolescent (e.g. coping skills) that can be used in developing an appropriate treatment plan, and (6) make specific recommendations for interventions or referral to treatment services.

Selection of Screening and Assessment Tools

A number of factors influence the use of a particular screening or assessment instrument, including the severity of the problem being assessed, the ability of the measure to identify the problem within the population of interest, and ease of administration (e.g. length and format of the measure). Selection of screening and assessment instruments for use with adolescents and young adults should be guided by several factors including (1) reliability and validity of the tool, (2) appropriateness to the target population, (3) type of

setting in which the instrument was developed, and (4) the intended purpose of the instrument. Important features of screening and assessment instruments include high test-retest reliability, evidence of convergent validity (i.e. the instrument is strongly correlated with other instruments that measure similar constructs), and ability to predict relevant outcomes, such as school performance, performance in treatment, and substance use relapse. Another consideration when selecting a screening or assessment tool is the availability of normative data for representative samples based on age, gender, race/ethnicity, and setting (e.g. school, clinic).

The use of a validated and brief screening tool is important to ensure accurate results while making the administration and scoring procedures user-friendly. Self-report is the most widely used source of information for screening and assessment, as this method yields valid and reliable data when confidentiality is assured and there are no consequences for responding honestly. Most self-report questionnaires are available in paperand-pencil format, and an increasing number of screening tools are becoming available for completion via a computerized, web-based questionnaire. Online screening strategies are becoming more favorable, particularly in college student populations, due to ease of administration and scoring. While research supports the validity and reliability of online screening of substance use, in-person comprehensive assessments that may incorporate multiple methodologies (e.g. diagnostic interview, urinalysis) are appropriate for addressing a wider range of biopsychosocial variables.

Assessment strategies generally consist of a combination of self-report scales and interviews. While selfadministered questionnaires are convenient, it may be necessary for the assessor to supervise and assist the adolescent, depending on their reading and comprehension skills. Comprehensive assessment interviews can be structured or semistructured based on the decision rules and the degree of clinical judgment required and allowed when determining symptoms and diagnoses. Most structured interviews can be administered by a well-trained layperson, although some standardized instruments and interview protocols are available that require little or no special training to administer. Important considerations that should be addressed in the context of screening and assessment with youth are how the results will be used and potential limits to confidentiality of results. Depending on the setting (e.g. school, court), screening and assessment results with young people may have academic, legal, and clinical consequences. Any limits to confidentiality should be addresses based on whether counselors, parents, or teachers are privy to screening and assessment results. Whenever possible, obtaining information from other sources (e.g. parents, teachers) about adolescents' substance use provides valuable supplemental data. When used appropriately, screening and assessment can identify the nature and severity of substance use to distinguish between problem and dependent substance users, while also determining the level of treatment indicated.

SCREENING AND ASSESSMENT TOOLS FOR ALCOHOL AND OTHER DRUGS

The following sections provide an overview of commonly used instruments available for screening and assessment of AODs among adolescents and young adults. Our selection was guided by a combination of psychometric rigor and user-friendliness, but should not be considered exhaustive in its coverage. A list of suggested readings and resources is provided at the end of this chapter. The features we were most interested in include strong psychometric properties, simple scoring, efficient length and administration time, and availability of user training. Other types of AOD screening and assessment tools, including measures of problem recognition, motives and expectancies of use, and readiness for change are also mentioned in the context of future research directions and clinical implications.

Alcohol

College Aged Students (Ages 18–22)

In response to the identified risk of heavy drinking and related consequences, increased attention has focused on implementation of routine screening procedures for alcohol use on college campuses. Effective brief interventions are available for college student populations, and an important component of these interventions is an effective screening program that serves as a first step in identifying students who are abusing alcohol and may need follow-up intervention. Results from a study published in 2004 that assessed alcohol screening policies across US college campuses indicated that among 249 four-year institutions, 32.5% of health centers routinely screened for alcohol use-related problems, and 11.7% used a standardized alcohol screening instrument. To expand upon these findings, a more recent study that assessed the use of alcohol screening tools across four-year US colleges found 148 of 333 colleges (44%) reported using at least one formal alcohol screening tool. Results indicated that the four most commonly used screening tools reported by campus health service directors were the following: CAGE (54%), Alcohol Use Disorders Identification Test (AUDIT) (33%), Substance Abuse Subtle Screening Inventory (SASSI) (28%), and Michigan Alcohol Screening Test (MAST) (16%).

The AUDIT is a 10-item instrument that assesses how often in the past year individuals have engaged in a number of behaviors indicative of unhealthy alcohol use. The AUDIT was developed by the World Health Organization to identify persons in primary care settings whose alcohol consumption has become harmful or hazardous to their health. The appropriate cutoff score to use for screening college students has been disputed. One study using DSM–III criteria for alcohol abuse and dependence has shown adequate sensitivity at a score of 11 (84%), whereas another study using DSM–IV criteria found that a cutoff score of 6 led to a similar degree of sensitivity (80%). A more recent study, using high-risk drinking as the criterion, suggested a cutoff score of 8 results in levels of sensitivity (82%) and specificity (78%) comparable to the earlier studies. Use of this cutoff score, however, may be more appropriate for universal screening efforts within this population, given the greater prevalence of high risk, heavy episodic alcohol consumption relative to clinically diagnosable alcohol use disorders.

The CAGE is a brief four-item measure that takes approximately 1 min to complete with "yes" or "no" response options. A score of two or more (at least two "yes" responses) have been used to indicate a positive screen for clinically significant alcohol-related problems. Specific items of the CAGE ask individuals if they have ever thought they should Cut-down on their drinking, found that others have *Annoyed* them for criticizing their drinking, felt Guilty about their drinking, or ever needed a drink to relieve a hangover (i.e. *Eye-opener*). While the CAGE has been used with college student populations, it has been criticized for lacking adequate sensitivity to detect the spectrum of drinking problems experienced by people in this age group. Alternatively, the CUGE questionnaire is a revised version of the CAGE in which three of the four items were retained, and only the second item (CAGE item: "Have people ever annoyed you by criticizing your drinking?") has been replaced by "Have you ever been under the influence of alcohol in a situation where it increased your chances of getting hurt?" Results of comparative evaluation studies with college samples indicates the CUGE has more favorable psychometric properties than the CAGE, researchers have identified the CUGE as a recommended alcohol screening tool for college students.

Another alcohol screen used with adolescents and young adults, the MAST, is a widely used instrument with versions ranging from 9 to 25 items. The longest version takes less than 10 min to complete. One study using a convenience sample of college students found that a cutoff score of 7 on the full 25-item version of the MAST resulted in perfect sensitivity (100%) and

reasonable specificity (87%) when compared with a score of 14 or greater on the Alcohol Dependence Scale (ADS), the criterion used to indicate the presence of alcohol dependence. A limitation of the MAST when used with adolescents and young adults is the scale's focus on more advanced and/or stable problems with alcohol (e.g. dependence) that are less prevalent in younger people.

Two instruments, the Young Adult Alcohol Problem Screening Test (YAAPST) and Brief Young Adult Alcohol Consequences Questionnaire (B-YAACQ), are used to screen for alcohol-related consequences. The YAAPST consists of 27 items evaluating the occurrence of drinking-related problems across different domains (e.g. academic, legal, social). The YAAPST takes less than 10 min to complete and has demonstrated good reliability and validity, with reasonable sensitivity and specificity when using a cutoff score of 4. The B-YAACQ is a 24-item measure that was created using a confirmatory factor analysis of a variety of alcohol consequences measures. Dichotomous items (yes/no) are summed for a total number of alcohol-related consequences experienced in the past month. In studies with college students, the B-YAACQ has demonstrated high internal consistency and good validity using a cutoff score of 5 to indicate risky drinking.

Another instrument designed to screen for alcohol-related problems in college students is the College Alcohol Problems Scale-Revised (CAPS-r). The CAPS-r is an 8-item self-report scale (the original CAPS had 10 items) that also estimates the relative frequency with which clients experience drinking-related personal and social problems. Advantages of using the CAPS-r compared to the YAAPST are its shorter administration time (2–3 min), and its ability to be scored immediately. The CAPS-r is available in pencil-and-paper self-administered and interview formats. In a general college student population, the CAPS-r has demonstrated good reliability and concurrent validity, as the total score correlated significantly with other measures of alcohol consumption and with the YAAPST.

Questions about alcohol consumption also can be used as a screening tool for alcohol problems. The National Institute on Alcohol Abuse and Alcoholism (NIAAA) produced four sets of questions ranging from three to six items that provide an increasingly detailed picture of a person's drinking pattern. The three-item version takes less than 5 min to complete and includes questions on the frequency of drinking occasions over the past 12 months, the typical amount consumed, and the number of binge-drinking episodes. Although these questions have not yet been used specifically for screening, people who endorse one or more of the behaviors assessed by these questions (i.e. binge drinking and frequent alcohol use) have been shown

to be at high risk for experiencing alcohol-related problems and therefore would be appropriate candidates to receive further assessment and brief intervention.

Adolescents Aged 12-17

In addition to alcohol screening tools that have been developed within college samples, there are a number of screening instruments that focus exclusively on alcohol use among adolescent populations. The Adolescent Alcohol Involvement Scale (AAIS) is a 14-item selfreport questionnaire that assesses alcohol consumption in addition to related behavioral and perceptual aspects of drinking. An overall score from 0 to 79 provides information on the severity of alcohol abuse ranging from minimal use to symptoms of abuse and/or dependence. Norms are available for 13- to 19-year-olds in both clinical and nonclinical samples, and studies have found scores on the AAIS are significantly related to substance use diagnosis and ratings from other sources, including comprehensive clinical assessments and parent reports of their teen's alcohol use. Estimates of internal consistency have been more favorable in nonclinical samples of adolescents and young adults compared to clinical samples.

The Adolescent Drinking Index (ADI) is a 24-item instrument that examines adolescent problem drinking by measuring psychological, physical, and social drinking-related problems, as well as loss of control. Written at a 5th grade reading level, the ADI takes approximately 5 min to administer and 10 min to score, and it yields a total score as well as two subscale scores that have been used for research purposes (self-medicating drinking and rebellious drinking). Research has shown that the ADI yields very good reliability and has demonstrated good validity in measuring and classifying the severity of adolescent drinking problems.

The CRAFFT is a brief screening test for alcohol and other drugs that was specifically designed at a developmentally appropriate reading level for teenagers. The CRAFFT is verbally administered, simple to score (each yes answer = 1 point), and the scale name is a mnemonic of the first letters of key words in the test's six questions: C: Have you ever ridden in a car driven by someone (including yourself) who was "high" or using alcohol or drugs (AOD)? R: Do you use AOD to relax, change your mood, feel better about yourself, or fit in? A: Do you ever use AOD while you are by yourself, alone? F: Has any friend, family member, or other person ever thought you had a problem with AOD? F: Do you ever *forget* (or regret) things you did while using? *T*: Have you ever gotten into trouble while using AOD, or done something you would not normally do (break the law, rules, or curfew; engage in risky behavior to you or others)? Based on a study in a large hospital-based adolescent clinic, including pediatric settings, scores from the CRAFFT were found to be highly predictive of the presence of a substance abuse or dependence diagnosis (as defined by an existing and valid measure of DSM-IV-defined SUD, the Adolescent Diagnostic Interview). When evaluated in a general pediatric setting, a cutoff score of ≥ 2 correctly classified in 86% of cases whether the youth did or did not have a current substance abuse or dependence disorder.

The 23-item Rutgers Alcohol Problem Index (RAPI) measures consequences of alcohol use pertaining to family life, social relations, psychological functioning, delinquency, physical problems, and academic functioning. Two versions of the RAPI currently are in use – the original 23-item version and a briefer 18-item version— both of which can be completed in less than 10 min. The RAPI has shown good internal consistency and test-retest reliability using 1-, 6-, and 12-month time frames, and it has been correlated significantly with a composite of drinking frequency, typical quantity, and frequency of intoxication. Another measure, the Adolescent Obsessive-Compulsive Drinking Scale (A–OCDS), was developed to identify problem drinking and is a 14-item instrument containing one scale that measures obsessive thoughts about drinking and a second scale that measures compulsive drinking behaviors. The A-OCDS has demonstrated favorable reliability, and scores have been used to differentiate adolescent problem drinkers from less severe groups of adolescent drinkers.

Alcohol and Other Drugs

Given the tendency for adolescents to use alcohol in conjunction with other drugs, a number of screening tools include questions about alcohol and other drug use, including the Drug and Alcohol Problem (DAP) Quick Screen, the Personal Experience Screening Questionnaire (PESQ), and the Substance Abuse Subtle Screening Inventory for Adolescents (SASSI–A). The 30-item DAP was tested in a pediatric practice setting, in which the authors report that about 15% of the respondents endorsed six or more items, considered by the authors to be a cutoff score for "problem" drug use.

The 40-item PESQ consists of a problem severity scale and sections that assess drug use history, select psychosocial problems, and response distortion tendencies ("faking good" and "faking bad"). Norms for nonclinical, juvenile offender, and drug—abusing populations are available, and the PESQ is estimated to have an accuracy rate of 87% in predicting need for further drug abuse assessment. The 81-item adolescent version of its adult companion tool, the SASSI—A yields scores for several scales, including face valid alcohol, face valid other drug, obvious attributes, subtle attributes, and

defensiveness. Validity data indicate that the SASSI-A cutoff score for "chemical dependency" corresponds highly with intake diagnoses of substance use disorders.

Drugs Other Than Alcohol

In order to independently screen for drugs other than alcohol, researchers have modified previously used alcohol screening tools or adult versions of drug screening tools, in addition to creating drug-specific screening instruments for adolescents and young adults. The Adolescent Drug Involvement Scale (ADIS) is a modified version of the AAIS. Psychometric studies on this 13-item questionnaire reveal favorable internal consistency for the drug abuse severity scale. Validity evidence indicates that the ADIS is strongly positively correlated with drug use frequency and with independent ratings by clinical staff.

The CAGE-AID (Adapted to Include Drugs) is a modified version of the CAGE that was designed as a screen for drugs other than alcohol. Like the CAGE, the CAGE-AID focuses on lifetime use; although individuals who are drug dependent may screen positive, individuals who are at risk may not. Limitations of the CAGE-AID are similar to the CAGE in that it does not distinguish between active and inactive problems and has not been validated for identifying hazardous or harmful use. The Drug Abuse Screening Test for Adolescents (DAST-A) was adapted from the adult version (Drug Abuse Screening Test, DAST). The 27-item DAST-A reveals favorable reliability data and is highly predictive of a DSM-IV substance use disorder when tested among adolescent psychiatric inpatients. The Assessment of Substance Misuse in Adolescence (ASMA) is an 8-item questionnaire that has been tested in a large nonclinical sample of general students. It has a very favorable internal consistency, and the total score was significantly related to several indices of drug and alcohol use.

The Cannabis Use Problems Identification Test (CUPIT) is a brief cannabis-screening instrument that is reliable, valid, and acceptable for use across diverse community settings and consumers of all ages. The 16-item CUPIT measures risky use (items 1 and 2), dependence/using behavior (3–10), and health and social problems (11–16), and scores can range from 0 (no use at all) to 82 (daily/more than daily use, severely problematic). Research suggests that it reliably classifies both currently diagnosable and potentially problematic cannabis use among respondents.

The Adolescent Cannabis Problems Questionnaire (CPQ-A) was adapted from the adult version of the CPQ. The original 58-item CPQ-A comprises 30 "core" items, with 28 additional items grouped into four topic areas relevant to young people: parental issues, personal

relationship issues, school performance, and employment issues. The CPQ-A is intended to supplement DSM-IV diagnostic and other data in the exploration of cannabis-related problems among young people. In addition to providing assessment data and, potentially, an instrument with which to measure change (e.g. preand post-treatment), the CPQ-A may be useful as a clinical tool in highlighting potential problem areas and encouraging problem recognition and self-assessment. The Cannabis Problems Questionnaire for Adolescents, Short Form (CPQ-A-S) is a shorter 12-item version that was developed in 2010. Psychometrics of the shorter scale were evaluated through factor analysis, and logistic regression was used to demonstrate scale validity. This is the first short scale of cannabis problems derived for adolescents, and it should prove a useful tool for clinical and research purposes.

The Cannabis Use Disorders Identification Test (CUDIT) is a 10-item, self-report screening instrument that is a modification of the AUDIT. It was recently developed, and its ability to accurately assess cannabis abuse or dependence was tested on a sample of alcohol-dependent outpatients who reported some use of cannabis in the past 6 months. The maximum score possible is 40 with a cutoff of 8 demonstrating a positive predictive value of 81% and a sensitivity of 73%. In 2009, the CUDIT was revised (CUDIT-R) to be shorter (down from 10 items to 8–4 items from the original CIDT and 4 new items). The CUDIT-R has improved psychometric properties over the original scale and appears well suited to the task of screening for problematic cannabis use and has potential as a brief outcome measure.

Comprehensive Assessments and Diagnostic Interviews

Comprehensive assessments of substance use are more time consuming and require greater training to administer and score, but yield more in-depth diagnostic data, while also evaluating other domains of functioning. The Adolescent Diagnostic Interview (ADI) is a 213-question structured interview based on *DSM-IV* criteria for substance use disorders. In addition to substance use, it evaluates psychosocial stressors, school and interpersonal functioning, and cognitive impairment. It can be used to identify the need for treatment and treatment planning. The ADI can be administered in 50 min and scored in 20 min by a counselor or trained interviewer.

The Global Appraisal of Individual Needs (GAIN) is a semistructured interview that measures recent and lifetime functioning in several areas, including substance use, legal and school functioning, and psychiatric symptoms. Favorable internal consistency, test-retest reliability, and construct validity data are associated with the GAIN, including evidence that GAIN scores are significantly correlated with independent ratings of drug involvement problem severity and that youths referred to drug treatment score higher on these core sections than youths not referred for treatment. The comprehensiveness and multidimensionality of the GAIN require a relatively long administration time and a lengthy and detailed training. The GAIN-Short Screen (G-SS) is a shorter 20-item version of the GAIN that also evaluates total severity and domain-specific substance use problems; it may be a more optimal screening tool given that it requires less administration time and scoring.

Adapted from the Addiction Severity Index (ASI) that was developed for use with adults, the Teen Addiction Severity Index (T-ASI) is a semistructured interview that consists of seven content areas: chemical use, school status, employment-support status, family relationships, legal status, peer-social relationships, and psychiatric status. Adolescent and interviewer severity ratings are elicited on a 5-point scale for each content area. Psychometric data indicate favorable interrater agreement and association of the various scales to existing valid measures of similar constructs. A computerized, Internet- and telephone-based, modified version entitled T-ASI-II and its psychometrics has been piloted on a large number of adolescents and will be available for clinical use.

Another multiscale questionnaire is the Personal Experience Inventory (PEI), which consists of several scales that measure drug use problem severity, psychosocial risk, and response distortion tendencies. Supplemental problem screens measure eating disorders, suicide potential, physical/sexual abuse, and parental history of drug abuse. The computerized report includes narratives and standardized scores for each scale as well as other clinical information. Norms for drug-clinic and nonclinical controls are provided. Psychometric data include internal consistency and test-retest reliability data and a range of convergent, discriminant, and criterion validity (e.g. scores compared with existing validated measures, independent clinician ratings, and archival data).

The 139-item Problem Oriented Screening Instrument for Teenagers (POSIT) is part of the Adolescent Assessment and Referral System developed by the National Institute on Drug Abuse (NIDA). It screens for 10 functional adolescent problem areas: substance use, physical health, mental health, family relations, peer relationships, educational status, vocational status, social skills, leisure and recreation, and aggressive behavior/delinquency. Cutoff scores for determining need for further assessment have been rationally established, and evidence of convergent and discriminant validity for the POSIT has been reported by several investigators.

Another instrument is the 159-item Drug Use Screening Inventory (revised) (DUSI-R), which includes items addressing AOD use problem severity and related problems. It produces scores on 10 subscales as well as one lie scale. Domain scores were related to DSM-III-R substance use disorder criteria in a sample of adolescent substance abusers, and published reports have indicated evidence of scale sensitivity. In addition, the Adolescent Self-Assessment Profile (ASAP) is a 225-item self-report instrument comprised of subscales that represent riskresiliency factors established in the literature, including family, mental health, school adjustment, peer influence, deviancy, and drug use symptoms. Another in-depth assessment of drug use is the Chemical Dependency Assessment Profile (CDAS), consisting of 232 items assessing 11 dimensions of drugs use (e.g. quantity and frequency, expectations of use).

Lastly, there are a number of structured and semistructured diagnostic interviews that are specifically used to assess DSM-IV criteria for substance abuse and dependence. The Structured Clinical Interview for the DSM (SCID) is a semistructured interview used to assess diagnostic criteria of a full range of psychological disorders. While the entire interview takes approximately 2 h to complete, the Substance Abuse Module can be completed in 30-60 min, and should be administered by a trained clinical evaluator or mental health professional. The Diagnostic Interview Schedule for Children (DISC) is a highly structured diagnostic interview designed to be administered by lay interviewers to assess most of the commonly occurring mental disorders of children and adolescents included in the DSM diagnostic system. The DISC is probably the most extensively tested of all the child and adolescent diagnostic interviews, and its performance has been evaluated using both clinical and community samples. Another interview that assesses DSM criteria for substance use disorders, in addition to specific patterns of use and consequences, is the Customary Drinking and Drug Use Record (CDDR). Evidence from psychometric studies suggests good reliability and validity of the CDDR.

CLINICAL IMPLICATIONS AND FUTURE DIRECTIONS

Implications for Prevention and Intervention Efforts

While the primary goal of AOD screening and assessment is to identify individuals who may be at risk for substance use problems, results inform prevention and treatment efforts with regard to the type and intensity of intervention that may be warranted for a given

population. Universal prevention and screening strategies are designed for the general population, regardless of whether individuals have engaged in substance use or appear to be at greater risk of substance use problems. Selective or targeted prevention addresses subsets of the population that are identified to be at increased risk for substance abuse, based on variables such as family history of substance use, academic or behavioral problems, and other risk factors. Indicated prevention is designed to identify individuals who are demonstrating early signs of substance abuse and other problem behaviors associated with substance abuse and to offer services to help prevent further substance use problems. For each of these levels of prevention, screening and assessment procedures inform the use of an appropriate referral or brief intervention to prevent the development of more severe substance use problems.

There are several effective prevention and intervention programs for adolescent alcohol and substance use that operate on a variety of levels. On the individual level, many programs target adolescent knowledge and skills related to alcohol and substance use prevention such as increasing adolescents' awareness of social influences on substance use and enhancing self-regulation, problem solving and decision making, assertiveness and resistance skills, and coping skills to manage stress and anxiety. On the family level, many programs target family functioning and parenting skills, including communication, monitoring, and limit-setting. On the community and societal level, several programs target social norms through mass media or restricting access to substances through public policy initiatives. The most effective programs are guided by psychosocial theory, target empirically supported risk and protective factors at a variety of levels (e.g. individual, family, social), and are developmentally appropriate.

Recent developments of brief alcohol and marijuana interventions demonstrate how screening and assessment results can be utilized in providing individuals with feedback about their alcohol or drug use. For example, protocols such as Brief Alcohol Screening and Intervention for College Students (BASICS) and the Teen Marijuana Check-Up provide feedback based on screening and assessment results, pertaining to use patterns and consequences, expectancies and motives for use, perceived substance use norms, and readiness to change. Results of treatment evaluation studies indicate reductions in alcohol and marijuana use over time following exposure to these brief interventions.

Conclusions and Future Directions

In response to the continued problems associated with adolescent and young adult substance use, significant progress has been made in developing more effective screening and assessment methodologies. Advances in knowledge about scale norms based on age, race/ethnicity, and gender are critical for standardizing the use of screening and assessment tools with diverse populations. Studies are needed that include adolescent and young adult samples from clinical and nonclinical samples (school, community) in order to adequately address the spectrum of treatment needs across groups and settings. Studies addressing the reliability and validity of screening and assessment tools across minority populations are extremely important given the changing demographic makeup of the United States.

In light of anticipated changes to the diagnostic criteria for substance use disorders within the DSM-V, further refinement of screening and assessment tools will likely be needed. More research is necessary to better understand factors that contribute to variability in the effectiveness of tools to identify substance use problems in young people, as well as factors that impact the actual use of valid and reliable instruments. It would be helpful to learn why schools, clinicians, and researchers decide to use one screening or assessment tool over another; these factors may include cost, convenience, and psychometric rigor of available instruments. However, many of the instruments reviewed in this chapter are free, widely available, and user-friendly, and have demonstrated good psychometric properties. Barriers to successful implementation may include little awareness about existing instruments, lack of clinical expertise, and limited access to adequate treatment services to address substance use problems. It would be useful to further explore these and other potential barriers to employing effective screening and assessment procedures with a standardized tool as the use of standardized tools is critical to accurately identifying problematic substance use and informing selective/ targeted and indicated prevention and brief intervention programs.

SEE ALSO

Screening and Brief Alcohol Intervention for Adolescents and Young Adults in Primary Care and Emergency Settings, Individual Prevention of College Student Alcohol Misuse, Substance Use Prevention Approaches for School-aged Youth

List of Abbreviations

AAIS Adolescent Alcohol Involvement Scale
ADI Adolescent Drinking Index
ADIS Adolescent Drug Involvement Scale
AOD alcohol and other drugs

AUDIT Alcohol Use Disorders Identification Test Customary Drinking and Drug Use Record CDDR CAPS-r College Alcohol Problems Scale-Revised **CPQ** Cannabis Problems Questionnaire **CUPIT** Cannabis Use Problems Identification Test DAP Drug and Alcohol Problem DAST Drug Abuse Screening Test DISC Diagnostic Interview Schedule for Children **GAIN** Global Appraisal of Individual Needs MAST Michigan Alcohol Screening Test

PESQ Personal Experience Screening Questionnaire

POSIT Problem Oriented Screening Instrument for Teenagers

RAPI Rutgers Alcohol Problem Index

SASSI Substance Abuse Subtle Screening Inventory YAAPST Young Adult Alcohol Problem Screening Test

Glossary

Binge drinking according to the National Institute on Alcohol Abuse and Alcoholism, a pattern of drinking that brings a person's blood alcohol concentration (BAC) to 0.08 g percent or above. This typically happens when men consume five or more drinks and when women consume four or more drinks in approximately 2 h.

Internal consistency an estimate of reliability (often assessed using Cronbach's Alpha) based on the grouping questions in a questionnaire that measure the same concept. Items that are highly correlated with each other are said to have a higher internal consistency

Reliability the consistency of a measure or the degree to which an instrument measures the same way each time it is used under the same testing conditions. A measure is considered to have good testretest reliability if a person's score is similar when the test is administered on more than one occasion, assuming there is no change in the underlying construct being measured.

Sensitivity measures the proportion of actual positives that are correctly identified as such (e.g. the percentage of people with a substance use disorder who are correctly identified as having the condition).

Specificity measures the proportion of negatives that are correctly identified (e.g. the percentage of people without a substance use disorder who are correctly identified as not having the condition).

Validity the extent to which an instrument measures the construct (e.g. alcohol-related consequences) it is designed to measure or assess.

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Screening and Brief Alcohol Intervention for Adolescents and Young Adults in Primary Care and Emergency Settings

Ursula Whiteside*, Joyce N. Bittinger\$

*Group Health Research Institute, Seattle, WA, USA *Center for the Study of Health and Risk Behaviors, University of Washington, Department of Psychiatry, Seattle, WA, USA

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ALCOHOL, YOUNG PEOPLE, AND THE ROLE OF HEALTH CARE

Adolescence is broadly defined as the developmental stage that occurs between the age of 10 and upward to 25, with the upper range often referenced separately as young adulthood. Culturally derived, the concept of adolescence was first recognized in the beginning of the twentieth century. G. Stanley Hall wrote a hallmark

two-volume book describing the nature of teens and characteristics/needs of this stage of life. As the structure of society has changed (e.g. rise in industrialization, child labor laws), this developmental stage has shifted the role of teenagers and young adults. Adolescence is marked by changes across physical, social, emotional, and especially behavioral domains as youths transition from childhood to adulthood. During this phase of intense identity formation, adolescents are

making more independent decisions and experimenting with new behaviors and experiences. It is during this time when young people will begin to develop patterns of behavior and ways of relating that will shape the quality of health and well-being throughout their lifespan. The pivotal nature of this time frame potentiates the need for quality health care services to be widely available for adolescents. Health care services have historically not been designed to address the unique needs of adolescent populations, resulting in a missed opportunity to positively influence health behaviors, promote good mental health, and impact disease prevention.

The health care community has, more recently, turned focus to adapting services to the needs of adolescents and young adults. This shift is grounded in the understanding that, indeed, the dramatic biological, social, and psychological transition of adolescence impacts adult function. Therefore, intervening at this point in development is critical for impacting health behaviors, and furthermore addressing intervention across context (e.g. family, community, economics, provider training, policy) is essential. While models of health services for adolescents have been generated and implemented, in reviewing the 21 Critical Health Objectives for ages 10–24, the lack of progress made in the health status of adolescents since 2000 has been noted by the Centers for Disease Control. In their 2009 Adolescent Health Services: Missing Opportunities report, the World Health Organization identified five key characteristics to guide responsive adolescent health services. Namely that (1) the services are broadly accessible, (2) policies are culturally and socially acceptable, (3) they appropriately fulfill the needs of all young people, (4) services reflect evidence-based standards of care and appropriate professional guidelines, and (5) services availability be equitable. Evidence-based screening and brief intervention (SBI) for problem alcohol use has been identified as a needed standard of care for adolescents during this highly transitional period.

MISSED OPPORTUNITIES FOR SBIS: ADOLESCENTS AND HEALTH CARE

Drinking and Alcohol Use Disorder Rates

With regard to impacting alcohol-related behaviors, health care providers have primary points of contact with adolescents and young adults in the context of acute care settings and hospitalization for alcohol-related accidents/incidents. In the US, alcohol consumption is the highest for individuals in their late teens and 20s, hence alcohol-related injuries are high in this subgroup as well. The 2010 National Survey on

Drug Use and Health (NSDUH) indicated that 3% of 12–13-year-olds reported drinking alcohol in the past month, 12% of 14–15-year-olds, 25% of 16–17-year-olds, 49% of 18–20-year-olds, and 70% of 21–25-year-olds. Rates of binge drinking, assessed as five or more drinks in one occasion in the past month, were 1% among 12–13-year-olds, 7% among 14–15-year-olds, 15% among 16-17-year-olds, 33% among ages 18-20, and peaked among those aged 21-25 at 46%. The rate of current alcohol use among youths aged 12-17 was 14% and binge and heavy alcohol use rates in this age group were 8% and 2%, respectively. Heavy alcohol use is defined as drinking five or more drinks on the same occasion on 5 or more days in the past 30 days. Overall, the rate of binge drinking was 41% for young adults aged 18-25. In addition, heavy alcohol use was reported by 14% of persons aged 18-25. With alcohol consumption rates being the highest in this age group, the survey reported that after people pass young adulthood (18-25 in this sample) rates of current alcohol use, binge use and heavy alcohol use steadily decline.

Based on analyses of 2002 NSDUH data by researchers at the George Washington University Medical Center, it was estimated that among the 35 million young people between the ages of 12 and 20 in America, almost 3.5 million of them met criteria for an alcohol use disorder. Rates vary by adolescent age group, with 3% of those ages 12–15, 12% of those ages 16–17, and 17% of those ages 18-20 meeting criteria for an alcohol use disorder. Up to 85% of those aged 12-20 with an alcohol use disorder have not received treatment. This is troubling, especially when considering the increased risk these individuals experience and to which they expose others. Specifically, these individuals are nine times more likely to drink and drive, nine times more apt to have serious problems with other drugs, six times more likely to be arrested, twice as likely to smoke, 1.5 times as likely to have a C+ average or lower in school, are likely to miss twice as much school, and are 1.5 times more likely to visit an emergency department (ED).

Death and Disability Related to Alcohol

According to the Centers for Disease Control (CDC) National Center for Chronic Disease Prevention and Health Promotion and Control, 72% of death and disability among those ages 10–24 can be attributed to one of four following causes: motor vehicle accidents (MVA)/crashes (30%), other unintentional injuries (15%), homicide (15%), and suicide (12%), indicating that MVAs are the leading cause of death for US teens. In 2009, MVAs claimed the lives of approximately 3000 adolescents aged 15–19 with many more surviving these

incidents with and without injury. In the prior year (2008), more than 350 000 adolescents were seen and treated in EDs for MVA-related injuries. Medical care and productivity losses due to injury and death among adolescents ages 15–19 are estimated at \$14 billion annually.

Notably these outcomes are highly associated with adolescent choices and behaviors, the majority of which are suitable if not ideal targets for prevention/ intervention. For example, the 2009 national Youth Risk Behavioral Survey, found that in the past 30 days, 28% of 9th through 12th grade students rode with a driver who had been drinking alcohol, 10% endorsed driving when drinking, and 10% endorsed never or rarely wearing a seat belt when riding in a car. For 2010, the NSDUH found that past year driving under the influence for ages 16-17 was 6%, 18–20 was 15%, and 21–25 was 23% (the highest of any age group across the lifespan). In 2009, 35% of fatal automobile crashes among ages 18-24 involved a driver with a blood alcohol concentration (BAC) of 0.08 or higher. This was true for 19% of fatal automobile crashes among ages 16–20. Further, a great number of falls, violence-related injuries, and family abuse, which require medical treatment, involve someone who is drinking excessively. While limited because the data were collected between 1990 and 1992, National Comorbidity Study results analyzed by researchers at George Washington University Medical Center indicated that those with serious alcohol problems who were between the ages of 15 and 20 were 5 times more likely to attempt suicide, 4.5 times more likely to get into a serious fight, 3.5 times more likely to carry a weapon, 3 times more likely to be hospitalized for psychiatric reasons, 3 times more likely to meet criteria for conduct disorder, 1.5 times more likely to get into an accident, injure, or poison themselves, and almost twice as likely to have multiple sexual partners.

Health Care Utilization Rates

Outpatient Care Visits

Approximately 60% of office visits for health care by Americans are to primary care providers (versus specialty and emergency care). In 2008, 15–24-year-olds made 74 million visits for outpatient medical treatment (13% of visits were injury-related). Of these visits, 41% were for a new problem, 20% were for a chronic problem (routine or flare up), and 33% were for preventative care. Ninety-five percent of preventative care visits in 2008 made by 15–24-year-olds were provided by primary care providers. Over 80% of visits in this age group were made by White adolescents, and 13% were by Black adolescents. Analyses of 10 years of

data (1994–2003) from the annual National Ambulatory Medical Care Survey and the National Hospital Ambulatory Medical Care Survey (NHAMCS) yielded key data on the frequency and type of health care visits by adolescents (described here as ages 11-21 years) with examination of visits by differing age groups, sex, and rudimentary ethnic breakdown (i.e. White, Black, Other). Adolescents' visits accounted for 9% of all outpatient visits in the US, with an yearly average of 80 million outpatient visits from 1994-2003. Approximately 70 million (88%) of visits were to office-based settings and nearly 10 million (12%) to hospital-based settings annually. Overall outpatient visits by adolescents increased from 69 million in 1994 to 92 million in 2003 (33%). Across age groups, differences in the type of visit differed by both ethnic category and sex. Adolescents seen in outpatient hospital settings (as opposed to clinic settings) were more likely to be Black (24%), female (62%), and to have Medicaid coverage (35%) than those seen in office settings. Overall 9% of visits represented preventative care, with a somewhat higher proportion for preventative visits for early adolescents (aged 11–14 years) than for late (aged 18–21 years). Analysis of the same data sources from 1993–2000 found that in 2000 adolescents aged 13-18 years averaged 1.9 visits an year with those aged 19-24 averaging even fewer.

ED Visits

Almost one-third of all patients seen in the ED, and up to 50% of patients arriving with severe trauma, test positive for alcohol use. The 2008 NHAMCS estimates that there were 124 million ED visits across America: 11 million of these were visits by those ages 5–14, and 20 million were by those ages 15–24. Among the 20 million ED visits by those ages 15–24, 40% were injury-related, almost 60% were made by females, and approximately 70% were by White and 25% Black patients. Youth with alcohol problems reported use of hospital emergency services nearly 50% more often than their peers. They report an average of 0.75 ED visits annually compared to adolescents with no serious alcohol problem rates of 0.56 times annually.

SUMMARY OF GUIDELINES AND RECOMMENDATIONS

Guidelines and recommendations for intervention with adolescents and young adults vary somewhat, however, all guidelines stress the importance of intervention and are consistent in spirit.

 As interventions vary by length and number of sessions, the US Preventative Services Task Force (USTPF) has classified the range of interventions that are available as follows:

- **1.** Very brief interventions one session, up to 5 min in length.
- 2. Brief interventions one session, up to 15 min long
- **3.** Brief multi-contact interventions one initial session, up to 15 min long, plus follow-up contact(s).
- In 2002, the National Center for Education in Maternal Child Health recommended screening for all adolescents at every primary care visit.
- In 2011, the American Academy of Pediatrics (AAP) released a policy recommending annual screening for alcohol and substance abuse in primary care encounters.
- In 1997, the American Medical Association produced guidelines for adolescent preventive services which recommended screening all adolescents at least annually at primary care visit and counseling to avoid the use of alcohol or other substances while using motorized vehicles, or where impaired judgment may lead to injury.
- As of 2004, the USTPF recommends Screening, Brief Intervention, and Referral to Treatment (SBIRT) for adults based on available empirical data. However, the USTPF does not recommend for or against SBIRT for adolescents in primary care settings, as they found a lack of sufficient data to make such recommendations.
- The Substance Abuse and Mental Health Services Administration (SAMHSA) recommends that health care professionals provide universal screening and brief intervention, and/or referral for treatment for substance use.
- In 2006, the World Health Organization (WHO) supports SBIRT health care interventions to address alcohol and substance use, and mental health in adolescents and young adults ages 10–24.

SBI AND SBIRTS FOR ADOLESCENTS IN HEALTH CARE SETTINGS

Despite the enormous opportunities for identification and prevention of risky drinking and alcohol use disorders in adolescents and young adults, it is estimated that very few receive such an intervention when visiting either their primary care providers or when receiving emergency treatment for an alcohol-related injury. While efforts targeting substance-related issues in these contexts have increased, screening and brief intervention for alcohol use disorders is, for the most part, not happening in an organized and efficient manner in health care settings. Below we discuss opportunities

and roadblocks to incorporate these services in varied medical settings.

Most heavy episodic and alcohol use disorder prevention efforts, to date, have focused on primary or community-level prevention (such as school-based alcohol and drug education efforts) and clinical or tertiary prevention (e.g. Alcoholics Anonymous, inpatient detox services). Research supports clinical or tertiary treatments for alcohol use disorders (e.g. motivational interviewing, discussed below), but it is probable that these clinical interventions have only a minimal effect on overall population rates of alcohol use disorders. In part, this is likely due to their limited availability. Secondary or indicated prevention for alcohol (e.g. intervention for those showing symptoms of a behavior or disorder identified for prevention) is beginning to show promise for greater reach in health care settings. For long-term effective secondary prevention of risky drinking and alcohol use disorders on a population level, early intervention would require accurate methods for identifying those at risk, efficacious interventions suitable for delivery on a large scale, and acceptable and efficient models for populationbased intervention delivery.

In 2011, the AAP, Committee on Substance Abuse, published a policy report directing routine medical care in primary care settings to facilitate the comanagement of adolescents with addictions by primary care providers and mental health/addictions specialists. Dividing substance use into stages on a spectrum of substance use and impact (i.e. Abstinence, Experimentation, Limited use, Problematic use, Abuse, Addiction) the spectrum is to be applied to characterize risk and severity based on a qualitative assessment of adolescents' use and level of negative impact. The guidelines further offer stage-based goals (e.g. prevent or delay initial of substance use, enhance motivation to make behavioral changes) of intervention and provide stepby-step instruction for assessment, referral, and intervention. In addition, the report of guidelines provides recommended criteria for the selection of a substance abuse treatment program for adolescents requiring intervention beyond screening and brief intervention, as well as addressing billing and payment issues for pediatricians, often a roadblock for intervention in primary care settings. The report provides theoretical and empirical bases for recommendations and is clearly compiled and written for use by the medical health professional.

SBIs are typically one-session interventions to target and change problematic alcohol-related behaviors. As stand-alone interventions, their effectiveness is not reliant on further engagement in treatment. Although demonstrated to be effective, the lack of focus on further intervention in SBIs may miss an opportunity to SCREENING METHODS 793

maximize the patient-provider contact. Hence, SBI interventions may be less effective for those who need more intensive intervention to assist in their attempts to reduce problematic alcohol use and for those with more contextual barriers to reduced alcohol use or lack of skills to reduce drinking. SAMHSA developed an intervention framework, which includes an additional component for referral, the SBIRT. The SBIRT protocol was developed to be applicable in a range of medical environments including emergency rooms, primary health clinics, or other health care venues. As with SBIs, patients automatically undergo a brief screening to assess alcohol (and drug) use. Those identified as being at risk for developing a serious substance-related problem receive a brief motivational intervention. In the SBIRT protocol, however, patients who could benefit from more extensive treatment receive further referral to specialty care.

Clark and colleagues reviewed data on 459 599 mostly adult patients screened at a variety of medical settings (including individuals in six states where SBIRTs are in use). Of those screened, approximately 23% either had alcohol/drug problems or were determined to be at high risk to develop them. Of those, approximately 16% received a brief intervention, 3% received a form of brief substance use treatment, and a further 4% received referral to specialized care. Patients endorsing items suggestive of heavy drinking during the initial brief screen subsequently reported 39% lower rates of heavy alcohol use at 6-month follow-up. Those receiving either brief intervention or referral to specialty treatments reported fewer arrests, more stable housing, improved employment status, fewer emotional problems, and improved general health.

SBIRTs have demonstrated cost-effectiveness as well. The Washington State Department of Social and Health Services, Research and Analysis Division, determined that after at least a brief intervention (or more), Medicaid costs were reduced by \$185–\$192 per member per month. The majority of the cost reductions were determined to be associated with a reduction in subsequent inpatient hospitalizations from ED admissions. The report indicated that the potential reductions in Medicaid costs could be as high as 2.8 million a year for working-age disabled clients who receive a intervention or referral, should the program continue once federal funding ended.

One challenge to the implementation and utilization of SBIRT protocols in the US is facilitating reimbursement for these services. In January 2007, the US Centers for Medicare and Medicaid Services began reimbursement for alcohol and drug SBIRT. Reimbursement codes for brief interventions are available through commercial insurance CPT codes, Medicare G codes, and Medicaid HCPCS codes; however, some codes may vary from state-to-state and not all providers may be aware of

billing codes that allow reimbursement for SBIRT. To address this limitation, SAMHSA is working with the Centers for Medicare and Medicaid Services to educate medical professionals/practitioners about SBIRT coverage and Medicare billing rules related to alcohol intervention services.

SCREENING METHODS

Screening, more universally, is a process of identifying members of a population who meet specific criteria for the targeting of prevention and intervention services. While symptoms are assessed, typically a formal diagnosis is not made, rather, screening procedures in health care guide subsequent decision-making. Screening of adolescents for alcohol-related disorders assesses alcohol use and related problematic behaviors to determine an associated level of risk for alcohol-related problems. Other than obtaining BAC to measure current intoxication, there are currently no feasible lab-based medical screening tools that could be used regularly in primary care settings for accurate assessment of risky drinking and alcohol use disorders. Therefore, most related information is gathered in an unstructured manner that may or may not illicit information useful for accurate screening. In the absence of standardized text, providers may inadvertently ask leading such as "You have not been drinking have you?" or questions of a too general nature such as "What has your drinking been like?" To yield more comprehensive and accurate results, health care providers should use standardized questions or questionnaires, such as the Alcohol Use Disorders Identification Test (AUDIT), to assess drinking. The validity of brief screening tests, such as the AUDIT, Problem Oriented Screening Instrument for Teenagers substance use/abuse scale (POSIT), CAGE (which stands for Cut down, Annoyed, Guilty, Eye-Opener), and CRAFFT (which stands for Car, Relax, Alone, Forget, Friends, Trouble) have been assessed with adolescents. The AUDIT, POSIT, and CRAFFT have acceptable sensitivity (the percentage of individuals who are correctly identified as having the condition) for identifying alcohol problems or disorders in adolescents, but the CAGE is not recommended for use in this age group. The AUDIT and POSIT are written assessments and thus can be taken without the clinician present (e.g. in the waiting room prior to meeting with the provider). The CRAFFT is a screen for alcohol and other drug use administered orally by the provider.

The most well-validated screening instrument for adults, the AUDIT, was developed by the WHO in order to assess the continuum of unhealthy drinking behaviors and identify those who might benefit from brief interventions. The AUDIT is commonly used in health care settings

including annual administrations to patients in VA hospitals. The measure is comprises three items assessing amount/frequency of consumption, three items assessing alcohol dependency, and four items assessing problems caused by alcohol use (alcohol-related consequences). Scores can range from 0 to 40. In US primary care research, "4 or more" is considered a good indicator of risky drinking. In adolescent populations, sensitivity ranges from 54 to 87% and specificity (the percentage of healthy people who are correctly identified as not having the condition) from 65 to 97%. The AUDIT-C (which includes the first three items of the AUDIT) has been validated to assess alcohol use disorders among adolescents. The more brief AUDIT-C includes the following questions: (1) How often do you have a drink containing alcohol?, (2) How many drinks do you have on a typical day when you are drinking?, and (3) How often do you have five (different than the full Audit which is six or more) or more drinks on one occasion?

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) recommends a two-item screener for use with children and adolescents. Specific wording depends on age category, but the first question asks about any alcohol use by the patient (not only use defined as binge drinking) and the second asks about alcohol use by the patient's friends. This second question is important because it provides the practitioner with valuable information about what the patient might consider normal drinking based on their social group. Adolescents who drink often think that they drink less than their peers, but typically individuals are comparing themselves to a nontypical drinker or group of drinkers.

The CRAFFT is a six-item screen used for alcohol and other drug use for adolescents, with the acronym representing the content of the six items. These are, "Have you ever ridden in a Car driven by someone (including yourself) who was high or had been using alcohol or drugs? (Car) Do you ever use alcohol or drugs to Relax, feel better about yourself, or fit in? (Relax) Do you ever use alcohol or drugs while you are by yourself Alone? (Alone) Do you ever Forget things you did while using drugs or alcohol? (Forget) Do your Family or Friends ever tell you that you should cut down on your drinking or drug use? (Friends) Have you ever gotten into Trouble while you were using alcohol or drugs? (Trouble)." Two or more positive answers are considered an indicator of a possible problem with alcohol or drug use. Research with adolescents indicates that the CRAFFT demonstrates 92% sensitivity and 64% specificity.

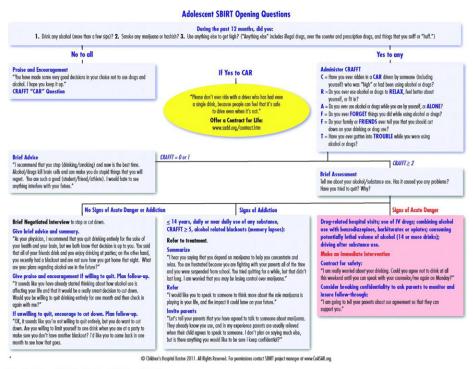
Brief standardized questionnaires and semi-structured interviews above provide effective, time-sensitive tools for health care professionals to use to gain the most relevant information in contexts where multiple health concerns are to be addressed. They also structure and reduce the amount and length of training needed to insure a wide range of providers (e.g. physicians, nurses, health care assistants) are competent to assess these issues in an effective manner, and allow for more standardized assessment of substance-related care needs of patients presenting to health care venues. These assessment tools may be used alone, and particularly in systems/clinics where more formal screening policies have not been established. They are likely most useful when incorporated into structured/semi-structured screenings and interventions applied system wide.

Below is a decisional flow chart, Fig. 80.1, from the guidelines of the American Academy of Pediatrics, Committee on Substance Abuse. It demonstrates the application of an adolescent SBIRT algorithm for practitioners to follow for assessing the stage of use, choosing a recommended brief intervention, and guiding the providers' referral strategy. The algorithm starts with a 2-step method of screening using the CRAFFT screening tool followed by a semi-structured brief intervention by the primary care provider and then appropriate referral, as indicated. The CRAFFT is a well validated and developmentally appropriate screening tool that, while easy to administer, has demonstrated good discriminative properties for assessing the level of risk and presence of substance use disorders in adolescents screened in the primary care and ED settings. Results of the CRAFFT screen identify adolescents without use, with no signs of acute danger or addiction, signs of addiction, and signs of acute danger within the SBIRT algorithm, supplying suggested intervention for each level of risk/severity.

Psychosocial Intervention Guides for Screening

The 2011 Policy on Substance Use Screening by the AAP recommends using existing psychosocial intervention schemes, such as Goldenring and Cohen's HEADSS (or HEEADSSS) or SHADESS, when incorporating SBIRT into primary care settings. As with CRAFFT, the HEADSS title represents the items for screening and the acronym itself can be used to guide the interview through questions about Home, Education, Activities, Drug and alcohol use, Sexuality, and Suicide/depression (HEEADSS adds an Eating and Safety assessment). The SHADESS interview framework further leverages patients' resilience by identifying patients' perceived and realized strengths before exploring environment context and risks. These guides also emphasize the importance of a discussion about confidentiality – both assessing the adolescents' understanding of confidentiality and providing a confidentiality statement based on the particular situation.

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PEDIATRICS

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FIGURE 80.1 Adolescent SBIRT algorithm. Reprinted with permission from the Adolescent Substance Abuse Program, Children's Hospital Boston

Motivational Approaches to SBI and SBIRTs

Approaches to intervention in medical settings differ, typically based on theoretical orientation and beliefs about substance use and treatment. For discussion purposes we can talk about interventions that stress motivational enhancement, based on the work of Miller and Rollnick, and those for which motivational interviewing (MI) approaches are not specifically incorporated (e.g. Johnson intervention). As MI is gaining traction in the substance abuse treatment community, motivational enhancement has been incorporated in many interventions, some more directly acknowledging MI techniques and some less. TrEAT (Trial for Early Alcohol Treatment) and BASICS (Brief Alcohol Screening and Intervention for College Students), discussed below are motivational approaches that have been either developed for, or applied to, adolescent populations. In addition, much of the research for development and testing of screening and brief motivational interventions for alcohol in adolescents and young adults has been conducted with college students (and not in a medical context) and therefore programs are primarily implemented in college (non-medical) settings. While college students are at heightened risk for binge drinking (approximately 42% binged in the past month in 2010 in the NSDUH sample), same-age adolescents, not in college, also engage in high rates of binge drinking (36%) further emphasizing the need to address this age group in primary care and emergency department medical settings.

The majority of research on brief motivational interventions (e.g. SBI, SBIRT) conducted in medical settings target populations 18 and older, which includes individuals characterized as both young adults and adolescents based on somewhat different definitions. These studies speak to the effectiveness of the interventions generally, and may somewhat characterize alcohol-using adolescents over the age of 18. More recent investigations have specifically targeted adolescent populations in health care settings yielding important findings that are applicable to individuals under 18. For example, Bernstein and colleagues evaluated a brief motivational interview in a pediatric ED with adolescents aged 14–21, randomized to conditions designed to examine assessment reactivity in addition to the effectiveness of a peer-conducted motivational intervention with referral to community resources and treatment, when indicated.

NIAAA and TrEAT

Project TrEAT examined the efficacy as well as the cost-effectiveness of a two-session intervention of 10–15-min counseling visits with problem drinkers (age 18–65) using a scripted workbook. Twelve-month follow-up data from the initial randomized control trial demonstrated significant reductions in 7-day alcohol use, number of episodes of binge drinking, and the frequency of excessive drinking compared to the control condition. Analyses of economic costs and benefits presented in subsequent reports indicated that the project TrEAT intervention demonstrated positive benefit–cost ratios with benefits such as subsequent reduction in hospital and emergency department use, fewer criminal and legal events, and fewer motor vehicle incidents.

The NIAAA Task Force on College Drinking offers online training curriculum for health care providers. This curriculum is comprised of four teaching modules covering epidemiology and prevention strategies, screening and assessment, brief intervention, and MI and can be used to train providers in a wide range of training settings (e.g. grand rounds, daylong seminars). The goal of the curriculum is to provide clear and comprehensive training materials for the training of a broad range of health care professionals (e.g. physicians, nurses, social workers, health educators) to identify and treat students at risk for, or having, alcohol-related problems. Materials are freely available as a web-based course for trainers with materials for both the training of medical professionals, and materials for use directly with students in medical settings. For example, the curriculum provides an intervention workbook, based on the TrEAT brief intervention, available to download and print for use with students.

Brief Alcohol Screening and Intervention for College Students (BASICS)

The BASICS approach is quite consistent with MI principles. The intervention consists of two sessions, approximately 45–60 min each. In the initial session, information about the student's alcohol use is gathered and self-monitoring cards are given for the student to complete in between sessions. At the second session personalized feedback regarding the student's alcohol consumption is provided, and the student's perception of other students' alcohol consumption is compared to actual data. The intervention discussion includes normative information regarding blood-alcohol levels and discussion regarding students' beliefs about alcohol, consequences, risk factors, and the use of a tool called the "readiness ruler." Developed for nonmedical settings (e.g. for high-risk students entering college), the intervention has more recently been implemented in the health care arena (e.g. student health centers).

To date, few studies have examined the use of motivational SBIs in college medical settings, in any manner (e.g. see work by Matt Martens and colleagues). Outside medical settings, data from motivational SBIs (e.g. BASICS) suggest that addressing students' motivation/ readiness for change and protective strategies appears to be important in reducing problematic alcohol use. The early empirical studies of motivational SBIs applied in medical settings suggest that these interventions can be feasibly provided in a university student health center, reduce quantity and frequency of alcohol consumption, and further reduce negative consequences of use among college student populations. Ehrlich and colleges, in the first randomized control trial of BASICS in a medical setting, demonstrated that the intervention delivered in a student health center was effective across demographic characteristics assessed and students' history of abuse, reducing quantity and frequency of alcohol consumption, and negative consequences of drinking.

Due to variations in the age ranges considered as adolescent or young adult, studies of intervention with adult patient populations (i.e. age 18 or greater) may have indications for older adolescents and young adults. However, without separate analyses of individuals in the adolescent/young adult age category (e.g. 18–25), ability to apply findings to adolescents is problematic. A smaller group of studies have been conducted that look at these age ranges more specifically, and these results can be interpreted with greater confidence. For example, Monti and colleagues compared a brief motivational interview to standard care among 18-19-yearold ED patients. Follow-up interviews at both 3 and 6 months indicated that patients in the MI condition reported a lower incidence of drinking and driving, were less likely to have been cited for a motor vehicle moving violation and were less likely to have an alcohol-related injury. Reported alcohol consumption in this study decreased in both groups. This study speaks to the efficacy of intervention older adolescents presenting for emergency care. Spirito and colleagues examined patients aged 13-17 treated in an ED for alcohol-related events/injuries. Adolescents in the MI condition with a baseline Adolescent Drinking Inventory score suggestive of problematic alcohol use reported a lower frequency of alcohol consumption and binge drinking during a 12-month follow-up period as compared to a standard care condition. Thus, preliminary studies of screening and intervention with adolescents under the age of 18 as well as 18-25-year-old young adults in medical settings indicate that motivational SBIs appear effective for targeting problematic alcohol.

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WHY INTERVENE IN MEDICAL SETTINGS?

The importance of therapeutic relationship in the delivery of behavior-change interventions has been well established, and may be particularly beneficial as a jumping off point in medical settings. Primary care providers and team members can utilize established relationships with patients as well as their role as potentially trusted experts to improve tailoring, relevance, and impact of SBI. Patients are generally willing to work with their physician or other health care provider to reduce alcohol use, and the acceptability of this approach may increase as the Medical Home (discussed below) approach spreads.

The strongest evidence for SBIs in medical settings includes trials where the patient's personal physician or nurse has delivered the intervention. While an adolescent or young adult is unlikely to receive treatment from a known provider in the ED settings, the urgency of the situation and authority of the health care provider could be impactful. Further, and as medical records become more available across sites, ED providers could make primary care teams aware of the visit and possibly set a follow-up primary care appointment while in the ED – an additional opportunity to provide SBI in a time period close to an emergency event.

Situations in which patients receive acute medical services for an alcohol-related injury (e.g. MVA) are considered by many to be unique teachable moments when substance-using individuals may be particularly open to intervention. Although it has been demonstrated that practitioners consider performing these interventions to be feasible and acceptable, lack of time is still cited as a frequent reason that the screens do not get performed in emergency care settings. Although ED visits present an opportunity to address problematic substance use, patients receiving care for physical injuries are often distracted by pain, treatment procedures, communicating with family members, or continued intoxication. In addition, after waiting for and receiving care, patients seen in the ED typically leave quickly after receiving care for their physical injuries, limiting opportunities for intervention or limiting the quality of intervention able to be provided. However, for patients who are hospitalized after arriving in the ED, interventions delivered at the hospital bedside in the days following the admission can be impactful.

In an influential study addressing these issues (not specifically targeting adolescents and young adults), Longabaugh and colleagues conducted an investigation with three conditions. Patients in the ED who screened positive for problematic drinking either received the ED standard care, a brief intervention, or a brief intervention followed by a booster session 7-10 days later. The booster session was added to overcome the time limitations and distractions often present in the delivery of emergency care. At the 1-year follow-up, ED patients who received the intervention plus booster had fewer alcohol-related problems and injuries compared to patients receiving the ED standard care. However, patients who received the brief intervention without a booster did not differ in alcohol-related negative consequences compared to the patients receiving the ED standard care. The application of booster sessions may be most useful in situations where time and ability to focus are constrained. Interventions for practitioners in ED settings have been developed that can be performed in 10 min or less. Offering subsequent booster sessions may be an important way to enhance the effectiveness of these interventions and include patients who might otherwise not be served. Other methods are being considered, as well, to address limitations of time in ED settings, such as computer-based approaches that make use of patients' waiting time for health promotion and to target patients at risk for varied health problems.

REFERRAL

The most empirically based treatments for adolescent individuals with established alcohol and other substance use disorders include group-based cognitive-behavior therapy, multidimensional family therapy, and functional family therapy. In medical settings, referral for treatment of adolescents is complicated by both physician- and age-related factors. It is suspected that most adolescents who receive treatment for alcohol and substance abuse treatment receive family therapy, 12-step programs, and therapeutic communities (long-term treatment, 12-18 months, for adolescents who have multiple severe problems). Most physicians and health care providers are unaware that many treatment options for problematic alcohol use have not been empirically tested nor evaluated for relative efficacy. Much of what is understood in popular culture about the treatment of alcohol and other drug problems come from television and film depictions. Even "reality television" conveys the message effective treatment necessitates that one must leave society for a period of 28 days or more in order to receive treatment for a substance use disorder. Often providers may be pressured to send a young adult to an inpatient rehabilitation facility or to stage a confrontational intervention, as families dealing with addiction issues in their children are, understandably, very concerned and emotionally aroused and feel comforted by what they view as the most intensive of treatments. While pressure from family and colleagues may be present, the role of the provider in this context is to help identify the best route for the patient and family, with the understanding that the most effective strategy may not be the route that the family expects. Adolescent patients are particularly unlikely to have detox needs that warrant inpatient hospitalization. Primary care doctors are still rarely trained to provide outpatient alcohol detoxification to their patients. Unfortunately, some patients needing alcohol detoxification end up in psychiatry inpatient units, which are not only costly, but may convey the message to the patient and family that the patient is incapable of managing themselves or their problem without hospitalization. This message may undermine future attempts to change problem behavior with outpatient support.

ROADBLOCKS TO SCREENING AND BRIEF INTERVENTION IN HEALTH CARE SETTINGS

Health Care Coverage

A limitation of delivery of SBI for young adults in the US is that their health care often changes when they leave home, and this is further restricted by limitations on insurance coverage for young adults (only recently extended to age 26 for young adults attending college and being covered by parental employer insurance). Young adults are among the healthiest group in the nation physically, but as discussed earlier, are at a critical time period for the prevention and treatment of mental health and alcohol problems. While providing insurance coverage for all adolescents/young adults may seem costly given relative good health, nationwide health and long-term health costs could be positively impacted by a commitment to screening, prevention, and intervention for mental health and addictive behaviors in this age group.

Confidentiality

Another potential roadblock to assessing and addressing alcohol use issues is the need, not only for general confidentiality of health-related information, but also for protection of specific information related to issues such as reproductive and sexual health, mental health, and drug and alcohol use for patients under the age of 18. Specific protections are in place to support adolescents' willingness to seek treatment for, and provide information related to, sensitive concerns. However, statutes addressing confidentiality of sensitive health information vary from state to state. Having protections in place also does not guarantee that adolescents will either be knowledgeable of their rights or

confident in the mechanisms to protect information from being shared with parents, teachers, and other school staff, or others that the minor fears will gain access to information. Therefore, efforts should be aimed at education and empowerment of adolescents, not only regarding services available, but also regarding their health care rights.

Health Care Cost

Health care costs are well identified as a pressing national issue in the US. Because it is difficult for prevention interventions to show immediate cost savings, they may be sidelined by insurance providers to prioritize programs that result in more immediate cost savings to the for-profit insurance industry. Therefore, at the core of successful assessment, prevention, and secondary intervention for substance use disorders is a well-integrated system of service delivery that has long-term accountability for quality and cost of care. An integrated delivery system is a network of health care providers and related organizations which coordinates to provide a continuum of care to its targeted population(s). Ideally, a fully integrated delivery system would be a single integrated entity providing a full range of services covering the entire spectrum of health and mental health needs that are well-integrated with the communities that it serves. Coordination of services is of interest to health care providers, as integration reduces redundancy in services, centralizes administrative tasks which reduces staffing needs, allows for a broader range of services/ specialties offered, and facilitates a higher level of strategic planning and generation of policies to better serve communities and consumers. These shifts help to reduce costs of care delivery and direct costs to the consumer. The strengths of such a well integrated system go beyond increased productivity, efficiency, and costeffectiveness. An integrated system facilitates continuity of care through more seamless referrals in a system that facilitates communication between providers and allows for tracking and accountability of referrals for specialty care. Integrated services help insure continuity of care and increase the likelihood of treatment engagement, treatment adherence, and improved quality of care.

Limits and Benefits of SBI in ED Settings

Some experts contend that the MI approach is not feasible for primary care and emergency settings due to the training and time needed to provide effective MI type interventions. Of note, even when providers in ED settings have the skills and time to provide such interventions, high levels of intoxication may preclude the usefulness of any "in the moment" type of intervention. If an

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individual presents in the ED with heavy intoxication, it is possible that the patient might not remember the motivational intervention delivered at that time. Although valid, these concerns should not curtail efforts for the development, testing, and dissemination of interventions in ED settings. It is well established that learning that occurs closer to the behavior targeted for change is more likely to lead to changed behavior. Further, patients often naturally abstain from alcohol for a time period following an ED visit or hospitalization due to an injury where alcohol was a contributing factor. In addition to person-to-person interventions, web-based interventions have been suggested as being possibly more adaptable for health care settings. In managed care organizations, for example, the combination of medical record tracking and payment structure could be utilized to incentivize such interventions. For example, if a young patient presents in an ED setting, they could receive a BAC test and if indicated, a follow-up intervention via secure e-mail messaging to address alcohol use. If the patient completed the intervention and followed up with their primary care doctor, their ED visit fee could be waived.

ALCOHOL, TRAUMA, AND SBIRTS

Excessive alcohol use, ranging from binge drinking to longstanding alcohol dependence, has been found to be a leading risk factor in admissions to hospitals for trauma. Hence, there has been an organized effort to institute screening and brief intervention in trauma-related injuries treated in Level 1 Trauma centers/hospitals. Chafetz and colleagues, in the first report on the use of brief interventions delivered in a hospital emergency department setting, indicated that interventions successfully motivated alcohol-dependent individuals to engage in subsequent treatment for their disorder. Harborview Medical Center in Seattle, in an effort to examine alcohol-related admissions to its trauma unit, found that alcohol screening and brief intervention delivered in the emergency department reduced the rate of alcohol use and repeated admissions for trauma by nearly 50%. Cost-benefit analyses conducted as part of this trial indicated that, if instituted nationwide, such interventions could lead to an annual direct medical cost savings of almost \$2 billion. Results from this CDC-funded research led to a mandate by the American College of Surgeons to require that Level 1 trauma hospitals provide alcohol screening for all injured patients arriving in emergency rooms and brief intervention for individuals who screen positive for problematic alcohol use. More specifically, trauma centers can test BAC when patients arrive with trauma. If the patient is subsequently hospitalized, the BAC information can then be used to provide personalized intervention delivery.

FORWARD THINKING

Patient-Centered Medical Home Models

One approach to improve patient care and lowering health care costs is the Patient-Centered Medical Home - an organization model for the delivery of the core components of primary health care. In 1967, the American Academy of Pediatrics first introduced the idea of a "medical home," in order to provide a central location for children's medical records. In 2002, the AAP expanded this concept by identifying "Joint Principles." The Patient-Centered Medical Home model is a teambased approach to care emphasizing patient support and empowerment, coordination and continuity of care, ease of communication between the patient and his or her and health care team, timely access to care, and "whole person" care. Whole person care assumes that the physician and his or her team are responsible for providing or arranging patients' care across the lifespan and considering patients' cultural traditions, personal preferences and values, family situations, social circumstances, and lifestyles. Each patient has a personal physician with whom they have an ongoing care relationship. This physician works with a team who collectively are responsible for the patient and includes a primary focus on quality and safety of care. Whole person care systems focus on prevention of costly ED visits and hospital stays, increasing one-to-one time with patients, patient-provider communication via alternative methods (secure e-mail and telephone), treating to target (having a tracking system for identifying those not within targets for health, such as depression scores, blood pressure ratings, and body mass index), and identifying those lost to follow-up. Whole person care further includes integration of the Chronic Care Model, a model that engages patients with chronic conditions to become more informed and active self-managers, and does so through a prepared, proactive primary care team and supportive delivery system design. The Joint Principles included an emphasis on the importance of reimbursement for physician care management, which is conducted outside of the office visit, a further benefit to the consumer. Because the medical home model is appropriate for organizations where health care delivery and coverage are combined into a single system, such systems have strong incentives to focus on both greater quality of care and cost of care.

Alcohol and Mental Health Screening

Literature largely from research with college students indicates that there are important relationships (we suggest transactional) between mental health problems (such as symptoms of depression and anxiety), drinkingrelated consequences, alcohol consumption, and drinking that is motivated to manage negative moods. Individuals with mental health problems are at greater risk for drinking to manage the moods associated with these problems and in turn are more likely to experience significant consequences due to their alcohol use. Although alcohol-related consequences cannot be totally disentangled from severity of alcohol use problem, these relationships are still important to consider. Individuals should be screened via PHQ-9 and GAD-7 (the Patient Health Questionnaire and Generalized Anxiety Disorder, respectively, seven items self-report, free online) at the same time as they are screened for alcohol use disorders. Above all, we recommend that health care practitioners emphasize (especially for young patients with mental health problems) the importance of avoiding drinking while in a negative mood state or for the purpose of managing mood, because of the numerous associated problems. Whiteside and colleagues have recently published research on an SBI (incorporating mental health feedback and coping skills training from dialectical behavioral therapy) for young adults experiencing both mental health and alcohol problems. Results of this pilot intervention indicate reductions in mental health symptoms and alcohol-related problems.

SUMMARY

Groundwork has established a platform for refining brief interventions in the medical arena for adolescent populations. Medical care settings have been identified as an important potential mechanism addressing the unique needs of adolescent populations. Although roadblocks and complicating factors are clearly evident, identifying these issues is key to development of services to maximize the potential for intervention with this age group. The potential psychosocial and economic benefits far outweigh costs of screening for alcohol-related problems and offering motivation for behavior change. Primary care and emergency department venues are key points of contact for alcohol screening to identify risk of developing alcohol-related problems and intervene early with individuals who may never otherwise seek alcohol or mental health treatment. Such interventions hold the promise that brief, cost effective interventions during youth can positively influence health trajectories and reduce substancerelated issues over the lifespan.

SEE ALSO

Motivational Enhancement Approaches, Individual Prevention of College Student Alcohol Misuse

List of Abbreviations

AAP American Academy of Pediatrics
ASAM American Society for Addiction Medicine
AUDIT Alcohol Use Disorders Identification Test

BAC blood alcohol concentration

BASICS Brief Alcohol Screening and Intervention for College

Students

CAGE Cut down, Annoyed, Guilty, Eye-Opener

CDC Centers for Disease Control

CRAFFT Car, Relax, Alone, Forget, Friends, Trouble

ED emergency department MI motivational interviewing MVA motor vehicle accidents

NHAMCS National Hospital Ambulatory Medical Care Survey NIAAA National Institute on Alcohol Abuse and Alcoholism

NSDUH National Survey on Drug Use and Health

POSIT Problem Oriented Screening Instrument for Teenagers

SAMHSA Substance Abuse and Mental Health Services

Administration

SBIRT screening brief intervention and referral for treatment

SBI screening and brief intervention
TrEAT Trial for Early Alcohol Treatment
USTPF US Preventative Services Task Force

WHO World Health Organization

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Relevant Websites

http://www.facs.org/trauma/publications/sbirtguide.pdf – Alcohol Screening and Brief Intervention (SBI) for Trauma Patients.

FURTHER READING 801

- http://www.niaaa.nih.gov/publications/ educationtrainingmaterials/youthguide – Alcohol Screening and Brief Intervention for Youth: A Practitioner's Guide.
- http://www.ama-assn.org//resources/doc/ad-hlth/periodic.pdf American Medical Association's Guidelines for Adolescent Preventive Services.
- http://www.sbirttraining.com/ ASAM SBIRT Training for Primary Care Providers.
- http://motivationalinterview.org Motivational Interviewing.
- http://www.samhsa.gov/prevention/ Prevention.
- http://rethinkingdrinking.niaaa.nih.gov/ Rethinking Drinking.

- http://www.cdc.gov/InjuryResponse/alcohol-screening/pdf/SBI-Implementation-Guide-a.pdf SBI Implementation Guidelines.
- http://www.samhsa.gov/prevention/sbirt/ Screening, Brief Intervention, and Referral.
- http://www.samhsa.gov/prevention/sbirt/SBIRTwhitepaper.pdf Screening, Brief Intervention and Referral to Treatment (SBIRT) in Behavioral Health Care.
- http://www.alcoholcostcalculator.org/kids The George Washington University Medical Center.
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Individual Prevention of College Student Alcohol Misuse

Jessica M. Cronce, Mary E. Larimer

Center for the Study of Health and Risk Behaviors, University of Washington, Seattle, WA, USA

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EPIDEMIOLOGY OF COLLEGE STUDENT DRINKING

By the time young adults enter college in the United States (US), over 70% have consumed alcohol at least once, over 50% have "been drunk" on at least one occasion, and approximately 4% report drinking on

a daily basis. Over a third of college students at least occasionally misuse alcohol, engaging in heavy episodic or *binge* drinking. A binge episode is typically denoted as consumption of five or more standard drinks by a man or four or more standard drinks by a woman during a single drinking occasion. In the US, one standard drink is currently defined as

0.6 oz of 100% pure (or 200 proof) alcohol, which is equivalent to 12 oz of beer (5% alcohol by volume (ABV)), 5 oz of wine (12% ABV), or 1.5 oz of liquor (40% ABV). However, this definition has changed over time and differs from country to country.

Despite the fact that most college students mature out of heavy drinking around age 21 or 22, the harmful consequences of alcohol use, in particular, chronic heavy drinking and binge drinking, can have lasting effects. Acute alcohol-related consequences, such as impaired academic, athletic, and work performance, injury, weight gain, blackouts, physical unplanned pregnancies, can divert students' natural developmental course, contributing to lost potential and long-term harm. Students who misuse alcohol are at higher risk for these and other more severe consequences including academic failure, alcohol dependence, sexual victimization, infection and disease, accidental death, and suicide. Although the damage caused by alcohol is often greatest to the individual drinker, others are frequently affected. Consequences of student alcohol misuse are also evident at the institutional and societal level including costs associated with property damage, student attrition, healthcare utilization, and involvement in the legal system. Collectively, the damage attributable to college student drinking makes it a significant public health concern.

COLLEGE STUDENT DRINKING PREVENTION

Myriad preventive and interventional approaches have directly targeted college student drinking in an effort to stem the tide of harmful consequences. These efforts can be roughly divided into two categories: (1) environmental and (2) individual-focused. Environmental programs aim to reduce drinking and associated harms by modifying the drinking context, with the intent of changing the broader drinking culture within which individual drinking occurs. By comparison, individual-focused programs aim to reduce drinking and associated harms by modifying drinker-specific factors, with the intent of changing a specific individual's drinking behavior. Individual-focused programs that have demonstrated evidence of efficacy in reducing college student drinking are grounded in (1) an understanding of the individual factors contributing to the initiation and perpetuation of alcohol consumption and (2) broader theoretical frameworks that postulate how behavior is maintained and can be modified through manipulation of these factors. More prominent etiological models of college student drinking are subsequently discussed.

Etiological Factors Related to College Student Drinking

Perceived Risk for Alcohol-Related Consequences

Awareness and educational campaigns assume that students abuse alcohol due to a lack of knowledge or awareness of health and legal risks, and that remediation of this knowledge gap will result in behavior change. This assumption is largely unsupported. In fact, students are often acutely aware of the possible consequences of drinking, and in particular, the more extreme negative outcomes such as alcohol poisoning, traffic fatalities, and legal involvement. However, a large body of research suggests that individuals tend to perceive that they are at lower personal risk for negative consequences relative to others and relative to their actual level of personal risk. Available theory suggests that perceived susceptibility to harm may therefore be more influential in the choice of behavior.

Cognitions

Beliefs about the effects of alcohol on behavior, also known as alcohol expectancies, have been repeatedly shown to influence drinking. These expectations may be particularly important in determining drinking behavior in social situations, as many of the most common positive expectancies cast alcohol as a social lubricant. Other common expectancies include that alcohol will increase confidence/assertiveness, increase sexual attractiveness/prowess, reduce inhibition, and reduce negative mood states like boredom, worry, or stress. Expectancies are often directly related to personal motivations or reasons for drinking. For example, a student who normally feels shy may specifically choose to consume alcohol in order to reduce social anxiety. Experimental manipulation of alcohol expectancies in laboratory studies has demonstrated a direct association between expectancies and alcohol consumption, such that increasing positive expectancies leads to increased alcohol consumption and increasing negative expectancies leads to decreased alcohol consumption.

Social Influences

Social influences on drinking behavior are primarily related to peers, including peer modeling of inappropriate use and direct or indirect pressure to use, and inaccurate perceptions overestimating the prevalence and acceptability of drinking in the college culture at large (e.g. beliefs such as "all college students drink") and more proximal peer groups (e.g. "all my friends drink, and they drink more than I do"). Misperception of drinking norms is often considered a cognitive etiological factor, but it is grounded in selective observation of actual peer behavior. Students who are drinking may engage in other behavior (e.g. sustaining an injury,

causing a disturbance) that is more likely to be noticed and to bother nondrinkers and drinkers alike, making drinking look more prevalent due to the ease with which such events are brought to mind. Moreover, students tend to estimate norms based on the behavior of proximal peer groups who most often engage in similar drinking behavior. Students who estimate drinking norms based only on their proximal peer group are ignoring the large percentage of students whose drinking behavior they have not observed. Studies suggest that approximately 20–30% of US college students abstain from alcohol use, and these individuals are the most likely to be discounted when students try to estimate the behavior of "typical college students."

Coping or Protective Behavioral Skill Deficit

Unlike other behaviors, such as driving a car, young adults typically do not receive explicit instruction on how to drink safely. Students often learn how to drink through passive observation of others' drinking behavior, and thus their skill repertoire for moderating consumption may be limited. Students who lack the ability or self-efficacy (perceived ability) to judge their level of intoxication (estimate their blood alcohol concentration (BAC)) and limit their consumption (e.g. refuse drinks, pace and space drinks, set and adhere to a predetermined limit) are at greater risk for misusing alcohol. Students may also be at greater risk for misusing alcohol if they lack general life management skills, such as stress management, and instead rely on alcohol as a primary coping mechanism.

Motivation

Low motivation to change behavior is a key factor in the maintenance of risky drinking. Many students are inherently ambivalent regarding their drinking behavior. On the one hand, they may see the potential harms and have personally experienced undesirable consequences, while on the other hand, they often experience immediate positive benefits that reinforce their drinking (e.g. I want to get good grades, but I do not think hanging out with my friends would be as fun without alcohol). It is often assumed that motivation is a stable trait of the individual - someone either possesses motivation or they do not – and that intervention is not possible until the person "finds" the motivation on their own to receive and make use of the help available. In contrast, certain theoretical perspectives view motivation as a product of the interaction between individuals (e.g. a therapist and client). This perspective forms the basis for humanistic, person-centered approaches such as Miller and Rollnick's motivational interviewing (MI), which is rooted in the transtheoretical model of change. The transtheoretical model of change and MI are described along with other theories of behavior and behavioral interventions, respectively, in subsequent sections of this chapter.

Biology

Students may be predisposed to alcohol misuse due to genetics. Unlike the aforementioned etiological factors, genetic risk is not directly modifiable via intervention. However, knowing about a student's family history can help to elucidate an individual's own behavior. Children of alcohol-dependent individuals (COA) may exhibit acute sensitization and/or acute tolerance to alcohol. Acute sensitization refers to an increased sensitivity to alcohol's subjective stimulating effects, whereas acute tolerance refers to a decreased sensitivity to alcohol's depressant effects on the central nervous system. In essence, the person may experience "higher highs" and "diminished lows." As a consequence of finding alcohol use to be pleasurable without necessarily experiencing the negative physiological consequences (e.g. nausea) students may be more likely to drink heavily and develop an alcohol-use disorder. The finding that COA are more likely to develop an alcohol-use disorder themselves is consistent within the literature, and the role of genetic factors in this risk is evident. Research suggests that COA may differ from children of nonalcohol-dependent individuals in other potentially important ways including personality (e.g. impulsivity, negative affectivity), behavioral tendencies (e.g. hyperactivity, antisocial behaviors), and cognitive factors (e.g. lower verbal and problemsolving abilities, greater positive alcohol expectancies). However, findings are not consistent, and it is less clear if these differences are due to genetic or environmental influences.

Theories of Behavior Related to College Student Drinking

The etiological models discussed above rely on broader theories of behavior to postulate how these individual factors may individually and interactively contribute to college student drinking. These theories include classical learning theories (classical conditioning, operant conditioning, and Bandura's Social Learning Theory), as well as extensions and variants of these models including Prochaska's and DiClemente's Transtheoretical Model of Change, Rosenstock's Health Beliefs Model, and Ajzen's Theory of Reasoned Action and Theory of Planned Behavior. This section reviews some of the basic tenants of these theories.

Classical Conditioning

Learning that occurs through classical conditioning is based on pairing. Classical conditioning can occur intentionally or unintentionally. When done intentionally, a neutral stimulus (e.g. ringing of a bell) that does not evoke the desired response is purposefully paired with an unconditioned stimulus (e.g. meat powder) that naturally evokes the desired response in all members of the organism's species (e.g. salivation in all canines). For maximum learning, the neutral stimulus is consistently presented immediately before and in conjunction with the unconditioned stimulus. In this way, the organism learns that the presentation of the unconditioned stimulus is contingent on presentation of the neutral stimulus, and it produces a conditioned response (e.g. salivation) when presented with the formally neutral, now conditioned, stimulus because it anticipates the presentation of the unconditioned stimulus.

With respect to alcohol use, unintentional learning occurs when external stimuli (e.g. tastes, smells, surroundings, friends/peers) get inadvertently paired with alcohol consumption. As alcohol use naturally produces physiological changes associated with subjective feelings of stimulation and disinhibition, the body activates opposing processes in order to maintain homeostasis. Over multiple pairings, the sensory and social stimuli that frequently precede and co-occur with alcohol consumption come to evoke these opposing processes before alcohol is even consumed. That is, the individual develops tolerance, which prompts greater consumption of alcohol in order to elicit the desired subjective feelings of stimulation. Classical conditioning methods may be used to extinguish alcohol use by pairing alcohol with stimuli that naturally evoke an aversive response. This method of aversive counterconditioning is most often seen in the use of medications that produce physical illness when alcohol is consumed.

Operant Conditioning

Learning that occurs through operant conditioning is based on reinforcement and punishment. Edward Thorndike's Law of Effect suggests that operant conditioning is generally unintentional. That is, behavior is initially performed at random, and behaviors that are followed by desirable consequences are repeated whereas behaviors that are followed by undesirable consequences are discontinued. Of course, operant conditioning can be used to intentionally increase desired behaviors through application of reinforcers or to extinguish undesirable behaviors through withdrawal of reinforcers (or application of punishment). Reinforcers and punishers are not absolute or universal within a species, and as such are defined functionally within a given organism. A reinforcer is any consequence desirable to the individual that increases the likelihood the behavior will be repeated. Conversely, a punisher is any consequence undesirable to the individual that decreases the likelihood the behavior will be repeated. Reinforcers and punishers are deemed positive or negative depending on if something is added to or subtracted from the individual.

Operant conditioning underlies most cognitive-behavioral models that suggest that alcohol consumption is coupled with positive and/or negative reinforcement (e.g. increased perceived enjoyment, acceptance by peers; decreased social anxiety), which serves to maintain the behavior despite intermittent negative consequences (i.e. punishers). At the level of intervention, alcohol's operant function is explored through discussion of perceived benefits and consequences of drinking, and behavior change may be supported through substitution of alternate behaviors that provide similar positive reinforcement without associated harms.

Social Learning Theory

Unlike classical and operant conditioning, Social Learning Theory holds that neither pairing nor direct reinforcement is necessary for learning to occur. Instead, according to this theory, individuals are capable of learning indirectly through observation of others' behavior and ensuing consequences; the anticipation of reward or punishment is sufficient to shape behavior. In addition, this theory holds that learning may occur without being evident in subsequent behavior. That is, someone may learn how to drink and form expectations for how alcohol affects individuals through observation of proximal (e.g. parents, peers) and distal (e.g. media) models without directly engaging in drinking themselves. The influence of this learning is posited to subsequently emerge if and when the individual decides to engage in drinking. This model underlies cognitivebehavioral models that suggest alcohol use is initiated and maintained due to positive expectancies and underlies intervention approaches that challenge these expectancies and perceived norms for peer-drinking behavior.

Transtheoretical Model of Change

Fundamentally, the transtheoretical model of change suggests that motivation for behavior change is a state, rather than a trait, and lies along a continuum with five distinct stages. Individuals who are comfortable with the status quo are considered to be in the precontemplation stage. That is, they have no motivation for behavior change and are not considering altering their behavior. Individuals who recognize that their behavior has both pros and cons may feel ambivalent, simultaneously wanting the benefits and preferring not to experience the harms. These individuals are considered to be in the contemplation stage. Once this decisional balance is tipped in the direction of behavior change, individuals enter the preparation stage, wherein they amass the

resources necessary to change their behavior. With respect to alcohol use, preparation may involve exploration of alternative activities to drinking or renewal of friendships with peers who would support decreased drinking. When ready, individuals enter the action stage and actually change their behavior, for example, reducing the amount they drink or the time spent drinking. An individual is thought to enter the final stage of maintenance when behavior change is sustained for an extended period of time, usually 6 months.

Health Beliefs Model

The Health Beliefs Model suggests that individuals will alter their behavior if they perceive that (1) they are susceptible to a negative health condition resulting from the behavior, (2) that the condition resulting from the behavior is severe, (3) that they possess the requisite resources to prevent or mitigate the condition, and (4) that the benefits of changing their behavior outweigh the costs. Applied to alcohol use, this model assumes that individuals must be aware of the consequences of use; perceive that they are likely to experience these consequences and that the overall outcome is significantly detrimental to their well-being; feel a sense of self-efficacy to avoid or lessen these consequences as well as possess any necessary external resources to support decreased alcohol use; and perceive that their life will be better overall if alcohol use is reduced. This model informs intervention approaches that address perceived risk for alcohol consequences, reinforce benefits of alternate behaviors, and teach skills to reduce the likelihood of drinking-related harm.

Theories of Reasoned Action and Planned Behavior

The Theory of Reasoned Action and the Theory of Planned Behavior share an emphasis on perceived subjective (injunctive) norms (i.e. perceptions related to the approval of behavior by a relevant reference group) and personal attitudes about engaging in a behavior as predictors of intentions to engage in the behavior. Several researchers have recommended extending the Theory of Planned Behavior to include perceived objective (descriptive) norms (i.e. perceptions of the degree to which a relevant reference group engages in a specific behavior). Research with college students indicate the greater one's perception of others' drinking, the greater the occurrence of drinking and related problems for the individual. Research also reliably indicates that alcohol use is associated with overestimation of how frequently and how much other people drink. This model underlies normative reeducation approaches that juxtapose an individual's perception of drinking norms and actual drinking norms to highlight this overestimation. Correcting this misperception has been shown to result in reductions in perceived

norms and reductions in the individual's drinking behavior consistent with the revised norm.

INDIVIDUAL-FOCUSED PREVENTIVE INTERVENTION APPROACHES

This section describes individual-focused preventive interventions, rooted in the etiological models and behavioral theories discussed above that have been applied to college student drinking. These interventions can be roughly divided into four broad categories based on their primary target: (1) educational/awarenessbased, (2) cognitive-behavioral skills-based, (3) motivational/feedback-based, and (4) pharmacological. However, interventions are increasingly blurring the lines between these categories, incorporating elements from various efficacious programs. For example, although historically focused primarily on alcohol education, recent versions of multicomponent alcohol education-focused interventions have included elements of motivational/feedback-based approaches, including graphic presentation of the individual's drinking behavior, correction of normative misperceptions of others' drinking behavior, and tips regarding protective behavioral strategies that serve to reduce harmful drinking consequences. This overlap between the content of different interventions notwithstanding, each of the four broad intervention categories and representative exemplar programs are described below.

Educational/Awareness Programs

Information/Knowledge Programs

As previously mentioned, programs that focus on alcohol-related information and knowledge tend to highlight the type of negative consequences that may be experienced as a result of alcohol use. These programs are solely didactic (instructive) and may also include information on the likelihood of experiencing specific consequences. However, more often than not these programs give emphasis to the severity of consequences, rather than likelihood, as severity and likelihood are often inversely related (e.g. death is the most severe consequence of alcohol use, but the percentage of individuals who die from all alcohol causes each year is comparatively low relative to the percentage of individuals who experience more minor consequences such as nausea). These programs also frequently include information on the range of BACs associated with specific alcohol effects, and directly challenge commonly held myths regarding how alcohol is absorbed and oxidized (e.g. coffee may decrease subjective intoxication, but will not decrease actual BACs).

Values Clarification Programs

In comparison to traditional information/knowledge programs, values clarification programs are typically more interactive. They may contain general alcohol information, but they focus on helping students to consider their own personal values (e.g. being a good student, being financially responsible) and evaluate how choices related to alcohol use may facilitate or hinder attainment of specific goals related to these values (e.g. scholastic achievement, saving money). For example, a prototypical values clarification program may include exercises that help students to define and determine the relative importance of their values, recognize and appreciate the interindividual diversity of values, increase awareness of discrepancies between their values and current behavior, and develop plans to promote greater consonance between their values and future behavior.

Normative Reeducation Programs

Although normative reeducation programs often rely on didactic presentation of factual information about alcohol, the focus is almost exclusively on the actual frequency and acceptability of drinking behavior within a circumscribed reference group (e.g. college students at a given campus). For example, students may be told that less than a certain percentage of students on their campus (e.g. 10%) engage in binge drinking or that more than a certain percentage of students on their campus (e.g. 80%) perceive that public intoxication is not acceptable. When used as a primary prevention strategy, reeducation programs are often referred to as social norms campaigns, and would be considered an environment-level intervention. Individual-focused normative reeducation programs contain the same information as social norms campaigns but additionally highlight discrepancies between personally held perceptions of drinking behavior and the actual behavior of the reference group. Personalized normative feedback (PNF) interventions share many common elements with normative reeducation programs, but as subsequently detailed in the motivational intervention section differ in important ways.

Cognitive-Behavioral Skills-Based Programs

Cognitive-behavioral skills-based programs tend to blend elements of information/knowledge, values clarification and normative reeducation programs with didactic skills instruction and/or interactive skills practice. As the name implies, these skills target cognitive and behavioral factors that promote or maintain highrisk drinking. Some programs focus on teaching specific skills, while others focus on teaching a broader constellation of related skills.

Specific Alcohol-Focused Skills Training

These programs typically focus on teaching a single skill directly related to alcohol use with the intent of decreasing drinking and/or bringing it under greater conscious control. For example, behavioral selfmonitoring assumes that excessive behavior will decrease if brought into conscious awareness through consistent tracking. Students are taught the definition of a standard drink; how to calculate the number of standard drinks in various beverages; strategies for keeping track of their alcohol intake in social situations (e.g. placing tokens such as bottle caps in their pocket when a beverage is consumed); and how to document their drinking behavior for later examination (e.g. keeping an alcohol diary). Documentation is usually most accurate and effective in reducing behavior when it is done contemporaneously with the target behavior, but this is usually not preferred by students due to the perceived stigma of recording drinking behavior and may be complicated by the CNS depressant effects of alcohol (e.g. cognitive impairment, lethargy) if done at the end of a drinking occasion. As such, determining a covert strategy for tracking alcohol use that the student is willing and confident in using is paramount to the success of this intervention.

BAC discrimination is another specific alcoholrelated skill. This approach trains individuals to determine their approximate BAC using external information (e.g. BAC chart, breathalyzer) and internal cues associated with different levels of BAC. Use of external information and internal cues are both necessary as alcohol reduces attentional capacity, restricting the individual's ability to recognize and make use of available information (e.g. individuals may fail to recognize how extensive their motor coordination is impaired despite having fallen down or knocked over their glass), and internal cues associated with different BACs change as the person increases or reduces his/her level of tolerance to alcohol. BAC discrimination is most useful for regulating alcohol intake to achieve an "optimal level" of intoxication in which the stimulant effects of alcohol are maximized and the negative consequences associated with the CNS depressant and biotoxic effects of alcohol are minimized (approximately equal to a BAC of 0.05–0.06 g%). Past this point, the negative effects are much more dominant and no greater stimulant effects can be achieved.

Alcohol expectancy challenge (AEC) programs specifically focus on evaluation of personally held beliefs about the effects of alcohol. Students are guided to consider which effects are truly attributable to the pharmacological effects of alcohol versus which effects are produced by an individual's expectations on how alcohol will affect them. This challenge may be conducted experientially (in vivo), by proxy, or via didactics and discussion. In vivo AEC comprises actual and

perceived alcohol administration to different students in a group setting. Students who merely perceive that they received alcohol typically exhibit the same social effects as those who actually received alcohol (e.g. being more talkative), which serves to demonstrate the influence of expectancies on behavior. Because alcohol is served, this intervention is only appropriate for students who are of legal drinking age. In comparison, AEC by proxy involves watching a video of another group of students undergoing an in vivo AEC, and may be used with students of all ages. Finally, AEC may be conducted through didactic presentation and group discussion alone. As detailed later, not all AEC protocols are equally effective.

Multicomponent Alcohol Skills Training

In contrast to specific alcohol skills training programs, multicomponent programs provide instruction on a range of alcohol-related skills. These skills include, but are not exclusive to, combinations of the specific alcohol skills detailed above. For example, the Alcohol Skills Training Program incorporates elements of all of these specific skills into a one-to-eight session didactic protocol. Students learn a given skill or set of skills each week and are encouraged to practice skills between sessions. Multicomponent programs also target real and perceived deficits in general life skills. For example, students who feel socially inept may report using alcohol to facilitate social interaction, or students who have difficultly balancing multiple role responsibilities may experience stress, which they choose to alleviate through alcohol use due to perceived lack of, or low confidence in the efficacy of, alternative options. The World Health Organization (WHO) defines life skills as those "abilities for adaptive and positive behavior that enable individuals to deal effectively with the demands and challenges of everyday life."1 The WHO suggests that these skills include decisionmaking, goal-setting, and problem-solving; creative and critical thinking; effective communication, empathy, assertiveness, negotiation and other interpersonal skills; and intrapersonal skills including maintaining selfesteem, awareness and concordance of personal values with behavior, adaptive coping and emotion regulation. When used, these skills are thought to help students make informed, responsible choices with respect to their drinking behavior.

Motivational/Feedback-Based Approaches

Motivational/feedback-based approaches may include elements of information/knowledge, values clarification and normative reeducation as well as

cognitive-behavioral skills training. However, their hallmark is a focus on increasing students' readiness to change problematic behavior through use of motivational enhancement strategies and personalized feedback regarding behavior.

Brief Motivational Interventions

Brief motivational interventions (BMIs) are usually delivered over one or two sessions. They are facilitated by a trained interventionist whose goal is to increase the student's motivation and commitment to change high-risk drinking. The interventionist may be a clinical professional, a paraprofessional, or a peer. The most important element is that the interventionist uses a MI style when discussing alcohol use.

MI is a therapeutic approach built around a core "spirit," or a way of being, that is denoted by (1) fostering collaboration, (2) supporting/respecting autonomy, and (3) evoking versus imposing motivation/goals on others. The MI spirit is embodied in action that serves to (1) express genuine empathy, (2) develop discrepancy between an individual's values/goals and their current behavior, (3) roll with resistance to change, and (4) support the individual's self-efficacy. Application of MI requires strategic use of four specific skills: (1) asking open-ended questions, (2) affirming individuals' strengths/values, (3) listening reflectively, and (4) summarizing individuals' responses. Adherence to MI style serves to elicit self-motivational statements known as "change talk."

Within MI, motivation is viewed as a mutable state that can be strengthened or weakened through the verbal and nonverbal behaviors of the individuals involved. Certain behaviors, such as argumentation, blaming, and prescribing solutions, tend to evoke resistance or psychological reactance. That is, when people believe an outside force is threatening their freedom of choice ("You need to stop drinking."), they will act in a way that is opposite of the outside force ("No I don't."). Conversely, other behaviors, such as acceptance, empathy, and asking permission to offer solutions, pull for open discussion, leaving room for the individual to find reasons for change.

The actual content of a BMI is usually structured around a personalized feedback form, ranging from one to several pages in length depending on the number of target behaviors and level of detail included. Personalized feedback may include the individual's self-reported drinking behavior and related consequences; their perceptions of others' drinking behavior and the acceptability of drinking; their expectancies regarding, and motives for, drinking; their familial risk for alcohol-use disorders; strategies that they have used to minimize

¹http://www.who.int/school_youth_health/media/en/sch_skills4health_03.pdf

harms associated with drinking; and domains in which they feel more or less confident to resist drinking.

With the student's permission, general alcohol education is usually provided in tandem with discussion of personalized feedback (e.g. information regarding the cognitive effects of alcohol, the impact of alcohol expectancies on behavior, gender differences in BAC, and defining a standard drink). Depending on the student's readiness for change, the session also includes discussion of alcohol-specific coping and harm reduction skills and/or general life skills (e.g. how to moderate drinking and associated BACs; how to reduce tolerance; how to avoid high-risk situations; adaptive coping strategies for managing stress). Regardless of what specific elements are discussed within the session, all students are provided with a copy of their personalized feedback form along with written material covering general alcohol education and harm reduction tips. The Brief Alcohol Screening and Intervention for College Students (BASICS) program is a prototypical example of a BMI (see Further Reading section for BASICSrelated resources).

Personalized Feedback Interventions

The personalized feedback component of BMIs can be used as a stand-alone intervention without the benefit of an interventionist. Like the personalized feedback used in BMIs, personalized feedback interventions (PFIs) provide a written summary and graphic representation of an individual's drinking behavior, including his/her typical and peak frequency, quantity and calculated BACs; a comparison of the individual's behavior with his/her perceptions of the drinking norm and the actual drinking norm for a given reference group; positive beliefs about alcohol use; an enumeration of selfreported alcohol-related negative consequences; and other protective and risk-related behaviors. As the information in a PFI must speak for itself, information on an individual's typical and peak BACs is typically presented in relation to BAC-specific effects, such that risk for specific consequences (e.g. impaired judgment and motor coordination, blackout, respiratory depression, coma) is apparent. Additionally, relevant general alcohol education and harm reduction tips may be incorporated directly into the feedback or optional links to this information may be offered to students if the PFI is delivered in an electronic or web-based format. Stand-alone PFIs include, but are not exclusive to, commercially available programs such as eCHECKUP TO GO (a.k.a. eCHUG) and BASICS Feedback. Free web-based programs are also available, such as Check Your Drinking.

Personalized Normative Feedback

The PNF component of a personalized feedback form in a BMI or a PFI can also be used as a stand-alone

intervention. As in a BMI or PFI, PNF contrasts the student's self-reported drinking behavior with that of the typical drinking behavior of a relevant reference group (e.g. typical female student, typical fraternity member). Inclusion of PNF facilitates examination and development of discrepancies between an individual's perception of his or her drinking as "typical" and actual drinking behavior of other college students, which is generally much more moderate. As indicated previously, PNF shares similarities with normative reeducation programs insofar as it presents accurate drinking norms for a given reference group. However, PNF differs from normative reeducation programs in that it juxtaposes an individual's personal drinking behavior with his/her perception of the drinking norms for the reference group and the accurate drinking norms. Many normative reeducation programs also incorporate discussion of the acceptability of drinking behavior in addition to its prevalence whereas this information is not typically included in PNF.

Multicomponent Alcohol-Education-Focused Programs

These programs represent a relatively new hybrid of traditional alcohol information/knowledge-based programs and efficacious elements of BMI, PFI, and PNF interventions, such as personalized feedback, normative reeducation, challenge of positive drinking expectancies, and tips for harm reduction. These programs could also be considered multicomponent skills-based interventions. However, their inclusion of personalized feedback makes them more similar to stand-alone PFI and PNF interventions than more skills-focused programs. They are most often delivered via an electronic medium, either a CD-ROM or over the web. These programs include, but are not exclusive to, commercially available interventions such as College Alc, Alcohol 101, AlcoholEdu and Alcohol Wise (which directly incorporates eCHECKUP TO GO as an intervention component). Earlier versions of some of these programs were almost exclusively focused on alcohol information/knowledge, and as such should be considered separately from more recent versions that incorporate the elements of BMI, PFI, and PNF enumerated above.

Intensive Treatment and Medication

For individuals with more extensive alcohol-related problems who exhibit diagnosable alcohol abuse or dependence, more intensive treatment may be required. This treatment may take the form of inpatient detoxification, inpatient rehabilitation, intensive outpatient chemical dependency therapy, individual outpatient therapy, participation in 12-step focused or other support groups,

and/or medication. Approval of medication for alcohol dependence varies by country. Within the US (which has historically tended to be among the most conservative countries with respect to drug approval), four medications are currently approved for the treatment of alcohol dependence: disulfiram (Antabuse®), oral naltrexone, extended-release naltrexone (Vivitrol®), and acamprosate (Campral[®]). Disulfiram produces immediate physical discomfort and nausea when alcohol is consumed, leading to aversive counterconditioning. In comparison, naltrexone blocks opiate receptors, diminishing the stimulating effects of alcohol, leading to operant extinction (lack of reinforcement). Acamprosate's mechanism of action is less well understood, but it appears to restore homeostasis between excitatory (glutamatergic) and inhibitory (GABAergic) neuronal pathways in the brain, which is disrupted through chronic alcohol use. More intensive forms of treatment and use of medication have not been well studied in college student populations. Targeted use of naltrexone (i.e. on isolated days in anticipation of drinking events) may serve to further enhance the effects of brief motivational interventions but considerably more research is needed before this can be firmly established.

EVIDENCE OF EFFICACY FOR SPECIFIC INDIVIDUAL-FOCUSED PREVENTIVE INTERVENTION APPROACHES

Current State of the Science

Prevention science is constantly advancing, leading to somewhat different conclusions over time about which preventive intervention approaches are most efficacious. At the time this chapter was written, three intervention approaches had sufficient evidence to warrant classification as efficacious among college students. Specifically, (1) cognitive-behavioral multicomponent skills-training approaches, (2) BMIs incorporating personalized feedback and normative reeducation (PFI/PNF), and (3) AEC intervention protocols. Evidence supporting the efficacy of these programs has been documented in numerous qualitative and quantitative literature reviews. These reviews have additionally demonstrated support for the efficacy of stand-alone PFIs and PNF interventions, although more research is needed.

The support for AEC approaches, although considerable, has been less consistent and points to particular efficacious modalities and potential moderators of intervention efficacy. Specifically, in vivo (experiential) AECs appear to work well for men, may work for women when delivered in a gender-specific format, and tend not to work when delivered by proxy or via didactics/

discussion only. Other specific alcohol skills programs, including BAC feedback/discrimination training and self-monitoring, have also demonstrated efficacy, but evidence supporting these approaches is considerably more mixed, perhaps due to the high variability of content and administration protocols evident across these approaches.

There has consistently been an absence of support for programs solely including alcohol education. These programs produce changes in alcohol knowledge, but not alcohol-related behavior. In comparison, multicomalcohol-education-focused programs ponent include educational elements in conjunction with personalized feedback and normative reeducation components inherent to BMIs, PFIs, and PNF interventions have started to amass greater support, but evidence of efficacy ranges greatly within and across different programs. Part of the variability in the evidence of efficacy for a given electronic program may be due to evaluation of different versions of the same program (e.g. a study may show no support for version 7.0 of a program, but strongly support version 9.0 of the same program because it included additional or refined intervention elements). Additional variability in efficacy may be due to differences across studies with respect to target population (e.g. all students regardless of age vs. only students age 18 or older) and intervention intent (e.g. universal vs. indicated prevention). As such, more research is needed to determine what specific configuration of intervention elements (i.e. program version), for what students, and under what circumstances such programs may be most efficacious.

As previously indicated, research evaluating the efficacy of intensive treatment and medication for college student drinking has been limited. To date, targeted use of naltrexone in combination with a BMI has been tested in a single open-label trial. Although the findings are promising, significantly more research is necessary before firm conclusions can be drawn regarding efficacy.

Barriers to Intervention Implementation

Barriers exist that may impede or complicate implementation of efficacious individual-focused alcohol interventions on college campuses. First, with the exception of commercially available programs, most intervention protocols are not easily accessible or immediately useable by key stakeholders (e.g. campus health professionals, peer interventionists, college administrators). Although a published manual and measures necessary to generate personalized feedback are available for the BASICS program, campus personnel may not have adequate human resources (e.g. staff with expertise in MI who can deliver the intervention and/or provide

supervision), data (e.g. campus-specific drinking norms), or technological resources (e.g. access to programs that can generate personalized feedback) to implement the program with sufficient fidelity.

These barriers can be lessened through interdepartmental coordination, connecting campus health professionals with academic faculty who have expertise with program implementation and evaluation. Personalized feedback can be developed within basic word processing and spreadsheet/database programs, and normative data can be gleaned from secondary sources (e.g. national epidemiological and behavioral health monitoring research studies) or through implementation of routine alcohol screening in campus health centers. Finally, existing methods for distance learning (e.g. video or web-based conferencing) could be adapted to support implementation of in-person facilitated BMI protocols (e.g. provide initial training and ongoing supervision).

Future Research Directions

Although the balance of the published evidence supports the efficacy of BMIs, more research is needed to elucidate for whom in-person BMIs are more or less efficacious in comparison to PFI/PNF-only interventions. The absence of intervention effects on alcohol behavior and consequences in some studies of BMIs and PFIs/PNF interventions may indicate a failure to include critical intervention components, a lack of fidelity in delivery of the intervention, and/or the presence of potential moderators of intervention effects (e.g. gender, Greek or athletic affiliation, mandated student status). Additionally, despite growing support for the efficacy of PFI/PNF-only interventions, further research is necessary to determine which specific elements and/ or delivery modalities are associated with change in alcohol-use and/or -associated consequences.

Both BMIs and PFIs/PNF interventions have demonstrated variability in the duration of effects on alcohol outcomes, ranging from weeks to years. Short-term reductions in drinking behavior (e.g. changes lasting 1–6 months) are far more common and future research is needed to determine how to extend these effects and enhance the impact of these interventions on negative alcohol-related consequences. Recent research suggests that effects on alcohol-related consequences may emerge subsequent to changes in alcohol use behavior. Preliminary evidence suggests these emergent effects may be most related to in-person BMIs, but further research with longer follow-up periods is necessary for other intervention approaches. Additional research is also needed to evaluate the efficacy of BMIs in combination with interventions targeting environmental drinking factors, parental communication regarding alcohol use,

and psychiatric comorbidity (e.g. depression, anxiety, other substance use, disordered gambling). Ultimately, no single approach may be sufficient and multiple intervention strategies may be required to produce lasting effects on college student drinking and related harm.

Finally, the existence of barriers to implementation suggests that further research focused on increasing the reach of evidence-based alcohol intervention approaches is warranted. Specifically, more research is needed to (1) develop efficacious approaches to train intervention providers and evaluate the fidelity of intervention delivery, (2) increase the effect of interventions delivered in written or electronic form in the absence of a trained facilitator, and (3) test the necessity for, and efficacy of adaptations of, existing efficacious programs to reach college students from varying cultural backgrounds and educational contexts (e.g. community college, minority-serving institutions, online distance learning programs).

SEE ALSO

Examining the Role of Parents in College Student Alcohol Etiology and Prevention, Understanding Individual Variation in Student Alcohol Use, Using the Internet for Alcohol and Drug Prevention, Harm Reduction Approaches, Evidence-Based Treatment, Evaluating Treatment Efficacy, Dissemination of Evidence-Based Treatment into Practice, Screening and Brief Alcohol Intervention for Adolescents and Young Adults in Primary Care and Emergency Settings, Internet Screening and Intervention Programs, Screening and Interventions in Medical Settings Including Brief Feedback-focused Interventions, Cognitive Behavioral Therapies, Motivational Enhancement Approaches, Brief Feedback-Focused Interventions

List of Abbreviations

ABV alcohol by volume

AEC alcohol expectancy challenge BAC blood alcohol concentration

BASICS Brief Alcohol Screening and Intervention for College

Students

BMI brief motivational intervention

COA Children of alcohol-dependent individuals

MI motivational interviewing

PFI personalized feedback intervention PNF personalized normative feedback WHO World Health Organization

Further Reading

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- http://www.motivationalinterview.org/ Motivational Interviewing. http://www.nrepp.samhsa.gov/ – SAMSHA's National Registry of Evidence-based Programs and Practices.
- http://www.commed.uchc.edu/match/pubs/monograph.htm Project MATCH Manuals.

82

Etiology and Prevention of Stimulants (Including Cocaine, Amphetamines and Misuse of Prescription Stimulants)

Michael J. Herkov, Mark S. Gold University of Florida, Gainesville, FL, USA

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HISTORY OF STIMULANT USE

Stimulants are a class of substances that represent the most misused products in the world. This class of drugs range from widely used and accepted over-the-counter products such as caffeine and nicotine, to prescription medications used to treat medical conditions such as attention deficit hyperactivity disorder (ADHD), obesity, and narcolepsy, to illicit drugs such as cocaine and methamphetamine. While all of these drugs result in increased energy and vigilance, the capacity of some of these substances to create a "high" involving a sense of euphoria, gregariousness, and excitement has resulted in them being sought after by humans for thousands of years, resulting in stimulants comprising one of the largest categories of drugs of abuse.

Use of legal stimulants such as caffeine can be traced from the discovery of tea in China in 2750 BC to the

present annual per capita consumption of coffee in the United States. Today, caffeine finds its way into a variety of products ranging from soft drinks to ice cream to candy, with the average adult consuming 200 mg of caffeine a day. Use of nicotine, another stimulant found in tobacco, could be traced back over 2000 years with over 20% of Americans smoking cigarettes. While products such as coffee, tea, and tobacco have addictive properties and (especially in the case of tobacco) associated health concerns, they have not been associated with the personal and societal destruction of more powerful stimulants such as cocaine and illicit and prescription amphetamines.

Use of cocaine can be traced back to 3000 BC to the inhabitants of the Andes Mountains. To the Incas of Peru, cocaine, because of its ability to increase energy and elevate mood, was viewed as a gift from the Gods. Cocaine use consisted of chewing coca leaves,

a process that would likely have delivered between 200 and 300 mg of cocaine to the brain over a 24-h period. However, with the development of organic chemistry in the 1800s and the introduction to cocaine to Europe, pure forms of cocaine became available and quickly started showing up as medicinal products (e.g. toothache drops) or in retail products ranging from wine to soft drinks. As with the Incas of Peru, cocaine was initially touted as a panacea for a variety of ailments, marketed as an "intellectual beverage" as Coca Cola and endorsed by a number of influential people ranging from Pope Leo XIII to Thomas Edison. However, the addictive qualities of the drug soon became apparent, resulting in governmental regulation (i.e. Harrison Act of 1914) and eventual (1970) classification of cocaine as a Schedule II drug (a drug with some medical use, but high potential for abuse and dependency) in the US.

Use of cocaine significantly declined in America for over half a century. However, there was resurgence in cocaine use in the mid to late 1970s when it was again viewed as a safe drug. In fact, in the 1980 edition of the Comprehensive Textbook of Psychiatry, Grinspoon and Bakalar opined, "Chronic cocaine abuse usually does not appear as a medical problem." During the 1980s, new forms of delivering cocaine to the brain such as freebasing and crack emerged, increasing addiction potential and personal destruction by delivering higher doses of the drug with a reduced latency from ingestion to drug effects. Modern technology now provided users with dosages of cocaine reaching the brain up to five times higher than that of the Incan, delivered to the brain in seconds rather than hours. This deadly combination led to a cocaine epidemic of unparalleled proportion and associated violence and mortality that ripped at the fabric of American society.

Use of Ephedra majaung, a plant with stimulant and appetite suppressant properties can be traced back to 3000 BC in China. The active ingredient of amphetamine was first synthesized in 1887 from a series of plant compounds related to ephedrine. A related compound, methamphetamine, was synthesized in Japan in 1918. While structurally similar to amphetamine, methamphetamine differs from amphetamine in that at comparable doses, higher levels of methamphetamine get into the brain; thus making it a more potent drug. Both drugs are classified as Schedule II drugs.

Amphetamine had little medicinal use until the mid-1930s when it was marketed as a decongestant and treatment for narcolepsy. Known for creating a sense of alertness, energy, and euphoric properties, it was widely used to counter fatigue in combat troops in World War II. Its ability to suppress appetite resulted in it being marketed as a weight loss agent known as Dexedrine beginning in the mid-1940s. However, its

addictive properties soon became apparent and legislation regarding its use and distribution started to emerge in the 1950s.

Amphetamine and methamphetamine became popular in 1960 both in terms of legal prescription and as part of the 1960s drug culture in the US. These substances were used by people ranging from truckers to students to housewives for increased stamina, alertness, and appetite suppressant qualities. Between 1958 and 1970, the US production of amphetamine pills grew from 2.5 billion to over 10 billion, greatly exceeding the legitimate medical demand. Known by a number of street names including speed, ice, meth, bennies, etc., these substances quickly became popular drugs of abuse with an estimated one half to two-thirds of the pills manufactured between 1960 and 1971 being sold on the black-market.

The Controlled Substances Act of 1970 greatly restricted the availability of traditional sources of amphetamine related drugs. In fact, an analysis of black-market street drugs in the mid-1970s revealed that less than 10% of samples actually contained amphetamine. Users were now turning to clandestine laboratories of amateur chemists who "cooked" available over-the-counter products such as ephedrine, commonly found in cold medicines, and other compounds into D-methamphetamine using a "pseudoephedrine reduction" process, the recipe for which is readily available via the Internet.

More recently, users have begun to abuse stimulant medications used to treat attention deficit disorders. These medications (Adderall, Ritalin, etc.), when used in the proper dosage, increase central nervous system arousal and attention in ADHD patients. These drugs are becoming more popular among high school and college students as a study aid due to their ability to improve stamina and focus. However, when used in higher dosage, these medications can produce the same euphoric effects seen with other amphetamines. Rates of ADHD drug abuse mirror that of the increase in prescriptions for the medication; both of which increased over 75% between 1998 and 2005.

CURRENT EPIDEMIOLOGY OF STIMULANT USE

Historical analysis of cocaine use indicated rampant use in the early 1900s with a sharp decline following government control over the drug. Use of these drugs began to increase in the 1970s when it was perceived to be relatively safe and nonaddictive. However, during the late 1970s and early 1980s the use of cocaine dramatically increased.

Use of cocaine among 12th grade students dramatically increased in the late 1970s and remained fairly stable until the mid-1980s. After a sharp decline, cocaine use increased again during the mid-1990s when rates again increased. Since 2009, cocaine use among 12th graders has slowly declined with 12-grader use in 2009 being 3.4%.

Use of cocaine by youth is affected by a variety of factors that can provide valuable information for prevention programming. One of the factors associated with use is that of the perceived risk of the drug. Perception of cocaine as dangerous by 12th grades was relatively low during the 1970s and mid-1980s. However, in 1987 perceived risk significantly increased. This was likely associated with the death of NBA first round draft, Len Bias, following his first use of cocaine. Perceived risk remained high until the 1990s, consistent with the above noted increase in use. Since 2000, perceived dangerous of cocaine has increased, again mirroring decline in use.

Cocaine use may also be tied to perceived availability. For example, while 33% of 12th graders reported that cocaine was "fairly easy" or "very easy" to obtain in 1977, 59% so responded in 1989. In 2009, 39% of 12th graders endorsed these categories.

Tables 82.1 and 82.2 clearly show the inverse relationship between perceived risk and use.

Trends in amphetamine use indicate peak usage by 12th graders in 1981 with 26% reporting use within the past year. There was then a gradual decline until the early 1990s when use of a variety of illicit drugs increased. Rates of abuse again began to peak after the mid-1990s and have steadily declined to the present time with 7.8% of 12th graders reporting use within the last year in 2009. Again, similar to that of cocaine, usage rates of amphetamine are inversely related to their perceived dangerousness.

Use of methamphetamine rose from 1.9% of 12th graders in 1976 to 3.7% by 1981. It was not until 1990 that the Monitoring the Future questionnaire began asking questions specific to crystal methamphetamine use. As illustrated in Table 82.3, crystal methamphetamine use

TABLE 82.1 Cocaine Use and Perceived Risk*

	91	93	95	97	99	01	03	05	07	09
% who used in the last 12 months	2.2	2.3	3.3	4.3	4.5	3.5	3.3	3.5	3.4	2.5
% seeing "great risk" in using once or twice	59.4	57.6	53.7	53.6	52.1	50.7	51.0	50.5	51.3	53.1

^{*} Data adapted from Johnston, L.D., O'Malley, P.M., Bachman, J.G., Schulenberg, J.E., 2010. Monitoring the Future National Results on Adolescent Drug Use: Overview of Key Findings, 2009 (NIH Publication No. 10-7583). National Institute on Drug Abuse, Bethesda, MD.

TABLE 82.2 Amphetamine Use and Perceived Risk*

	91	93	95	97	99	01	03	05	07	09
% who used in the last 12 months	7.5	8.4	10.0	10.1	9.0	9.6	8.0	7.0	5.5	5.9
% seeing "great risk" in using once or twice	36.3	31.3	28.8	31.0	32.2	34.7	36.8	37.7	41.3	41.9

^{*} Data adapted from Johnston, L.D., O'Malley, P.M., Bachman, J.G., Schulenberg, J.E., 2010. Monitoring the Future National Results on Adolescent Drug Use: Overview of Key Findings, 2009 (NIH Publication No. 10-7583). National Institute on Drug Abuse, Bethesda, MD.

peaked in the late 1990s and has steadily declined over the last 5 years with the 2009 12th grade use remaining at 1%. Again, usage rates decline as perceived dangerousness of the drug increase.

Use of stimulants by young adults (aging 18–25 years) and adults (age 26 and older) are similar to those observed as with the 12th graders. Cocaine use by young adults within the last month declined between 2002 and 2008 from 2.0 to 1.5%, while amphetamine and methamphetamine in this group declined from 1.3 to 1.1% and 0.6 to 0.2%, respectively. Cocaine, amphetamine, and methamphetamine use among adults have remained relatively stable with 0.7% reporting cocaine use and 0.3% reporting methamphetamine use within the last month.

Rate of abuse of prescription stimulants such as Adderall and Ritalin are more difficult to calculate. However, there is clear evidence that these medications, primarily used to treat ADHD, are increasingly being used for nonmedical use. In 2000, 19 million prescriptions for ADHD drugs were written, a 72% increase from 1995, and 34% of children 11–18 years who were on these drugs reported being approached by peers to sell or trade their medication. Research on college students reveals that 6.4% admitted to using the ADHD stimulant Adderall nonmedically within the past year. While these drugs are not associated with abuse when used within their prescribed dosage, in excessive amounts they can create the same euphoric

TABLE 82.3 Methamphetamine Use and Perceived Risk*

	91	93	95	97	99	01	03	05	07	09
% who used in the last 12 months	_	-	-	-	4.1	3.4	3.0	2.4	1.4	1.3
% seeing "great risk" in using once or twice	61.6	57.5	54.4	54.4	51.2	52.7	51.2	54.6	60.2	63.4

^{*} Data adapted from Johnston, L.D., O'Malley, P.M., Bachman, J.G., Schulenberg, J.E., 2010. Monitoring the Future National Results on Adolescent Drug Use: Overview of Key Findings, 2009 (NIH Publication No. 10-7583). National Institute on Drug Abuse, Bethesda, MD.

and energizing effects as other stimulant drugs of abuse.

NEUROBIOLOGY OF STIMULANTS

Of the thousands of chemical compounds available, only a small number are abused by people. All drugs of abuse share the common property of being able to cross the blood–brain barrier (BBB) and affect the action of neurotransmitters within the brain leading to the core of all addictions, brain reward.

The concept of brain reward is complicated and involves several brain areas and multiple neurotransmitters. While a thorough discussion of this process is beyond the scope of the present chapter, a brief explanation of the process will help the reader understand why these substances are so addictive. Once in the brain, stimulants like cocaine and amphetamine affect the release of various neurotransmitters within the brain. Neurotransmitters are chemicals within the brain that allow communication between neurons. Neurotransmitters released by one neuron flow across a space between neurons called a synapse, and then they attach to another neuron. Much like a lock and a key, different neurotransmitters have specific sites on neurons to which they can attach. This process stimulates various parts of the brain, some of which produce feelings or energy and euphoria. Once the action has taken place, the neurotransmitters must then be reabsorbed back into the sending neuron for later use in a process known as reuptake. Amphetamine-type drugs achieve their euphoric effects primarily through their impact on the release or reuptake of the neurotransmitter dopamine in specific structures in the brain, known as the "reward pathways." These areas, which include structures such as the nucleus accumbens (Nacc), ventral tegmental area, substantia nigra, and amygdala are present in the brain so that certain behaviors important to the survival of the species, such as eating and sex are rewarding, leading to an increase in the probability of the occurrence of those behaviors. However, drugs of abuse like stimulants hijack this area of the brain by having more impact on neurotransmitter release. Thus, it is not surprising that individuals addicted to these drugs often forgo typical survival behaviors such as eating or sex in favor of drug use.

While cocaine, amphetamine, and methamphetamine affect the action of dopamine (DA) within the brain, they do so differently. Cocaine achieves its increase in DA in the brain primarily by blocking the reuptake of DA at the synapse. While methamphetamine also blocks DA reuptake, it increases the release of DA at the synapse. This leads to higher concentrations of DA at the synapse, which accounts for the increased neurotoxicity of

methamphetamine to the nerve terminals compared to

A number of different delivery systems are used to supply cocaine and amphetamine to the brain. The various routes of administration are important in that they play a significant role in drug effects and addiction. For example, 96 mg of cocaine administered intranasally (snorted) results in peak venous plasma levels of 150–200 mg ml⁻¹ within 30 min, while intravenous use of 32 mg of cocaine produces peak venous plasma levels of 250–300 mg ml⁻¹ within 4 min. Smoking 50 mg of crack cocaine produces a pattern similar to intravenous use. Methamphetamine can be used in pill form, intranasally, intravenously, or smoked in a form often referred to as "ice." Similar to cocaine, smoking or injecting methamphetamine produces a faster and more intense high, although because of its longer half-life, a methamphetamine high tends to be longer than those experienced from cocaine. Prescription stimulants such as Adderall, taken orally, reach peak plasma concentrations in approximately 3 h. Unfortunately, individuals using these drugs also snort and inject them with effect profiles similar to that of cocaine and methamphetamine.

TREATMENTS

Research has identified a variety of evidence-based treatments for cocaine and amphetamine addiction. These include traditional 12-step recovery programs, pharmacotherapy, and behavioral interventions. Given the widespread knowledge of 12-step models, this chapter will focus on pharmacologic and behavioral therapies.

Medical Treatments for Cocaine Addiction

Immunization

One approach involves the use of "super" cholinesterase or immunotherapy designed to reduce brain exposure to ingested cocaine through increased metabolism or preventing cocaine from crossing the BBB. While these approaches are promising, research is still limited.

Agonist Medications

Another approach involves the use of agonist medications. Agonists are chemicals that function similar to neurotransmitters by attaching to a specific neurotransmitter receptor (e.g. DA) and mimicking the action of that neurotransmitter. In other words, they function like a spare key that goes into the keyhole and opens the lock. These therapies involve the use of oral cocaine (e.g. tea, tablets), psychostimulants (e.g.

methylphenidate, levodopa), and DA monoamine uptake inhibitors (bupropion) designed to retain some aspects of cocaine's effects while reducing abuse potential and toxicity. Results have been variable and often contradictory and confounded by the presence of comorbid psychiatric issues. There is also concern that the use of these drugs may perpetuate the reinforcing effects of cocaine in the brain.

Agonist/Antagonist Medications

Another pharmacologic approach to the treatment of cocaine addiction involves the use of agonist and antagonist medications in relapse prevention. Unlike agonists, antagonists attach to a specific neurotransmitter receptor but do not result in the activation of the receptor as the actual neurotransmitter would. This action is analogous to a key which will fit into a lock but not result in the opening of the lock. These medications that involve use of cannabinoid receptor antagonists, DA agonists and antagonists (e.g. atypical antipsychotics), gamma-aminobutyric acid (GABA) agonists, and opiate agonists are designed to reduce the perception of cocaine euphoria and relapse triggered by stress of drug-associated cues. Results have been mixed. While opioid agonists appear to provide some efficacy and cannabinoid antagonists and some DA agonists (D1) show some promise, other interventions such as atypical antipsychotics or GABA agonists appear ineffective or result in contradictory outcomes.

Medical Treatments for Amphetamine Addiction

Agonist Medications

Similar to cocaine treatment, agonist therapy is available for amphetamine addiction. Research has shown that use of D-Amphetamine generally leads to a decrease in drug use, injecting behavior, and dependence severity. Similar results were also found for methylphenidate. While amphetamine agonist replacement therapies do appear to be successful in treating amphetamine dependence, this approach, similar to that of opioid replacement in heroin users, is controversial and may never gain wide acceptance due to clinician reluctance to use amphetamine derivatives to treat methamphetamine dependence. Medications like bupropion, however, appear to having less potential for abuse than other opioid agonists, while still having the potential to reduce their use in amphetamine-dependent patients.

Use of GABA agonists is thought to have an antagonizing effect on dopaminergic systems under the inhibitory control of GABA. While patients using medications such as baclofen and gabapentin did not show

a statistically significant difference in terms of negative methamphetamine urine samples, the baclofen group negative urine samples were in the predicted direction (i.e. 50% negative for baclofen versus 38% negative for placebo).

Agonist/Antagonist Medications

Antagonist treatments have involved the administration of compounds that directly or indirectly antagonize the effects of amphetamines on the monoamine systems of the brain. These have included the use of atypical antipsychotics, such as risperidone (Risperdal) and aripiprazole (Abilify), GABA agonists, opioid agonists, and the use of calcium channel blockers. While these medications tend to attenuate the behavioral effects of amphetamines, they have demonstrated little efficacy in the treatment of amphetamine dependence. In fact, some research indicates that these interventions may actually decrease the success of treatment outcome through the dropping out of patients who dislike the sedating effects of the drugs.

The discovery of opioid receptors in the Nacc and ventral tegmental areas of the brain and the evidence of interaction between the central DA and opioid receptors raises the possibility that opioid antagonists such as naloxone could have an impact of stimulant addiction. Opioid antagonists such as naltrexone have been shown to attenuate DA levels in amphetamine-induced increases in DA as well as reducing the behavioral effects of amphetamine. While research has been limited, findings do suggest that opioid antagonists may be effective in managing amphetamine dependence, with treated patients evidencing decreased use and cravings compared to placebo patients.

PSYCHOLOGICAL INTERVENTIONS FOR COCAINE AND AMPHETAMINE ADDICTION

Contingency Management

Another intervention for cocaine and amphetamine-dependent patients involves an array of behavioral approaches and interventions. One intervention involves contingency management techniques based on psychological principles of operant conditioning. In these models, reinforcers, usually involving vouchers redeemable at local stores, are provided based on some predetermined desired behavior (e.g. negative urine drug screen). Contingency management techniques are successful in initiating abstinence from a wide variety of drugs including cocaine and amphetamines. Metanalytic studies consistently demonstrate the effectiveness of these interventions, with results indicating that

the magnitude of the incentive is positively correlated with the rates of abstinence.

Cognitive-Behavioral Therapy

Cognitive-behavioral therapy (CBT) techniques have also been used with stimulant-dependent patients. These strategies help the patient examine cognitive distortions (erroneous beliefs) related to their drug use. CBT also helps individuals by providing increased problem-solving and stress management skills. Research has shown that CBT is an effective method for dealing with stimulant abuse. Research comparing CBT to contingency management interventions generally indicate the latter to be more effective in the treatment of stimulant dependence.

PREVENTION

Prevention is an important component of any comprehensive substance abuse program. Not surprisingly, most of the prevention programming has focused on adolescents. This is not surprising in that research is clear that most individuals who develop substance-use disorders began their drug use in adolescence or young adulthood. Obviously, there is no need to direct treatment resources to address something that has never occurred. Thus, preventing someone from ever using a substance will guarantee no need for later treatment. Research has shown that every dollar effectively utilized in prevention of drug use saves \$10 dollars in treatment costs.

The research literature and clinical experience are clear that age of initiation of use is related to later severity of substance-related problems. Whether examining alcohol or illicit drugs, students who started their substance use in high school or college had lower substance-related problems than those who began in elementary or middle school. This phenomenon may be due to several factors. First, research is clear that the human brain continues to develop, especially within the frontal lobes, well into the mid-20s. Thus, the earlier the drugs are introduced into the brain, the larger the potential for impaired development. Second, the earlier the adolescent uses substances as a coping behavior, the less likely they are to develop other problem-solving skills; thus making them more reliant on the substance in the future.

Early prevention models, which began in the 1920s, focused on informing youth on the dangers of drugs through vivid exaggeration. The 1936 film, Reefer Madness, was a movie about a group of teens who went insane from marijuana use. In the 1970s, programs such as Scared Straight targeted youth who had delinquent

or drug offenses and exposed them to inmates in an attempt to deter further problematic behavior. However, research on programs that attempt to deter drug use through the creation of fear and catastrophic consequences do not appear to have long-term beneficial effects, with some studies actually indicating an increase in the undesired behavior.

Another strategy in drug prevention has been providing youth and society information regarding the negative effects of drug use. These programs, the most popular of which is D.A.R.E (Drug Abuse Resistance Education) with over 3 million participants, have not been particularly effective, and in some studies have actually shown an increase in substance use over time.

Before examining the various prevention strategies employed for stimulants, it is worthwhile to look at some basic philosophical differences in the prevention movement. The first issue has to do with what is the ultimate goal of the prevention program. While most programs are designed to bring about total avoidance/ use of the drug (abstinence), this is not the only approach. There are experts in the field who see the goal of such programming as not general prohibition of any drug use, but rather the reduction of harm, suffering, and long-term negative consequences associated with drug use. This model proposes that these strategies may be more effective in a population that has witnessed substance use by peers without long-term negative consequences. These interventions, while encouraging abstinence, focus on identification of harmful use patterns. While some literature suggests that this type of approach may have more saliency with youth in terms of their own goals and expectations, it is fraught with several major problems. First, much of the variability identified in addiction, as indicated above, is based on brain neurobiology and genetically determined personal vulnerabilities. Because it is not possible at this time to determine who does or does not possess vulnerability to a particular drug, the program may attempt to solicit use in moderation in a group that is incapable of such use. The second problem is that these programs are difficult to implement due to illegal status of the drugs, political pressures, and the unwillingness of parents, schools, and communities to adopt such a model, fearing such programming as a direct or indirect acceptance or even promotion of drug use.

There are several systems for the classification of prevention programs. The Substance Abuse and Mental Health Services Administration and the Center for Substance Abuse Prevention classify prevention programs on six dimensions. These include information, education, alternatives, problem identification and referral, community-based process, and environmental change. The Information component involves printed or multimedia material on various substances, addiction

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and consequences of substance use. While ineffective in isolation, Information is useful when part of a more comprehensive prevention model. The Education component differs from Information in that there is a communication process between the presenter and the audience. This type of intervention involves skill building (e.g. assertiveness training, coping strategies, etc.). Alternative programming seeks to provide youth with alternative activities that are incompatible with drug use or provide a healthy environment and include programs such as athletics, after school programming and job training. Problem identification programs focus on individuals who have already engaged in substance use and refer them to an intervention program consistent with their needs.

The last two classifications, Community-based Process and Environmental intervention focus more on larger system intervention. The Community-based approach identifies and incorporates stakeholders in the community to provide an integrated, comprehensive resource for combating substance use. The Environmental classification looks like a public policy both written (e.g. laws) and unwritten (e.g. community attitudes) that can affect substance use.

Prevention programs can also be classified in terms of the overall population goal. The Institute of Medicine created a classification in 1994 based on Universal Prevention Strategies (i.e. programs that target the whole community, regardless of risk factor – the entire school). Selective prevention strategies target subsets of the population determined to be at some special risk (e.g. failing students, abused children, etc.). Indicated prevention strategies focus on specific individuals such as children who have already started using drug court, etc.

Most comprehensive drug prevention programs adhere to several accepted tenets of intervention. Some of the basic beliefs involve recognition that drug abuse represents a complex relationship between risk and protective factors and that prevention programs should reduce risk while promoting protective factors. Effective programs also recognize the importance of the family and the school and seek to utilize, nurture, and enhance these constituencies in any programming. Effective programs are also identified as being specific to the community within which they will be implemented of sufficient intensity and duration for change and cost effective.

Examples of selective prevention efforts include targeting nonmedical use of ADHD drugs by college students. These programs incorporate drug-free activities, social norms that reject stimulant use and limit availability through working with campus police, government policy makers and campus health professionals.

Research is clear: prevention programs that meet the above criteria of work. For example, cocaine prevention programs implemented early in the school process have been shown to reduce later cocaine use between 10–50%, depending on the particular model and length of follow-up. Similar effectiveness has been seen in treatment programs for other stimulants, including methamphet-amine. One study that utilized the Life Skills Training and Strengthening Family Programs for Parents and Youth examined the effectiveness of these programs in 667 families, and found that none of the 12th graders who participated in the program had abused methamphetamine in the following years compared to 3.2% of controls who used the drug.

CONCLUSIONS

Abuse of stimulants such as cocaine and amphetamine are, unfortunately, seen throughout human history. Like most drugs of abuse, these substances are seen as safe and even recommended for improving various human maladies. However, society soon becomes aware of much physical, psychological, and social devastation associated with the drug use. At this point emphasis is placed on education, treatment, and prevention of use of the drug. This usually leads to a reduction in drug use.

Unfortunately, lessons learned by one cohort are soon forgotten and it is not long before another generation succumbs to the same deception of the safety of the substance, starting the process again. Review of epidemiological data suggests that the last decade has seen a general decline in cocaine and amphetamine use among youth as effective education and prevention programs have alerted them to the danger of the drugs. However, the use of a new class of prescription medications for treating ADHD may be emerging as a new threat

This chapter identified how stimulants "hijack" the brain by altering neurotransmitter function. This leads to changes in behavior and cognition and a "new brain" where presence of the drug is now "normal" and absence of the drug is abnormal. In this case, most users fail to achieve the brain reward associated with their initial use of the drug, and engage in current use partly to maintain the status quo of the "new drug adapted brain."

While addiction is devastating to the user, their families, and society in general, the good news is that there are proven treatments that can help the person free themselves from their chemical dependency. In addition to proven psychosocial interventions, new medications are being developed that can help to minimize the effects of cocaine and stimulants on the brain.

The most powerful treatment, however, is prevention. Over the last 20 years, researchers and clinicians have developed prevention programs that can have an impact upon convincing youth never to try these dangerous substances as well as reduce relapse in people who have been treated. What is clear is that prevention is not an event, but a process. The most successful programs utilize a variety of components, enlist community support and provide follow-up prevention over time. While these programs are expensive, they are economic bargains when one examines the financial and human cost of drug abuse.

SEE ALSO

Cognitive Behavioral Therapies, Twelve-Step Facilitation Therapy, Contingency Management, Community Reinforcement Approaches: CRA and CRAFT, Agonist-Like (Substitution) Treatment for Cocaine and Other Stimulant Dependence

List of Abbreviations

DA dopamine

GABA gamma-aminobutyric acid **Nacc** nucleus accumbens

Glossary

Attention Deficit Hyperactivity Disorder (ADHD) a psychiatric diagnosis marked by either symptoms of inattention or symptoms of hyperactivity and impulsivity. Prevalence rates range from 3–7% in school age children. Common treatment includes use of stimulant medication.

Blood–Brain Barrier (BBB) a naturally occurring network of blood vessels and cells within the brain that prevents many substances from crossing from the blood system into the capillaries of the brain. All drugs of abuse have the ability to cross the barrier.

Cognitive-Behavioral Therapy (CBT) a form of psychotherapy that is based on the premise that faulty or maladaptive thinking leads to maladaptive behavior and emotional distress. The therapy focuses on changing these thoughts into more adaptive and effective cognitive patterns.

Crack cocaine Powder cocaine that has been mixed with water and another substance such as ammonia or sodium bicarbonate and then boiled. The resulting substance is then dried and cut up and sold into 0.1–0.5 g pieces called rocks. The rock is then smoked in a special glass tube pipe. It supplies a faster, more intense, but shorter-lasting "high."

Methamphetamine a stimulant drug similar to amphetamine. However, its chemical structure is slightly different and the addition of the *N*-methyl group alters its characteristics, allowing it to penetrate the blood–brain barrier easier and resulting in more intense brain effects. It metabolizes down in the body to amphetamine.

Reuptake a process that involves the reabsorption of a neurotransmitter back into the neuron after it has transmitted a neural impulse. The process involves special transporters that attach to the neurotransmitter and take it back into the presynaptic neuron. Many drugs of abuse affect this process by attaching to the transporter, leading to increased presence of neurotransmitters in the synapse.

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www.hhs.gov/kids – Health and Human Services for Kids. www.nida.nih.gov – National Institute on Drug Abuse. www.teens.drugabuse.gov – NIDA for Teens: The Science Behind Drug Abuse.

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Etiology and Prevention of Marijuana Use among College Students

Eric R. Pedersen*, Jason R. Kilmer^{\$}, Christine M. Lee^{\$}, Denise D. Walker**

*RAND Corporation, Santa Monica, CA, USA **Innovative Programs Research Group, University of Mexico,

Mexico City, Mexico *University of Washington, Seattle, WA, USA

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Marijuana use among college students has gained research attention in recent years. Despite studies suggesting that marijuana use can lead to a multitude of consequences in the collegiate context, there are few empirically based interventions that address abuse of marijuana among students. This chapter reviews the available research on the etiology of marijuana use in college and provides suggestions for future research work needed to help inform the development of empirically supported interventions. The available literature on marijuana intervention research with adults and adolescents is reviewed, and suggestions for the transfer of empirically based alcohol interventions in college are presented.

PREVALENCE AND DEVELOPMENT OF MARIJUANA USE AMONG COLLEGE STUDENTS

Prevalence

Marijuana is the most common illicit drug used among US college students. Most recent data from 2010 indicate that approximately 33% of college students reported any marijuana use in the past year. Approximately 18% of students report past 30-day use, with 4.4% reporting daily use. As in the United States, marijuana, or cannabis, has the highest prevalence of illicit drugs in other countries, such as Australia, the

United Kingdom, and Canada. For example, cannabis use was found to be more prevalent among Australian tertiary students than in the general Australian population, with monthly use rates higher than in the United States. Other countries have found lower rates of marijuana use among college students compared with US college samples (e.g. Austria, Spain).

College students are typically within the age range when initiation of marijuana use may occur and patterns of use can develop. Use of marijuana is typically initiated and at its heaviest during late adolescence and young adulthood, with the most frequent users between ages 19 and 22. While marijuana use may begin prior to college for some, approximately one-third of US college students reported initiating use at age 18 (i.e. likely during first year of college).

Risk during Transition

The transition to college may place individuals at increased risk for developing heavier marijuana-using patterns. Increased freedoms during college may influence substance use behaviors. For example, students may live away from home in on-campus residence halls or with friends in apartments. This independent living may lead to increased freedom and reduced parental supervision. Increased access may also contribute to the initiation and development of use patterns, with peers being a major source of influence over decision making among young adult college students. College students are also in a developmental stage where peers serve an important component in identity formation and the choice to engage in substance use contributes to identities connected to such use.

Researchers have suggested that approximately half of marijuana users report their first opportunity to use marijuana as occurring in late adolescence or young adulthood. Additionally, a substantial proportion of young adults who are offered marijuana eventually try the drug. Studies have also suggested that first-year college students may be at particular risk and may even use to a greater extent than upperclassmen. In an examination of developmental trends, researchers outlined six different marijuana use trajectories among young adults from high school graduation to age 24 over four assessment periods. The trajectories included students who abstained from using throughout the duration of the four assessment periods, those who used infrequently, those who experienced a period of frequent use at one point during the assessment periods, those who increased their use over the assessment periods, those who decreased their use over the assessment periods, and those who used frequently throughout the assessment periods. While threequarters of the 20 000 participants in the study reported

abstinence or infrequent use over the four waves of data collection, 5% reported continued heavy use throughout the assessment, with an additional 5% reporting increased use over time. Compared to noncollege graduates, graduates were overrepresented in the group that increased over the assessment period.

Fortunately, many students who use marijuana or other substances in college substantially reduce or quit using once they graduate and mature into adult roles (e.g. marriage/family, career). In addition, the long-standing claim that marijuana serves as a "stepping-stone" or "gateway" to other harder drugs such as opiates and cocaine has not been sufficiently supported by empirical data. However, it is estimated that approximately 9% of those who have tried marijuana may go on to develop cannabis dependence and marijuana is the illicit drug with the highest rate of past year dependence.

DEPENDENCE RISK AND MARIJUANA-RELATED CONSEQUENCES

Cannabis Dependence Symptoms and Prevalence

According to the *Diagnostic and Statistical Manual for Mental Disorders*, Fourth Edition, Text Revision (*DSM-IV-TR*), cannabis dependence symptoms include tolerance (i.e. needing more of the drug to feel the effect), physical withdrawal (e.g. anxiety, loss of appetite), unsuccessful attempts to cut down or quit, reducing other activities to use the drug, spending a good amount of time using, obtaining, or recovering from the drug, using in greater quantities than intended, and using the drug despite knowledge that it could exacerbate a psychological or physical problem (e.g. smoking marijuana despite problems with breathing/lung damage). Most recent estimates of cannabis dependence in the general population aged 12 and older was 4.3% in 2010.

Within the general population, prevalence rates of cannabis dependence in the United States are highest among youth and young adults aged 15–24. In addition, college students may be at risk for developing a cannabis use disorder during college. One recent small study found that 10.1% of first-year students who had used marijuana at least once in the past year met criteria for cannabis dependence (according to the *DSM-IV-TR*), while 14.5% met criteria for cannabis abuse. Those who used marijuana at least six times in the past month reported dependence and abuse rates of 38.6 and 28.6%, respectively. In further work, researchers found that 19% of students tracked over 3 years of college met criteria for cannabis dependence during at least 1 year of the study. Of the students meeting criteria for substance

use disorders involving both alcohol and marijuana, only 11% took steps to actively seek help (e.g. entered treatment). None of the students reporting struggles with marijuana use only sought help.

Risk for Consequences

While dependence risk may not be a concern for all students who use, students who use marijuana are at increased risk for a variety of short- and long-term consequences, such as injuries and accidents, decreased academic performance and missed classes, cognitive difficulties such as memory loss, risky sexual behavior, physical complications such as poor lung capacity and difficulty breathing, lower self-confidence and selfesteem, and psychological difficulties such as increased depression and social anxiety. Marijuana-related problems have been shown to increase across the transition from high school to college and marijuana users who use alcohol report heavier drinking and more substance-related consequences than drinkers who do not report marijuana use. Marijuana users who report frequent use consistently from senior year of high school through the age of 24 reported higher rates of consequences such as interpersonal aggression, risk taking, criminal behavior, and heavier use of alcohol. Despite the complications, students who report use generally do not believe marijuana will lead to significant risk of consequences. In fact, those who use marijuana tend to rate use-related consequences as less negative than do those who abstain (who perceive the consequences more negatively). Heavier users cite the perceived low risk associated with smoking marijuana as a reason for choosing to use. Thus, as initiation and development of marijuana use begin for many during the college years, college students represent a population in need of prevention strategies to reduce the short- (e.g. academic complications) and long-term consequences (e.g. risk for cannabis dependence) of using marijuana.

INTERVENTION AND PREVENTION PROGRAMS FOR COLLEGE STUDENTS

Limited Available Intervention Studies

Alcohol abuse has received substantial attention among researchers and funding agencies, with dozens of prevention and intervention studies aimed at reducing the harms associated with heavy drinking among college students. However, marijuana interventions for college students have received much less attention. To date, there appears to be only one randomized clinical trial primarily targeting marijuana use among college students. In this study, researchers developed and

evaluated a web-based personalized feedback intervention for incoming first-year college students who indicated current marijuana use (defined as any use in the last 90 days). The intervention was based on many of the components in the harm reduction-based, alcoholfocused intervention, Brief Alcohol Screening and Intervention for College Students (BASICS), and utilized a motivational framework for presenting information. The web-based feedback was individually tailored and based on student responses to a prior baseline assessment. Feedback for current users included information about their marijuana use (e.g. pattern of marijuana use, amount of money spent on marijuana), experienced consequences of use, perceived and actual descriptive norms for marijuana use, perceived pros and cons of using marijuana, and participants' own cost-benefit scale. Results indicated no overall reduction in marijuana use as a function of the web-based intervention relative to control at either 3-month or 6-month follow-ups. However, results did provide some promise for students who reported a family history of drug use, and to a smaller extent those who had greater readiness to change at baseline. While there are several commercially available web-based projects on the market for college student marijuana use (e.g. electronic THC Online Knowledge Experience [e-TOKE]), to date these programs have not been evaluated for efficacy. Encouraging results for reducing marijuana use have been found among a few selective and indicated programs targeting college student drug use in general in the United States and the United Kingdom (e.g. McCambridge and Strang, 2004; Miller et al., 2001; White et al., 2006).

Possible Considerations for Marijuana-Focused Interventions

Since there appears to be only one randomized clinical intervention study for marijuana use among college students, researchers have the choice of looking at three areas for ideas to design effective preventive interventions with college students. These areas include (1) the efficacy studies targeting adolescent marijuana use (i.e. high school and middle school students), (2) the efficacy studies targeting cannabis use disorders among treatment-seeking adults, and (3) the extensive literature on efficacious components of interventions targeting college drinking behavior.

Efficacious Interventions Targeting Adolescent Marijuana Use

"CHECK-UP" MODELS

There have been multiple trials examining the efficacy of brief and long-term interventions with marijuana-using adolescents. Because only a minority of adolescents abusing marijuana voluntarily seek treatment, there is a need to create programs designed to encourage heavy marijuana users who do not identify as "in need of treatment" to self-refer. The Teen Marijuana Check-Up (TMCU) is a motivational enhancement therapy (MET) intervention adapted from the Drinker's Check-Up. The TMCU is aimed at eliciting voluntary participation from heavy marijuana-using adolescents and includes a tailored advertisement strategy and a two-session intervention. The advertisements for TMCU emphasize elements of the program designed to decrease barriers to participation, including the brevity of the intervention, confidentiality, as well as the fact that the program is not labeled as "treatment" but rather as an "opportunity to take stock" of use and is for "people who have questions or concerns about their use." Originally delivered in high schools, recruitment included educational presentations made to classes about marijuana. At the end of the presentation, details of the TMCU study were shared, and students could indicate in a confidential manner to the presenters if they were interested in learning more about the program. Sessions were held at school during regular class hours.

The MET intervention consisted of a computerized assessment and two individual sessions with a counselor. Counselors utilized principles and techniques of motivational interviewing (MI), such as open-ended questions, reflective listening, developing discrepancy between where one is presently and where one wants to be (e.g. the teens state they want to go to college and also are falling behind in their grades due to using), and building self-efficacy (e.g. helping teens believe in their ability to change their behavior). In the second session, the counselor reviewed a personal feedback report (PFR) that was created for each person from his or her individual responses to the assessment questions. The PFR consisted of a history of marijuana use; recent use patterns of marijuana, alcohol, and other drugs; normative data on marijuana; problems related to marijuana use; potential costs and benefits of reducing marijuana use; situational confidence in avoiding marijuana; and life goals. The PFR was printed in booklet format with graphics and accompanying descriptions of risk factors for developing problems with marijuana. The PFR booklet was reviewed with the counselor utilizing MI skills throughout the session.

Two pre-post design pilot studies have evaluated the acceptability of this model in the United States and Australia. Both demonstrated that nontreatment-seeking adolescents could be attracted to voluntarily participate in the TMCU and that reductions in marijuana use were evident. A randomized clinical trial involving 97 high school students who used marijuana heavily was conducted to determine if the MET

intervention could produce reductions in marijuana use greater than an assessment control condition. Both conditions reported lower marijuana use at a month follow-up assessment, and the lack of differential effect between conditions raised questions about whether the pre-intervention assessment accounted for the reductions in use. The assessment package in the study was carefully constructed to include questions involving both the positive and the negative aspects of marijuana use, and in some ways it was similar to a writing exercise to explore the pros and cons of marijuana use, that is, a decisional balance that is a potential active ingredient in MI. Similar findings were reported with an Australian sample recruited from the general community. Lack of a comparison group to control for counselor contact and other nonspecific factors was a limitation of both studies. Less is known about the durability of a MET intervention's effect due to the short follow-up periods in these studies.

While findings are encouraging, perhaps an important component of these models to use with college students stems from researchers' ability to recruit young people via "the check-up" model. College students who report marijuana use (and those who meet the criteria for a substance use disorder) generally report little interest in treatment. In addition, many do not see marijuana as a particularly harmful drug and report that positive effects of the drug are more likely to occur than negative ones. Thus, it may be important for preventive and intervention approaches to consider motivational factors around decreasing use. Presenting interventions as "check-ups" may help recruit particularly resistant populations who may indeed benefit from intervention. Considering the stages of change model, which suggests individual's cycle through a series of motivation stages when considering behavior change, helping to motivate college students to reach higher levels of change readiness (e.g. moving individuals from contemplation into action) using MET techniques may help prepare them for lasting behavior change. As shown in the only published marijuana intervention with college students, those with greater readiness to change behavior responded best to the online intervention. "Check-up" models with brief motivational components may assist college students to begin exploring their decisions and ambivalence regarding marijuana use.

Efficacious Interventions Targeting Treatment-Seeking Adults

Despite the prevalence of marijuana use throughout the world, there are limited interventions solely targeting cannabis dependence and cannabis abuse among adults. Interventions for marijuana are even more important, as recent research has demonstrated the physical withdrawal effects of marijuana, thereby refuting the claim that marijuana has no physiological addiction risk. Although continued research is warranted, efficacious interventions do exist and show promise; of particular interest are behavioral interventions based on MET, cognitive-behavioral skills training, and contingency management.

MET, COGNITIVE-BEHAVIORAL SKILLS TRAINING, AND CONTINGENCY MANAGEMENT

Randomized control trials of MET have been efficacious in reducing marijuana use among treatmentseeking adults. Although studies have supported both short- and long-term MET interventions, these interventions appear to work best when combined with cognitive-behavioral skills training.

Cognitive-behavioral skills training interventions based on relapse prevention ideals have also shown some promise with marijuana-using adults. These interventions generally help individuals to recognize triggers for use and to learn and practice coping skills for dealing with risky situations (e.g. going for a walk instead of marijuana when stressed). Interestingly, researchers have documented equivalent success between a 28-h, 14-session support group and a 3-h, 2-session MET in targeting abstinence from marijuana. Also, researchers have found a relapse prevention intervention to successfully support abstinence rates comparably to a support group with minimal didactic training. Contingency management interventions, in which participants receive vouchers for cash or prizes in increasing value the longer they remain abstinent, have also been shown to be efficacious alone, but appear to support longer term abstinence rates when coupled with both MET and relapse prevention approaches.

These studies suggest that a combination of the three approaches (MET, cognitive-behavioral skills training, and contingency management) may lead to more sustained abstinence. As contingency management predicted better abstinence rates initially, perhaps these approaches are more successful in helping individuals enter treatment and begin working toward goals (i.e. tangible rewards), while MET and relapse prevention components help build motivation for lasting change while individuals learn skills for coping with risky situations once the contingencies diminish. When working with students, perhaps it may be helpful to offer some form of incentive for entering treatment, particularly since so few students seek treatment for marijuana use. Perhaps advertising and offering treatment as "a check-up," as in treatment studies successfully recruiting adolescent marijuana users and adult drinkers, may help spark student interest in exploring personal use. Once students are available and interested, using MET may help build motivation to further explore their choices around marijuana use. Indeed, even singlesession interventions utilizing MI have the potential to reduce both established patterns of use and future intentions to continually abuse marijuana.

Will What Works for Preventing College Alcohol Abuse Work for Marijuana?

In an effort to design efficacious interventions to prevent marijuana use and resultant negative consequences with college students, it may be helpful to consult the vast literature on alcohol use interventions with college student drinking. Examining the successful components of these interventions and empirically investigating if these components will translate across substances may be helpful in the prevention effort. These components include utilizing motivational enhancement techniques, discussing personal reasons for use, correcting misperceived norms of peer behavior, challenging expectancies, discussing marijuana's impact on mood and anxiety, and providing psychoeducation about physiological effects.

MOTIVATIONAL ENHANCEMENT TECHNIQUES

In alcohol research, the most efficacious alcohol interventions with college students have come from a harm reduction standpoint. Harm reduction approaches state abstinence as an ultimate goal, but any reductions in use are seen as important steps toward reducing harms from substance use. As stated previously, these harm reduction approaches utilize the style and techniques of MI, a client-centered approach to help individuals change behavior by exploring ambivalence, reducing resistance, and supporting self-efficacy through the expression of empathy and reflective listening. Reviews of alcohol interventions with college students have cited MI-based interventions as the most efficacious in reducing and preventing heavy and risky drinking behavior.

BRIEF ALCOHOL SCREENING AND INTERVENTION FOR COLLEGE STUDENTS BASICS has been recognized by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) as an empirically based effective intervention for college student drinkers. The program, based within a harm reduction framework, combines an MI approach with cognitive-behavioral skills training in a two-session, one-on-one intervention with personalized feedback tailored to the individual's needs and interests. There is strong research evidence supporting BASICS in individual and modified group formats. Thus, modifying the components of BASICS intervention and adapting them to target marijuana use may be an important first step in addressing marijuana use among college students.

Before applying or extending interventions such as BASICS to other substances, it is important to examine the mechanisms behind each component of these interventions to determine whether marijuana use would be similarly impacted. The following includes a review of the components included in alcohol interventions that may be translatable to marijuana. In more cases than not, more research is needed to determine whether what works for reducing college alcohol use will also help reduce college marijuana use. While in reviewing the research below we may suggest ideas that may be helpful when working with students, clinicians and other individuals working with students are cautioned against using any practice that does not have empirical support as an efficacious treatment technique.

DISCUSSING PERSONAL REASONS FOR USE

Motivational models of substance use suggest that behavior is motivated by different reasons (e.g., social enhancement and affect regulation), leading to theoretically distinct behaviors that are important for understanding the context and circumstances of marijuana use. Until recently, research examining motivations for marijuana use has been based on measures designed for alcohol use. Research highlighting differences in the nature of alcohol and marijuana use motives supports the need for marijuana-specific research. Recently, 12 unique motives related to marijuana have been identified based on college students' self-reported reasons for using marijuana. There are several reasons why a student may use marijuana, and these motives differ depending on context. This research also highlights differences in motives across substances. Among a large sample of incoming first-year college students, several motives for marijuana use were identified, including the perception of marijuana being a low-risk substance, enjoyment, assistance with sleep, altered perceptions, relief of boredom, celebration, coping, relief of social anxiety, availability of marijuana, conformity, alcohol-related reasons, and experimentation. More specific results indicate that when controlling for other reasons, enjoyment, boredom, altered perceptions, relative low risk, and sleep were uniquely related to more marijuana use among college students, whereas experimentation and availability were uniquely related to less use.

Focusing on the different reasons students have for using marijuana may be helpful in carrying out college student interventions. That is, helping students to understand their personal reasons for using may be helpful as they gain more insight into their patterns of use. For example, a student may not recognize that they only smoke marijuana when in social situations. Combining the MET approach with cognitive-behavioral skills training can help others understand how their reasons for use may be particularly more harmful than they think (e.g. using marijuana to sleep

and learning that cannabis disrupts the rapid eye movement (REM) sleep cycle).

CORRECTING MISPERCEIVED NORMS OF PEER BEHAVIOR

Given that college students are representatives of the "Emerging Adult" population, a developmental period that focuses on peer acceptance and fitting in, it has been theorized and empirically supported that students' own alcohol use is impacted by how they perceive their peers' drinking behavior. Targeting alcohol use specifically, efficacious interventions have been designed both within multicomponent interventions and as stand-alone personalized normative feedback presentations.

MISPERCEPTIONS OF **MARIJUANA USE** NORMS Perceptions of marijuana use, however, may function differently than those of alcohol in the college environment. There are clear misperceptions of the prevalence of marijuana use (or "descriptive" norms). Studies document that less than 10% of students accurately estimated that the average student does not use marijuana. One study indicated that although 67% of students never used marijuana (and, therefore, "students in general" typically do not use), 98% of students perceived "students in general" to use at least once per year. Additional research suggests that there are more pronounced misperceptions about the prevalence of marijuana use among those who use marijuana than among nonusers. Research indicates that perception of the use of one's friends and of students in general is associated with one's own frequency of use, and that these perceptions are also predictors of drug-related consequences. However, the relationship between "injunctive" norms (e.g. how acceptable you think typical students feel about using marijuana often) and behavior is less clear. The few studies that have looked at injunctive norms have found that these perceived attitudes have generally been associated with actual marijuana use to a lower degree than perceived descriptive norms (i.e. behaviors). Among a sample of Australian university students, cannabis users perceived higher approval of their use among close friends, siblings, parents, and workmates compared to those students who didn't use cannabis. Those with beliefs that marijuana use was both deviant (i.e. low descriptive) and undesirable (i.e. low injunctive) reported the greatest degree of abstinence. These findings suggest that beliefs that others use infrequently and that others would be disapproving of such behavior may influence one's decision to abstain from the behavior.

Although there is some evidence to suggest that perceived descriptive and injunctive norms are influential components of use in college students, the research is nascent and the connection between perceptions and actual behavior is not as fully understood as it is in the alcohol literature. Theorists assert that for individuals who smoke marijuana more than occasionally, being a marijuana smoker may be an integral part of their self-identity. They may view their behavior as deviant and yet choose to engage in the behavior despite knowing that others may be less accepting of the behavior. Since social norms interventions are based on the idea that individuals care about what peers think about their behavior, marijuana users who perceive themselves as different from the general student population may not be influenced to use less if they learn they are in the minority. Thus, while some evidence supports the utility of targeting misperceived peer norms during preventive interventions with college students, there is not enough available research to suggest that perceived norms have the great influence over behavior as they do for alcohol use.

WILL NORMS INTERVENTIONS WORK FOR MARI-**IUANA USERS?** More research is needed to examine how presenting students with information to challenge their beliefs about perceived peer norms can be helpful in preventing or reducing marijuana use. Studies show that incoming first-year college students already have skewed misperceptions about marijuana use on campus. This suggests the potential benefit of efforts to correct misperceived norms immediately upon entering college or perhaps during late adolescence. It is possible that selective studies (e.g. collecting a random sample of data from students and presenting marijuana prevalence rates to students within interventions only) would be one possibility for impacting norms. Given the importance of peer acceptance in young adulthood, learning that approximately 85% of young adults disapprove of daily marijuana use could potentially have an important impact on some students' use. It may be more useful for students to learn about actual norms early on in college (or in high school) before they initiate stable patterns of use that may lead to their identifying with others with similar patterns.

CHALLENGING EXPECTANCIES

Individuals may expect marijuana and other drugs to have a particular effect on their behavior, mood, cognitions, or affect. In alcohol research with college students and young adults, challenging expectancies about the positive and negative effects of drinking behavior through experimental manipulations has had some short-term success in reducing drinking rates. These "placebo studies" use a 2×2 balanced design whereby some students are told they are drinking alcohol but are actually consuming nonalcoholic drinks. Participants in these studies believe and act as if they had actually consumed alcohol.

MARIJUANA-USE EXPECTANCIES Young adults also have expectancies regarding the positive and negative effects of marijuana. Studies have shown that young adults who reported primary use of marijuana (compared to primary users of alcohol or primary user of stimulants) expected marijuana to lead to less negative effects (e.g. cognitive and behavioral impairment) and more positive effects (e.g. relaxation and tension reduction). Additional studies have found a link between relaxation/tension reduction expectancies and frequency of use among college students, as well as between general positive expectancies (e.g. social and sexual facilitation, enhancement) and use.

Using a balanced placebo design, researchers recruited 20 college students to pilot-test the experimental manipulation of expectancies for marijuana. All participants who were told they had smoked marijuana but in actuality received a placebo reported a belief that they had smoked marijuana. Rates of satisfaction were impacted by what students expected (i.e. overall, those who were told they were using marijuana reported greater satisfaction) and what they received (i.e. overall, those who received marijuana reported greater satisfaction), with no significant interactions. This study demonstrated that experimental manipulation with marijuana is possible, and suggested that additional research is needed to explore ways in which such expectancy challenges could be used.

MARIJUANA'S IMPACT ON MOOD AND ANXIETY

Using marijuana to cope with stress has been linked to greater marijuana use, and more frequent users report more depressive and anxiety symptoms than occasional users. Social anxiety was revealed to serve as a risk factor for marijuana dependence even when controlling for other Axis I disorders. Additionally, social anxiety has been linked to the experience of marijuana-related problems among undergraduate users - a finding that was mediated by reasons for using marijuana related to coping with negative affect. These studies indicate that social anxiety may have more of an association with marijuana use problems than actual frequency of use. This finding suggests that students using as a way to connect with peers are struggling to avoid problems from their behavior – perhaps due to the findings that negative expectancies (impairment and global negative) functioned as a mediator for the relationship between social anxiety and marijuana use problems.

Although research supports a clear connection between marijuana use and anxiety, it is still unclear whether more anxiety leads one to use marijuana or if using marijuana leads one to develop anxiety. Multiple physiological studies indicate that use of marijuana can induce panic-like anxiety symptoms. Researchers have observed that more frequent marijuana users with high anxiety sensitivity experienced increased general anxiety symptoms, while marijuana users with greater anxiety sensitivity reported more catastrophic thinking (e.g. I may go crazy, I may act foolish) than nonusers with similar high levels of anxiety sensitivity. Examining a large community sample of adults, researchers found a predictive relationship between cannabis dependence and panic attacks. With regard to symptoms of panic specifically (e.g. increased heart rate, hyperventilation, feelings of unreality), one hypothesis is that once someone experiences the anxiety sensitivity resulting from marijuana intoxication they may begin to notice subtle changes in their physiology (e.g. breathing, heart rates) and believe that these changes are precipitating a panic attack.

It is likely important to target negative mood states during preventive interventions with college students. For social anxiety, students may learn how to connect with new peers through the use of marijuana. Teaching social skills and developing a plan for engaging their peer environment without the use of substances may be an important topic to discuss with students. Those with higher levels of panic disorder can be helped to understand that marijuana use may perpetuate the fear cycle of perceived threatening bodily sensations. That is, it may be important to help students with panic symptoms to realize that using marijuana only exacerbates the anxiety symptoms they may experience. In addition, if students are using regularly to reduce incidences of depressed mood or anxious effect, a discussion about the negatively reinforcing power of marijuana may be important. As in Relapse Prevention approaches, helping students develop alternative activities and behaviors to engage in when feeling stressed, down, or anxious may be a helpful component of prevention approaches.

PROVIDING PSYCHOEDUCATION ABOUT PHYSIOLOGICAL EFFECTS

A range of consequences associated with marijuana use could be relevant to a college student considering the impact of use. While a positive association exists between marijuana use and negative consequences, students who smoke marijuana may not think this behavior poses any significant risk. Thus, consistent with a motivational enhancement theoretical framework, presenting students with one-sided information about the harmful effects of marijuana will likely not lead to changes in use. In alcohol intervention research, information-only approaches are typically ineffective, and a healthy balance of didactic and motivational components (e.g. BASICS) appears to be the most effective.

IMPORTANCE OF OBJECTIVE PRESENTATION OF EFFECTS When discussing the effects of marijuana use with college students during interventions, presenting them with information straight from the federal government (e.g. National Institute on Drug Abuse (NIDA)) may be dismissed by students or may be perceived as one-sided or as a scare tactic. Thus, while the information presented in such reports is accurate, clear, and accessible, students may dismiss the information if presented without a motivational enhancement framework. Conversely, referring students pro-marijuana websites with one-sided information about the health benefits of marijuana will likely strengthen their belief that marijuana is a harmless drug. Therefore, presenting students with an objective review of the research evidence on physiological effects may help reduce resistance. For example, there are objective books presenting marijuana research on memory, learning, and cognitive effects in three categories representing tasks that are probably unaffected by marijuana use, possibly affected by use, and probably affected by use. Objective sources such as this may be helpful references to distribute to students if they are interested in learning more about the effects of marijuana.

Perhaps the most objective way to discuss the effects of marijuana with students is to review the source of the scientific research. That is, students can review with counselors relevant research literature targeting the effects the student may find particularly interesting. Rather than teaching students about the effects of marijuana that they may care little about, counselors can find out what information students would like more about and refer them to relevant sources for objective materials regarding one's specific interests. Suppose through the course of a discussion with a user that the student mentions having recently noticed some impairment in his memory. In MI style, the counselor could ask the student if he would be interested in learning about some of the effects of marijuana and memory and collaboratively find and critique research evidence discussing these effects.

CHALLENGES

Study and prevention of marijuana abuse poses several challenges. Related to research on marijuana use and consequences, continued development of assessment tools and measures is indicated. A particular challenge involves assessment of quantity of use; unlike alcohol, in which standard drinks can be defined, the numerous ways in which marijuana can be used (and the inability to confirm potency on the part of the person using the substance) lead to many assessments focusing

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on frequency only. Additionally, any concerns students might have about the confidentiality or intent of a screening or study, combined with existing possible limitations to self-report data, contribute to research challenges.

College and university administrators may be concerned that directing resources or attention toward marijuana in some way suggests that there may be a "problem" at the institution. However, with rates of past year marijuana use exceeding rates of past year tobacco cigarette use, it is evident that some response is warranted. Although clearly misperceptions surround the prevalence of marijuana use, there are less clear guidelines as to how to correct and address these misperceptions effectively across campus. The social norms mass media campaigns that continue to be evaluated for impacting alcohol perceptions would likely not work in the same way for marijuana. Instead of acknowledging that "most" students abstain or use moderately, the message with marijuana could exclusively be a focus on those who abstain compared to those who use. However, colleges would be documenting, quite publicly, prevalence of a Schedule I illicit drug, which could have implications for liability, funding, and public perception. Finally, in view of marijuana's illicit status, there may be challenges for adoption of prevention or intervention efforts that focus on reducing the risks or harm for those who do choose to use marijuana. Clearly, additional research is indicated to help overcome these challenges and to advance understanding of addictive behaviors, especially marijuana use and abuse.

CONCLUSION

Many of the efficacious treatments and techniques used to target marijuana use among adolescents and treatment-seeking adults may be translatable to the college population. However, further research is needed to determine whether empirically supported multicomponent interventions for alcohol abuse (e.g. BASICS) will work just as well for marijuana use. Although some of the empirically supported techniques used to reduce risky drinking behavior among college students could possibly be adapted to target marijuana use, research is needed to examine the specific components that may help prevent risk for a different substance. The reviewed literature suggests that exploring students' personal motives/reasons for using marijuana, correcting their perceptions about what others around them think and do regarding use, challenging their expectancies about what effects they believe will result from use, exploring the mood and affective components related to use, and helping them

understand the physiological effects and consequences resulting from use may assist in the prevention effort. Research can identify and determine whether multicomponent interventions can effectively reduce use or whether single-component interventions (e.g. expectancy challenges) are successful within this population. Furthermore, utilizing interventions based in efficacious MET, release prevention, harm reduction, and contingency management ideals should be examined within the college population.

SEE ALSO

Medications for Treatment of Marijuana Dependence

List of Abbreviations

BASICS Brief Alcohol Screening and Intervention for College

Students

MET motivational enhancement therapy

MI motivational interviewing PFR personal feedback report TMCU Teen Marijuana Check-Up

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Performance-Enhancing Drug Use (Including Anabolic Steroids) by Adolescents and College Students: Etiology and Prevention

Jack Darkes*, Rick Collins^{\$}, Jason Cohen**, Daniel Gwartney[§]
*University of South Florida, Tampa, FL, USA ^{\$}Collins, McDonald & Gann, PC, Mineola, NY, USA
**Private Practice, San Luis Obispo, CA, USA [§]Private Practice, Columbia, MO, USA

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INTRODUCTION

The transition through adolescence into young adulthood involves rapid biological, psychological, and social changes, setting the stage for adult physical, psychological, and social function. This transition also provides the context in which secondary and postsecondary student drug use, specifically, performance-enhancing drug (PED) use, is embedded. During this period, adolescents and young adults exhibit increased susceptibility to peer influence and adult (nonparental) role models as they establish their identity in relation to the world around them. Concerns regarding adolescent and college student PED use emerge not only from these developmental tasks and vulnerabilities, but also the potential for exogenous hormonal PEDs, most notably anabolic-androgenic steroids (AAS), to disrupt brain development with long-term repercussions. Tragedies associated with the use of PEDs and public condemnation of high-profile athletic role models who have allegedly used PEDs to "cheat" in sports have also been focused attention on PED (mostly AAS) use. To understand and address PED use during this stage requires an examination of its context, prevalence, and consequences.

THE SOCIAL CONTEXT

Society values performance, whether cognitive/ academic, emotional/social, sexual, or athletic/physical. Cognitive/academic performance enhancement, even for normal function, via supplements (e.g. Ginkgo biloba) or drugs (e.g. methylphenidate, modafinil) is generally accepted. Licit (e.g. paroxetine, alcohol) and illicit (e.g. marijuana) drugs modulate emotional/social performance. A profitable industry offering enhanced sexual performance to older adults has also spread to young adults. Surgical and pharmaceutical treatments are used to enhance youthfulness. Beta-blockers are used by musicians to improve audition performance. Performance enhancement strategies are ubiquitous and historically documented transculturally. Despite shared moral/ethical issues, none has achieved the notoriety of PED use; "performance enhancement" is synonymous with athletic/appearance enhancement. PED use is embedded in this sociocultural context, as drugs are used for specific functional purposes.

Appearance/Performance-Enhancing Drugs

PEDs fall within the larger class of performance-enhancing substances (PES) encompassing both dietary supplements (e.g. creatine, protein) and prescription drugs such as hormonal products (e.g. AAS, human growth hormone (HGH)). AAS, which are man-made variations of testosterone, the primary male sex hormone or "androgen," are available in oral, topical, and injectable drug forms. Thus AAS have androgenic (e.g. masculinizing or virilizing) effects as well as anabolic/muscle-building effects. AAS administration over a period of weeks or months increases protein synthesis to build skeletal muscle. HGH is produced in the body by the pituitary gland and is available as an injectable, synthetically produced drug. It is sometimes used concomitantly ("stacked") with AAS.

Among PEDs, hormone abuse presents the greatest potential for harm and AAS have dominated PED research. Dietary supplement use poses less or no risk (beyond issues of purity), but often evokes discussions of the Gateway Hypothesis. That is, supplements (or strength training) might "cause" later AAS marijuana hypothetically provides misuse, as a "gateway" to "hard drugs." Although intuitively appealing, such causation has not been demonstrated. Supplement use or weight training may typically predate AAS use, but a vast majority of weight trainers or supplement users do not subsequently use hormonal PEDs.

PREVALENCE OF PED USE

Understanding the risk and prevention of PED use requires examining prevalence. Concerns over rates of PED use, primarily AAS, emerged in the mid-1980s when high school use was first reported. Population estimates of adolescent AAS usage are routinely obtained via surveys administered in school environments.

Monitoring the Future

The most highly regarded national survey of drug use among young people in the United States is the Monitoring the Future (MTF) study, which annually surveys approximately 50 000 8th, 10th, and 12th grade students. Since 1989 MTF has asked: "Steroids, or anabolic steroids, are sometimes prescribed by doctors to promote healing from certain types of injuries. Some athletes, and others, have used them to try to increase muscle development. On how many occasions (if any) have you taken steroids on your own – that is, without a doctor telling you to take them ...?" (In 2006, the text "to promote healing from certain types of injuries" was changed to "to treat certain conditions".) Although non-AAS PED use is not assessed, MTF provides over two decades of information on prevalence of adolescent steroid use.

Lifetime prevalence of AAS use among all grades peaked about 8–10 years ago in the United States and has generally declined since. Among 8th graders, lifetime use peaked at 3.0% in 2000, declining every year thereafter to a record low of 1.1% in 2010. Among 10th graders, it declined consistently from a high of 3.5% to an all-time low of 1.3% in 2009 with a slight rebound in 2010 (1.6%). Among 12th graders, the decrease was from a high of 4.0% to a steady 2.2% in 2007 through 2009 and further to 2.0% in 2010. This overall decline in lifetime prevalence belies concerns of a recent

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epidemic; the percentage of 8th–12th grade students who have ever used AAS have fallen by roughly half over the last decade, even with a slight increase in 10th grade lifetime prevalence in 2010 recently.

Youth Risk Behavior Survey

The Centers for Disease Control and Preventions' Youth Risk Behavior Survey (YRBS) monitors healthrisk behaviors among 9th-12th grade students in the United States. However, anomalous AAS prevalence estimates from the YRBS have raised validity concerns. For example, YRBS lifetime prevalence estimate of AAS use among 9th grade girls was 7.3% in 2003, sparking justifiable concern of an epidemic among adolescent girls. However, if valid, a 7.3% lifetime rate among 9th grade girls would, of necessity, yield a similar or greater estimate among 11th grade girls 2 years later (i.e. would reflect the 7.3% of 9th graders (2003), plus initiators in the intervening 2 years). Yet, 2005 lifetime estimates for 11th graders were only 2.8%. Consensus in the literature suggests that lifetime prevalence of AAS use among adolescent females is likely less than 1%.

The 2009 YRBS estimated that 3.3% of students (4.3% of boys and 2.2% of girls) had "taken steroid pills or shots without a doctor's prescription" during their lifetime using a single question that asks "how many times" the respondent has used "steroid pills or shots without a doctor's prescription." The term "anabolic steroid" is not defined or clarified, allowing confusion with corticosteroids or other medicines or even dietary supplements with suggestive "steroidlike" names. Some respondents may even confuse nonsteroidal performance-enhancing supplements (e.g. creatine) with AAS due to media misreporting and misleading advertising copy. Still, despite these concerns, trends in overall YRBS estimates are consistent with MTF trends, showing an approximate 50% decline, from a high of 6.1% overall in 2003 to the current level of 3.3%.

Prevalence of Adolescent Steroid Use Compared to Other Drugs

The most recent (2010) MTF figures reveal that, compared to AAS, three to four times as many 12th graders have used ecstasy (7.3 versus 2.0%), cocaine (5.5 versus 2.0%), or hallucinogens (8.6 versus 2.0%); over 20 times as many have used marijuana/hashish (43.8%). Over 16% of 8th graders reported consuming alcohol to intoxication, and more have used crack (1.5%) and powder cocaine (2.6%) than AAS (1.1%). Such comparisons do not mitigate concerns over teen

AAS misuse, but provide a reference for interpreting the prevalence of AAS use and potential for relative harm

Use of Nondrug PESs

In 2005, data from the Growing Up Today Study were analyzed to examine the use of AAS and non-AAS PESs including dietary supplements. Boys (n = 4237) and girls (n = 6212), 12–18 years of age, reported their use of protein powder/shakes, creatine, amino acids, dehydroepiandrosterone (DHEA, an adrenal androgen), HGH, or anabolic/injectable steroids to improve appearance, muscle mass, or strength. While 12.3% of boys and 8.4% of girls had used at least one product in the past year, fewer (4.7 and 1.6%, respectively) used them weekly, suggesting use was not consistent across the year. The most popular products were protein powder/shakes; 10.2% of boys and 8% of girls had used them in the past year, while 3.4 and 1.4%, respectively, used them weekly. Creatine was used by 4.3% of boys during the past year, but only 0.4% of girls. Use of hormonal PEDs was very low: Only 0.7% of boys and 0.2% of girls used DHEA, HGH, or AAS in the past year.

Summarizing Adolescent Prevalence

Adolescent AAS use is rare, both overall and compared to vast majority of other illicit drugs, and has largely and consistently declined over the past decade. Use of nondrug PESs, while more common, is also a low base rate phenomenon. Although a major concern, adolescent AAS use has shown an encouraging decline in recent years.

Prevalence among College Students

Many studies of prevalence among college students reflect specific campuses or geographical locales, which may not generalize to the wider population, and single point estimates that preclude an examination of trends. However, national college data suggested that nonmedical use of AAS was rare (lifetime prevalence <1%) and fairly stable during the 1990s. Approximately 2% of males and 0.2% of females reported lifetime use. As with adolescents, AAS use prevalence was lower than rates for nonmedical use of other drug classes. Interestingly, the overall estimate (<1%) is lower than MTF lifetime estimates for 12th graders, although this sample excludes high school students not matriculating. Collegiate athletes' use was slightly higher (1.4% in 2001) but had declined from 4.9% in 1989.

ETIOLOGICAL CONSIDERATIONS

Risk Factors

The pathway to PED use is complex and the literature on risk for PED (most often AAS) use relies mostly on case studies, convenience samples, and cross-sectional methods that fall short of explaining etiology. This section briefly reviews factors *associated* with AAS use among adolescents and college students. The true utility of this work lies in mitigation of harm via identifying risk and building protective factors.

Gender

Predictably, males are two to six times more likely to use AAS than females. Females are more likely to use fatburning PEDs than AAS, although males may be more likely to use both. Although female AAS use is rare it poses even greater risks due to possible masculinization.

Sports

Although the efficacy of some PEDs has been questioned, AAS' muscle-building properties are well-documented. Consequently, adolescents and young adults involved in strength-dependent sports, where muscle and strength are desirable, are at higher risk for use. It is crucial to note that this does not mean nonathletes are not also at risk.

Peer Influence

Those offered AAS or associated with AAS users exhibit greater risk, although not all such instances need result from pressure; some adolescents may seek out such associations. Hence, indirect pressure may be felt when aspiring athletes are exposed to or competing against peers with superior natural abilities or who are using AAS. Further, pressure may be implicitly or explicitly exerted via questioning one's dedication to a team if they fail to "do whatever it takes" to win. Each possibility may lead to active drug-seeking.

Social Pressures

Parents, coaches, and communities place considerable pressure on athletes to perform, even at younger ages. Culture imparts early lessons on success, whether actively, via parental expectations, or subtly, through exposure of young males and females to unrealistic images (e.g. anorectic models, action figures, cartoons) that affect body image and risk for PED use. Considering also the need for success, approval, recognition of achievements during this period, the popular exhortation to "be all you can be" taps into this desire to excel, or self-actualize. To fulfill this desire western cultures have, in many areas of performance, subscribed to "better living through chemistry" and these messages

are not lost on young adults, who, while potentially ambivalent regarding use, may value short-term success over nuanced moral arguments and distal and uncertain negative social or physical outcomes.

Media

Broad exposure to scandals involving seemingly healthy elite professional athletes may normalize, if not justify, PED/AAS use. Media coverage often contains mixed messages, highlighting PED use as physically harmful and morally aberrant, yet normative and seemingly accepted among successful and fit athletes. Thus, young adults may come to overestimate the likelihood of use and positive outcomes among both models and peers.

Prior Use of Dietary Supplements

Supplement users are more likely to endorse intentions to use AAS and, as noted above, supplement use may precede AAS use. However, intentions only marginally predict future use and although supplement use does not cause later AAS use, it may increase or co-occur with exposure to activities (e.g. weight training in gyms) and associations with users, thus increasing risk and signal the appropriateness of increased vigilance for signs of emerging PED use. Another important consideration is the possibility of mislabeled or poorly manufactured supplements.

Individual Characteristics

Signs of risk for adolescent/college student drug use, such as increased risk taking and low harm avoidance, low self-esteem, high self-monitoring or poor academic performance, are also associated with AAS use. These individual characteristics predict a wide range of risky behaviors and, rather than specific risk indicators, may, in combination with more AAS-specific indicators (e.g. weight training, body image concerns) suggest further assessment and monitoring.

Summary

The above factors indicate risk, but are not etiological in nature; they are not perfect predictors and their sensitivity and specificity have not been definitively determined. For example, sport participation is associated with AAS use. However, more than 50% of high school students play sports while current lifetime AAS use among 12th graders is 2%. Perhaps up to 1/3 of adolescent AAS users are not playing organized sports, but engage in weightlifting. Other processes are also involved.

Reasons for Use

Desire for enhanced performance can be alarming; as many as 15% of 12th grade males expressed willingness to take a supplement that would promote their fitness goals even if it harmed their health; >8% would take it even if it would shorten their life span. Although this may baffle adults, it typifies many young adults' "here and now" thinking and reflects societal trends toward the use of drugs with potential aversive outcomes as a means for meeting ever-growing demands and accruing more proximal or salient payoffs. These reasons, motivations, or expectancies (anticipated effects) for PED use have etiological implications, suggesting a pathway from risk to use. The rewards for sports excellence or physical attractiveness may be highly valued and PEDs may represent a means that is anticipated to achieve them.

Adolescents and young adults consistently list increased muscle mass and strength as major reasons for using AAS, reflecting AAS' true effects and the perception of their functional use by aspiring athletes. However, aesthetics and appearance are also primary reasons; muscularity motivates the nonathlete as well. Given the developmental tasks of identity formation and the establishment of social position, the desire for improved physical performance, appearance of health, and increased stature is clear; lean muscle and body size signal dominance and social status.

Expectations for desirable outcomes from alcohol predict both initiation and levels/style of drinking (and can inform prevention). Adolescents' AAS expectancies remain uninvestigated, but are clearly reflected in the reasons cited (appearance/athletic improvement). Positive expectations predict college students' AAS use and negative expectancies appear protective. College-aged users expect positive psychological effects (e.g. assertiveness, confidence, positive outlook, and enhanced sexuality) as compared to nonusers. The effects of these expectations can be seen when young adults have exhibited both increased strength and changes in observed psychological function in response to placebo administration.

Maintaining Factors

Most drugs of abuse have immediate primary reinforcing effects i.e. they are naturally/biologically reinforcing. Secondary reinforcers function via association with specific reinforcing stimuli, such as praise from a boss that predicts a raise. Of course, money is not inherently reinforcing, but is a generalized reinforcer; it allows access to (is associated with) a broad range of reinforcing stimuli. Although most drugs of abuse are primary and secondary/generalized reinforcers, abuse/dependence potential is most often attributed to primary processes. This distinction is crucial to understand AAS use.

Evidence of AAS' primary reinforcing properties derives from animal models. Laboratory animals learn to prefer contexts in which AAS are administered and will, to varying degrees, self-administer AAS/testosterone via oral, intravenous (IV; into a vein) and intracerebroventricular (ICV; i.e. injected into the ventricles of the brain) routes. Reinforcement from AAS appears similar to mild drugs such as nicotine, caffeine, and benzodiazapines (a Schedule IV drug; AAS are listed under Schedule III), and significantly lower than highly addictive drugs (e.g. heroin, cocaine).

Experiments using animal models often do not mimic real world human use. For instance, humans do not selfadminister AAS through IV and ICV routes and most use considerably lower dosages over substantially shorter percentages of their lives compared to animal experiments using high-dose regimens that may extend across the full pubertal period. Furthermore, the processes underlying a pleasurable neural response to AAS have yet to be definitively identified, although dopaminergic pathways, which modulate most reward learning, have been implicated. Of course, AAS reinforcement may not result from psychoactive effects, but rather from somatic (e.g. quicker recovery time, reduced fatigue) enhancement. This highlights another difference between human use and animal models; unlike research animals, humans use AAS in pursuit of goals.

Human participants consistently deny a "rush" or "high" from AAS. This makes sense that given standard modes of administration; intramuscular (IM; into the muscle) and oral ingestion offer slowed absorption/ onset. Most commonly IM-injected AAS release into the body over a period of days. Those psychoactive drugs that are considered the most addictive employ routes of administration (e.g. IV, inhalation) and formulations that rapidly reach peak plasma levels (within seconds/ minutes). Humans endorse using AAS to improve appearance, strength and size, not for an immediate high. Such findings suggest that AAS are best viewed as secondary or generalized reinforcers; the reinforcement derived from AAS is most likely indirect - they are reinforcing as a means toward status, recognition, or reward.

Negative reinforcement (escape from or avoidance of noxious stimuli) also serves to maintain use. Drug use disrupts the body's homeostatic processes and, upon cessation, can create a state of withdrawal. To ameliorate this condition, many readminister the abused drug or one with similar properties. For instance, nicotine addiction is based less on gratification than amelioration of cravings. After weeks of AAS use, the body's natural production of testosterone is reduced and the unpleasant cognitive, emotive, and/or vegetative effects that emerge upon cessation may motivate readministration to alleviate symptoms. Many AAS users prepare for this "postcycle crash" which is discussed later.

CONSEQUENCES OF PED USE IN ADOLESCENTS AND YOUNG ADULTS

If the complete pharmacopeia is considered, a broad range of potential adverse events is associated with PED use. Although many PEDs garner little attention with regard to prevalence or risk, medical knowledge of their effects can inform a discussion of potential adverse events. It is unfortunate that, as AAS-associated adverse events have garnered the greatest attention due to editorial and political concerns, attention and resources may have been diverted from other PED-related issues (e.g. stimulants for weight loss, sustained attention and wakefulness, beta-blockers for anxiety management).

Most pharmaceutical PEDs are therapeutic medicines when used in the proper population at the recommended dose. Their effects follow a dose–response curve; greater effects emerge as the dose increases. Adverse effects are also dose dependent, particularly in hormone-based PEDs, although problems can also appear with doses that might be considered therapeutic in clinical settings; therapeutic effects of hormones may be considered adverse (e.g. virilization of females, premature closure of growth plates limiting skeletal growth) when used in a contraindicated manner.

Adolescence is a period of fluctuating sex steroid hormones and male pubertal changes may mirror some adverse drug effects. Excessive androgens can result in adverse levels of estrogen. For example, supraphysiologic (levels beyond physiological normal) dosages of AAS are associated with gynecomastia (the growth of glandular breast tissue in males) in adult men, due to conversion of androgens to estrogens via the enzyme aromatase. Similarly, pubertal gynecomastia can emerge in teenaged boys experiencing periodic surges in testosterone. Non-PED drugs also can induce gynecomastia, including certain antidepressants, and must be ruled out when evaluating cases of gynecomastia as adolescent antidepressant use is not uncommon.

Beta-adrenergic stimulants mimic the effects of adrenalin. As PEDs, they reduce fatigue, increase contractile force (strength), and quicken response; they are often a component of weight loss drugs. In excess, beta-adrenergic drugs can induce tachycardia (fast heart rate), tremors, irritability, and elevated body temperature. Deaths associated with ephedrine–caffeine product abuse/misuse caused the withdrawal of several effective over-the-counter (OTC) weight loss products in the United States, although the combination has been shown safe and effective when offered as a prescription medication or used in specified doses and timing. Many "energy" drinks are also often high in caffeine and other stimulants. As stimulant nutritional supplements, certain OTC medicines, and certain asthma medications may be accessible to

teens and young adults, it is nearly impossible to prevent exposure to this class of PED. Thus, it is vital that the signs of stimulant toxicity above be noted and medical attention sought if warranted. Further, stimulant PEDs are used recreationally, for weight loss, to counter sleep deprivation, and socially, expanding concerns beyond sports or performance use. Stimulant-induced deaths are typically cardiac in nature, and thus immediate.

AAS are the most commonly detected and reported PED at all levels of sport. Testosterone is an androgen, and a precursor to dihydrotestosterone (DHT; a potent androgen responsible for changes in secondary sexual features) and estradiol (the primary estrogen in males and females). Excesses in testosterone can therefore result in adverse changes from elevations in DHT and/or estradiol. Elevated testosterone and DHT can produce features in females that can be considered disfiguring (clitoral enlargement and deepening of the voice) and persist beyond cessation of AAS use. Endocrine disruption of the hypothalamic-pituitary-ovarian axis can result in amenorrhea (absence of menses). Facial hair growth, breast atrophy, and acne are the transient changes with significant potential impact on a young woman's selfesteem and social acceptance. If AAS are used during pregnancy, the potential for ambiguous genitalia in the fetus exists. Alterations in physiology or psychology resulting from in utero exposure to elevated maternal androgens or estrogens are suggested by certain animal data.

Elevated androgen presence can also affect male adolescents, inducing early puberty, and acceleration of progress through the stages of secondary sexual development, severe acne, as well as increased impulsiveness and aggression. Some animal models have administered large doses of testosterone across the full pubertal period and observed behavioral effects (e.g. aggression) that persisted even after the drug administration has been ceased. Abnormally elevated hormone levels at this critical time might disrupt brain organization and have lasting effects, although, as noted above, extrapolation to human use requires caution.

Estrogen excess is more of a factor for male AAS users, although premature closure of growth plates in the long bones can limit linear growth (height) in both sexes. Males can experience gynecomastia, as previously mentioned; water retention, adipose accumulation, and mood alteration can also be attributed to estradiol excess. Both DHT and estradiol can suppress natural testosterone production, leading to testicular atrophy and delayed restoration of normal gonadal function; rare cases of chronic hypogonadism (diminished gonadal hormone production) and infertility in adult male AAS users have been reported. This has implications for both continued use (as noted above) and treatment (noted below).

AAS can affect the structure/function of the liver. Oral AAS are particularly harmful due to chemical

modification called 17-alpha alkylation that allows the drug to be effective when ingested orally (otherwise it is "deactivated" by the liver). Prolonged or excessive exposure is associated with benign and malignant tumors of the liver, as well as signs of organ dysfunction and cellular stress (e.g. elevated liver enzymes, cholestasis – disrupted flow of bile from the liver). Interestingly, liver toxicity of oral agents is the main reason why AAS users prefer IM injection. However, any mode of administration which involves injection (IV or IM) has the risk of blood-borne or injection-site infections, although this is rare. Needle and multiuse vial sharing between AAS users is relatively uncommon and therefore, even though IM use has the potential for such transmission, it, in reality, poses little risk for this.

The lipid profile is a minor risk factor used in calculating vascular health including fractions of cholesterol and triglycerides. Certain AAS are associated with deleterious changes in (good) high-density lipoprotein (HDL)-cholesterol, though some reports have shown improvements with testosterone use in hypogonadal (abnormally low testosterone) adult males. The changes seen during AAS use appear to be transient, returning to baseline within weeks, making it difficult to determine the long-term harm that may follow limited AAS use. The heart is a muscle, but dissimilar to skeletal muscle in many ways. Nonetheless, it responds to AAS, augmenting the tissue-building effect of exercise on ventricular wall thickness.

The range of adverse effects highlighted within drug education programs demonstrate the diverse spectrum of tissue types affected by AAS. Although considered to be a two-dimensional hormone, affecting muscle and sexual features, testosterone and related AAS can affect nearly every tissue in the body, from classic changes, including those described above, to more covert changes rarely considered in young persons (e.g. elevated red blood cell volume, male pattern balding). Due to the wide range of PED-associated adverse effects, it is important to obtain a full and honest patient history when presented with a possible case. Due to social and legal repercussions, this is best handled in a nonjudgmental atmosphere during a medical or mental health encounter, treating the revelations as privileged communication. This can be accompanied by complex issues associated with privacy and confidentiality when working with minor children.

TREATMENT AND PREVENTION OF PED USE

Heightened awareness of the signs of risk or early onset of consequences can facilitate early detection of individual use. However, some signs of PED misuse/ abuse are less familiar or more subtler, making it vital that athletic trainers, nurses, and team physicians aid in monitoring for emergence of risk. Clearly, adolescents should be educated on the proper use of supplements and the potential problems associated with tainted or mislabeled supplements, and both parental and regulatory agency monitoring is appropriate. Given identification of use or risk for use, especially of AAS, concern shifts toward treatment (safe termination of use) and prevention (primary and secondary) strategies for AAS.

Treatment

The dependence-producing potential of AAS is a matter of ongoing investigation. Although the Diagnostic and Statistical Manual (DSM) allows diagnosis under "other substance dependence," the International Classification of Diseases considers AAS as "nondependence producing" (classified similar to the DSM Substance Abuse). The DSM criteria for dependence reflect more immediate psychoactive properties and may not account for, among other things, the cyclic nature of AAS use, including planned alternating periods of use and abstention. AAS use is also absent with the spontaneous loss of control typical of dependence. This disparity partially reflects the distinction between primary versus generalized reinforcement from AAS.

Ultimately, diagnostic considerations are a secondary concern; the suicides of teens and young adults terminating the use of AAS and suggestions that a significant minority of AAS-using adults have difficulty in controlling planned cyclic use have highlighted the need for empirically supported treatments of the desisting AAS user. Unfortunately, little empirical research exists on such treatment and no consensus treatment exists besides abstinence, which has the attendant issues previously noted. Also, such cases will likely be seen by general practitioners who may be ill-prepared to help such a patient; ineffective treatment may even exacerbate symptoms (such as antidepressant treatment which might enhance suicide potential) and adverse events.

As alluded to earlier, AAS are exogenous versions of testosterone and, via myriad feedback mechanisms, their use reduces or halts natural production of testosterone. However, most adult users are embedded in a subculture that has "trained them up" to use various patterns of administration (e.g. cycling on and off AAS, gradually "pyramiding" (escalating doses up to a peak concentration, followed by a taper to termination)) and ancillary drugs (e.g. antiestrogens, aromatase inhibitors) that favorably affect hormone levels and ratios to manage this dysregulation during and after use. Adolescents and younger adults may be less aware of or likely to

rely on such strategies. When AAS use is abruptly halted, the body cannot readily increase testosterone production to compensate, resulting in a period of lower than normal testosterone, which can lead to physical malaise, muscle atrophy and depression, hopelessness, and potential suicide. Hence, treatment may require use of ancillary therapies to ameliorate these deficits and avoidance of treatments that might exacerbate potential negative outcomes, as well as close monitoring for and supportive treatments of emerging depression and suicidal ideation. As opposed to conventional wisdom in the treatment of other drug dependence, it may also involve controlled administration of testosterone analogs. Therefore, treatment of desisting AAS users is both a specialized area of expertise and a matter of great debate and contention, fraught with obstacles.

Prevention

Few empirically tested PED prevention programs exist. Some theory-based proposals incorporate the Transtheoretical (stages of change) model to conceptualize how adolescents and young adults might move toward use, what might be done to reduce their likelihood of use (e.g. early intervention) or, if using, how they might be motivated to cease use (hence requiring treatment). It has also been suggested that ambivalence in the decisional balance for use of PEDs might be capitalized on; attitudes toward PED use versus abstinence are not exclusive. Adolescents may have positive attitudes toward both use and abstinence and, while such ambivalence may enhance susceptibility to risky influences, it may also be useful in promoting behavioral decisions forestalling use. Another crucial factor may be parental education on early indicators of risk and problems; if parents know what to look for, parental monitoring and even intrusiveness can have protective effects against drug use and related problems.

Urinalysis has also been used in deterrence/prevention. Some states (e.g. Florida, Texas) instituted large scale AAS testing in high school athletic programs. However, high costs and rare positive tests have led many to rethink the effort. For instance, 3 years of tests in Texas revealed only 21 positives out of 51 000 tests costing \$7 million. Research on the deterrent effects of urine testing also is less than supportive. The Student Athlete Testing Using Random Notification (SATURN) study found no consistent deterrent effects of random urinalysis, but did observe potential increases in some risk factors for future use (e.g. perception of attitudes of authority figures). Responses to detection may inadvertently support this attitude by removing individual responsibility; blame for detected use is often immediately leveled toward an unethical coach, role model, or dealer. Despite the popular appeal of drug testing, great benefit from it has not resulted and numerous ethical questions remain with regard to the use of mandatory urine testing among high school students.

Perhaps, the most researched program for PED prevention is the Adolescents Training and Learning to Avoid Steroids (ATLAS) program, intended to educate young men on PED use. A similar program, Athletes Targeting Healthy Exercise and Nutrition Alternatives (ATHENA), targets healthy nutrition, exercise, knowledge of drug use and its effects, media education, and depression prevention among young women.

Adolescents Training and Learning to Avoid Steroids

The ATLAS program combines elements of several theories of human behavior change (e.g. social learning theory and the health beliefs model), providing education on sports nutrition and exercise-based alternatives to the use of PEDs, drug-refusal skills, and active participation in the creation of health-promoting messages. Sessions are led by peer educators and facilitated by coaches and strength trainers. Short-term reductions in intentions to use AAS have been reported, although actual use reduction was not significant. Other drug use (including alcohol), drinking and driving, and supplement use declined, while nutritional habits improved. Although prevention research suggests that increases in knowledge rarely predict decreased initiation of drug use, ATLAS appears to affect a number of risk indicators via increased knowledge and perceived severity of AAS effects.

The ATLAS program may capitalize on the ambivalence noted earlier, providing education on alternatives, such as proper nutrition and training strategies, may have a positive effect on acceptance of PED abstinence, while also diminishing positive attitudes toward drug use. To the extent such a procedure can introduce appropriate ways to fulfill the goals inherent in PED use, without unintentionally highlighting potential positive effects of the drugs, beneficial effects might accrue. Nonetheless, efficacy for reducing actual use, as opposed to intentions, remains to be validated. In addition, such programs must be mindful of the fact that there may be few universally negative consequences; what an adult might consider aversive (e.g. anger, aggression) may be a desirable outcome to some adolescent males; additionally, most aversive consequences are distal, while positive outcomes are proximal.

Athletes Targeting Healthy Exercise and Nutrition Alternatives

The ATHENA program addresses young females' disordered eating and use of drugs for body-shaping motives. It is a peer-led program incorporated within normal sports team activities. It has been shown to increase

a wide range of healthy- and safety-oriented behaviors (e.g. use of seat belts) and reduce a number of unhealthy practices (e.g. disordered eating), as well as the intention to use, initiation and ongoing use of PEDs. Many of these changes persisted over periods as long as 3 years.

Other Prevention Targets

Many other possible prevention targets might inform a multimodal approach. Of particular relevance may be motivations for use and expectations of AAS effects. General expectations for positive effects of AAS among college students predict risk; college students who believe they are taking an AAS exhibit strength increases as compared to known inactive placebo and similar effects have been seen for some psychological outcomes. Positive beliefs about the effects of AAS differentiate users from nonusers. Given these findings and the fact that methods for challenging alcohol expectancies have demonstrated utility in reducing alcohol use among college students and risky expectancies among elementary students, procedures that not only increase negative expectations but also decrease risky positive AAS expectancies might be a useful preventive component.

Criminalization

The classification of AAS as controlled substances under federal and nearly all state laws was motivated in large part by concerns over adolescent usage. In 1990, Congress placed AAS in the same legal class (Schedule III) as barbiturates, ketamine, LSD precursors, and narcotic painkillers (e.g. Vicodin), making simple possession without a valid prescription of crime subject to arrest, prosecution, and imprisonment. This "criminalization" of the end user has been a favored US legislative approach to steroid prevention, but some commentators have been critical of this strategy and its militaristic enforcement. For example, reminiscent of alcohol prohibition, one effect of steroid criminalization has been the increased manufacture and distribution of black market products including homemade counterfeits and dubious or even contaminated foreign veterinary products. Further, criminalization may discourage illegal users, including teens, from admitting their steroid usage to physicians, thus exacerbating the physical dangers. It should also be noted that following, and despite, the enactment of the federal criminalization legislation in 1990, lifetime adolescent steroid use generally increased, peaking in 2000-2002 (MTF).

Harm Reduction

Given that, despite attempts to prevent PED use, a small percentage of adolescents and college students continue using them, how might we prevent the harm their use may cause? Although often raised as a viable or even preferred option, and one that has recently made inroads into American culture, harm reduction strategies are often controversial, whether applied to risky sexual behavior (e.g. provision of condoms to prevent spread of sexually transmitted diseases) or IV drug use (e.g. needle exchange programs). Harm reduction is not a substitute for primary or secondary prevention, but an acknowledgment of their partial success. Clearly not an option for younger adolescents, among AAS-using young adults, harm reduction may take the form of needle exchanges as a means to reduce bloodborne infections. In fact, needle exchanges initially established for opiate injectors have served AAS injectors. Concerns that harm reduction approaches will increase risky behavior and drug use have largely been unfounded; conversely, evidence suggests that they significantly reduce negative outcomes. Although this approach, more widely accepted in several other countries, has begun to gain some acceptance in the United States, it has not yet made an impact on AAS treatment wherein moral judgments and legal sanctions of drug use (themselves a potential source of harm) have thus far hindered its adoption.

DISPELLING THE MYTHS OF PED USE

A wide range of substances is used by a minority of adolescents and college students to enhance appearance and performance. Most often they are dietary supplements that have few serious adverse consequences and do not inevitably lead to use of "hardcore" PEDs. This review has focused mostly on AAS, as they are both the most well-researched and notorious of the PEDs. Additionally, their efficacy as appearance/PEDs is settled science. Lastly, tragic teen suicides and tribulations of tarnished sports heroes have pointed the spotlight clearly at AAS. These concerns and suggestions that exogenous androgens may have long-lasting effects on brain development among adolescents, and thus adult behavior across several domains, have justifiably led to increased scrutiny.

It is a positive sign that AAS use is rare and has recently grown rarer among adolescents in general; lifetime prevalence rates are lower than those for other drugs of abuse and have largely and steadily declined over the past decade. Available US data suggest that lifetime prevalence among college students is also relatively low and stable, although more and more recent data would clarify trends. Individual factors associated with AAS use seem to fall into two general categories; those that are general risk indicators for drug use and risky behaviors (e.g. gender, low harm avoidance,

disinhibition) and those that might be more specific to PEDs (e.g. body image concerns, sport participation, PED-using peers). Motivations for use center on the documented effects of these substances; increased muscle and improved body composition.

While most of our knowledge of prevalence and risk for PED use reflects the relative focus on AAS, our understanding of the potential consequences of the range of PEDs is more complete, given an understanding of their physiological effects and the history of most as therapeutics. Although of paramount importance, the literature on treatment and prevention, while it encompasses much speculation, may be the least evolved of all. It is not at all clear precisely what factors underlie the fortuitous decline in AAS use in recent years; perceptions of great risk from use as assessed in MTF do not mirror this trend. Ultimately, an understanding of established risk factors can be applied to foster early monitoring/identification of those in jeopardy for potential harm and knowledge of motivations and maintaining factors can inform our prevention efforts. Still, accepting that perfect prevention of PED misuse is improbable (as it has proven for other drug use), of potentially greater import is the possibility of putting moral considerations and legal sanctions aside in favor of reducing harm among those who use despite our best efforts. This does not suggest tolerance, acceptance, or promotion of use, only recognition that although PED use can never be perfectly prevented, its potentially tragic consequences can often be averted.

List of Abbreviations

AAS anabolic-androgenic steroids

ATHENA Athletes Targeting Healthy Exercise and Nutrition

ATLAS Adolescents Training and Learning to Avoid Steroids

DHEA dehydroepiandrosterone DHT dihydrotestosterone

DSM Diagnostic and Statistical Manual

HGH human growth hormone ICV intracerebroventricular

IM intramuscular IV intravenous

MTF Monitoring the Future OTC over-the-counter

PED performance-enhancing drugs

PES performance-enhancing substances
YRBS Youth Risk Behavior Survey

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Relevant Websites

www.steroidlaw.com – An informational resource on performance enhancing drugs and the law.

www.monitoringthefuture.org – Monitoring the Future: A Continuing Study of American Youth.

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Substance Use Prevention Approaches for School-Aged Youth

Steve Sussman*, Yue Liao\$, Susan L. Ames**

*University of Southern California, Los Angeles, CA, USA \$University of Southern California, Los Angeles, CA, USA **Claremont Graduate University, Claremont, CA, USA

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Overview of Substance Use Prevention Prevention Definitions and Classifications Prevention versus Cessation Programming Message Content, Modality of Delivery, and Implementer Type Message Content Modality of Delivery Implementer Type Consideration of Age of Program Recipient History of Drug Abuse Prevention Programming	843 843 844 844 844 844 844 844 845	Cognitive-Information Errors Cognitive Processing Limits Belief—Behavior Congruence Errors Contextual/Situational Distortions Social Group-Related Prevention Programming Overview Elements of Comprehensive Social Influences/Life Skills Programs Community Unit-Based Involvement Large Social and Physical Environment Prevention	847 848 848 849 849 849
Substance Use Prevention for Youth: A Multi- Level Approach Neurobiological Relevant Prevention Programming Overview Emotional Learning Sensation-Seeking Self-Control Targeted Drug Abuse Prevention Cognitive Processes in Prevention Programming Overview	845 846 846 846 847 847 847	Programming Overview Community Coalitions Mass Media-Based Prevention Programming Obtaining Social and Physical Environmental Resources Supply Reduction Summary	850 850 851 851 851 852 852

OVERVIEW OF SUBSTANCE USE PREVENTION

Prevention Definitions and Classifications

Substance use prevention interventions are programs tailored to address the needs of specific groups and are often designed for use in a particular setting or settings. Different prevention programs are tailored for persons

at various points across the life span. In general, the goal of these programs is to prevent drug use and abuse from occurring (i.e. of alcohol, tobacco, or other drugs; ATOD). Chronologically, prevention programs have been delineated into "primary prevention" (before the problem behavior starts), "secondary prevention" (before the disease starts), and "tertiary prevention" (before death occurs). Substance use prevention may

also be considered as "universal" (to affect the general population), "selective" (to affect subgroups at elevated risk for developing a drug problem; e.g. children of alcoholics), or "indicated" (to affect high-risk subgroups already identified as having some detectable signs or symptoms of a developing drug problem). Selective and indicated programs, taken together, also have been referred to as "targeted" programs. There are several parameters of prevention programming, as is presented next.

Prevention versus Cessation Programming

Both drug prevention and cessation approaches encourage adoption of alternative, healthy behaviors and prevention of premature death. However, prevention work focuses its impact on antecedents (e.g. neurobiological, cognitive, social, or large physical and social environmental variables) of the problem behavior, whereas cessation work focuses on stopping a current behavior from continuing to arrest ongoing consequences, helping sufferers to learn to live with some experienced consequences, and permitting recovery of functioning.

Drug use prevention programs teach participants how to anticipate the impacts of antecedents (e.g. such as desiring to feel good or accepted by others) and counteract potential influences with instruction of protective cognitions, behaviors, or access to protective social units (e.g. drug-free communities). Cessation programs instruct participants how to cope with psychological dependence on a drug and with physiological withdrawal from a drug. Cessation activities can appear with prevention activities in the same program to maximize program effectiveness since some youth may already be abusing or addicted to a substance (e.g. cigarette smoking), but may not be using or dependent on another substance (e.g. alcohol).

Message Content, Modality of Delivery, and Implementer Type

Message Content

Message content refers to the various strategies offered to prevent or stop drug abuse. Hansen hypothesized 12 mediating variables that act as change agents in substance use prevention programs, most of which have shown to have potential effects to prevent the onset of drug use (see Table 85.1). Certainly, there are many types of substantive content areas addressed in prevention programs, which are presented later on in this chapter, grouped by level of analysis: neurobiological, cognitive, micro-social, and macro-social and large physical environment.

Modality of Delivery

Modality of delivery involves utilization of the different settings or contexts within which the programming is offered. Prevention programming has been implemented primarily in schools, and it has also been utilized in medical clinics, prisons, family based home or agency settings, other community-based settings (e.g. boys and girls clubs), and various media-based settings (e.g. computer-based, television, print ads).

Implementer Type

Implementer type is the term used in characterizing the persons who deliver prevention programming. Implementer selection is important in maintaining good quality delivery of drug abuse prevention programs, which, in turn, is relatively likely to achieve preventive effects. For example, in school-based prevention work, high-fidelity implementation of prevention programs is positively associated with implementer characteristics including having favorable attitudes toward the program, comfort with program content and approach, perceived self-efficacy to implement the program, independence, innovativeness, a confident and nonauthoritarian teaching style, good overall teaching skills, and other personal characteristics such as being outgoing, adventurous, and well-organized. Implementers who build interactive methods into their teaching (as opposed to using a didactic approach) also tend to be more likely to achieve program effects, because an interactive process reduces youths' resistance to messages and encourages discussion and consensus among group members.

Consideration of Age of Program Recipient

Many researchers believe that prevention programs should be delivered to young adolescents since tobacco and alcohol experimentation increases dramatically during this critical period. Moreover, the younger a person is when he or she starts smoking or using other drugs, the more highly drug dependent he or she is likely to become, making it more difficult to quit later in life. Most drug use prevention programs therefore have focused on combating social influences, relatively immediate antecedents of drug use during young adolescence.

Others have argued that prevention should focus on the very young (preschool or elementary school age), so that those at high risk for drug abuse can be recognized early and receive assistance. Researchers have found early intervention to be beneficial in directing individuals away from problem behaviors and to prosocial activities. In particular, teaching youth how to bond with institutions and family members has been found to be an important early preventive function.

TABLE 85.1 Twelve Mediating Variables as Change Agents in Substance Use Prevention Programs

Mediating variables	Description
1. Normative beliefs	Perceptions about the prevalence of drug use among close friends and same-age peers at school, and the acceptability of substance use among friends
2. Lifestyle/behavior incongruence	The degree to which an individual views substance use as incongruent with personally held current lifestyle and future aspirations
3. Commitment	Effortful, possibly public commitment regarding not using substances
4. Social, psychological, and health beliefs	Individual's beliefs about, for example, what it means to be a part of a group, what it means to have fun, and one's conception of health risk behaviors
5. Resistance skills	The perceived ability to identify and resist pressure to use drugs
6. Goal-setting skills	The degree to which one is able to engage in goal-setting behaviors
7. Decision-making skills	The degree to which one understands and applies a rational strategy for making decisions
8. Alternatives	Awareness of and participation in enjoyable activities that do not involve substance use
9. Self-esteem	The degree to which one feels personal worth and perceives possessing characteristics contributing to a positive self-evaluation
10. Stress management skills	Perceived skills for coping with stress including skills for relaxing as well as for confronting challenging situations
11. Social skills	The ability to establish friendships, be assertive with friends, and get along with others
12. Assistance skills	The degree to which an individual believes in one's ability to give assistance to others who have personal problems

Note: See Hansen (1992).

Yet, others suggest that drug abuse prevention programs would also be effective if implemented when drug misuse was truly beginning to become problematic, among older teens for most people. If the person continues to use drugs, then motivation enhancement to not misuse drugs, skills to engage in other nondrug-related activities, and decision-making to take effective action appear to be important strategies for successful prevention.

Possibly, targeting youth with different types of prevention programming at different points in development would bolster overall effects, though such an assessment remains for future research. However, there is some consensus that substance use prevention programs are found to be most beneficial when an individual is developmentally able to learn specific material, when the content of the material is meaningful and relevant to the individual, when the material is provided in contexts that permit exposure to most of the material, and when implemented by highly trained or effective facilitators.

History of Drug Abuse Prevention Programming

Drug education programming for adolescents and youth in the United States can be traced at least as far back as the early 1900s when every state and territory

in the United States had passed legislation mandating some form of temperance instruction to be taught in the public schools. This instruction focused on the moral evils of using alcohol, tobacco, opium, and other drugs. Since then, different drug use prevention strategies have been developed and implemented (see Table 85.2). In the 1960s, most of the prevention programs were based on the premise that if youth knew why drug use was bad for them, they would choose to not start using. However, the effects of these programs were found to be either ineffective or equivocal. More recently, comprehensive social influences/life skills programs were developed and evaluated, showing effects lasting an average of 5 years post-program. These programs are conceptualized primarily at a micro-social level, as is discussed later on.

SUBSTANCE USE PREVENTION FOR YOUTH: A MULTI-LEVEL APPROACH

The following sections discuss prevention programming strategies from four general substantive perspectives: neurobiological relevant, cognitive processes, social groups, and the large social and physical environment. For each perspective, an overview of the perspective is provided, and evidence-based strategies or potentially effective strategies from within that perspective are provided. In practice, many prevention

TABLE 85.2 Timeline for Substance Use Prevention Program Message Contents

Drug use prevention program	Key concepts
1900s	
Temperance instruction	Focuses on the moral evils of using alcohol, tobacco, opium, and other drugs
Scare tactics	Use of graphic descriptions of physical consequences and moral degradation associated with drug use
1930s	
Responsible use programs	Waiting until one is grown up (18 years of age) so that one can make a responsible, mature choice
1960s	
Fear-based model	If youth were frightened about the potential negative effects of drugs, then they would not want to experiment with drugs
Information-based model	Providing youth with factual information about drug use would prevent them from engaging in the behavior
Affective or values-based model	Addresses global attitudinal changes such as enhanced self-esteem, improved decision-making and goal-setting, and clarification of one's life values
1970s	
Social influence-based programs	Expose young people to social pressures involving tobacco or other drug use in a safe environment and to teach them skills that could then be transferred to the real-world; expanding to include general life skills and coping enhancement

programs are composed of elements of each of these domains, so the division herein provides insight into assumptions behind different strategies rather than delineating different programs per se. In addition, it is likely that some strategies may impact multiple substantive perspectives. Thus, some strategies presented in the following sections are repeated across perspectives.

Neurobiological Relevant Prevention Programming

Overview

Some individuals are more susceptible to the reinforcing effect of drugs due to variation in phenotypes of neurobiological systems. Therefore, prevention programs may need to be tailored to these at risk people. For example, sensation-seeking individuals may require fast-paced programming and healthy sensation-seeking alternative behaviors, whereas anxiety-sensitive individuals may require emotional learning or mood management programming including behavioral, contextual, or medication options. Approaches discussed herein that might be considered neurobiologically related include: emotional learning, sensationseeking strategies, self-control strategies and a targeted motivation-skills-decision making prevention model. Certainly, neurobiological-related prevention programming is only recently being directly investigated and relatively little empirical support is available.

Emotional Learning

It is becoming more evident that social and emotional competence is important in successful neural development. Some believe that prevention programming should be applied to very young children to enhance social and emotional learning when the brain is still rapidly developing. At this time, developing the ability to competently express oneself emotionally and socially through education programs that provide instruction on emotional regulation may help individuals minimize a sense of emotional discomfort that might otherwise promote drug use. There are some evidence-based programs suggesting such effects. An example of a program for young children that focuses on social and emotional learning is the I Can Problem Solve (ICPS) program. Words that are precursors to understanding consequences and problem-solving are instructed. Some research indicates that through the ICPS, young children learn alternative ways to solve interpersonal problems.

Sensation-Seeking

Youth may attend to and process information differently due to variation in neurobiologically based traits. The reinforcing effects of drugs play a key role in promoting continued drug-use behavior, especially for sensation-seeking and novelty-seeking individuals. Since individuals higher in sensation-seeking may have a neurobiologically based need for stimulation, it is

likely that drug abuse prevention messages need to be novel and exciting enough to get their attention. For example, Palmgreen and colleagues utilized sensation-seeking as a risk factor for drug misuse in the development of a mass media marijuana-use prevention campaign. Five professionally produced 30-second television spots that involved material likely to appeal to youth high in sensation-seeking (e.g. fastpaced and novel) were produced and aired extensively. After program development was completed, the campaign was implemented and evaluated using a controlled interrupted time-series design in two matched communities. The campaign reversed upward developmental trends in 30-day marijuana-use among high-sensation-seeking individuals; in other words, about a 10% decrease in use was observed the year following the campaign.

Self-Control

Executive cognitive functions are mediated by prefrontal brain regions implicated in behavioral regulation and decision-making processes. Brain-based neurocognitive functions implicated in behavior regulation and decision-making may moderate prevention program outcomes. Findings from studies on neurological development suggest that youth decision-making ability and emotion-regulation skills are not fully developed. However, relatively poor executive cognitive functioning has been found to be associated with current drug and alcohol use, lower social competence, and predicts the onset of drug-use disorders among adolescents. Training of self-control skills may include instruction on assertiveness, impulse control, and anger management. For example, in assertiveness training, youth may learn, through modeling, behavioral rehearsal and role-play instruction, statements that include in combination acknowledgment of the other person, self-statements of preference, and action statements. By learning assertiveness, the youth may be able to better inhibit neurobiological tendencies to express anger. Youth may also be instructed to learn to think ahead and anticipate problem situations, as well as avoid high-risk situations. Some prevention programs that include such strategies do find effects on drug use; however, these strategies generally are included along with many others and component effects have not been isolated. A few research studies have shown that pre-existing neurocognitive proficiency may enhance prevention outcomes, whereas neurocognitive deficits may attenuate program effects. Therefore, prevention programs might need to consider supplemental materials for youths with neurocognitive deficits who do not respond as well to the general core curriculum.

Targeted Drug Abuse Prevention

While not well-grounded in neurobiological research, some researchers and practitioners assume that targeted programs are neurobiologically relevant because they target at risk youth (who may be more vulnerable to later drug abuse). Sussman and colleagues reviewed 29 evidenced-based, targeted drug abuse prevention programs and concluded that effective targeted programming (1) motivates the at-risk recipients to not desire to misuse drugs, (2) teaches skills to bond to more conventional venues, and (3) trains at-risk recipients in decision-making to tie motivation material to skills material and take self-fulfilling action. This has been labeled a motivation-skills-decision making model of drug misuse prevention.

Cognitive Processes in Prevention Programming

Overview

Cognitive processes can influence behaviors through both rational and nonrational motivations. Many researchers view drug abuse as unlikely to be motivated by (only) rational decision-making. Therefore, some cognitive-based prevention strategies include both rational and nonreflective cognitive processes. This section addresses drug abuse prevention strategies that focus on counteracting (1) cognitive-information errors, (2) cognitive processing limits, (3) belief-behavior congruence errors, and (4) contextual/situational distortions.

Cognitive-Information Errors

Cognitive-information errors associated with youth drug use include drug use prevalence overestimates and error-related myth formation. Drug use prevalence overestimates can be counteracted through an "overestimates reduction" prevention activity. For example, youth can self-report their drug use in the past week and poll their perceptions of the numbers of peers who have used the drugs over the same period of time. Then a comparison of the actual prevalence of drug use among peers derived from their own selfreports (in a group setting) with the mean perceived estimate of peer drug use prevalence are presented to them. By becoming aware that they tend to overestimate their estimates of their peers' drug use (a cognitiveinformation error, due in part to a biased encoding of novelty-type inputs), youth may be able to reduce their prevalence estimates and also reduce their expectations that they should use drugs in the future. A conservative shift in cognitive information/beliefs is an important preventive effort, and in general, relatively low prevalence estimates are predictive of less drug use in the future. While perhaps a primarily cognitive-based strategy, prevalence overestimates reduction has been found to be a main mediator of the impact of comprehensive social influences/life skills drug abuse prevention programs (such as the Alcohol Abuse Prevention Trial and the Midwestern Prevention Project).

Elaborative processing of information can be used to counteract cognitive-information error-related myth formation. For example, as used in the curriculum, Project Towards No Drug Abuse (TND), a discussion about the "kernel of truth" is provided for popular drug-use myths (e.g. when one no longer gets sick after trying cigarette smoking couple of times, one has subjectively "gotten used to the effects"). Youth discuss the myth and then discuss why the myth is, in fact, a myth (e.g. no longer getting sick means that the body is no longer providing danger signals about poisons invading the body and is the beginning of addiction). In order to construct meaningful memories, it is important to elaborate the difference between more immediate subjective gratification and the impact of longer-term negative consequences of drug use. One caveat needs to be noted in presenting myths and truths to youth: myths might be retained as facts after the program is completed if memory processes are not considered. For example, it has been shown that myths about alcohol use can be retained as facts after 24 hours. Therefore, it is important to use elaborative processing strategies so that myths are more likely to be retained in memory over time as being myths.

Cognitive Processing Limits

As discussed in the neurobiological section, executive functions are higher order cognitive constructs that are involved in the planning, initiation, and regulation of goal-oriented behavior. Executive functions are related to inhibitory control over behavior and counteracting the influence of more spontaneous cognitions and implicit processes. To enhance the effects of prevention interventions, newly learned program information must compete with relatively automatic, existing memory associations. Drug use prevention materials often encourage executive planning and judgment in high-risk, drug-related social situations. Program material that helps youth cope with cognitive challenges faced in high-risk situations, for example, practice in self-instructional training (to elicit protective cognitions when needed) may be an important element of drug use prevention programs.

The Promoting Alternative Thinking Strategies (PATHS) project provides elementary school youth with opportunities to practice self-control strategies including verbal mediation (self-talk) and inhibitory control via curriculum lessons and the integration of a "Control Signals Poster." The red light signals "Stop-Calm Down", yellow light signals "Slow Down-

Think", and green light signals "Go-Try My Plan." Students significantly improved their perceived efficacy in managing emotions and problem-solving skills. While there is some evidence that various self-instructional training strategies decrease impulsive behavior among youth (e.g. Meichenbaum's Self-Instructional Training protocol, the PATHS project stoplight protocol), research is needed to assess more specifically cognitive mediation skills application to drug abuse prevention.

Belief-Behavior Congruence Errors

Belief-behavior discrepancies occur when an individual engages in self-destructive behaviors that may be contrary to their basic beliefs about themselves because they often do not think about how their beliefs relate to different behaviors. There are three classroombased strategies that attempt to make youth aware of their own belief-behavior discrepancies and be induced to reduce these discrepancies through healthful action. These three activities are contained in Project TND. The stereotype activity consists of having youths explicitly stating the discrepancy between how deviant they view themselves versus how deviant they think others view them and their peers (generally youth see others as viewing them and their peers as more deviant than they actually are). Then youths consider reacting against a self-fulfilling prophesy by not acting more deviant, and decreasing drug use. The attitudinal perspectives activity is one where youth identify their general sense of self as a moderate person (most people view themselves as moderate people). When they engage in an exercise that places drug use on a traditional, moderate, radical continuum, they may realize that to continue to view themselves as moderate person, they need to decrease their drug use (which tends to be viewed as radical behavior). Finally, the health as a value activity involves asking youths what they want to accomplish in the near future. Most will say that they want to improve their lives (e.g. through continued education). They are asked to consider how important their health is to reach their goals. Then they are asked to consider if drug use will injure their health. Youth realize that to achieve their goals they may need to maintain their health and decrease their drug use (see Table 85.3).

Contextual/Situational Distortions

People prone toward drug misuse may distort situations to make them seem more positive than they are. For example, stories about youths being drunk and losing their car for a couple of hours often are told as if they are humorous rather than being difficult situations. These distorted meanings of behavior, or mystification processes, may be counteracted by direct confrontation. For example, humorous cartoons can be presented and

TABLE 85.3 Strategies to Increase Awareness of Belief-Behavior Discrepancies

Strategy	Description	Examples
Stereotyping	Tendency to rebel against the stereotype when discrepancy is brought to awareness	Counteracting stereotype by engaging in pro-social action and informing others of one's healthful pursuits
Attitudinal perspective	Tendency to change behaviors rather than change self-perception as a moderate person	Recognizing a specific attitude that drug use is consensually considered radical behavior so that one should not engage in drug use in order to be a moderate person
Health as a value	Tendency to not want to give up life goals so that health as a value becomes more important, and one thinks more seriously about drug misuse as health deterring	Considering what they want to accomplish in the future and whether health is important to accomplish these goals and whether drug use can interfere with their health

discussed in a group setting; that reveal situational distortions. Also, use of psychodramas or "talk shows" (a social group activity that can induce a cognitive change) can assist in eliciting responsibility and consequences information and achieving healthy changes. These two strategies are instructed in Project TND.

Social Group-Related Prevention Programming Overview

Applying prevention programs in social settings (e.g. in groups) is essential to induce and maintain change among youth. It not only can help correct youth's cognitive misperceptions, but also provide a venue for practicing newly learned behavioral skills with corrective input from educators and feedback from peers that may mimic real-world social situations. This section discusses several prevention program strategies that involve social groups, including the elements of comprehensive social influences/life skills programs and community unit-based involvement.

Elements of Comprehensive Social Influences/Life Skills Programs

These programs aim to create awareness of the impact of social influences on behavior and to counteract these influences by enhancing social skills (e.g. listening and communication skills training, refusal assertion training, social decision-making, and activism skills) and correcting social misperceptions (e.g. correction of use prevalence overestimates, normative restructuring, and media literacy; see Table 85.4).

Project Towards No Tobacco Use (Project TNT) is a model comprehensive social influences/life skills tobacco use prevention program that targets young adolescents. The 10-day, classroom-based core curriculum provides detailed information about health consequences of tobacco use and addresses topics including building self-esteem, active listening, communicating effectively, refusal assertion learning and practice,

noncompliance coping to enhance self-confidence and decrease perceived social influence to use tobacco, counteracting advertising images and social activism to change norms, and decision-making/public commitment. Five homework assignments, classroom group competitions, and a two-lesson booster program provided the following year are used to maintain student involvement.

To evaluate the Project TNT curriculum, 6716 7th grade students from 48 junior high schools in Southern California were randomized into five conditions (four programs and one control). Four curricula were developed and examined. Three were designed to counteract the effect of separate (single) program components (normative social influence [direct pressures to be liked by using tobacco], informational social influence (indirect pressures to adopt beliefs facilitative of tobacco use), and physical consequences). The fourth was a comprehensive curriculum that designed to counteract all these three components. The comprehensive curriculum showed the largest effects on behavior and is now being disseminated throughout the United States. Compared to the control group, this program exerted significant effects at 1- and 2-year follow-ups on initiation (30% relative reduction) and weekly use (60% relative reduction) of cigarettes and smokeless tobacco. More recently, the comprehensive curriculum was found to be effective over a 1-year period when delivered among 6th and 7th graders in 14 East Texas countries, and it has been demonstrated to be cost-effective.

Community Unit-Based Involvement

Most social influence-based prevention programs occur in the school classroom setting. There is evidence showing that school-based programming can be successful. Indeed, school-based programming is a central means of delivery since youth are a captive audience to this type of programming. However, as introduced earlier in this chapter, other community units may exert preventive effects. In particular,

TABLE 85.4 Eleven Components of Comprehensive Social Influences Programming

Components	Description
1. Listening and communication skills	To improve listening and communication skills by demonstration of appropriate behavior, modeling of appropriate behavior, behavioral rehearsal, and feedback components
2. Refusal assertion	Training on how one might best refuse a drug offer or request of someone else (e.g. to refuse drug offers assertively but not aggressively or passively)
3. Short- and long-term physical consequences information	Although not directly addressing social influences, group activities are used to discuss short- and long-term physical consequences of substance use and to explain why it is important to not misuse drugs
4. Peer group unacceptability of drug misuse	Use group activities to make it known among group members that drug misuse is not as widely accepted by their peers as they may perceive (e.g. taking group polls on acceptability of drug misuse among peers)
5. Correction of use prevalence overestimates	Activities to reduce prevalence of use overestimates which involve clarifying the true prevalence of drug use among peers and correct overestimates of perceptions of drug use prevalence among peers
6. Awareness of adult influences	Discussions with the focus on adult drug use as a problem behavior with grave consequences among youth since youth often attempt to copy adult role models when they use drugs
7. Media literacy	Make youth aware of adult advertising influences so that they are less likely to yield to pro-drug use images portrayed in the media
8. Activism	Encourage youth to participate in anti-drug use activism (e.g. writing letters to tobacco and alcohol industry) in order to personalize knowledge, become active learners, and encourage belief change in society
9. Self-confidence building and decision-making	Information on cognitive techniques such as making positive affirmations to self and others, and help youth learn how to rationally combine information to make positive decisions in different problem areas
10. Making a commitment to not use drugs	Encourage youth to make public commitments (e.g. before a group of peers) not to use tobacco and other drugs with the assumption that such commitments put their self-respect at stake in order to discourage them from drug use
11. Smoking and other drug use cessation materials for older teens or adults	Provide materials to older teens or parents who are regular smokers or drug users and need information on how to cope with withdrawal symptoms

regarding the micro-social climate, it is important to recognize the influence of the family unit because of the close and historical patterns of interaction within the unit. Family involvement-based programming is a relevant way of providing prevention material outside school and can lead to a 15% relative effect in compliant families (e.g. the Strengthening Families Program and Family Matters are two examples). Strategies to strengthen family dynamics in such programs include instruction in family skills training and resource acquisition instruction, family therapy, cognitive and behavioral parent training, contingency management, stimulus control, and family support training to prevent drug use.

Large Social and Physical Environment Prevention Programming

Overview

Available research suggests that program effects are most likely to be maintained by utilizing multifaceted approaches to prevention, whereby youth receive a consistent message across community contexts and over time. For example, tobacco and other drug use access reduction, family programming, mass media programming, involvement of community organizations, and school-based programming may combine to achieve a system-wide approach for the largest

intervention effects (possibly doubling effects achieved by single-unit programs). Prevention programming that permeates the larger social environment can have wide-ranging influences since it could affect various micro-groups and individual perceptions, attitudes, and behaviors through monopolization of messages being provided to youth. However, much research still remains to determine which modalities, administered for how long, are needed to increase system-wide prevention programming effectiveness.

Large physical and environmental influences on drug use include presence or level of drug manufacturing and distribution channels and presence of pro-social/physical environmental resources. Pro-social resources availability such as teen centers and libraries, might lead youth to seek out options other than drug use. In addition, supply reduction approaches (e.g. policy enactment and enforcement) may decrease or redirect drug distribution, thus, drug use may decrease. This section discusses larger social and physical environmental approaches to drug use prevention programming including use of community coalitions, mass mediabased prevention programming, obtaining social and physical environmental resources, and supply reduction.

Community Coalitions

Large community interventions may involve a range of program channels (e.g. schools, family groups, media, community agencies, local governments, church, and health groups) that demand coordination to provide consistent and sustained prevention messages. Coalition building involves formation of partnerships among key organizations and individuals, regular meetings among partners, and action planning to carry out change. Hallfors and colleagues examined 12 coalition sites that were involved in a large-scale drug and alcohol demand reduction program in the United States and found that strategies aimed at youth or community outcomes failed to have significant effects, and many coalitions did not last very long. For coalitions to be most effective, they should be well-organized, focused on specific goals, manageable, select evidence-based prevention programs to promote, and obtain expert assistance while facilitating implementation of these programs. In addition, to make sure that appropriate actions are taking place at each step of coalition building and action, coalitions should consider their role as being primarily to coordinate units, restrict environmental access, and maintain good communication with researchers, health educators and evaluators. Community Anti-Drug Coalitions of America (CADCA) is an umbrella organization for more than 5000 antidrug coalitions that began in 1992. It holds numerous media events, anti-drug gatherings, engages in information dissemination through newsletters, engages in lobbying efforts, and coordinates partnerships with other coalitions and anti-drug organizations. While research is needed, CADCA's coordination efforts may have an important, indirect/coordinating effect on drug use prevalence among youth.

Mass Media-Based Prevention Programming

The mass media can affect a very large range of social regions because of its potentially very broad reach. Media literacy strategies that enhancing youth's logical responses to media messages (e.g. movies that appear to glorify alcohol use) and raising their awareness of their own emotional responses have been shown to help prevent a variety of risky behavior outcomes, including substance use, among middle and high school students, as well as among elementary school students. It has been found that for mass media campaigns to have the strongest effects on drug misuse, the contents may depict a dramatic true consequence of drug use, take an activism stance, advocate for greater autonomy experienced by non-drug use lifestyles, appeal to sensation-seeking youth by fast-paced material with descriptions of exciting activities (e.g. as was described in the neurobiological section), attempt to provide a media literacy impact, or correct misperceptions of drug use norms.

Internet-based prevention programming provides a very pragmatic way of surveying and intervening with various populations since its use is inexpensive and convenient, and information can be processed quickly. A study by David Buller and colleagues to test the effectiveness of Internet-based programs to reduce smoking prevalence and positive smoking-related outcome expectancies found a decrease in 30-day smoking prevalence and lower expectation for smoking in the future among its Australian but not American adolescent subjects, respectively (behavioral results were obtained only in the Australian sample, a 26% relative reduction). In addition, newer technology interventions are being considered in ongoing research such as virtual reality simulations, interactive computer and other communication devices, and portable computer devices (e.g. the use of cell phones, text messaging).

Obtaining Social and Physical Environmental Resources

A meta-analysis of the Center for Substance Abuse Prevention high-risk youth and family programs suggests that increases in drug use have resulted from engagement in certain recreational activities such as rock band concerts, sports that involve peer or adult drug users, and some vocational or community-service activities (e.g. housing construction and house painting, where adult drug users might be involved with youth). On the other hand, academic achievement and aspiration-related activities, religious activities, anti-drug

activism-related involvement and active personal hobbies are inversely related to drug use. Therefore, establishing facilities that provide youth opportunities to obtain access to pro-social (e.g. drug-free recreation alternatives/hobbies, jobs) and physical environmental resources (e.g. libraries, gymnasiums) may be an effective community-level strategy. In addition, direct instruction, modeling, and structured practice in resource acquisition skills may also help youth to increase their knowledge and self-efficacy on how to obtain pro-social resources and to readily access resources when needed. Certainly, research is needed on manipulation of resource acquisition and drug use prevention effects.

Supply Reduction

Supply reduction involves legal regulation of substances and can be accomplished by environmental prevention strategies such as prohibitory policy mechanisms (of production or distribution) and regulatory policy mechanisms (setting conditions of use, information about use, sanctions). Some other regulatory manipulations include the use of large warning labels (which actually is a demand reduction-oriented regulation), and enforcement of underage use laws at convenience stores. For example, Reduce High-Risk Drinking is an environmental intervention to increase community awareness, prevent access to alcohol for underage drinkers, and enforce laws regarding alcohol use and sales. This project has reported that individuals living in the intervention community sites reduced drinking compared with individuals living in comparison sites (51% relative decline in self-reported driving over the legal limit, 6% reduction in DUIs).

Supply reduction or regulation strategies not only reduce access; they may alter demand in the larger social climate (e.g. that drug use is good or bad because it is legal or illegal). Until recently, the primary supply reduction method was interdiction (i.e. forbid use by actions of authorities). However, interdiction has been expensive and not very successful. Domestic enforcement costs four times more than treatment for a given amount of user reduction, seven times more than consumption reduction, and 15 times more than societal cost reduction.

SUMMARY

This chapter addressed different approaches for drug use prevention programs targeting school-aged youth, considered from the lens of neurobiological, cognitive, social group, and large social and physical environmental-related perspectives. A focus on implementing interventions that address neurobiologically based trait

variations for individuals who are highly vulnerable to reinforcing drug effects and incorporating components that address cognitive mediators and moderators of drug misuse may provide preventive program impact at the individual-level. Micro-social group strategies also impact individuals' cognitions and behaviors, and are key foci of programming. Aggregated, macro-social level effects may be larger than the impacts of individual community units. In addition, larger social and physical environmental climates "set the stage" for culturally expressed group and individual perceptions and attitudes that impact illicit drug use policy change and make resources available for drug use prevention programs. Future research and programmatic efforts may be guided by considering all the above four perspectives.

SEE ALSO

Etiology and Prevention of Stimulants (Including Cocaine, Amphetamines and Misuse of Prescription Stimulants), Etiology and Prevention of Marijuana Use among College Students, Performance-Enhancing Drug Use (Including Anabolic Steroids) by Adolescents and College Students: Etiology and Prevention, Using the Internet for Alcohol and Drug Prevention, Examining the Role of Parents in College Student Alcohol Etiology and Prevention, Mobilizing Communities for Alcohol, Drug, and Tobacco prevention, The Impact of Price and Taxation on Drinking and Related Problems among Youth and Young Adults

List of Abbreviations

ATOD alcohol, tobacco, and other drugs

CADCA Community Anti-Drug Coalitions of America

DUI Driving under the InfluenceICPS I Can Problem Solve

PATHS Promoting Alternative Thinking Strategies

TND Towards No Drug AbuseTNT Towards No Tobacco Use

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- http://www.strengtheningfamiliesprogram.org/ Strengthening Families Program.

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Using the Internet for Alcohol and Drug Prevention

Heleen Riper*, Robert Tait\$

*VU University Amsterdam, Amsterdam, the Netherlands and Leuphana University, Luneburg, Germany

The Australian National University (ANU),

Centre for Mental Health Research, Canberra, ACT, Australia

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INTRODUCTION

Problem drinking, in all its facets, lies at the heart of a major health and socioeconomic burden worldwide. Individuals whose alcohol consumption exceeds the accepted guidelines for low-risk drinking can be defined as problem drinkers. Various gradations of substance use disorders may underlie their alcohol consumption. (see Box 86.1 for an overview of specified alcohol use disorders, and *see* Alcohol Use Disorders and Symptoms and Course: Alcohol Use Disorder in Adulthood.)

Screening and brief intervention procedures (SBIs) have been found to be cost-effective in curbing adult problem drinking notably in primary care populations. Yet the number of problem drinkers reached by SBIs in primary care is very small (5–10%). This is due largely to a host of implementation barriers, including time, money, professional training constraints, and the fear of many general practitioners of confronting patients with their drinking habits. The uptake of SBIs by problem drinkers themselves is also low. Many feel shame and loss of privacy, and such perceptions inhibit them from seeking professional help. From a public

BOX 86.1

ALCOHOL USE DISORDERS

- Abstinence is defined as refraining from drinking alcoholic beverages.
- Moderate use is conceptualized as drinking less than 21 drinks per week for men and less than 14 drinks per week for women.
- Heavy use is defined as drinking levels in excess of 21 drinks per week for men and in excess of 14 drinks per week for women.
- Hazardous use [ICD-10 code Z72.1] is a pattern of heavy drinking and/or binge-drinking that carries with it a risk of harmful consequences to the drinker. These consequences may be detrimental to physical or mental health, or have adverse social consequences to the drinker or others. Other potential consequences include worsening of existing medical conditions or psychiatric illnesses, injuries caused to self or others, due to impaired judgment after drinking, high-risk sexual behavior while intoxicated, and worsening of personal or social interactions.
- Harmful drinking [ICD-10 code F10.1] is a pattern of drinking that is causing damage to health. The damage may be either physical (e.g. liver cirrhosis from chronic drinking) or mental (e.g. depressive episodes secondary to drinking). Harmful patterns of use are often criticized by others and are sometimes associated with adverse social consequences of various kinds. Harmful drinking has persisted for at least 1 month or has occurred repeatedly over the past 12-month period; subject does not meet criteria for alcohol dependence.
- Alcohol dependence [ICD-10 code F10.2] is determined if the drinker has at least three of the following: tolerance; withdrawal symptoms; impaired control; preoccupation with acquisition and/or use; persistent desire or unsuccessful efforts to quit; sustains social, occupational, or recreational disability; use continues despite adverse consequences.

Based on the publication by Saunders et al. (1993)

health perspective, then, the current impact of SBIs in the real world is limited. SBIs not only need be effective in themselves, but large populations of problem drinkers would have to use them before the envisioned health and economic gains could be achieved.

Broad public access to the Internet has now opened new avenues to reach out to the large but yet uncontacted group of problem drinkers. One such opportunity involves Internet-delivered screening and brief intervention programs (ISBIs) aimed at curbing adult problem drinking and other substance use disorders. The availability of such ISBIs, especially those for problem drinking, has meanwhile expanded rapidly in many high-income nations, including the United States, Canada, Australia, and many Western European countries. These have both high levels of Internet penetration and a strong public health focus on problem drinking. This chapter discusses ISBIs designed for adult problem drinkers (see Adolescent Substance Use: Symptoms and Course, Developmental Risk Taking and the Natural History of Alcohol and Drug Use among Youth, Screening and Assessment of Substance Use Disorders in Youth and Young Adults, Individual Prevention of College Student Alcohol Misuse and Substance Use Prevention Approaches for School-aged Youth for young people). For the prevention of illicit drug use, our chapter deals with ISBIs for both adults and adolescents.

INTERNET-BASED SCREENING AND BRIEF INTERVENTION RESOURCES FOR ADULT PROBLEM DRINKING

Screening and brief intervention procedures (SBIs) are available in different modalities, including face-to-face encounters between a health professional and an individual or a group of problem drinkers. These procedures can also be delivered by telephone or mail. More recently, screening and brief intervention programs have been provided by the Internet on PCs or smart phones. Like the more conventional SBIs, these ISBIs target adolescent and adult individuals that consume alcohol. Such groups may also be targeted via specific environments, such as school, community, workplace, or primary care settings.

Universal, Selective, and Indicated ISBIs

The various ISBIs may be distinguished into universal, selective, and indicated interventions, in accordance with Marzek and Haggerty's classification of prevention strategies from 1994. *Universal* ISBIs are designed to inform everyone in a particular population (such as a school or community); in relation to alcohol, this implies all individuals, regardless of whether and how much they consume. National alcohol awareness campaigns providing links to

PROS AND CONS OF ISBIS 857

online resources are examples of universal prevention strategies (see, for instance, the US site http://www. samhsa.gov/). Selective ISBIs target subgroups of specific populations that are at additional risk for problem alcohol use. Web-based self-help interventions designed for pregnant women in the community would be an example of selective ISBIs, given the greater health risks of alcohol to both mother and baby. Indicated ISBIs are focused on people who already drink alcohol in amounts that exceed the recommendations for low-risk drinking, but who do not have a clinical diagnosis of alcohol abuse or dependence (such as from DSM-IV). Examples of indicated prevention for problem drinkers are the Dutch ISBI entitled MinderDrinken and the Canadian Drinker's Check-Up (DCU), both of which are designed to help problem drinkers curb their alcohol use and diminish alcoholrelated problems.

Minimal and Extended ISBIs

ISBIs are available in minimal and more extended formats. Personalized normative feedback (PNF) interventions consist of screening and self-help, often in a single session. Participants receive personalized feedback based on their personal alcohol consumption as compared to recommended guidelines for low-risk drinking. Often this includes normative feedback, whereby problem drinkers compare their own drinking patterns (in terms of frequency, quantity, or other measures) to those in their peer group. One purpose of PNF interventions is to correct misperceptions that problem drinkers often have about low-risk drinking guidelines or about drinking prevalences among their peers. More extended forms of ISBI include protocol-driven self-help treatments based on principles of behavioral self-control, cognitive-behavioral therapy (CBT), motivational interviewing, or a combination (see Motivational Enhancement Approaches, Cognitive Behavioral Therapies, Twelve-Step Facilitation Therapy, Contingency Management for a detailed description of treatment principles). Self-help refers here to a type of psychological treatment in which participants work through the procedure more or less independently. Although the exact components may differ for each intervention, most contain several common elements. These include (1) self-assessments of alcohol consumption patterns, (2) psychoeducation on cognitive and behavioral change strategies, (3) goal setting for alcohol moderation or abstinence, (4) self-monitoring of daily alcohol consumption, (5) strategies to maintain alcohol reduction patterns, and (6) relapse prevention techniques. ISBIs often also make use of online, moderated peer-to-peer discussion groups. The recommended duration of use for extended ISBIs is 4-6 weeks, a time frame in which positive behavioral changes in problem drinking are expected to occur.

Unguided and Guided ISBIs

Online prevention and treatment for problem drinking can be delivered with different amounts of support from health professionals. At one end of the continuum we find online self-help interventions without professional guidance. Unguided ISBIs are currently being delivered on a broad scale in routine alcohol prevention practice. At the other end of the scale there are therapist-guided online therapies consisting of multiple sessions and self-help exercises. The guidance may take place in asynchronous webbased communication (e.g. e-mail exchanges) or in real time through web-based chat sessions. Such guided online treatment is only available on a very small scale as of yet, for example, in the Netherlands. ISBIs with more limited guidance by coaches or therapists have scarcely been implemented for adult problem drinking, in contrast to their use for disorders such as depression and anxiety. ISBIs may also be used as a component of face-to-face SBIs or more intensive treatment (as a partial replacement or as an adjunct), in order to expedite the therapeutic process, improve its quality, and/or reduce costs. Guided ISBIs can be provided by different types of certified professionals (GPs, counselors, psychotherapists, substance use prevention workers), depending on the nature and intensity of the desired therapy and the prevailing legal requirements.

PROS AND CONS OF ISBIs

Screening and brief interventions delivered over the Internet have a number of advantages over other modes of SBI delivery (face-to-face, postal, or telephone). Advantages involve user acceptability, aspects of service delivery such as cost savings and intervention quality, and research optimization.

User Acceptability

ISBIs can potentially reach broad groups of problem drinkers without regard to geographical distance or time (24/7). Participants can work with the programs in their own time, at their own speed, and often free of charge. They can perform them in virtual anonymity, allaying fears of stigmatization and privacy violation. The high level of privacy may help persuade large groups of problem drinkers to work on their alcohol problems, something they might not have done in a more traditional SBI.

Intervention Qualities

Timely accessibility is not only an important feature from the standpoint of participant convenience, but it serves a therapeutic goal as well. Help-seeking behavior and motivation to change are often fleeting in nature. In many cases, an actual decision to seek help is a consequence of unforeseen situations, adverse effects of alcohol use, or both. Giving problem drinkers access to help at the right moment may therefore strengthen their motivation and thereby their likelihood of successful change. ISBIs make this timely access possible. Other qualities of ISBIs relate to the delivery of the intervention as intended. Treatment fidelity is high for ISBIs, owing to the protocol-based, structured, and automatic features that minimize delivery differences. ISBIs can provide immediate automated feedself-reported information. back They automatically monitor and report on participants' progress, both to the participants themselves and (in guided treatment) to the facilitating professionals. The Internet also facilitates various options that may heighten the appeal of ISBIs to participants, such as graphic, audio, and video features to complement text-based components.

Service Delivery and Research

Although the costs of developing ISBIs may be considerable, most programs, especially those without guidance, offer cost benefits, as they can be delivered to large numbers of problem drinkers at a low marginal cost per additional user. Even if they provide therapist support, ISBIs still may save time for both therapists and participants when delivered as stand-alone interventions or as components of face-to-face therapies (e.g. by reducing the number of sessions needed). Other features that increase the economic attractiveness of ISBIs include shortened waiting lists and saved traveling time. ISBIs also greatly simplify the process of effectiveness research, as both participant recruitment and data collection can be carried out automatically through the Internet.

Disadvantages

Some of the current disadvantages of ISBIs are likely to be overcome through future research and practice. Web-based interventions may not be suitable for all problem drinkers, such as those that are computer illiterate or have low reading levels. Others may find online help disagreeable or inconvenient, whether it is with or without professional support. For yet another group, the complexity of the alcohol problems may preclude treatment with ISBI, and more intensive or inpatient treatment may be required. Some coaches or therapists may also not possess the specific skills needed for giving online therapy.

AVAILABILITY, ACCEPTABILITY, AND USER PROFILES OF ISBIs

Internet-delivered SBIs have grown rapidly in number, particularly in the United States, Canada, Australia, and in European countries such as the United Kingdom, Finland, Sweden, and the Netherlands. Since 2000, process evaluation studies have reported on the availability, user acceptability, and user profiles of (mainly unguided) ISBIs for adult problem drinkers in the general population. These studies afford ample evidence that a sizable adult population seeks web-based help for problem drinking and is satisfied with that type of intervention. To illustrate, it is not uncommon for an ISBI to reach 10000 participants within a very short time. Such successful outreach has never been achieved with conventional modes of SBI delivery. These numbers should not only be compared to the reach of the usual prevention or treatment strategies but also to the potentials of the various modes to reach the overall intended group. A conservative estimate in 2009 found that a single low-cost, unguided self-help intervention could reach around 2.5% of the target group, even without active recruitment. This is high, as the overall percentage of this population of problem drinkers reached by health care services is only 5–10%.

ISBIs generally appear to attract similar groups of problem drinkers in terms of sociodemographic profiles and severity of alcohol use. The majority of adult participants belong to the 35- to 55-age group. They are relatively more likely to be female, with an ISBI gender participation ratio of 1:1, as compared to a male–female ratio of 4:1 in problem drinking prevalence in many Western societies. In comparison to the general population, ISBI participants have relatively high educations, high incomes, and stable relationships. Those who actively take part in ISBIs, and especially in the extended self-help interventions after screening, drink well above the guidelines for low-risk alcohol consumption, having a mean weekly alcohol consumption from 30 to 50 standard units (of 10 g of ethanol). Their mean scores of 18–22 on the Alcohol Use Disorder Identification Test (>8 AUDIT) reveal a strong likelihood of alcohol abuse or dependence (see Alcohol Use Disorders and Internet Screening and Intervention Programs). Most participants are first-time-help seekers and are usually self-referred. Hence, ISBIs for problem drinkers indeed appear to address an unmet public health need.

ARE ISBIs EFFECTIVE IN CURBING ADULT PROBLEM DRINKING?

A limited number of randomized controlled trials have assessed the effects of ISBIs in reducing alcohol

consumption among participants. For unguided selfhelp in comparison to nonintervention, available evidence from meta-analyses suggests small- to medium-effect sizes (Cohen's d = 0.40) for alcohol reduction up to nine months postintervention (for an explanation of effect sizes and Cohen's d, see Evidence-Based Treatment). These results translate to a very favorable number needed to treat (NNT) of 5, indicating that about five drinkers must receive an ISBI to generate one positive intervention response. A fading of effect size differences in the longer term (12 months or more) has been observed, but more studies are needed to verify it. Even so, within-group differences still indicate that a substantial group of problem drinkers are consuming less alcohol at follow-up than at baseline. The small- to medium-effect sizes for unguided ISBIs compare well with those reported for face-to-face adult brief interventions in primary care and for unguided postal self-help.

Extended unguided self-help ISBIs show a medium impact in meta-analyses (d = 0.60), greater than that of minimal PNF-based unguided ISBIs, which have effect sizes in the small range. Such findings were not confirmed, however, in a large-scale randomized controlled trial (N = 7935) published in 2011. It found no significant difference in terms of alcohol reduction between a group receiving minimal psychoeducational information only and a group receiving an extended self-help ISBI procedure at any of the three assessments (at 1, 3, and 12 months). Both groups decreased their mean weekly alcohol consumption by 20 units (from 46 to 26), thus suggesting potential benefit from access to either minimal or more extended ISBIs. Differences in findings compared to other studies might possibly be attributable to differing study designs. One striking difference involves the blinding of participants to their group allocation. In most studies on unguided ISBIs, researchers inform participants to which group they will be assigned as they inform them about study aims during recruitment. Nondisclosure of group allocation is preferable, as such knowledge may influence treatment outcomes and bias results.

The effectiveness of Internet-based multiple-session therapist-guided self-help treatment has also been assessed in two studies in comparison with nonintervention. One of these found a medium effect (d = 0.59) for chat-based therapy, and the other found a large effect (d = 1.21) for asynchronous e-mail therapy in terms of weekly alcohol consumption and conformity with low-risk guidelines at 3 months after the start of treatment. Such outcomes may be initial evidence for a potentially stronger impact of guided self-help treatments as opposed to unguided ones. A 2011 study found that although unguided self-help was as effective as guided chat-based treatment at 3 months, the chat-based group fared better at 6 months in terms of a further reduction in mean weekly consumption. The medium to large effects

found for guided online treatment are similar to those found in meta-analyses for face-to-face treatments (d = 0.80). More research is still needed to try to replicate findings that compare guided online treatment to unguided online interventions in terms of alcohol consumption and related outcomes.

ISBIs for Problem Drinking at the Workplace

Work environments seem to be promising venues to deliver screening and brief intervention, as they potentially afford easy access to large groups of problem drinkers. It is this large population of problem drinkers in employment that is responsible for the bulk of the health and economic burden associated with alcohol misuse. Only a few studies have assessed the user acceptability or the effectiveness of workplace interventions; their outcomes are not overwhelmingly positive. One explanation for the disappointing results lies in the low percentage of employees who are willing to participate. They may fear loss of privacy or other negative consequences if they disclose themselves as problem drinkers at their place of work. ISBIs could help to overcome some of their fears, as confidentiality can be much better safeguarded in ISBIs than in conventional SBIs. When ISBIs are delivered via the workplace (mainly done up to now in large US or Australian companies), they are often components of overall employee health programs. Such ISBIs target the general employee population with preventive messages and with screening for problem drinkers and at-risk employees. Not surprisingly, such ISBIs are particularly effective for problem drinkers, delivering small to medium effects in terms of reduced alcohol consumption. Yet studies on ISBIs at the workplace are hampered by constraints similar to those affecting conventional SBIs, including limited sample sizes due to recruitment difficulties. Like conventional SBIs, ISBIs appear more acceptable to employees in work settings where alcohol use is strictly regulated, such as in the military. One study has illustrated the positive impact of two ISBIs among military personnel: Alcohol Savvy, a universal, primary prevention program aimed at adults in the workplace; and the PNF-based Drinker's Check-Up. The latter was found more effective than Alcohol Savvy, and both were superior to nonintervention.

SUMMARY, FUTURE DIRECTIONS, AND CONCLUSIONS

Summary

Internet-based screening and brief intervention programs (ISBIs) are effective, feasible, and acceptable

for delivery to many problem drinkers in the general population. The majority of people who actively use ISBIs drink well above the recommended guidelines for low-risk drinking. Most are adults between 35 and 55 years of age, relatively well educated, and in paid employment; most are first-time help seekers. Overall, ISBIs not guided by a professional have been found to produce small to medium effects compared to nonintervention. Studies of online guided treatment resources are scarce, but results suggest they may have a greater impact than unguided ISBIs. Whether the intensity of treatment will predict treatment outcomes and whether particular groups of problem drinkers will respond better to particular kinds of ISBIs needs to be examined further. The effectiveness of unguided ISBIs in reducing problem drinking is apparently comparable to that of face-to-face or telephone SBIs in primary care and of SBIs delivered by mail to adults in the community. The longer-term (more than 1 year) effectiveness of ISBIs has yet to be assessed. Differences between the outcomes of groups receiving unguided ISBIs and nonintervention control groups appear to narrow over time, though both groups tend to moderate their alcohol consumption.

Studies also show that a substantial percentage of ISBI participants do not succeed in reducing their alcohol intake. Even if they do, not all of them manage to stay below the low-risk guidelines. Yet even a reduction of one standard unit per person per day would generate substantial health and economic gains if large numbers of drinkers could be reached at low costs. Negative consequences of alcohol misuse, such as traffic accidents, injuries, and work absenteeism, could be diminished. Long-term detrimental health effects, such as cirrhosis of the liver, cardiovascular disease, major depression, and suicide, could also be mitigated. ISBIs could thus prove to be a viable component of an overall public health approach to problem drinking. That is especially true of ISBIs that require no professional guidance, as these can be disseminated on a wide scale with minimal investments of time and money.

Future Directions

Evaluating and expanding the evidence base for ISBIs requires further research. The robustness of current insights needs to be tested, and many questions remain unanswered. Most findings are still not generalizable to the average problem drinker, based on the characteristics of existing ISBI participants. It is also unclear for which types of problem drinkers ISBIs might be more effective and in what settings ISBIs might be most successfully delivered. Improvements in study design and conduct should also make the results more generalizable to daily practice.

For Which Problem Drinkers Are ISBIs Effective?

ISBI user profiles based on study participation data suggest that most users would have relatively high income and education levels. It is therefore not clear to what extent the outcomes of the currently available studies can be generalized to groups that are insufficiently reached at present, such as people of low socioeconomic status, the elderly, or ethnic minorities. Reaching such groups may require interventions with different formats or modalities as well as innovative recruitment strategies. Predictor studies that investigate whether low education or income is a barrier to successful engagement with ISBIs have yielded an incomplete picture, as have those that assess whether ISBIs might be less effective for very heavy drinkers than for moderately heavy ones (as has been found for offline SBIs). More research is therefore needed on these issues. Studies on mediators and moderators of behavioral change in problem drinking and on the most effective components of ISBIs might create more insights. Incorporating diagnostic interviews into randomized controlled trials of ISBI participants (in addition to the current self-report screening measures) could produce more in-depth knowledge about many of these issues and about the severity level of the individual drinking problem. Research on additional aspects of ISBIs, such as the possible role of natural recovery mechanisms and the potential adverse effects of unguided interventions (including the postponement of professional help), will further strengthen the ISBI evidence base.

Improving Treatment Compliance and Discouraging Dropout

Most ISBI studies are hampered by high dropout rates and low intervention adherence by participants. Study dropout is often well over 40%, while as few as 15% of participants may actually complete the intervention as intended. Dropout rates of this magnitude may bias study outcomes even if missing data are accounted for statistically. Improving adherence and reducing sample attrition will enhance the validity of research results and decrease the likelihood of bias. Some studies have reported contradictory associations between the level of adherence and the severity of problem drinking: Some found that the more serious the problem, the greater the engagement of the participants; others found that study dropouts had significantly greater alcohol-related problems than completers. Other reasons for dropout or noncompliance could be that participants attain their goals early or are dissatisfied with the ISBI itself. Although one might understandably presume that low adherence means poorer treatment results in ISBIs (as has been shown for offline SBIs), any such relationship needs to be substantiated in research. These investigations, too, will contribute to the evidence base for the rapidly growing field of Internet screening and brief intervention for problem drinking.

Assessing the Cost-Effectiveness of ISBIs

Several economic studies have evaluated the cost-effectiveness of brief face-to-face interventions for problem drinking, and most have found favorable benefit-to-cost ratios. Although comparable studies on ISBIs are very few in number, these, too, suggest promising economic outcomes in terms of both the low delivery costs of ISBIs and the indirect cost savings accruing from reduced production losses and improved job performance by problem drinkers. Further studies are required to investigate the economic implications of ISBIs more rigorously.

Conclusion

Internet-based screening and brief intervention (ISBI) is a feasible and effective strategy to curb adult problem drinking. Its potential could be enhanced by integrating such online intervention resources into approaches that combine public health prevention strategies with treatment strategies in primary and secondary care. Such approaches could be based on a "stepped-care" model to address problem drinking. Unguided, free-access ISBIs would be a cost-effective first step. Problem drinkers might then move up to guided interventions, if necessary, or even to more intensive treatment and medication. Low-threshold monitoring of client progress is, however, a key requisite for successfully implementing a stepped approach. Monitoring would ensure that treatment for problem drinkers is stepped up in a timely and efficient manner. More intensive treatment might consist of guided ISBIs or face-to-face treatment modalities, or combinations of both. Adjunctive online peer support may enhance the effectiveness of ISBIs throughout all such stepped-care stages. Studies on the use of ISBIs by primary care providers or hospital emergency departments are still rare, and it is not yet known whether ISBIs could help overcome the general constraints of SBIs in such settings. Given their demonstrated advantages, we expect they may do just that. The study and implementation of ISBIs may therefore help to build a public health strategy that provides a full range of effective prevention and care services for problem drinkers in a cost-effective manner.

INTERNET INTERVENTIONS FOR ILLICIT DRUG USE

This section reviews the literature on web-based interventions to assess the progress and the evidence regarding the effectiveness of Internet intervention for illicit drug use and the misuse of licit (e.g. prescription or over-the-counter) drugs. The potential benefits of ISBI found for problem alcohol consumption are likely to extend to interventions for illicit drug use. Although this field lags behind the developments of ISBI for alcohol, there are still examples of universal, selective, and indicated programs that have been evaluated. Given the range of substances under investigation and the current stage of development, this section includes programs evaluated in both adult and adolescent settings.

A search for peer-reviewed papers on Internet interventions revealed reports of interventions that covered a wide range of target groups – from universal preventive approaches to those targeting people fulfilling DSM-IV criteria for substance use disorders. Most studies reported outcomes for several classes of drugs (often including alcohol and tobacco), but there were specific interventions for users of benzodiazepines, cannabis, cocaine, and opioids.

Interventions for illicit drug use have adopted a range of methodologies, including computer-generated letters and facilitated video conferencing, but generally they are used to deliver programs in a standard fashion to replicate the input from a therapist. These draw on a number of theoretical or treatment frameworks, including social learning theory, motivational interviewing, community reinforcement approach, family interactional approach, and CBT.

INTERVENTIONS FOR CANNABIS USE

Cannabis is the most widely used illicit drug in the world with about 4% of the adult population having consumed cannabis in the last year. This compares about 1% for opiates, cocaine, and amphetamine-type stimulants combined with the prevalence in the developed world ranging from 0.1% in Japan to 16.8% in Canada. Unlike the interventions for alcohol, among the interventions that included cannabis use as an outcome, there were diverse theoretical approaches underpinning the programs. This diversity may reflect the age range of participants. First, as with alcohol, among adults, cognitive-behavior therapy and motivational approaches were used. Personalized feedback alone did not appear to be effective. Brief interventions that include incentives, produce short-term improvements, and extended intervention can be successful in reducing cannabis use to 12 months. Other interventions have involved mother and (teenage) daughter dyads, and via extended programs based on family interaction theory, these have achieved significant reductions in cannabis use to 24 months, plus reductions in measures of other substances. Further trials with extended interventions include educational approaches, which show little effect and programs drawing on social influence and social learning theory that were successful in reducing cannabis consumption to 6 months.

> INTERVENTIONS AS ADJUNCTS TO PHARMACOTHERAPY

Opioid substitution therapy for heroin dependence with methadone or buprenorphine is well established. However, this requires the collection of medication on a (near) daily basis from a clinic or pharmacist. Attendance for psychotherapy would be an additional burden, especially as agonist therapies are meant to permit recipients to return to everyday activities, such as employment or education. The provision of Internet-based therapy would alleviate this burden while providing an additional support in the transition away from heroin dependence. However, initial research has only provided limited support for this proposition. Studies published in 2008 and 2009 by Bickel and Chopra found that contingency reinforcement for drug-free urine samples improved abstinence whether delivered by therapists or computers compared with standard care. A comparison of video conferencing with face-to-face care found no significant difference in outcomes, albeit with a small sample.

LIMITATIONS OF EXISTING RESEARCH

These studies typically have had small samples, with the median being 120 participants. As a result, there has been little opportunity to evaluate the key characteristics of successful interventions or to identify whether there are critical features of those who would benefit most from face-to-face interventions or computer support. In addition, these interventions often use short-term outcomes, with the median follow-up being 6 months, ranging from as little as 2 weeks to 24 months. Although, most studies had rates of attrition that would be considered low for Internet interventions, these should be considered in light of the length of follow-up. Furthermore, some studies included incentives (such as medication or voucher contingency schemes) or were delivered in combination with methadone or buprenorphine maintenance programs. Nevertheless, retention of over 90% at 24 months, as reported for one German program, would be meritorious in any circumstance. Most studies used self-reported drug use, which is often used as an outcome measure in the substance use field. However, some of the studies, especially those including drug substitution programs, were able to include "objective" measures such as urine screening tests to provide a more rigorous outcome.

CONCLUSIONS

Internet interventions for substance use are still in their infancy, although the initial reports appear to be favorable. Characteristic of this stage is the diversity of approaches, even though these were typically underpinned by the notion of replicating existing face-to-face therapies. However, the development of interventions that use multiple features of web content (e.g. blogs, chat, games) and have the potential to create a new paradigm in treatment still seems to be problematic.

Concerns exist about the cognitive capacity of substance users to benefit from treatments such as CBT that require insight and complex cognitive tasks. The use of computer-aided treatment, particularly if it requires strong literacy skills or lacks the potential to clarify misunderstandings, could be a further barrier to effective treatment. Nevertheless, the potential for exercises to be repeated as required, progression at the participant's own pace, and the presentation of multiple vignettes modeling behavior could be beneficial compared to face-to-face interventions.

In sum, the breadth of target groups, ranging from universal prevention to those with dependence, suggests considerable utility of this approach. However, the universal prevention approach is the most likely to exploit the advantages of computerized interventions with greatly extended reach and fidelity compared with standard care. The ISBI approach can be successfully integrated into the school curriculum, but it remains to be seen whether this explicitly harm-minimization model will be acceptable in all jurisdictions, such as the United States, where abstinence models predominate.

Overall, the use of ISBI has yet to establish a strong empirical basis for its use as either a treatment or an adjunct to pharmacotherapy among illicit drug users. However, the potential benefits offered by this approach warrant further investigation, in particular its use in universal prevention (e.g. within the school curriculum) and as a means of engaging marginalized and stigmatized client groups, which are currently reluctant or unable to access conventional treatment.

List of Abbreviations

CBT cognitive-behavioral therapy

ISBIs Internet-based Screening and Brief Interventions

PNF personalized normative feedback

SBIs screening and brief intervention procedures

FURTHER READING 863

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Relevant Websites

http://www.alcoholdebaas.nl - Alcoholdebaas.

http://www.beacon.anu.edu.au – Beacon is a portal that reviews online applications for mental and physical disorders.

http://www.downyourdrink.nl - Down Your Drink.

http://www.drinkerscheckup.com – Drinkerscheckup is a program for problem drinkers including comprehensive assessment, objective feedback, and help with making a decision.

http://www.jellinek.nl – Jellinek Retreat offers exceptional care for those with addiction problems, burnout, or depression.

http://www.minderdrinken.nl – MinderDrinken is an interactive self-help intervention for problem drinkers, based on cognitivebehavioural and self-control principles.

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Examining the Role of Parents in College Student Alcohol Etiology and Prevention

Rob Turrisi, Kimberly Mallett, Lindsey Varvil-Weld, Kelly Guttman The Pennsylvania State University, University Park, PA, USA

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INTRODUCTION

For some students, alcohol consumption begins after college matriculation. For others, it represents a continuation of established behavior. Further, there is evidence that some alcohol-related consequences increase in older students aged 21–24 years. In response, more intensive campus and community programs have been implemented. In spite of these efforts, college student alcohol problems in the United States have not decreased significantly.

Numerous factors have been implicated in college alcohol misuse. These include expectancies and motives, environment, and background factors. In addition, drinking attitudes and peer norms are among the strongest correlates of alcohol abuse. While peer influences are significant predictors of alcohol socialization, a growing literature has emphasized the importance of parents. Although some reports show that parents'

influence may recede, others suggest the continued value of parental involvement.

To date, there is no review on the role of parents in college student alcohol etiology and prevention. Thus, the aim of this article is to fill this gap in the literature. Our analysis is organized into three sections. Section 1 focuses on the role of parents in the etiology of college student drinking. This section covers parental approval and permissibility of teen drinking (Is it okay for parents to permit their teens to drink?), parental communication (Can and do parents communicate effectively with their college students about alcohol use?), parental monitoring (How do parents keep in touch with their sons and daughters?), parental modeling of alcohol use (Are there certain types of modeling behaviors that are risky or protective?), family history of alcohol abuse and alcoholism (Is there evidence that parental history of alcoholism is uniquely harmful to college students?), parenting styles (Are there specific styles that increase or reduce harm?), and gender (Is there a difference between mothers and fathers when it comes to college student drinking?). Section 2 focuses on the literature examining the efficacy of parent-based interventions (PBI) designed to reduce the onset or usage of alcohol (Are parents an important part of comprehensive prevention efforts and effective as targets for prevention?). Finally, Section 3 is a discussion of the current state of parenting research in relation to college student drinking, limitations, and future directions.

THE ROLE OF PARENTS IN THE ETIOLOGY OF COLLEGE STUDENT DRINKING

Parental Approval/Permissibility of Drinking

The topic of parental approval and permissibility of underage drinking has been recently associated with two opposite viewpoints. One viewpoint is that the legal age of 21 is appropriate and parents who permit underage drinking may be increasing their child's risk of engaging in risky drinking behavior. The opposing second perspective is that it is better to supervise underage teens in order to teach them to drink in a responsible manner as they transition into adulthood. While this debate is prominent in media outlets, the scientific evidence consistently supports the positive relationship between parent permissibility of alcohol use and students' risky drinking behavior in college.

Research has shown that parental approval of underage alcohol use is related to increased consumption and related consequences among college students. Abar and colleagues found that college students whose parents were more permissive about drinking while they were in high school (as measured by limit setting and approval of drinking in general and in special circumstances) were more likely to engage in alcohol misuse and experience more consequences than students who had less-permissive parents. Further, complete parental disapproval of alcohol consumption was the optimal strategy to reduce high-risk consumption among students during their freshman year. Interestingly, no gender effects were observed. In a longitudinal study conducted by Livingston and colleagues, the authors examined whether parents allowing their daughters to drink alcohol at home during senior year of high school reduced the risk of heavy drinking in college. The authors examined the following three types of permissibility: not permitted to drink at all, allowed to drink at home during family meals, and allowed to drink at home in the company of their friends. The findings indicated that students who were allowed to drink at home during high school in both categories (during family meals and with friends) engaged in more high-risk drinking during the first semester of college than those who reported not being allowed to drink at all. However, students who were permitted to drink at home with friends reported the heaviest alcohol consumption. Further, the relationship between alcohol permissibility and college drinking was mediated through perceptions of parental alcohol approval. Research has also examined the relationship between parent and peer approval and college student drinking and found that both are significant predictors. Additional research has shown that if a large disparity between parent and peer approval of drinking exists, individuals with friends who approve of drinking and parents who disapprove are at a higher risk of drinking heavily and experiencing problems.

In sum, research demonstrates a consistent positive relationship between parental permissibility and approval of alcohol use and high-risk drinking in college. Students of parents who disapprove of underage drinking are at a lower risk of engaging in high-risk drinking and related problems. No research to date has shown increased parental approval or permissibility of alcohol consumption to be protective against harmful drinking in college. In addition, studies have indicated the importance of consistency between normative reference groups. Specifically, parents can promote responsible alcohol behavior by encouraging their son or daughter to choose friends who share their value system.

Parental Communication

Communication is another avenue through which parents may influence their children's alcohol use. Researchers have examined alcohol-specific parental communication and found that it is associated with less drinking and fewer alcohol-related consequences. On a related note, general positive communication between mothers and their teens has been identified as protective against high-risk college drinking. Conversely, negative parent-teen communication has been linked to negative alcohol outcomes among college students. One study found that parent-child communication conflict was linked to alcohol-related consequences in a sample of college students. Conflict with fathers was more strongly predictive of consequences than conflict with mothers for male students. However, the association between conflict and alcohol-related consequences was stronger for female students.

The specific content of alcohol-related communication may also be important. Turrisi and colleagues found that among a sample of college student athletes, communication about the legal, social, and academic consequences of alcohol use was actually linked to heavier drinking. On the other hand, communication

about the physical consequences of alcohol use was associated with less drinking. Another study found that parent–student communication about the negative effects of alcohol use was unexpectedly associated with more excessive drinking in a sample of college students. It may be that overly negative parental messages about alcohol cause their teens to discredit them. Future research could help identify specific communication content that is most protective with respect to reducing high-risk college student drinking.

While it is clear that parent communication about alcohol is important with respect to college student drinking, further clarification is necessary to determine the relevance of timing of communication. Parents may initiate conversations about alcohol during high school, in the summer prior to college matriculation, or while in college. One paper has examined frequency of communication at these different time points; however, college student alcohol use was not examined as an outcome.

Similar to alcohol-specific communication, general openness to communication may also be protective. Open communication between parents and their children could be an indicator of overall relationship quality, which in turn influences student drinking. For example, children who report an established pattern of good communication may be more likely to communicate with their parents when they are faced with decisions about drinking or choice of peers. While there is little in the literature addressing overall tone of communication between parents and college students, one study found that students' perceptions of family openness to communicate were associated with parent-child discussions about alcohol, which in turn were related to fewer risky drinking behaviors in one sample of college students.

In sum, both alcohol-specific and general parent communication have been consistently linked to less drinking and fewer consequences among college students. Future directions should explore content and timing of communication to determine their relevance to drinking outcomes.

Parental Monitoring

Parental monitoring is generally conceptualized as parents' knowing where their children go at night, what their children do during the day, and also what they try to know about their children's drinking. Monitoring of students' activities, and also specifically drinking, has been shown to be related to lower\first-year college student drinking. Another study examined parental monitoring and two types of college alcohol outcomes. The first binomial model examined the influence of parental monitoring on initiation of drinking and

experiencing consequences. The second linear regression model tested monitoring as a predictor of drinking and consequences, which were continuous outcomes. Students who perceived greater parental monitoring during the summer before college entrance were less likely to report experiencing consequences in the binomial analysis and reported less binge drinking and fewer consequences in the linear model.

Specific factors that have been identified as important in the relationship between monitoring and alcohol use outcomes are drinking history and peer influences. Researchers have found that parental monitoring was protective against drinking in college and this relationship was explained by high school drinking. The authors also found that students who resided in their parents' home while attending college consumed less alcohol. With respect to peer influences, research has shown that the impact of parental monitoring on second semester college alcohol use is mediated by friends' alcohol use. This suggests that one way in which parents exert indirect influences on their college students' alcohol use is by monitoring their choice of friends. Similarly, Wood and colleagues found that the relationship between monitoring and alcohol-related consequences was moderated by number of alcohol offers from peers. At lower levels of monitoring, alcohol offers significantly predicted consequences, but at higher levels of monitoring, there was no such association. Finally, students who perceived that their parents had both an awareness of their drinking and cared about their drinking tended to drink less in terms of both quantity and frequency during the first semester of college.

In sum, parental monitoring has consistently been linked with reduced alcohol use and related consequences among college students. The majority of this work has focused on monitoring prior to college entrance or during the first semester of the freshman year; therefore, future efforts could elucidate the impact of longer-term monitoring throughout the college experience.

Parental Modeling

Research investigating the parental modeling of alcohol use has primarily focused on adolescent samples, and the literature on modeling's impact on young adults is limited. One longitudinal study followed adolescents into their early 20s, and the authors used growth curve analysis to model trajectories of alcohol use. They found that parental modeling of alcohol use was a stronger predictor of teen drinking than parenting behavior itself, such as monitoring. Mother's modeling was more predictive than father's modeling, indicating that mothers and fathers have independent and distinct influences on their teen's drinking.

There is scant research investigating the parental modeling of alcohol use specifically among college students. Abar and colleagues examined parental modeling and alcohol use among first-year college students and did not find a significant association. However, their measures of modeling captured drinking quantity and frequency only and did not include other alcohol-related behaviors (e.g. reasons for drinking, risky or protective drinking behaviors such as drinking shots or pacing drinks, or behavioral consequences such as drinking and driving).

Despite the body of work investigating the parental modeling of alcohol use among adolescents, there is very little examining modeling among college students. In addition to determining the relationship between modeling and college student drinking, future directions could include more detailed measures of modeling that capture behaviors beyond drinking itself. A second area that requires further exploration is how modeling impacts antecedents of college student alcohol use, such as alcohol-related expectancies or willingness to drink.

Family History

The link between family history of alcoholism and college student alcohol use is well documented. More specifically, *parental* history of alcoholism is also related to alcohol use and problems among college students. Authors examined parental history of alcoholism and found that it significantly predicted alcohol use disorders in a sample of college students.

Parental risk for alcohol-related problems may be transmitted through different pathways. Two pathways that have been identified are expectancies and personality characteristics. In one study investigating expectancies, positive parental history of alcoholism was significantly related to greater alcohol problems. This relationship was moderated by positive expectancies for alcohol use such that students with a positive parental history and more positive expectancies were at greatest risk. Another study in a sample consisting primarily of college students examined personality factors (social deviance and excitement-seeking) and found that these characteristics accounted for a significant proportion of the variance in the association between parental alcoholism and alcohol abuse.

A third possible mechanism through which parental alcoholism transmits risk to college-age children is exposure to childhood stressors. Scientists examined a sample of college students with and without a history of paternal alcoholism. They found that those with an alcoholic biological father were more likely to have experienced childhood stressors related to their fathers' drinking, such as verbal or physical abuse. The effect

of paternal history of alcoholism was stronger for women than for men, suggesting that females experience more stress related to their fathers' alcoholism than males. Exposure to childhood stressors was significantly related to later problems with alcohol; again, this effect was stronger for women with respect to certain stressors. These childhood stressors partially mediated the relationship between paternal history and development of problem drinking during young adulthood.

To summarize, parental history of alcoholism has been identified as a risk factor for high-risk college drinking. Possible mediators of this pathway are cognitive and personality factors and exposure to stressful experiences in childhood.

Parenting Styles

Parenting styles encompass many of the factors previously discussed, including monitoring, communication, and approval of alcohol use. Baumrind identified four types of parenting styles: (1) authoritative, (2) authoritarian, (3) permissive, and (4) indifferent. These four parenting styles can be conceptualized in terms of warmth and structure. Authoritative parents provide both warmth and structure. Authoritarian parents also set rules and boundaries; however, they are not as warm and are more punishment focused. Permissive parents are very warm and supportive but provide few rules or structure. Finally, indifferent parents provide little warmth, support, or structure. There is a rich literature focusing on parenting styles in relation to child and teen development; however, less is known about the relationship between parenting style and drinking behavior during emerging adulthood.

In a recent study, scientists observed the presence of all four parenting styles among college students. Nearly half of the parents in the sample were classified as authoritative (48%), while the following percentages represented the rest of the sample: authoritarian (14%), permissive (27%), and indifferent (11%). Further, the study found that individuals with authoritarian parents were at a significantly higher risk of heavy episodic drinking during their freshman year compared to the other groups.

The work of Patock-Peckham and colleagues has explored the relationship between parenting styles (authoritative, authoritarian, and permissive) and drinking behavior in the context of mediating and moderating variables. Findings from these studies are summarized below.

1. Authoritative Parents. The authoritative parenting style has been shown to be a protective factor in relation to college student alcohol consumption and problems. For instance, both males and females with authoritative parents have lower rates of alcohol

problems. Specifically, males with an authoritative father report less impulsiveness and depression, a stronger parental bond, and increased autonomy, resulting in fewer alcohol-related problems. Males with authoritative mothers also have fewer alcohol problems mediated through higher self-esteem and lower depression. Females with authoritative mothers have higher self-regulation and drinking control that are related to reduced alcohol outcomes. Similarly, females with authoritative fathers report fewer alcohol problems mediated through depressive symptoms.

- 2. Authoritarian Parents. In contrast to authoritative parents, research has found that authoritarian parenting is significantly associated with increased risk and has no protective qualities. For males, having an authoritarian father is associated with increased alcohol-related problems that are mediated through increased neurotic symptoms and depression. Females with authoritarian mothers report more impulsivity and those with authoritarian fathers have higher rates of depressive symptoms, both resulting in increased alcohol-related problems.
- 3. Permissive Parents. Studies have shown that permissive parenting can have risky and protective qualities in relation to college alcohol use. In terms of risk, males who have a permissive father tend to be more impulsive and have lower self-regulation, resulting in increased alcohol use and problems. Females with a permissive mother exhibit the same pattern. In contrast, both males and females with permissive parents had increased autonomy. For both genders, fathers' permissive parenting style was associated with lower levels of depression as mediated by increased autonomy. Depression was positively associated with alcohol problems.

Interestingly, Patock-Peckham and colleague's work showed that there were differences in terms of which parent was more influential, which varied depending on the gender of the target child, the personality construct under study, and the parenting style. These findings make a strong case for examining mothers' and fathers' independent influences on their college students' drinking.

Gender

As suggested above, the issue of parent gender is becoming more salient in both etiological and intervention research among college students. A large portion of previous work that examined parental influences on adolescents' drinking outcomes did not account specifically for gender. Studies are now more consistently examining differences between mothers and fathers in

terms of impacting young adult alcohol use. Studies that have included gender have shown mixed results in terms of which parent is more influential. Some authors have found that mothers tend to be more influential figures than fathers in relation to adolescent and young adult behavior. Other recent research examining family history and parenting styles has highlighted the distinct influence of both mothers and fathers on emerging adult drinking behaviors. More research examining the unique influence of gender influences in terms of both parents and children is needed.

EXAMINING THE EFFICACY OF PBI

Several studies have been conducted over the past decade examining the efficacy of PBI to prevent the onset of or reduce previously established drinking tendencies. In this body of research, the format of the PBI was an informational handbook that was developed to assist parent communication about drinking with their emerging adult children. The theoretical underpinnings of the handbook were heavily influenced by psychosocial theories of behavioral decisionmaking (e.g. intentions, attitudes, and norms toward drinking and the alternative behaviors) and the specific format of the handbook contained different sections to increase parental motivation to communicate, bolster parenting skills (e.g. communication, assertiveness training, dealing with resistance, decision-making), and alcohol knowledge. Fidelity of the PBI is assessed through parental evaluations of the interest, value, readability, utility, and ease of comprehension for each of the sections and self-reports on whether they had talked with their teen about each of the major topics discussed in the handbook. Typically, it has been observed that an overwhelming number of parents discussed the different topics with their sons and daughters (e.g. over 80%) and the evaluative ratings of the handbook were universally positive. The studies that have implemented the PBI will be reviewed in turn.

In the earliest study focusing on a PBI for emerging adults, Turrisi and colleagues examined the effect of the intervention on college freshman drinking tendencies approximately 3 months post-baseline. Despite the fact that all respondents were below the legal age for drinking, approximately one in three individuals indicated that they drank alcohol weekly and consumed five or more drinks 2 weeks prior to the data collection. Comparisons between treatment group and controls, controlling for baseline drinking and gender, were all significant in the hypothesized directions. For example, individuals in the treatment condition had lower levels of drinking and drunkenness episodes, lower perceived

parent and peer approval of drinking, and experienced fewer alcohol-related consequences. Follow-up comparisons at approximately 9 months post-baseline (spring semester assessments) revealed no significant time by condition interactions suggesting the effects did not decay across the first year of college.

Researchers conducted an in-depth analysis examining variables from the theoretical models underlying the original Turrisi PBI. Attitudes toward diverse drinking and nondrinking activities (e.g. drinking at a sporting event, bar, or party; getting drunk at a sporting event, bar, or party; going to a sporting event, campus event, or coffee shop, and not drinking) were included as mediators. First, the analyses of the PBI and the mediators revealed that individuals in the control condition had more favorable attitudes toward the drinking activities and less favorable attitudes toward the nondrinking activities. Second, in the analyses of the mediators and the drinking outcomes, it was observed that as individuals' attitudes toward drinking activities became more favorable, their drinking increased and as individuals' attitudes toward nondrinking activities became more favorable, their drinking decreased. Finally, the comparison of analytic models controlling for and not controlling for the mediators revealed that the effect of the PBI was partially mediated by the attitudinal constructs, suggesting that the PBI also had an impact on emerging adult drinking via factors other than decision-focused constructs.

In another extension of the original PBI research, Turrisi and colleagues examined a PBI in combination with an individually delivered motivational enhanced intervention (BASICS) with a high-risk subgroup (athletes). Athlete status, by comparison to the other risk factors, had been relatively under-examined in college student alcohol interventions. Participants (n = 1275) were randomized to one of four conditions (BASICS, parent, combined BASICS and parent, or assessment-only control) using a computerized algorithm. The followup assessment was conducted at approximately 10 months post-baseline (spring semester; 85.5% retention). Analysis of covariance examined mean differences in drinking outcomes at follow-up by treatment condition, controlling for baseline drinking. Results indicated that participants randomized to the combined condition reported significantly less drinking and consequences compared to the control group. Participants in the combined group also reported significantly fewer consequences. Beliefs about alcohol, attitudes toward drinking, descriptive norms, and injunctive norms with respect to both peers and parents were explored as mediators of intervention efficacy and drinking outcomes at follow-up. Results revealed that descriptive norms and injunctive peer norms were significant mediators of the relationship between the intervention and all drinking outcomes. Relative to the control group, those who received both the parent and BASICS intervention perceived that typical college students drink less and perceived their peers to be less favorable toward their drinking behaviors and in turn reported drinking fewer drinks per week, fewer drinks per weekend, experiencing fewer consequences, and were estimated to have a lower peak blood alcohol concentration (BAC) at follow-up.

In a secondary analysis of the combined intervention for college athletes study, latent profile moderator analyses determined whether there were parent subgroups for whom the interventions were more effective versus less effective on peak drinking BACs. The latent profile analyses revealed a four-class solution, with consistently high probabilities (all >0.86) that participants were assigned to the most likely class. The first profile, labeled authoritative, was characterized by high relationship quality, monitoring, and alcohol knowledge, and below average negative communication and approval of underage drinking. The second parent profile, labeled permissive, consisted of low negative communication, monitoring, and alcohol knowledge, and high relationship quality and approval of underage drinking. The third parent profile, labeled authoritarian, consisted of low relationship quality, approval of underage drinking, and alcohol knowledge, and high negative communication and monitoring. The final parent profile, labeled indifferent, was characterized by low relationship quality, monitoring, and alcohol knowledge; high negative communication; and average approval of underage drinking. Follow-up analyses revealed that control participants in the authoritarian and permissive profiles had a significantly higher mean peak BACs compared to the combined intervention participants in these profiles (no significant differences were observed for authoritative or indifferent parenting styles). Together these findings suggest that the interventions had the largest impact on those students who came from authoritarian and permissive parents.

Ichiyama and colleagues examined the efficacy of the original Turrisi PBI in the context of environmental risk. In this study, approximately 95% of the sample resided on campus near a documented environmental risk factor: close proximity to the border of the United States and Mexico, where studies have reported higher than average rates of college student high-risk drinking and alcohol-related consequences. First-year students were randomly assigned to the PBI or the no-PBI condition and assessed on drinking outcomes prior to college and again 4 and 8 months post-baseline. There was an active comparison condition in which all first-year students' parents received materials on alcohol policies, consequences of policy violations, and information on college drinking during orientation, and

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were encouraged to be actively involved in conversations with their students. An analysis of a latent growth mixture model revealed that female students in the PBI condition were significantly less likely to shift to drinking; however, the growth for males was nonsignificant. Thus, the trial seemed to replicate the benefits of the original PBI, at least for females. The authors cited the lack of a true control group, the possible confounding influence of an environmental risk factor, and the differences in the proportions of students who were commuters versus residents as plausible reasons for the differences in findings from the original study.

Modifications to the Original Turrisi PBI

As noted above, there have been several studies conducted on modified versions of the Turrisi PBI. Researchers examined the efficacy of a modified PBI in combination with an individually delivered brief motivational intervention (BMI) based on the BASICS program for a universal college sample. Modifications of the PBI included reduced emphasis on drinking abstinence and increased emphasis on protective factors (e.g. clear expectations about alcohol use, monitoring, and drinking-specific communications). In addition, the design of the study included a 2-year post-baseline follow-up. With these notable innovations, the findings were similar to those of the original study. The lowest level of alcohol-related harm was observed for individuals receiving both the PBI and the BMI interventions, relative to either the PBI-only or the BMI-only interventions.

Testa and colleagues examined the efficacy of an adapted version of the PBI designed to increase mother-daughter communication to reduce alcoholinvolved sexual victimization. The study had four conditions: traditional PBI, enhanced PBI (adding a component covering college dating, sexual assertiveness, and partner selectivity), assessment-only control, and a post-assessment-only control. Assessments of drinking and sexual victimization were conducted at pre-intervention baseline prior to college matriculation and during the fall and spring semesters of the first year in college. The findings revealed that both PBI conditions were associated with lower incidences of incapacitated rape relative to controls. Path analyses also revealed that the intervention increased parentstudent communication, which in turn influenced lowered drinking and incapacitated sexual victimization.

In sum, taken together, the PBI studies indicate some benefits of targeting parents alone or in combination with other evidence-based intervention efforts. These findings are very promising as administrators and public health officials are seeking potential solutions to reducing the high-risk drinking and consequences that are so common on our campuses.

DISCUSSION

During the past two decades, both etiological and prevention research has shown that parents are influential in college students' alcohol use. Prior to the year 2000, the accepted view was that parents were largely irrelevant in terms of impacting college student drinking behavior and much of the research examined peer influence in relation to college student drinking. However, as highlighted in the current review, parents can and do impact students' alcohol consumption by virtue of their approval, communication, monitoring, modeling, style, and history, and are also an efficacious mode of intervention delivery.

Overall, the current review highlighted ways in which parental behaviors can serve as both protective and risk factors in relation to risky drinking among their sons and daughters as they transition to college. In summary, with regard to parental approval, research consistently found that students whose parents approve of and are permissive of underage alcohol consumption are at a higher risk of engaging in risky drinking behaviors. No study to date has supported the idea that parents supervising or "teaching" their sons or daughters how to drink responsibly is beneficial in reducing excessive consumption. Research has also found that students who engage in more general and alcoholrelated communication with their parents drink less and experience fewer consequences, particularly if the communication is more positive in nature. Increased parental monitoring in high school and during the first semester of college has been associated with less drinking and fewer problems in students' early transition to college. In addition, research suggests that parental modeling of alcohol use is positively associated with students' alcohol consumption; however, more work is needed to better understand this relationship. A parental history of alcohol problems has been identified as a risk factor for problematic drinking in college; however, more work is needed to explore mediators of this relationship in order to better understand these underlying mechanisms of influence. Finally, studies examining parenting styles tend to indicate authoritative parenting as a protective factor in preventing high-risk drinking among college students. Research was somewhat variable in this area based on gender and personality differences among both the parents and their children.

The research to date on the role of parents in prevention efforts is also promising. The majority of trials in the area have shown benefits of engaging parents and

emphasizing the benefits of communication. Further, there is emerging evidence that parent-based efforts that are initiated during the teen years may have long-lasting benefits into college. It is interesting to note that almost all the literature in this area has focused on first-year college students. The role of parents needs to be examined beyond the first year, as do efforts to involve parents in the prevention of drinking.

LIMITATIONS AND FUTURE DIRECTIONS

Although the literature on parenting and college student drinking has grown significantly over the past decade, a relative lack of research in this area in comparison to other life stages remains. In addition to the gender differences mentioned previously, areas that need future attention include understudied constructs that are important in the development of risky or protective drinking behaviors, time course and measurement issues, and a more inclusive examination of different college populations.

The majority of parenting research up to this point has focused on a limited variety of student outcomes, such as quantity and frequency of drinking or consequences, or both. Future work should explore parenting factors as they relate to correlates of drinking and consequences, such as drinking attitudes and beliefs, and consequence-specific constructs. Another future direction would be to examine how parenting might relate to engagement in protective behaviors that have previously been identified in the literature, such as alternating drinks with water.

With respect to time course, the majority of previous work has studied parenting behaviors immediately before college entrance and, in some cases, into the fall of freshman year. Similarly, student drinking and consequence outcomes have been shorter term and have generally not been assessed beyond the freshman year. Future work should examine the influence and changing dynamics of parenting in relation to longer-term student outcomes throughout the entire college experience.

A third limitation of the previous body of literature is the prevalence of teen-reported measures of parenting. While teens' perceptions of their parents' behavior are certainly important, parent-reported experiences, attitudes, beliefs, and behaviors would provide a useful and more comprehensive picture of the parent-student relationship during the college years.

Finally, future work could benefit from a more inclusive definition of the college student population. Previous studies have focused exclusively on traditional 4-year college students who attend college away from home and live on campus. Almost no literature on

parenting and students attending community colleges or technical schools exists. In addition, due to the convenience of using registrar data to contact students for research purposes, most previous studies have ignored students who leave or transfer from school. Future work should address parenting and teen alcohol use in the context of school leaving, re-entry, and transfer.

In sum, the body of research in this area indicates that parents significantly impact students' drinking behavior and alcohol-related consequences, are important targets of future efforts of study, and warrant inclusion in comprehensive intervention efforts.

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SEE ALSO

Individual Prevention of College Student Alcohol Misuse, College Student Gambling: Etiology, Consequences, and Prevention Strategies, History and Impact of Minimum Legal Drinking Age Laws on Alcohol Use and Consequences Among Adolescents and College Students, Understanding Individual Variation in Student Alcohol Use, Brief Feedback-Focused Interventions

List of Abbreviations

BAC blood alcohol concentration BMI brief motivational intervention PBI parent-based interventions

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Universal, Indicated, and Selective Prevention for Youth Gambling

Francine Ferland*, Nadine Blanchette-Martin\$

*Centre de réadaptation en dépendance de Québec, Québec, QC, Canada \$Centre de réadaptation en dépendance de Chaudière-Appalaches, Lévis, QC, Canada

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The topic of gambling and pathological gambling is an area of study that has increased its field of expertise over the years. Thirty years ago, knowledge of gambling was still very small, but the arrival of the 2000s coupled with increased gambling offerings and availability of gambling activities via the Internet have led many researchers to look at this problem and simultaneously allowed significant growth of knowledge in this field. Thus, we know quite well the characteristics of adults with gambling problems, the consequences that this problem may bring to the gambler, his social network and society, as well as the factors associated with the development of problem and pathological gambling in adults. However, despite an increasingly large and diverse literature, relatively little is known yet about how pathological gambling takes place among youth and how the presence of such a problem is reflected in their lives. As a consequence of the relatively few epidemiological studies estimating the prevalence of pathological gambling among youth conducted in recent years, prevalence rates currently available may poorly reflect the situation of 2012. The arrival of Internet gambling, cell phone gambling, and the rise of poker in recent years require further studies to establish the actual picture of the needs for prevention and intervention for youth. Despite this fact, previous research continues to guide preventive actions. This chapter aims to present a portrait of preventive practices that can be implemented with youth as well as some examples of preventive interventions that are already in place. We invite readers to consult the article entitled "Preventing the Incidence and Harm of Gambling Problems" published in 2008 by Dickson-Gillespie, Rugle, Rosenthal, and Fong in the *Journal of Primary Prevention*. This paper presents a comprehensive model of the different prevention possibilities targeting public health and different clienteles.

GAMBLING AND PATHOLOGICAL GAMBLING AMONG YOUTH

When talking about gambling, we think of an array of diverse activities. In fact, the word "gambling" includes all activities for which a person may bet or wager money or an object of value. In general, we can divide gambling activities into two categories: the "legal" gambling activities and "private" gambling activities. Legal gambling

activities are usually managed by the State or by a private enterprise and are controlled by legislation or regulation that has to be followed by managers of these activities. These legal gambling activities refer mainly to lotteries, horse racing, video lottery terminals, and casinos. In regard to the second category of gambling activities, the private gambling activities, it includes all the activities done with family or friends and for which no or very little legislation is in place to control them. Besides playing cards or playing dice with friends that spontaneously come to mind, private gambling activities may also include a variety of more or less unusual activities; for example, betting money on sporting events, on the result of a monopoly game, on the result of a video game, on the speed of an automobile, on the number of flies that will arise on the table in 10 min, on the result of an exam, etc. Thus, this is not the activity that defines the presence of gambling, but rather the context surrounding its practice. In fact, three elements must be present to determine the activity an individual participates is a gambling activity. The person (adolescent or adult) must wager money or something that has value on the result of the activity. The result must be based wholly or partly on chance (as in cards, for example) and the bet must be irreversible, so that nobody can recover their money if they lose.

The use of such a broad definition of gambling activities allows us to better understand how participation in gambling may be present in the lives of youth. Based on the previous definition, several everyday activities can become gambling activities that are readily available for youth. Once accepted the idea that the bet can be a valuable thing (in the owner's perspective), the more limited financial resources of youth are no longer an obstacle to gambling, because they can bet valuable items such as IPods, MP3 players, clothing, food, or cigarettes if they do not have money. It is therefore utopian to believe that the regulations that restrict youth access to the legal gambling activities prevent them from gambling participation. In fact, most studies conducted among youth indicate that approximately 80% of them have already participated in gambling activities while between 24 and 65% of high school students report having annually participated in these activities.

Obviously, not all young gamblers will develop pathological gambling. However, it is possible to believe that gambling in childhood or adolescence may lead young people to develop a positive attitude toward this activity, which will continue throughout the adulthood. In fact, one of the few longitudinal studies conducted among youth demonstrated the stability of the proportion of young regular gamblers between 16 and 23 years of age (Winters et al., 2002).

The criteria currently used to determine whether an individual, young or adult, presents or not pathological gambling are those listed in the DSM-IV-TR. There are 10 criteria and the diagnosis of pathological gambling is present when the gambler meets 5 of these 10 criteria. This diagnosis should be assigned in a face-to-face interview with the gambler. However, as it is difficult to make a face-to-face assessment in population studies, the latter typically use screening questionnaires, which are completed through telephone interview or selfreported questionnaires during group meetings (e.g. in schools). The questionnaires currently used in most of the studies addressing the prevalence of pathological gambling among youth are the DSM-IV-J or its MR-J version (Fisher, 2000), the South Oaks Gambling Screen-Revised Adolescent (SOGS-RA) (Winters et al., 1993), and the Massachusetts Gambling Screen (MAGS) (Shaffer et al., 1994). All these questionnaires are based on the diagnostic criteria for pathological gambling listed in earlier versions of the Diagnostic and Statistical Manual of Mental Disorders and they give an estimate of the intensity of the gambling problem. While the Diagnostic and Statistical Manual of Mental Disorders classifies gamblers in terms of pathological or nonpathological gamblers, screening questionnaires have the advantage of distributing the respondents into several distinct categories depending on the intensity of the negative consequences they have to face because of their participation in gambling. The classifications most often encountered in epidemiological studies counted four categories and are placed on a continuum. These are as follows:

- **1.** Nongamblers: People who never participate in gambling activities.
- 2. Occasional or recreational gamblers: People who gamble primarily for fun and socializing and who do not suffer consequences because of their participation in gambling activities.
- 3. At risk gamblers: People who gamble above average (more frequently or more money) and who have few negative consequences because of their participation in gambling activities.
- 4. Probable pathological gamblers: People who suffer several negative consequences because of their participation in gambling activities. It should be noted that the term "probable" is used to clarify that the assessment was done by questionnaire and that it is an estimate and not a formal diagnosis.

Besides these standard categories, it is also common to find the expression "problem gamblers" which, according to the authors, put together in one category at risk and probable pathological gamblers, or place all the gamblers in a single group who reported at least one negative consequence related to their gambling participation. UNIVERSAL PREVENTION 877

Population studies conducted with youth indicate that between 1.7 and 8% of them met the criteria for probable pathological gambling and between 4 and 14% are at risk of developing gambling problems. It is important to note here that in the last few years, the field of youth gambling has hosted several debates concerning both the criteria that is used to assess the presence of gambling problems among youth and the questionnaires used to do this assessment. The most important arguments were the lack of the definition of pathological gambling adapted to youth and the youth's difficulties in understanding the screening questionnaires. This is perhaps not unrelated to the fact that prevalence studies among youth have declined in quantity in recent years. Because gambling now occupies an important media space and activities such as poker appeal particularly to young people, it is quite possible that the prevalence rates currently available are not representative of what the reality really is. Further epidemiological studies will be needed in coming years in order to draw a picture of the recent situation of youth and ensure that preventive interventions that would be implemented continue to meet the needs. The arrival of a new screening questionnaire for problem gambling among youth could help do this. Indeed, as the items that compose the Canadian Adolescent Gambling Inventory (CAGI) (Tremblay et al., 2010) were developed following focus groups with youth, many of the items retained in the final version target impacts that a youth may suffer due to an important participation in gambling activities. In addition, the CAGI having been part of an exhaustive process of validation in both English and French, there is every reason to believe that future epidemiological studies that will use it, will allow a better overview of the youth's gambling profiles.

Despite all the methodological and ideological debates surrounding the epidemiological studies and prevalence rates of gambling among youth, it is important to remember that abusive/excessive/pathological gambling can lead to serious consequences that could impinge the cognitive, personal, social, and academic development of youth. Although not all young people who participate in gambling activities will develop gambling problems during their adolescence or adulthood, the fact remains that exposure to gambling activities is the first step towards acquiring such a habit. It is to reduce the likelihood that youth develops gambling problems so that prevention programs were developed and implemented over the years. One way to classify preventive interventions is to divide them in terms of universal, selective, and indicated prevention based on the populations targeted by the interventions. The universal prevention strategies are designed to reach the entire population, without regard to individual risk factors, and aims at preventing or delaying the beginning or abuse of gambling; selective prevention strategies target subsets of the total population that are deemed to be at risk for gambling problems by virtue of their membership in a particular population segment. Indicated prevention interventions identify individuals who are experiencing early signs of gambling abuse and other risk factors associated with pathological gambling and target them with special programs. An approach, like the harm reduction approach is also part of the preventive approaches introduced in recent years and it is predominantly found in the indicated preventive intervention category.

The next sections focus on each of the three categories of preventive interventions and, when possible, provide examples of interventions that have been proved effective. It is, however, important to note that although all preventive interventions should be evaluated before being implemented on a large scale, yet few interventions targeting the prevention of gambling were assessed and published in the scientific literature so far. This document is not an exhaustive presentation of every preventive intervention actually available. It is rather meant to describe the types of preventive interventions available to youth under 18 years old.

UNIVERSAL PREVENTION

Universal prevention strategies are designed to reach the entire population, without regard to individual risk factors. These programs are intended to reach a very large audience and aim to prevent or delay the onset or the abuse of gambling. Universal prevention programs targeting gambling problems may have different objectives. Indeed, some of these programs will aim to provide nonerroneous knowledge about gambling activities in order to help youth better understand what are the real odds of winning, while others aim to raise awareness about the consequences of an abusive participation in gambling and about the resources available if the youth or his or her relative needs help. However, regardless of the proximal goal of universal prevention programs, their distal goal is always to prevent or lessen the risk that youth develops a gambling problem.

Often implemented in schools, universal prevention programs targeting youth attempt to reach all the students and convey a consistent message to all, and this in a relatively short period of time. As these programs are relatively easy to implement and they easily reach many people, it is not surprising that they are the type of preventive intervention that can be found the most frequently.

Although the basic assumption of universal prevention is to reach all youth, it might be important to question the age at which these programs should be introduced and the type of information they should transmit. A study from Messerlian and Derevensky (Messerlian et al., 2005) showed that youth would not be affected by the same type of message depending on their age and gender. According to these researchers, girls are more sensitive to prevention campaigns based on emotions, while boys prefer more direct messages that present statistics and use humor. These researchers also noted that the younger teens prefer prevention messages including humor while older ones prefer more dramatic messages. Besides this difference on the content of the message that varies with age and gender, it is also important to question the relevance of meeting students of all ages as part of gambling prevention initiatives. Indeed, studies conducted with teenagers and pathological gamblers indicated that participation in gambling begins around 10-11 years of age and that most parents of children 5–17 years old gamble with their children (92%) and listen to television lottery shows with them (72%). Such statistics are indicative of the place that gambling activities takes in everyday life and of the trivial characteristic that is associated to this activity. However, although these figures include many young people, they do not indicate that all 10 year olds know and participate in gambling activities. Depending on the family environment in which youths are raised, it may happen that 10 year olds do not have contact with gambling. The great diversity of individual experiences thus leads to an additional problem regarding the age when universal preventive intervention should be initiated. It would indeed be inappropriate to have to teach kids how to play poker in order to demystify the role of chance and knowledge in this activity!

Although few prevention programs are evaluated, some experiments have shown interesting and positive results for youth. The *Dicey Dealings* program developed and implemented in some schools in Australia in 2004 is one of them. The evaluation of this program (Department of Education and Children's Services, 2005) involving a control and an experimental group showed that youth who received the intervention had gained a better understanding of chances of winning in gambling activities and a better knowledge of the resources available to gamblers, while reducing the number of their erroneous beliefs related to gambling. Despite the positive impacts of the program at the cognitive level, it has not succeeded to reduce the gambling behavior of youth. Apart from this Australian experience, other preventive interventions implemented in schools have also been tried and most of those which were evaluated showed positive impacts on knowledge and attitudes toward gambling but did not have an impact on youth gambling behaviors. To our knowledge, only one preventive intervention addressing problem gambling in a universal approach has reduced the gambling behavior of participants. This program is called *Gambling: A Stacked Deck*. It has been evaluated with high school students (Grade 9–12) and showed a reduction of the time spent on gambling and the money wagered 3 months after completing the intervention (Williams et al., 2003).

The results obtained with the prevention programs evaluated clearly demonstrate the importance of ensuring the impact of those programs prior to broadcasting them to a wider audience. Prevention of gambling among youth is relatively new and it is important to learn from prior experiences of prevention in the field of addiction because some of them revealed that an intervention aimed at reducing the occurrence of a behavior might in fact increase its occurrence or the curiosity for it. As mentioned by Shaffer, Hall, and Vander Bilt (1997), "The need for program evaluation is dictated by a simple premise: unless a program is evaluated, we do not know whether it is producing positive, neutral or negative results." However, in order to have this information one needs to conduct the assessment over a period of time long enough so that youth would be faced with the possibility of gambling. Moreover, to estimate the effectiveness of a preventive intervention it is also important to determine the extent of what would be "acceptable" gambling involvement to conclude whether there has been a positive impact of the intervention. Will it be considered effective if youth have not started gambling 1, 5, 10, or 15 years after the intervention? Will it be considered effective if youth gamble without reaching the at risk or pathological gambling levels? This great difficulty maybe explains why there is still no universal prevention program for gambling among youth that was evaluated long enough to demonstrate its effectiveness on the gambling behavior.

As demonstrated by the results of evaluations, universal prevention programs are highly effective in changing knowledge and attitudes of youth toward gambling, but the lack of long-term evaluation does not allow an assessment of their impact on eventual participation in gambling that would or not meet the criteria for at risk or pathological gambling. Furthermore, individual differences in the age of initiation, experience, and exposure to gambling activities vary extremely from one youth to another. Therefore, exposing all the youth of the same age to the same preventive intervention may translate to a first exposure to gambling for some of them. A selective prevention approach is therefore an interesting avenue for

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gambling. More difficult to implement than universal prevention, it could however allow better results.

SELECTIVE PREVENTION

Selective prevention strategies target subgroups of the general population who are deemed to be at risk for gambling problems by virtue of their membership in a particular population segment. Generally, these programs do not take into account the level of risk of developing a gambling problem. They are more interested in the belonging of the participant to a specific subgroup. It should be noted that the choice of the subgroup that would be targeted by the intervention would color the content of the selective preventive intervention.

The scientific literature on gambling identifies several risk factors associated with the development of gambling problems. These factors are numerous and the main ones are among the demographic and personal characteristics of youth. Thus, being a boy, being young, having only completed primary or secondary school, and having school problems are all well-documented demographic characteristics. Other risk factors related to personal characteristics associated with the presence of gambling problems are impulsivity, sensation seeking, drug, alcohol and cigarettes use, and having done illegal acts and delinquency. Besides these factors, there are also economic factors (e.g. having a family allowance), social factors (e.g. having friends who gamble, having easy access to gambling activities), and familial factors (e.g. low parental supervision, having a family member who has or had a problem with alcohol, drugs, or gambling). Risk factors directly linked with the gambling history are also often seen as being precursors of a gambling problem. Among these, we find the gain of a large amount of money at the beginning of gambling participation, the type of gambling activities engaged in, and the early onset of gambling involvement.

While all youth with these risk factors could benefit from preventive interventions tailored to their needs, there are still no guidelines supporting the choice of who should be privileged among these subgroups. Without being contradictory, opinions are still quite varied. For example, Derevensky and colleagues (2005) underlined the importance of targeting youth with multiple risk factors, because the accumulation of risk factors in one individual is linked to the development of a gambling problem. Other researchers put more emphasis on the importance of focusing prevention efforts on children whose parents or siblings have a problem with gambling or substance abuse.

Like previous reviews, our research did not identify selective preventive interventions conducted with youth who have been empirically evaluated and published. (This does not mean that no intervention of this type is currently available. Several organizations are implementing preventive interventions that are not advertised or available through scientific journals.) Although it is difficult to explain the rarity of this type of intervention with youth, the fact that they are more difficult to implement than universal programs is probably no stranger to this. A school that wishes to organize a preventive intervention for a subgroup of at risk youth on regular school hours would face several challenges including the need to remove youth from class on regular school time. Moreover, the same intervention established outside the regular school hours would require the organization to organize a transportation service for the targeted youth. Despite these difficulties, the selective prevention approach remains an interesting option because it allows a focus on subgroups of youth who share similar experiences and therefore allows a more personalized response.

INDICATED PREVENTION

Indicated prevention programs aimed at youth who show signs of excessive gambling and at youth who have risk factors for developing gambling problems without meeting criteria for pathological gambling. Unlike youths who participate in universal prevention programs, those targeted by the indicated programs will be screened before being included in these programs. Although the purpose of indicated prevention, as of any prevention program, will always be to prevent the development of gambling problems, the measures implemented to achieve the goal as well as the program content will vary depending on the characteristics of the youths that we want to reach.

Here, the first selection criteria is the extent of youth gambling participation and the importance of the negative consequences experienced as a result of gambling participation. Thus, youths who meet the criteria of at risk gambling (which may lightly vary depending on the questionnaire used) would be privileged under indicated prevention programs. According to data currently available, they account for 4–14% of youth in the general population.

As for selective prevention, the scientific literature on gambling does not contain any indicated prevention experience for the youth clientele. Again, the difficulty of implementing this type of intervention in a school setting may explain why these programs are hard to find among youths. The relatively low prevalence rate of at risk or pathological gamblers among youth also makes it difficult to set up an indicated intervention when few youths in the same sector could attend the intervention. However, there are several examples of this type of preventive intervention available for adult casino gamblers. Many of these programs use a harm reduction approach in putting forward controlled gambling or responsible gambling to ensure that the gambler remains or returns to an area of nonpathological gambling causing him or her little or no negative consequences. A similar approach could also be an option for youth gamblers because the majority of youth who gamble do not develop gambling problems and remain recreational gamblers. It would therefore be interesting to study the impact of the harm reduction approach with youth at risk and pathological gamblers.

CONCLUSION

Although years of research on youth gambling habits have improved the knowledge toward this population, yet today most prevention programs designed for them use a universal approach and are introduced in school settings. Following the information gathered to write this chapter, we can only underline the absence of evaluated selective and indicated prevention programs in the scientific literature. We believe that this situation is mainly due to the fact that there are still few prevention programs for which the effectiveness is evaluated and even less which are published in scientific journals. The field of gambling prevention, however, needs that prevention efforts be evaluated, because only the results of such evaluations could confirm whether or not a program is effective and which components of the program are really effective. It is worth noting Williams et al. (2003) who were able to identify elements of their prevention program that were associated with decreased gambling behavior. Such information is valuable and can guide the development of new preventive interventions. Thus, although the evaluation of preventive interventions takes time and is sometimes difficult to implement, dissemination of the results is necessary to improve future preventive interventions addressing gambling.

SEE ALSO

Evaluating Treatment Efficacy, Harm Reduction Approaches, College Student Gambling: Etiology, Consequences, and Prevention Strategies

Glossary

Youth the term "youth" used throughout this chapter includes all individuals aged 18 and under as well as all young adults who

study on a full-time basis, who are under their parents/guardians' responsibilities, or have a way of living that meets what one would actually expect from adolescents.

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College Student Gambling: Etiology, Consequences, and Prevention Strategies

Ty W. Lostutter, Jacqueline K. Holmes, Mary E. Larimer University of Washington, Seattle, WA, USA

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GAMBLING OVERVIEW

Gambling Definitions

Gambling is placing something of value (typically money) at risk on an event with an element of chance in the outcome, with the potential to win a substantially larger prize. Gambling requires one to bet on the outcome of some event or specific game such as lottery tickets, cards, bingo, slots, machines, instant scratch tickets, races, animal tracks, sporting events, dice, and roulett. The list could be endless of the ways in which one could bet. This chapter uses the term disordered gambling, coined by Howard Shaffer and colleagues, to refer to a range of gambling behavior, from behavior that places individuals at risk for developing more serious problems (subclinical) to those behaviors that would meet Diagnostic and Statistical Manual of Mental

Disorders (Fourth Edition) (DSM-IV) diagnosable criteria for pathological gambling (PG). The term disordered gamblers refers to individuals who engage in gambling behavior within this range.

Disordered Gambling as a Mental Health Disorder

Although problem gambling has been around for centuries and was described by one of the founders of modern psychiatry, Emil Kraepelin, as "gambling mania," it was not officially recognized as a mental disorder until the American Psychiatric Association's publication of their *Diagnostic and Statistical Manual of Mental Disorders* (Third Edition) in 1980. In the past 27 years, the criteria have evolved from their inception, based solely on the clinical work of Robert Custer, to the

use of a more evaluative process involving surveying 222 self-identified compulsive gamblers and 104 substance-abusing social gamblers as the controls. Lesieur and Rosenthal conducted cluster analyses to identify a set of nine symptom criteria, which would distinguish between the two groups. After national and international meetings, many experts suggested a 10th criterion of "loss of control over gambling." A follow-up study was conducted with 453 subjects using these 10 criteria to attempt to correctly identify pathological gamblers. While the "loss of control" criterion was found not to significantly improve the diagnosis of PG, the item remained in the current set of 10 criteria used to define PG. Currently, according to the American Psychiatric Association's DSM-IV (Text Revision), PG is classified as an impulse control disorder, not elsewhere classified. The disorder is defined by the 10 symptom criteria designed to capture persistent and recurrent maladaptive gambling behavior, not better explained by a diagnosis of bipolar disorder, manic episode. An individual's gambling is determined to meet the threshold for diagnosis of PG if he/she meets five or more of the following: (1) is preoccupied with gambling (e.g. preoccupied with reliving past gambling experiences, handicapping or planning the next venture, or thinking of ways to get money with which to gamble); (2) needs to gamble with increasing amounts of money in order to achieve the desired excitement; (3) has repeated unsuccessful efforts to control, cut back, or stop gambling; (4) is restless or irritable when attempting to cut down or stop gambling; (5) gambles as a way of escaping from problems or of relieving a dysphoric mood (e.g. feelings of helplessness, guilt, anxiety, depression); (6) after losing money in gambling, often returns another day in order to get even ("chasing" one's losses); (7) lies to family members, therapist, or others to conceal the extent of involvement with gambling; (8) has committed illegal acts, such as forgery, fraud, theft, or embezzlement, in order to finance gambling; (9) has jeopardized or lost a significant relationship, job, educational, or career opportunity because of gambling; and (10) relies on others to provide money to relieve a desperate financial situation caused by gambling (American Psychiatric Association 2000).

Despite relatively stringent criteria in the *DSM-IV* for a diagnosis of PG, most clinicians and researchers recognize the existence of subclinical symptoms of PG and have used the terms "problem," "compulsive," or "potential PG" to refer to excessive gambling resulting in subclinical levels of negative consequences. A continuum model suggested by Korn and Shaffer conceptualizes gambling occurring along a continuum, ranging from no gambling (level 0) or nonproblem gambling (level 1), to at-risk gambling (level 2), to diagnosable PG (level 3). Disordered gambling refers to all

gambling at level 2 (at risk) or greater, which would include those individuals meeting *DSM-IV* criteria for PG. The most commonly used screening measure for disordered gambling is the South Oaks Gambling Screen (SOGS). The standard use of this measure suggests that a cutoff score of 5 or more indicates probable PG. Individuals scoring 3–4 have been termed at-risk or problem gamblers.

Despite being categorized as an impulse control disorder, PG is similar to other addictive behaviors in both its description and treatment. As addiction experts prepare for revising the Diagnostic and Statistical Manual of Mental Disorders for version 5, several have suggested recategorizing PG alongside substance use disorders, based on similarities in diagnosis and assessment, comorbidity, neurobiological overlap, and treatment practices. Regarding assessment, the diagnostic criteria for PG has more in common with substance abuse and dependence criteria than with the other impulse control disorders of intermittent explosive disorder, kleptomania, pyromania, and trichotillomania. Four of the 10 criteria for PG closely resemble the substance abuse criteria, including preoccupation, needing to gamble with increasing amounts of money to achieve the desired excitement (equivalent to tolerance), repeated unsuccessful efforts to cut down, and irritability when attempting to cut down (equivalent to withdrawal).

Recent biological studies have found a number of neurobiological features in common between pathological gamblers and substance users as identified by biochemical, functional neuroimaging, and genetic studies. Similarities between gambling and substance use disorders have been found in the neurotransmitter systems including dopamine, serotonin, and gamma-aminobutyric acid. Collectively, this evidence is being used to propose upcoming changes to the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* (Fifth Edition) in which PG is moved from the Impulse Control Disorders to a new category currently proposed to be called Behavioral Addictions.

PREVALENCE OF COLLEGE STUDENT GAMBLING

North America

Transitioning from adolescence to adulthood makes college students a unique population worthy of attention. College students have been found to gamble more than the general adult population. The current generation of college students has grown up in a culture with widespread legalization and promotion of

gambling as a socially acceptable behavior. Two metaanalyses conducted in 1997 and updated in 2001, including 19 college studies, estimated the prevalence rates in the United States and Canada as 10.88% of college students classified as at-risk gamblers and 5.56% classified as pathological gamblers. For example, Lesieur and colleagues in the early 1990s surveyed six universities and found that 85% of students gambled, 23% gambled once a week or more, and 10% experienced some problems associated with their gambling. More recently, studies not included in the Shaffer and Hall meta-analyses have reported somewhat higher rates of disordered gambling, perhaps fueled by the campus craze of poker play.

Winters and colleagues conducted a three-wave longitudinal study of 305 Minnesota mid-adolescents (time 1 [T1] in 1992, time 2 [T2] in 1994, and time 3 [T3] in 1997–98) through young adulthood (mean ages were 16.0, 17.6, and 23.8), and reported two main findings: (1) the prevalence at wave 3 (young adulthood) of problem gambling, defined as 4 on the SOGS, remained unchanged from the previous two waves (adolescence) and (2) there was a significant increase from adolescence to young adulthood of atrisk gambling, defined as an SOGS score of 2-3. Winters and colleagues expanded on these findings by examining individual trajectories over the threewave assessment. They classified their sample into five categorical behavioral patterns, which included resistors, persistors, desistors, new incidents, and others. Resistors were the largest group and made up 60% of the sample. Resistors never reached the threshold of problematic gambling over the three time points. Some of the resistors did engage in gambling, but report of their gambling behavior was consistently infrequent and nonproblematic. The least common behavior pattern, termed "persistors," represented 4% of the sample. Persistors were individuals whose status was at risk or problem gambling at all three time points. Their typological feature involved regular or frequent gambling; most reported gambling weekly. Thirteen percent of the sample was categorized as desistors. Desistors followed a behavioral pattern of at-risk or problem gambling at time 1 (mid-adolescence) but never reported gambling problems at either time 2 or 3. Three percent of the sample was considered other, in that their gambling behavior appeared more episodic and variable in pattern. These individuals reported problematic gambling twice in the three-wave assessment but with an interrupted period of nonproblem gambling during the second wave. The second largest group was the new incidents (21%), which supports that early adulthood seems to be a particularly important age period when gamblingrelated problems emerge in the form of at-risk

gambling. This suggests that young adults (including college students) are a population in need of further prevention programming.

In contrast to studies showing higher rates of disordered gambling among young adults and college students, some studies have questioned if these rates are inflated. Slutske and colleagues in 2003 reported following 468 first-time freshmen as part of a larger longitudinal study of alcohol use patterns at the University of Missouri-Columbia. The data used for the longitudinal analyses correspond to ages 18-19, 21-22, 24-25, and 28–29, and assessed students during the years 1987–88, 1990–91, 1993–94, and 1997–99. The rates of past year and lifetime incidence of problem gambling remained stable over the 11-year period. Two to three percent of the sample reported experiencing gamblingrelated problems in the past year, 1–2% experienced a gambling-related problem for the first time in the last 3-4 years at ages 18, 21, 24, and 28, and about 3-5% of participants had experienced a gamblingrelated problem in their lifetime. While the rates of disordered gambling were found to be lower than the 10% found in previous studies, these rates were still higher than the general adult population. Although the study had a strong, longitudinal methodology, the results might be outdated, given that the assessment period coinciding with college attendance was during the late 1980s and early 1990s, before the media explosion of college student poker and Internet poker took hold of college students' attention. In addition to the study's timing, location of the campus and regional differences might also have been factors in the lower rates for this particular study. Recently, Welte and colleagues conducted a national telephone survey and found that the South had the lowest rates of gambling and problem gambling compared to the rest of the country.

LaBrie and colleagues surveyed 10765 college students from 119 scientifically selected US colleges included in the 2001 Harvard Public Health College Alcohol Study. Their results indicate that 52% of males and 33% of females reported that they gambled at least weekly in the last school year. Those students older than 21 years were more likely to gamble, and students gambled more in those states in which they had greater availability of gambling venues such as casinos and card rooms. Despite these findings, the authors suggested that previous rates of disordered gambling among college students may have been overestimated. The study is commendable for its size and depth of analyses; however, the fact that the study assessed only gambling frequency and type of gambling (rather than symptoms of disordered gambling) warrants tempering of conclusions drawn from this study, especially given that over half of the men and one-third of the women in the sample endorsed weekly gambling. Research suggests that frequent gambling (i.e. weekly) is associated with an increased risk of gambling problem severity.

In light of the mixed results regarding college student prevalence rates, the most recent meta-analyses was conducted in 2007, focusing solely on US college student populations. The analyses included 15 studies and found the rate of PG (SOGS \geq 5) to be 7.89%. This estimate is slightly higher than the rates found by Shaffer and colleagues published 10 years earlier. The authors suggest that the increase in the prevalence rate could be due to the surge in gambling availability and an increase in the popularity of poker and other casino games among college students in the past 10 years. There is support for this hypothesis in that college students are in closer proximity to casino environments than ever before. Closer proximity to gambling venues has been shown to be a strong predictor of disordered gambling.

Another study of college student gambling attempted to define behavioral indicators associated with disordered gambling among college students. The authors concluded that gambling more than 1.2 times per month, gambling more than 2.1 hours per month¹, intending to wager more than 6.1% of monthly income, and wagering more than 10.5% of monthly income represented thresholds above which likelihood of disordered gambling increased. The combination of psychological distress, gambling frequency, and a history of parental gambling problems was significantly associated with diagnosis of PG in college students.

Other Countries

Gambling has proliferated around the world with a variety of ways to gamble, including governmentsponsored lotteries, casinos, pari-mutuels, sports betting, and online gambling appearing throughout Asia, Australia, Europe, South America, and regions of South Africa. However, the particular issue of college student gambling or specifically disordered gambling within this population does not appear prominently in the research literature from studies conducted outside North America or Australia at this time. The current international research literature on disordered gambling has tended not to focus on college students per se but rather on college-aged young adults (ages 18–26). The nascent international research literature that does exist suggests that this segment of the population does tend to report higher rates of problems compared to the general adult population, a finding that could be attributed to broader developmental issues for this population. For example, the results of the British Gambling Prevalence Study conducted in 2010 reported that problem gambling estimates were higher among college-aged men compared with older populations, 2.8 versus 0.4%, respectively. Among college-aged women, problem gambling estimates were 1.3% for those aged 16–24 years and 0.2% among those aged 65–74 years. Similar findings have been reported in several European countries, Australia, and Asia, suggesting that this age range may be more prone to gambling problems; however, more research needs to be conducted to see if the university environments may add unique contributing factors that add to the risk for this group.

Prevention programs aimed specifically at college student gamblers in other countries also do not appear in the published literature, perhaps due to the scarcity of research on the issue of disordered gambling among young adults outside North America or because of lack of awareness of disordered gambling in this age group as a public health issue. The lack of information on college student gamblers from around the world suggests that this is an area ripe for rigorous research to be undertaken.

ETIOLOGICAL FACTORS RELATED TO COLLEGE STUDENT GAMBLING

Behavioral Theories

Behavioral accounts of gambling overlap with behavioral psychology because of the principles of variable reinforcement, response costs, magnitude of reinforcement, and immediacy of reinforcement of gambling behavior. The writings of Ferster and Skinner describe the powerful technique of variable ratio schedules in training animals to press levers. A variable ratio delivers a reinforcer after a random number of responses, but based on a predetermined average. Rewarding the animal with food, an average of every fifth push on the lever increased the likelihood of the animal continuing to push the lever. The exact same principles of varying the ratio of reward can be found with gambling, especially slot machines. Fester and Skinner also established that once initiated and learned by the animal, the behavior becomes hard to extinguish. Priming, in which a learned connection can be accessed via an unearned reinforcer, can trigger the original behavior. In the case of gambling, a disordered gambler who is abstinent can relapse to gambling based on environmental cues or apparently irrelevant decisions landing the gambler back in the

Schneider discussed the limits of reinforcement in terms of magnitude. For example, most gamblers would not place a bet of \$100 if the payout were \$110. Hence, the gambling industry has found that using games that

are low cost with high magnitudes reinforces more play than high costs—low magnitude. Hence, this may explain why at casinos the penny slot sections are filled with more patrons than the high rollers slot sections. Likewise, gambling can also be maintained by modeling and second-order conditioning. Television, movies, and advertisements all provide models of gambling behavior, typically displayed as happy, successful gamblers with few or no negative consequences related to gambling. Money receives its value through a social construct agreed upon my members of a society, called a secondary reinforcer, since it is in fact merely paper and ink. Secondary reinforcers can be near wins or small payouts that can encourage continued gambling.

Immediacy of reinforcement is also an important factor in determining effects of a reinforcement schedule. For example, if a rat presses a lever but the reward is delayed more than 30 s, the rat does not associate the lever press with the reward. Similarly, gambling reinforcement immediacy is related to disordered gambling. The majority of people seen for treatment for disordered gambling engage in casino gambling, typically slot machines/video poker (which deliver immediate reinforcement) compared to lottery gambling (which is associated with delayed reinforcement).

There is also evidence that gambling can serve as a negative reinforcer. A negative reinforcer is one that takes away aversive stimuli. With disordered gamblers, this could be negative emotional state such as feeling sad, depressed, or bored. Research suggests that those who gamble to cope with negative effect have higher scores on gambling severity.

Biomedical Theories

Biological or biomedical theories of disordered gambling grew out of the psychodynamic approach, given that most psychoanalysts are trained in psychiatry or come from a medical background. The biomedical approach views disordered gambling as occurring due to a disease process or biological risk factors inherent in the person. This model has served to develop various theories of organic systems that could explain the difference between recreational and disordered gamblers. Early research focused on arousal and how gambling could influence the physiological systems involved in arousal. Studies have demonstrated that gamblers do report becoming aroused when involved in gambling. There are also corresponding physiological reports that have demonstrated that gambling behavior can increase heart rate and other measures, such as eletromyographic activity and skin conductance level, and assays of endocrine response including salivary cortisol.

While results to date suggest that gambling and physiological arousal are connected, what that connection is remains to be established, as the findings and interpretations regarding the determinants and effects of arousal are not always consistent. Gambling severity is found to be associated with degree of arousal, but not always. Several studies have demonstrated that winning is more arousing than losing and that winning real money (versus chips or playing just for fun) is more arousing. While the results have been mixed, there does appear to be a connection between arousal and gambling behavior, which may have a biological component.

Other research on the biological basis of disordered gambling has focused on structural or abnormal brain functioning that might affect information processing systems of the brain. Pathological gamblers have been found to have reduced hemispheric differentiation compared to controls according to electroencephalography readings, which has been suggested to mediate impulse control. The study, however, did not fully describe the eight pathological gamblers for substance use or other histories of psychiatric disorders, which have been associated with similar abnormalities. More recent neurocognitive work has found impaired concentration, memory, and executive function and non-left language dominance in gamblers hemispheric compared to non-gamblers. The results suggest that these abnormalities could be the result of early brain damage, given that 81% of the 17 gamblers tested positive for brain injury.

Other biological evidence has begun to focus on the serotonergic, noradrenergic, and dopaminergic neurotransmitters; endogenous opioid systems; and the mesolimbic reward pathway as potential causal mechanisms in disordered gambling and addiction in general. The studies of these systems suggest that there may be genetic or functional abnormalities, which result in either structural or functional differences between gamblers and disordered gamblers. The current studies in the literature lack any randomized clinical trials, are generally based on small and often not well-described samples, and make causal inferences tenuous at best. Rarely do biological findings lend themselves to behavioral prevention strategies.

Cognitive Theories

Cognitive theories of human behavior and decision-making models became popular in the early 1970s and 1980s as a response to behaviorism. The cognitive theories relevant to gambling focus on cognitive distortions related to gambling. The psychological literature supports that human beings maintain several thought distortions especially about gambling. *Illusions of control*

refer to a belief that one has a greater amount of control on the gambling outcome than would be expected. Early experimental work found that people would behave differently if given the appearance that they could control the outcome. For example, Langer demonstrated that people who picked their number for a lottery ticket placed higher monetary value on that ticket than people whose tickets had already been randomly chosen for them, despite the fact that the outcome would be completely determined by chance and the expected value of both tickets is therefore identical. A second type of cognitive distortion relevant to gambling situations is commonly known as attribution bias. Wagenaar demonstrated that people who won on a series of hands of blackjack would attribute their wins to their skill, as compared to those who lost several hands, who would not make a personal skill attribution. There has been some support for the contention that disordered gamblers have significantly more cognitive distortions or qualitatively differ in the types of distortions made compared to non-disordered gamblers. However, other studies have not found support for differences in the frequency of erroneous statements made by disordered or non-disordered gamblers. Overall, cognitive distortions appear to be common regardless of gambling severity.

Social Influences

Normative beliefs, also called social norms, have been significantly influential and central to several theories of behavior and behavioral change based on social psychology concepts, such as Bandura's Social Learning Theory, Jessor and Jessor's Problem Behavior Theory, and Ajzen's Theory of Planned Behavior. The common thread between these psychological theories is the central tenet that cognitive processing of normative information or beliefs drives individual behavior and decisions to change that behavior. The term "social norms" often has two different ways of use in the literature. Descriptive norms refer to perceptions of actual behavior of others, whereas injunctive norms refer to perceptions of the appropriateness of a behavior. Research suggests that both types of norms are related to individual risk behaviors, and research further indicates that these norms are often misperceived. In particular, individuals tend to misperceive the descriptive norm as being higher than it actually is across a wide variety of health risk behaviors, including alcohol use, tobacco use, and a variety of other substances. Larimer and Neighbors examined college students' perceptions of peer gambling (descriptive norms) and their views on the acceptance of this behavior (injunctive norms) and found a similar pattern of misperception. Findings indicated that gamblers overestimated the descriptive norm, assuming that other students gambled more often and with more money than students actually engaged. Both descriptive and injunctive perceived norms were related to self-reported gambling quantity, frequency, and negative gambling consequences in this study.

Integrated Pathway Model

The integrated pathway mode of PG builds an explanatory model of disordered gambling, which integrates psychological and social environmental factors. Blaszczynski and Nower offered a pathway model integrating empirical findings from biological, personality, developmental, cognitive, learning theory, and ecological determinants of problem and PG. The proposed model suggests three pathways, which add on to each other to create a subtype classification of disordered gamblers. In each of the pathway models, they suggest that the ecological factors of availability and accessibility must be present. The first pathway is a strict behavioral model, suggesting that operant and classical conditioning leads some people to form gambling habits, resulting in losses, which lead to chasing behavior and disordered gambling. The second pathway is the emotionally vulnerable model, similar to pathway 1 but with the addition of a biological abnormality leading to physiological resting states of hyper- or hypoarousal, and a history of negative childhood experiences, which interact and are influenced by the behavioral reinforcers inherent to gambling. This interaction again leads to disordered gambling. The third pathway is the impulsivity model. Similar to pathway 2 gamblers, this subgroup possesses both psychosocial and biologically based vulnerabilities, and features of impulsivity and antisocial personality disorder distinguish this third group. While the theoretical model provides a plausible explanation, given some of the existing literature, it remains to be scientifically tested.

HARMS ASSOCIATED WITH GAMBLING

Gambling Problems

Attempting to review all the health implications for gambling is beyond the scope of this chapter, and most of the research on health-related issues is conducted on older adults rather than college students. For many college students, gambling is an enjoyable pastime. Most college students will not experience serious problems or go on to develop disordered gambling from their gambling activities. Yet, for some students, gambling can lead to a variety of negative

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consequences. Disordered gambling has also been linked to having higher rates of other mental disorders, including substance/alcohol abuse/dependence, eating, mood, anxiety, and personality disorders. Gambling activities along with the other risky health behaviors associated with gambling can promote a more sedentary and stressful lifestyle. Disordered gambling has also been linked to poorer health outcomes in several studies of later adulthood. Specifically, disordered gamblers have been found to have significantly higher rates of tachycardia, angina, cirrhosis, and other liver disease. Other studies have found that pathological gamblers suffered from minor respiratory ailments, high blood pressure, intestinal distress, migraine headaches, fatigue, and insomnia. It should be noted that these physical health issues do not typically appear during one's college years, but many of these individuals may have started gambling in college or earlier; thus, the long-term health outcomes may be attributed to gambling behaviors that started in one's college years but do not impact health until years later. Further research is needed to evaluate the contributing factors that appear to link disordered gambling to impacts on physical health.

Beyond physical heath consequences, gambling has been linked to a host of social and economic consequences. There is very little in empirical research on the link between college student gambling and legal problems. Several anecdotal stories have appeared in the media, highlighting the legal issues that have arisen due to students' gambling problems, including theft, bank robbery, check and credit card fraud, insurance fraud, embezzlement, selling illicit drugs, illegal sports betting or book making, underage gambling or frequenting a casino, and college athletes fixing games.

Academic and work performance can suffer due to gambling and personal relationships as well. For many college students, the extended period of time at school presents a new freedom. Many students move away from the family home and engage in new activities such as gambling. However, if a student's gambling becomes problematic, it can put a strain on relationships with family and friends. Disagreements over finances and confrontations about gambling behavior can arise, causing stress to both the student and loved ones. It can be especially difficult for the student as they may withdraw from relationships and lose their support systems.

Perhaps the most common problem for disordered gamblers is the financial issues that arise from chasing losses. Many problem or PG college students bet away large sums of money needed for tuition or living expenses. There has been some research to show that credit card debt also provides the easiest way for players

to finance their gambling, which may allow the problem to fester for months to years without being addressed. Credit card debt among college students could potentially set up college students for financial difficulties later in life.

Again, there is very little empirical research on how gambling behavior affects students' academic performance. There have been a handful of college student studies conducted in the United States and Canada, showing that disordered college student gamblers report lower grades than non-disordered gamblers; however, no longitudinal studies have examined this question or offered a potential causal mechanism for this outcome. Some have suggested that as disordered gamblers spend more time gambling and less time studying, the result is poor grades. No studies have examined dropout rates of college students due to gambling-related issues. It is possible that some students leave college due to their gambling behavior and anecdotal stories have circulated of students leaving college in order to pursue life as a "professional gambler," typically to pursue their interest in

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Indicated Prevention Programs

Prevention programs are designed to alter behavior or change the trajectory, by either increasing positive health behaviors (i.e. getting more sleep, eating more vegetables) or decreasing negative health behaviors (i.e. reducing alcohol consumption, stopping smoking) in order to reduce or avoid future problems, thus leading to better outcomes than if nothing was done. In 1990, the Institute of Medicine described three-tiered classification levels of prevention based on the target populations. Universal prevention targets the entire population regardless of their individual experience with the problem. Selective programs target a specific population due to the group's status as high risk, again regardless of individuals' experiences with the problem. Indicated prevention targets individuals who are already experiencing indications of the problems at either subclinical or clinically significant levels. Typically, individual interventions focus on targeting risk and/or protective factors believed to be contributing to the problem behavior. The intervention is designed to either reduce the individual's risk or enhance their protective behaviors when being exposed to the problem.

Prevention programming can take many forms and many levels such as policy approaches aimed at preventing problems through the implementation of laws and regulations. For example, setting the legal age to gamble is a policy intervention. While this does impact college students, most prevention programming to date has not specifically focused on college students despite the evidence that they are an at-risk population for disordered gambling.

Despite the relative dearth of evidence in the area of college student gambling prevention, three recently published randomized trials evaluated the efficacy of prevention programming with disordered gambling college students. All three prevention programs approach college student prevention using a combination of motivational interviewing (MI)/enhancement and cognitive behavioral principles to guide their development. MI, developed by Miller and Rollnick, views ambivalence about behavior change as typical, and the intervention is designed to highlight the discrepancy between one's current problem behavior (status quo) and personal goals (future ideal self) in order to reduce ambivalence. The goal of prevention facilitators is to have the participant voice their need to change, thus engaging their intrinsic motivation to change the problem behavior. All three programs also incorporate normative feedback components to some degree as part of their prevention program. Normative feedback is based on a social psychology principle that people who engage in a behavior tend to overestimate the actual norm of a behavior, and this overestimation is in part driving their own behavior. Correcting the misperception should enhance an individual's motivation to reduce their gambling to be more in line with normative behavior. In this case, those who gamble problematically think that others gamble more often and lose more money than they actually do, and presenting the actual norms on gambling in a nonjudgmental framework may aid in reducing a participant's actual gambling behavior.

Two of the existing prevention studies based their prevention approach on an adaptation of efficacious alcohol prevention programming with college students, a program called Brief Alcohol Screening Intervention for College Students (BASICS). BASICS uses an MI framework combined with cognitive behavioral skills training to reducing harms associated with alcohol consumption. The findings of the studies varied in the degree in which students reduced their gambling frequency and quantity of associated negative consequences.

Takushi and colleagues conducted one of the first indicated prevention studies on gambling for college students. Their pilot study focused on adapting the BASICS intervention to reduce at-risk gambling for college students. Participants were randomized to either the intervention or the control group. The prevention program had an assessment phase in which participants completed a series of paper–pencil measures and

returned the following week to meet a program facilitator for a one-on-one personalized feedback session. personalized feedback sheet that contained a summary printout of participants' data combined with psychoeducational information for reducing alcohol and gambling harms was provided for each participant. Program facilitators reviewed each participant's feedback sheet as a guide for a discussion on gambling and alcohol use, using a MI style. Participants were followed up 6 months later to assess their level of gambling and alcohol use. The study was underpowered to show treatment effects, but results indicated that participants in the intervention group reduced their concurrent episodes of drinking and gambling compared with those in the control group. Data suggest that those who drink alcohol and gamble concurrently are more likely to gamble with more money, lose money faster, gamble for longer amount of time than they intended, and experience greater negative consequences compared to those who do not drink and gamble concurrently.

Petry and colleagues conducted a randomized prevention trial for college students, comparing three different types of prevention programs to an assessment-only control (AOC). The interventions tested included a brief advice condition; a brief Motivational Enhancement Therapy (MET) session, similar to the one described above by Takushi and colleagues; and an MET + four-session Cognitive Behavior Therapy (CBT). The brief advice condition was a 10-15 min discussion, which involved the facilitator assessing the student's involvement with gambling (frequency and quantity) and providing some general college student norms comparison data regarding how often and how much other college students gambled, ways to identify risky gambling behavior, and specific tips for reducing risky gambling (i.e. setting a budget, setting a time limit, and not to think of gambling as a way to make money). The MET condition was 50 min, focusing on the pros and cons of the student's gambling, providing a handout that contained national norms of gambling for college students, and completing a change plan worksheet aimed at reducing gambling-related harms. The MET + CBT condition was four, 50-min sessions. The first session was the same as the MET session, plus three additional CBT sessions focusing on (1) identifying triggers (internal and external) for gambling, (2) coping with internal triggers, and (3) coping with external triggers. Participants were followed over 6 weeks and 9 months. At the end of the study, those in any prevention groups reported less gambling severity and days spent or dollars spent on gambling compared to AOCs at the 9-month follow-up. Surprisingly, there were no differences on outcomes between the three conditions, suggesting that a 10–15 min of brief advice intervention FURTHER READING 891

was as effective as the four sessions of MET + CBT prevention programming.

The third empirically based prevention program was a follow-up to Takushi and colleagues program conducted by Larimer and colleagues. This program, called Project Chance, combined both gambling and alcohol prevention programming. Participants were a random sample of undergraduates who completed a screening survey, using a score of 3 or greater on the SOGS (lifetime timeframe) as the indicator of at-risk gamblers for inclusion in the study. Invited participants completed a longer baseline assessment, then were randomly assigned to receive one of three groups that were the following: an individual, in-person, single-session personalized feedback intervention (PFI) similar to the approach used by Takushi and colleagues; a four- to six-session group cognitive behavioral intervention (CBI) similar to Petry and colleagues; or AOC. Participants were followed up 6 months later.

Results suggested that the prevention programming of either the PFI or the CBI was efficacious for reducing gambling frequency, amount spent (lost) on gambling, and negative consequences compared to AOCs. The study also tested theoretically driven mediators of these interventions. Those in the PFI condition were expected to improve if normative misperceptions of gambling were reduced, whereas those in the CBI intervention were expected to improve via reductions in their cognitive distortions regarding gambling. However, only the correction of normative misperceptions was found to mediate the intervention effect for the PFI group. Though cognitive distortions were improved following CBI intervention, this did not appear to be the mechanism through which the CBI intervention impacted gambling outcomes. While there remains significant work to be done in the area of college student gambling prevention, there does appear to be emerging evidence that interventions based on sound psychological theory and incorporating elements of MI style, personalized normative feedback, and cognitive behavioral approaches such as cognitive correction and protective behavioral strategies may be efficacious in reducing gambling frequency, quantity, and harms. Further, there is some evidence to suggest that a single session of brief advice or motivational feedback may be more feasible and similarly efficacious to multisession, multicomponent approaches.

CONCLUSIONS

Although most students who gamble appear to do so without significant consequences, gambling nonetheless represents a significant public health concern among college students due to increased rates of disordered

gambling in college students and college-aged individuals relative to the general adult population. Research on gambling in young adults and college students is in its infancy, and there is relatively little research on this topic outside North America and Australia. Three recent randomized controlled trials in the United States demonstrate that brief interventions can be efficacious in reducing gambling frequency, amount, and harmful consequences of gambling among college students. Additional research is needed to better understand the prevalence, etiology, and prevention of gambling among college students and college-aged young adults worldwide.

SEE ALSO

Evidence-Based Treatment, Harm Reduction Approaches, Internet Screening and Intervention Programs, Motivational Enhancement Approaches, Psychological Treatments for Pathological Gambling, Brief Feedback-Focused Interventions, Using the Internet for Alcohol and Drug Prevention, Universal, Indicated, and Selective Prevention for Youth Gambling

List of Abbreviations

AOC assessment-only control

BASICS Brief Alcohol Screening Intervention for College Students

CBI cognitive behavioral intervention
CBT Cognitive Behavioral Therapy

DSM-IV Diagnostic and Statistical Manual of Mental Disorders

(Fourth Edition)

MI motivational interviewing

MET Motivational Enhancement Therapy PFI personalized feedback intervention

PG pathological gambling SOGS South Oaks Gambling Screen

Further Reading

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Relevant Websites

http://www.gamblinghelponline.org.au – Australia's Gambling Help Online Services.

http://www.ncpgambling.org/ - National Center for Problem Gambling.

http://www.ncrg.org/ - National Center for Responsible Gaming.

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Mobilizing Communities for Alcohol, Drug, and Tobacco Prevention

Abigail A. Fagan*, J. David Hawkins^{\$}, Richard F. Catalano^{\$}
*Florida State University, Tallahassee, FL, USA *University of Washington School of Social Work, Seattle, WA, USA

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Research has identified multiple risk factors that, when present, increase the likelihood of substance use among youth and young adults. These conditions or experiences include individual characteristics (e.g. displaying aggression at a young age or believing that using drugs is not harmful), peer influences (e.g. having friends who use drugs or who believe that drug use is acceptable), family experiences (e.g. drug use by parents or siblings or inadequate monitoring of children by parents), school factors (e.g. academic failure or having a low commitment to school or education), and neighborhood experiences (e.g. availability of drugs or community norms that support drug use). Protective or promotive factors, which ameliorate the negative influences of risk factors or directly reduce the likelihood of drug use, also exist in all areas of individuals' lives (e.g. attachment to prosocial others, having a resilient temperament, or having healthy beliefs and clear standards regarding substance use).

Prevention efforts aimed at reducing rates of substance use typically do so by minimizing one's exposure to harmful risk factors and/or by enhancing protective/promotive factors in order to reduce the negative impact of risk factors. While many prevention efforts have been found to reduce tobacco, alcohol, and drug use using this type of approach, these strategies are often limited in addressing risk and protective factors from just one developmental period or socialization domain. Most focus on the most proximal causes of drug use, such as peer or family influences, rather than targeting the larger contexts in which youth and young adults live. This narrow focus may reduce the overall impact and long-term effectiveness of drug use prevention strategies, given that multiple factors affect substance use and because the effectiveness of any intervention is likely to be compromised if the environments in which individuals live are unfavorable to or do not support intervention goals and activities.

Community-based efforts offer broad potential for impacting rates of substance use. Such programs rely on multiple strategies intended to change a variety of factors that place individuals at risk for engaging in substance use, thus potentially increasing their likelihood of success. Most also seek to alter the long-term,

structural, and environmental influences that are associated with drug use and abuse, along with more proximal influences, which increase their potential to make a significant and long-lasting impact on drug prevention. By saturating the environment with prevention strategies and messages, community-based efforts aim to reach many more individuals and thus have the potential to achieve population-level reductions in substance use.

Another potential advantage of community-based strategies is their reliance on members of the local community to plan, implement, and monitor prevention activities, usually via coalitions comprised of stakeholders from diverse organizations and backgrounds. By actively involving the community in the prevention effort, these approaches may enhance community buyin for prevention activities and may help to ensure that services are a good fit with local needs, resources, and norms. Levels of elevated or depressed risk and protective/promotive factors vary across communities, and what is most needed in one community to reduce youth drug use may not be what is needed in another community. Thus, prevention efforts that are based upon assessing local needs (i.e. risk and protective/ promotive factors faced by individuals in the community) and implementing prevention strategies that are best suited to address these needs may be more effective than implementing a single prevention program across all communities. Mobilizing the community also has potential for pooling information and resources across agencies and individuals, minimizing duplication of services, and potentially offering more cost-effective services that are better implemented and more likely to be sustained.

WHAT DOES IT MEAN TO MOBILIZE COMMUNITIES TO PREVENT DRUG USE?

Existing community-based drug prevention efforts are flexible and adaptable to local circumstances, which make it difficult to identify the specific components that define this type of approach. Nonetheless, community mobilization efforts have in common the goal of reducing drug use by changing the larger environment using approaches that are owned and operated by the local community. Most rely on coalitions of community stakeholders to collaboratively plan and coordinate prevention activities, which typically take one of two forms. In some cases, coalitions focus on implementing, in a coordinated fashion, multiple, discrete prevention programs and practices that seek to decrease elevated risk factors and enhance depressed protective/promotive factors related to drug use. Others focus on transforming the environment via changes in local ordinances, norms, and policies related to drug use. These efforts target a more limited number of risk factors; in particular, community norms and laws related to drug use, the availability of drug use in communities, and individual attitudes favorable to substance use. Some community-based efforts rely on a combination of these strategies.

WHAT COMMUNITY-BASED STRATEGIES WORK TO REDUCE DRUG USE?

A review of evidence from controlled and wellconducted evaluations of community-based interventions implemented in the United States has identified 12 community-based initiatives that have been shown to reduce rates of tobacco, alcohol, or drug use among youth and young adults. Table 90.1 lists these interventions and provides a brief description of each program, the population for whom the intervention was evaluated, and the program's significant effects in reducing drug use. These initiatives were identified via a systematic review of the literature. Programs were eligible for inclusion in the review if they included a substantial community-based component, and were evaluated using a quasi-experimental or true experimental design that involved, at a minimum, one intervention group (implementing the strategy) and one comparison group, and collected data on drug use outcomes at least two times during the research project (e.g. before and after the intervention was conducted).

The findings from the review indicate that a common feature of successful community-based prevention approaches is reliance on local coalitions to select and implement with fidelity preventive interventions that have evidence of effectiveness. The inclusion of universal, school-based drug prevention curricula is also associated with reductions in substance use. Environmental strategies, such as changing laws, norms, and policies related to alcohol access and use, do not appear to reduce alcohol use among adolescents when implemented independently of other community-based strategies. However, they have been a part of successful multicomponent interventions and, implemented on their own, have reduced the availability of alcohol in communities and lowered drunk-driving arrests among young adults.

RELIANCE ON COMMUNITY COALITIONS TO PREVENT DRUG USE

All of the effective community-based initiatives listed in Table 90.1 relied on local coalitions to plan and

TABLE 90.1 Community Mobilization Strategies with Evidence of Effectiveness in Reducing Substance Use

Study	Description	Study population	Significant effects
Kentucky Incentives for Prevention	Coalition-based prevention strategy targeting risk and protective factors related to drug use with effective programs	19 coalitions in Kentucky; 25 032 students in Grades 8 and 10	Reduced smoking, drinking, and binge drinking among 10th graders
New Directions	Coalition-based prevention strategy targeting risk and protective factors related to drug use with effective programs	23 coalitions in Vermont; 24 932 students in Grades 8–12	Reduced past month smoking and marijuana use
Communities That Care (CTC)	Coalition-based prevention strategy targeting elevated risk and depressed protective factors related to drug use with effective programs	24 communities in seven states; 4407 students in Grade 5	Reduced the initiation of smokeless tobacco, smoking, and alcohol Reduced past month use of smokeless tobacco, alcohol, and binge drinking
PROmoting School -community—university Partnerships to Enhance Resilience (PROSPER)	Coalition model relying on school and university staff to implement school-based and family-focused programs targeting risk and protective factors related to drug use	28 school districts in Iowa and Pennsylvania; 12 022 students in Grade 6	Reduced the initiation of marijuana, inhalants, meth, ecstasy, gateway drugs, and illicit drugs Reduced past year use of marijuana and inhalants
Midwestern Prevention Project	Combines community mobilization strategies with the implementation of schoolbased prevention curricula	42 schools in Kansas City; 5065 students in Grades 6 and 7	Reduced past month smoking and drinking
Project SixTeen	Combines community mobilization strategies with the implementation of school-based prevention curricula	16 communities in Oregon; 4438 students in Grades 7 and 9	Reduced smoking, drinking, and marijuana use
Project Northland	Combines community mobilization strategies with the implementation of school-based prevention curricula	24 school districts in Minnesota; 2953 students in Grade 6	Reduced binge drinking and alcohol sales to minors
Native American Project	Combines community mobilization strategies with the implementation of school-based prevention curricula	27 tribal and public schools in the Midwest; 1396 students in Grades 3–5	Reduced smokeless tobacco, alcohol, and marijuana use
Minnesota Heart Health Program	Combines community mobilization strategies with the implementation of school-based prevention curricula	Two communities in Minnesota; 2401 youth in Grade 7	Reduced smoking
DARE Plus	Combines community mobilization strategies with the implementation of schoolbased prevention curricula	24 schools in Minnesota; 7261 students in Grade 7	Reduced past year and past month smoking and drinking for boys and having ever been drunk for girls
Communities Mobilizing for Change on Alcohol	Coalition-led activities seeking changes to community policies, practices, and norms related to alcohol use	N = 15 school districts in MN and WI; 4506 students in Grade 12 and 3095 18–20 year olds	Reduced the provision of alcohol to minors and arrests for drunk driving among 18–20 year olds
Community Trials Project	Coalition-led activities seeking changes to community policies, practices, and norms related to alcohol use	N = 6 communities in CA and SC	Reduced heavy drinking among adults, alcohol sales to minors, and alcohol-related car crashes

implement prevention activities. This evidence indicates that to be successful, community efforts must ensure the presence of active, broad-based groups of individuals who believe it is possible to prevent drug use and who are willing to engage in collaborative prevention activities. Although coalitions vary in their structure, size, goals, and activities, a defining feature of such groups is their focus on facilitating desired changes through collaborative action. While the specific members of a coalition may vary depending on the focus of the group, coalitions usually seek to be broad based and to unite diverse stakeholders and key leaders from key agencies and sectors of the community that have a stake in creating a change. Coalitions focused on preventing drug use may include members from law enforcement, local government, health and human service agencies, youth service groups, business, religious groups, youths, and parents. Coalitions are typically formed around a common vision that inspires and motivates their actions. By working together to bring about change, coalitions allow intervention approaches to be tailored to local needs, as identified by coalition members. They also increase political alliances, foster communication among community members, and coordinate human and financial resources.

Although coalitions are a common element of effective community-based prevention, not all coalition efforts have produced significant changes in drug use. Some coalition initiatives have failed to reduce rates of drug use among youth and adolescents, even when groups were well funded and members were well intentioned and willing to make changes. Two evaluations of coalition efforts, the Fighting Back and Community Partnership initiatives, for example, both evidenced failures in bringing about changes in youth drug use. The evaluations indicated that the coalitions involved in these projects had insufficient guidance in how to enact prevention strategies, varied widely in the nature and amount of prevention services provided, and largely relied on locally created prevention strategies which likely had not been previously evaluated for effectiveness in reducing drug use. These studies suggest that the mere presence of an active, well-intentioned coalition is not enough to prevent drug use; that is, simply gathering local stakeholders and asking them to collaborate to do their best to solve local drug problems do not produce desired changes.

The evidence suggests that to be successful, coalitions must set clearly defined, focused, and manageable goals; have adequate planning time; base prevention decisions on empirical data about what needs to change in the community and on evidence from scientifically valid studies of what has worked to address those needs; implement prevention policies, practices, and programs that have been tested and shown to be effective; and carefully

monitor prevention activities to ensure implementation quality. Two programs that exemplify these principles are the Communities That Care (CTC) and the PROmoting School–community–university Partnerships to Enhance Resilience (PROSPER) coalition models. Evaluations of these initiatives have shown reductions in the initiation and prevalence of youth drug use.

CTC and PROSPER provide proactive training and technical assistance to community coalitions to ensure that they select and implement with fidelity prevention strategies that have been previously demonstrated as effective in reducing youth drug use. The CTC model involves a structured and guided intervention process involving five phases, in which coalitions (1) assess community readiness to undertake collaborative prevention efforts; (2) form a diverse and representative prevention coalition; (3) use epidemiologic data to assess prevention needs; (4) select evidence-based prevention policies and programs that target these needs; and (5) implement the new policies and programs with monitoring to ensure fidelity and evaluation to ensure that goals are being met. The coalitions are structured, ideally with chairs, co-chairs, and workgroups; employ at least a half-time coordinator; and are broad-based. Prevention activities selected and implemented by communities can take place in a variety of settings and may target individual, family, school, peer, and/or community risk and protective/promotive factors related to drug use. Community coalitions select prevention strategies from a menu of options that includes only policies and programs that have been shown in at least one study using a high-quality research design to significantly change risk and protective factors and reduce rates of drug use.

Unlike the CTC model, which makes no stipulations regarding the agency or individual best suited to lead the coalition, the PROSPER model is initiated by local university Cooperative Extension Service agents, who partner with school district personnel to facilitate coalition activities. Coalitions receive technical assistance from state-level extensive staff who are supported by university research scientists. PROSPER coalitions do not undertake an extensive needs assessment as is done in CTC. The PROSPER model assumes that youth in all communities will benefit from family- and schoolbased prevention programs, and communities select evidence-based prevention programs from a menu of options limited to these areas. Thus, prevention activities are centered in the school and involve the implementation of school-based prevention curricula and workshops for parents and/or children that focus on increasing parental supervision and effective discipline of youth, enhancing parent-child communication, and providing children with tools to effectively resist drug offers.

Several evaluations of the CTC coalition model have been conducted, including a randomized experiment involving 24 communities in seven states, which were randomly assigned to either implement the CTC system (n = 12) or to serve as control communities (n = 12). Intervention sites received training in the CTC model, proactive and intensive technical assistance, and funding for 5 years to plan and implement tested and effective prevention strategies. This study indicated that, after 4 years of the intervention, students in CTC communities had lower rates of substance use compared to students in control communities. They were less likely to initiate cigarette, alcohol, and smokeless tobacco use as well as delinquent behavior by Grade 8. In addition, 8th grade students in the intervention communities reported lower rates of drinking, binge drinking, smokeless tobacco use in the past month as well as delinquent behavior in the past year compared to students in the control communities.

An experiment testing the effectiveness of the PROS-PER model involved 28 communities in Iowa and Pennsylvania which were randomly assigned to implement PROSPER (n=14) or to act as control communities (n=14). Eighteen months after the intervention began, when students were finishing Grade 7, significantly fewer youth in the PROSPER communities had initiated the use of marijuana, inhalants, methamphetamine, and ecstasy compared to those in the control communities. Students in the PROSPER communities also reported significantly less marijuana and inhalant use in the past year compared to students in the control communities.

These studies indicate that when local community coalitions are provided with proactive training and technical assistance, have clear goals and guidelines, and ensure that they effectively implement prevention strategies that have prior evidence of effectiveness, they have the potential to significantly reduce substance use community wide. The particular strategies that are implemented appear to matter less than the process by which programs are selected and the manner in which they are implemented. That is, coalitions may enact a variety of previously tested and proven prevention policies and programs targeting a variety of risk and protective factors and still be successful, as long as efforts maintain the focus on using methods that have themselves been demonstrated effective and ensure that prevention activities are carefully implemented, monitored, and coordinated.

INCLUSION OF SCHOOL-BASED CURRICULA IN COMMUNITY-BASED EFFORTS

Implementation of universal, school-based drug prevention curricula as part of the larger community effort appears to predict reduced rates of substance use among middle and high school students. All of the community-based initiatives listed in Table 90.1 that were effective in preventing or reducing youth substance use involved the implementation of a school-based curriculum. In the PROSPER and CTC initiatives, for example, school programs were selected by community coalitions as one element of their comprehensive prevention strategies. The PROSPER coalition model mandates the implementation of such curricula in order to reach a large percentage of the youth population and to target individual-, peer-, and school-related risk and protective factors. While the CTC prevention system does not require the use of school curricula, all of the coalitions involved in the randomized evaluation of CTC implemented a school curriculum during the study in order to target particular risk factors identified as too high or protective factors identified as too low by the local coalition.

Other successful community-based prevention initiatives have involved the implementation of a particular school curriculum offered to students in conjunction with the implementation of environmentally focused strategies targeting community risk factors related to drug use. An evaluation of the Project Northland program in Minnesota, for example, demonstrated the reduced rates of drug use in communities that implemented a multiyear school curricula and made changes to local policies and practices associated with youth alcohol use. The school program focused on decreasing students' views regarding the acceptability of alcohol use, increasing students' skills in refusing drug offers, and increasing parent-child communication about alcohol use through homework, assignments, and information mailed to parents. Environmental strategies included increased identification checks by retail liquor establishments and legal consequences for selling alcohol to minors. The evaluation of Project Northland found that, after receiving services in both middle and high school, students in Project Northland communities had lower rates of binge drinking (i.e. drinking five or more alcoholic beverages on one occasion) compared to students in control communities. In addition, retail establishments were less likely to sell alcohol to minors in intervention versus control communities.

A similar combination of activities is advocated in the Midwestern Prevention Project (MPP). This program involves the implementation of a 2-year middle school curriculum to promote students' drug resistance skills, along with parent education, media campaigns to reinforce antidrug messages throughout the community, and local policy changes to reduce demand and supply of drugs. When implemented in schools in Kansas City, MPP demonstrated reductions in past month smoking and alcohol use for students receiving the intervention

compared to students in control schools. Long-term effects were also found on past month tobacco and marijuana use when students were in Grades 9 and 10.

In Project SixTeen, small communities in Oregon implemented a five-session school-based program targeting reductions in youth tobacco use, along with media campaigns and responsible beverage training for alcohol retail outlets. The evaluation showed a significant reduction in past week smoking and marijuana use for 7th and 9th grade students in intervention compared to control communities, and less alcohol use among 9th graders. A similar initiative, the Minnesota Heart Health program, combined the implementation of a 1-year school-based program focused on tobacco prevention with 5 years of community education and mobilization efforts intended to improve diet, exercise, and reductions in smoking among community residents. An evaluation of this program found significantly less smoking among students in the intervention versus control communities at the end of high school.

These studies indicate that the inclusion of schoolbased prevention programs in comprehensive, community-based initiatives can contribute to reductions in drug use among adolescents. These results are not particularly surprising, given that a variety of schoolbased prevention programs have shown evidence of effectiveness when evaluated independently of other prevention efforts occurring in communities. These curricula target an array of risk factors for drug use using a variety of methods, but also have certain characteristics in common. Most successful school-based programs move beyond teaching students about drugs and their consequences using primarily didactic teaching techniques. Instead, they rely on interactive teaching strategies that engage students in the material and allow them to practice mastery of new skills. Rather than simply delivering content or seeking to increase knowledge, such programs focus more broadly on increasing general social and life skills, such as enhancing students' ability to effectively communicate with others, make good decisions, set goals, positively cope with stressful situations, and skillfully refuse offers of drug use. While they may include information about drugs and their harmful effects, such programs tend to focus on short-term rather than long-term consequences of drug use. They also aim to change students' normative beliefs about drug use; for example, by providing students with statistics regarding the actual rates of adolescent drug use in order to counteract teenagers' perceptions that the majority of their peers are using drugs.

Currently, most schools in the United States provide some type of drug prevention programming to students, but not all school districts implement strategies that have evidence of effectiveness, despite the fact that the Safe and Drug Free School (SDFS) legislation mandates the use of effective substance use prevention curricula. Coalitions can help school districts fulfill the SDFS mandate by helping them identify and adopt strategies that are effective and by helping to ensure that the new programs are well suited to addressing the needs of local students. In addition, coalitions can partner with schools to find the needed resources to initiate and sustain new effective prevention strategies and can help oversee the implementation of the new strategy to ensure that it is well implemented. Inclusion of school-based programs in a larger community prevention initiative thus provides multiple advantages, including the ability to reach much of the youth population and thus increase the potential of achieving community-level changes in desired outcomes.

TARGETING ENVIRONMENTAL RISK FACTORS FOR SUBSTANCE USE

The initiatives just described combined the implementation of school curricula with community mobilization efforts that target environmental risk factors in order to reduce the availability of and demand for tobacco, alcohol, or other drugs. Such efforts include changes to community-level policies, practices, and norms, such as creating ordinances to restrict smoking in public settings, increasing alcohol pricing, creating drug-free zones, limiting alcohol sales in venues easily accessible to youth, requiring keg registrations, and increasing the use or severity of community laws related to drug use by minors or adults. Changes to community practices may involve responsible beverage service training; that is, educating merchants about the negative consequences of providing tobacco or alcohol to minors or serving intoxicated patrons, encouraging identification checks, and ensuring that merchants who violate rules are appropriately sanctioned. Media campaigns may also be used in conjunction with these activities to educate the public about the negative effects of drug use, increase support for drug prevention, and counter norms favorable to drug use. Media increases public awareness by saturating the community with print, radio and television advertisements, mailing informational fliers to businesses or homes, or by holding community forums to discuss substance use issues.

Evidence is mixed regarding the effectiveness of environmentally focused prevention strategies. As discussed in the previous section, when offered in conjunction with school-based prevention curricula, they appear to be effective in reducing rates of youth substance use. However, efforts that focus exclusively on changing environmental risk factors, without also targeting more proximal risk factors related to drug use, have not been associated with reductions in alcohol use among youth under the age of 18. For example, an evaluation of Communities Mobilizing for Change on Alcohol (CMCA) found no changes in drug use among 12th grade students or 18-20 year olds in communities implementing CMCA compared to those in control communities. In this project, community coalitions coordinated a variety of activities aimed at limiting alcohol sales to minors, increasing enforcement of under-aged drinking laws, and changing alcohol policies at community events, as well as increasing public attention to problems associated with under-age drinking. Although rates of alcohol use were not changed by the intervention, the evaluation showed that 18- to 20-year-old youth from intervention sites were less likely to provide alcohol to minors and were less likely to be arrested for drunk driving compared to those in control sites.

The Community Trials Project used similar environmentally focused prevention strategies to reduce alcohol use and related risky behaviors among young adults. A quasi-experimental evaluation of this program in six communities indicated no differences in rates of drinking among youths less than 18 years old in intervention versus comparison sites. Among adults (those aged 18+ years), a greater proportion of those in communities implementing the program reported having one or more drinks in the past year versus those in comparison communities. However, among those who reported any drinking, adults in intervention sites had lower rates of heavy drinking and drunk driving. The evaluation also showed fewer nighttime injury car crashes and drunkdriving crashes and fewer sales to minors by alcohol sales establishments in intervention versus comparison sites.

The mixed evidence for environmentally focused strategies makes it difficult to draw firm conclusions regarding their ability to reduce substance use. Among those under 18, there have been effects in existing studies only when they included a school curriculum. There have been very few evaluations of community-based prevention efforts that rely solely on changing community policies, practices, and norms, and more research is needed to assess the impact of environmental strategies when used independently and when combined with other types of prevention strategies.

CHALLENGES OF COMMUNITY MOBILIZATION EFFORTS

There is much public support for community mobilization efforts that seek to reduce substance use, and many communities have coalitions in place to coordinate community-based prevention strategies. However, implementing, evaluating, and sustaining such efforts can be challenging. Ensuring the adoption and high-quality implementation of a single prevention program or practice is demanding, and problems are likely to be multiplied when adopting a multiple-component strategy enacted in a variety of settings by numerous service providers. It is often difficult to engage and ensure collaboration among community members from diverse backgrounds who may have different skills, needs, resources, and ideas about what is needed to prevent substance use. Compared to single prevention programs, community-level strategies are likely to be costlier to implement and evaluate, as they entail more components and require longer term interventions in order to achieve communitywide outcomes. It can also be difficult to recruit entire communities to participate in research studies and to measure processes and outcomes that may vary across communities. Community-based prevention strategies are intended to be owned and operated by the community, which can create tension between local practitioners and scientists who may differ in their ideas about what is most needed to prevent drug use.

The many challenges related to the implementation of community-based prevention efforts are likely responsible for the relatively small number of interventions that have demonstrated evidence of success, as seen in Table 90.1. In addition, evaluations of some community prevention programs have failed to demonstrate significant effects on substance use, sometimes due to problems related to program implementation and intensity. For example, the initial evaluation of the Project Northland program in Minnesota indicated that the 3-year intervention implemented in middle schools was not enough to lead to sustained effects on drug use, and additional services were added in high school, which reduced rates of alcohol use through Grade 12. A replication of this program in Chicago failed to produce positive effects, which led the evaluators to recommend that in lower income, urban populations, in which problems other than youth drug use (e.g. gangs, violence, and housing) may take precedence, longer term and more intense community-based strategies may be needed to bring about change.

The Project Northland replication in Chicago and other evaluations have noted that implementation challenges, such as difficulty in engaging community members in the initiative and challenges in moving from planning to action, may compromise the ability of community-based efforts to produce significant effects. Nonetheless, evaluations of the CTC and PROS-PER prevention systems have shown that communities can successfully mobilize volunteers, create high functioning and goal-driven coalitions, and ensure the high-quality implementation of prevention strategies

that target salient risk and protective factors. Success is more likely when community coalitions are provided with proactive and high-quality training and technical assistance from system developers. Establishing close relationships between research scientists and community practitioners can be mutually beneficial. By observing firsthand the challenges and successes faced by the community, researchers gain a better understanding of how their interventions work and can make refinements as needed. At the same time, direct access to program developers allows practitioners to have their questions answered, feel supported when problems arise, and ensure that the intervention is well aligned with their particular needs and resources. In the absence of training and technical assistance, common implementation challenges are likely to threaten implementation and the likelihood of realizing desired reductions in drug use.

NEED FOR MORE RESEARCH

While this review has identified 12 community mobilization strategies with the evidence of effectiveness in reducing substance use, more research is needed to clarify the particular types of community-based strategies that are effective and to identify new models that may also reduce drug use. Most of the initiatives reviewed involved a combination of prevention strategies, and more studies are needed that can scientifically compare the relative effectiveness of these components in order to identify the particular strategies and/or sets of strategies that are most likely to lead to reduced drug use. Ideally, these and other evaluations will employ a true, randomized experimental research design which can best assess the effectiveness of the intervention. Additional information is needed to assess the extent to which interventions have different effects for different groups of individuals (e.g. males versus females) or for different types of communities (e.g. urban versus rural). Some of the programs included in this review did identify variation in effects; for example, some found greater reductions in drug use for males versus females, or for individuals who had already initiated drug use prior to the intervention. More complete information about how and for whom interventions work can reveal whether or not programs have iatrogenic effects (i.e. leading to *increased* rates of drug use) for certain individuals, can aid in the selection of programs by communities, and can be used by program developers to refine their interventions.

Finally, further research is needed to provide information on the financial costs versus benefits of community-based efforts. The National Center on Addiction and Substance Abuse (CASA) (2009) estimated that

over \$467 billion was spent in the United States in 2005 in responding to the negative consequences of drug abuse and addiction. Only two of the programs included in this review have been rigorously evaluated for cost-effectiveness, and in both cases, fiscal savings were demonstrated. According to the Washington State Institute for Public Policy, for every dollar spent on Project Northland in Minnesota, the program produced a savings of \$2.45 in later treatment, morbidity, mortality, and criminal justice costs, while the Midwestern Prevention Project produced a savings of \$1.27. Given that cost is a major factor influencing community decisions to adopt new programs, information on financial benefits may help to increase the dissemination of community-based prevention strategies, and, in turn, their potential to substantially reduce the rates of drug use among young people.

SEE ALSO

Substance Use Prevention Approaches for Schoolaged Youth, Alcohol Advertising and Underage Drinking, Impact of Tobacco Control Policies on Youth Smoking Rates

List of Abbreviations

CMCA Communities Mobilizing for Change on Alcohol

CTC Communities That Care
MPP Midwestern Prevention Project

PROSPER PROmoting School-community-university Partnerships

to Enhance Resilience

SDFS Safe and Drug Free School

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http://www.sdrg.org/ctcresource/ - Communities that Care.

http://www.pire.org/communitytrials/index.htm - Community Trials Intervention.

http://www.hazelden.org/web/public/projectnorthland.page – Project Northland.

http://www.prosper.ppsi.iastate.edu/ - PROSPER.

http://www.casacolumbia.org - The National Center on Addiction and Substance Use.

http://www.wsipp.wa.gov/ - Washington State Institute for Public Policy.

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Impact of Alcohol Policies on College Student Health (Including Alcohol Access Restrictions, Policy Enforcement, Amnesty Policies)

Traci L. Toomey, Kathleen M. Lenk, Toben F. Nelson, Alexis M. Jones University of Minnesota, Division of Epidemiology and Community Health, Minneapolis, MN, USA

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INTRODUCTION

Alcohol use among college students is associated with many problems, including traffic crashes, falls, fights, sexual assaults, poor grades, and alcohol overdose. Rather than focusing on preventing each type of problem individually, the most efficient approach to reducing these problems simultaneously is to reduce rates of alcohol use and/or change drinking patterns among college students. Alcohol control policies can effectively change drinking rates and patterns among the entire population of student drinkers.

Some college students drink very heavily on a regular basis; and some of these students may meet diagnostic criteria for alcohol abuse or alcoholism. These students are at a very high risk for experiencing alcohol-related problems and require some type of intervention. However, other college students are also at risk for alcohol-related problems. In 2008, approximately 40% of college students in the United States reported binge

drinking – in other words, they consumed five or more drinks in a row on at least one occasion in the past 2 weeks. While some students who binge drink meet a diagnostic criteria for alcohol dependence, the majority of these students do not. However, these students are also at risk of experiencing alcohol-related problems; in fact, these binge-drinking students account for the largest number of alcohol-related problems and the majority of damage, deaths, and societal costs related to college student drinking.

The drinking behavior of the entire continuum of college student drinkers may be affected by implementing policies that influence access to alcohol. Research shows consistently that as access to alcohol increases, rates of alcohol use and related problems also go up. Following an assessment of the research literature in the early 2000s, the National Institute on Alcohol Abuse and Alcoholism (NIAAA) recommended that colleges and surrounding communities implement a variety of policies and enforcement practices that reduce college

student access to alcohol. At that time, most of the research evidence pertained to the general population rather than the college student population specifically. Since that review, alcohol policy research focusing on the college student population has significantly increased.

In this chapter, we provide an overview of policies affecting alcohol access among both underage students and among all students in general. We also review several other campus policies, such as alcohol advertising restrictions that can shape the degree to which a campus environment encourages or discourages heavy alcohol use. The policies described in this chapter can be implemented at the campus, community, state, and/or federal levels.

Once a policy is enacted, it also needs to be actively enforced to maximize the policy's effectiveness in reducing college student drinking and related problems. Enforcement actions that increase the perceived certainty of getting caught for violating a policy are most effective, but meaningful consequences for this violation that are swiftly applied should also be addressed.

Table 91.1 provides a list of policies identified to reduce alcohol access among underage college students; Table 91.2 provides a list of policies identified to reduce alcohol access among all college students in general; and Table 91.3 describes other promising policies addressing college student drinking. A brief description and rationale for each policy are provided in these tables as well as information about the possible levels at which the policy could be implemented (college, community, state, and/or federal levels) and whether research studies have addressed the policy. When research studies have addressed a particular policy, we summarize the research findings in the text. Finally, while it is important to consider each of these policies individually, combinations of policies may be necessary to create sustained reductions in college student alcohol use and related problems. We also provide a brief summary of research evaluating the effects of multipolicy interventions.

POLICIES TO REDUCE ACCESS TO ALCOHOL AMONG UNDERAGE COLLEGE STUDENTS

The minimum legal drinking age is one of the most well-evaluated alcohol policies. Many studies have found that that when the legal drinking age was lowered during the 1970s in the United States, consumption and traffic crash deaths increased among 18–20 year olds; when the drinking age was raised to 21 in many states, consumption and traffic crashes

decreased. Although all states in the United States currently have a minimum legal drinking age of 21, underage youth and young adults continue to drink alcohol and experience alcohol-related harms. One reason is that legal drinking age laws - including laws that restrict purchase, possession, and consumption of alcohol as well as provision and sales of alcohol to underage individuals – are often not well enforced. Hence, underage individuals can obtain alcohol from various sources including social sources and commercial sources. Social sources are individuals (either over or under the age of 21), who illegally provide alcohol to underage persons. Social access to alcohol among underage college students may occur at parties, in residences, at campus or community events, in bars and restaurants, and in public areas such as parks, beaches, or outside of stores that sell alcohol. Commercial sources are retail alcohol establishments such as restaurants, bars, and liquor stores that sell alcohol illegally to underage patrons. While research studies have shown that most underage individuals obtain alcohol through social sources, the likelihood of underage individuals purchasing alcohol from establishments increases with age. Also, underage individuals who are able to purchase large quantities of alcohol (e.g. a beer keg) may then illegally provide that alcohol to other underage individuals. Policies, and active enforcement of these polices, are needed to reduce social or commercial access to alcohol among underage college students (Table 91.1).

Reduce Social Access to Alcohol

As indicated in Table 91.1, a variety of policies can be implemented to reduce social access to alcohol among underage college students. These policies may reduce social access to alcohol through several mechanisms, including: (1) prohibiting alcohol in certain locations (e.g. residential halls) where underage drinking may occur, (2) prohibiting alcohol at parties or other campus events, (3) placing restrictions on alcohol use and service at campus events (e.g. not allowing self-service of alcohol), (4) deterring adults from providing alcohol to underage students, and (5) enabling police to break up underage drinking parties. Of these policies, we only identified research pertaining to policies designed to deter adults from providing alcohol to underage persons.

To decrease the likelihood that individuals will illegally provide alcohol to underage individuals, it is important to increase the likelihood that they will be caught and penalized for this illegal provision of alcohol. To help identify individuals who provide alcohol to underage individuals at parties, communities and states can implement beer keg registration laws that

TABLE 91.1 Policies That May Help Reduce Access to Alcohol among Underage Students

Policy	Policy description	Policy level	Policy rationale	Research evidence for underage persons?
REDUCE SOCIAL A	ACCESS TO ALCOHOL			
Prohibition of alcohol in certain locations	Alcohol is prohibited from being consumed or brought into certain public locations where monitoring of underage drinking may be difficult (e.g. community and state parks)	S, L, C	Fewer locations allowing alcohol consumption = fewer underage parties, less access	None
Prohibition of alcohol at campus events	Alcohol use is prohibited at all campus events or at events where underage students are present	С	No alcohol at events where underage students are present = less access	None
Restrictions on service and use of alcohol at campus	Self-service of alcohol is prohibited at events	С	 Requiring alcohol to be served rather than available for self-service can ensure only students of legal drinking age have direct access = less access 	None
events	 Alcohol service is limited to one drink per person per request 		 Limiting the number of drinks students are served will reduce opportunities to obtain extra drinks for underage students = less access 	None
	 Alcohol consumption is allowed only in specified areas restricted to individuals 21 and older 		 Not allowing underage students in areas where alcohol is consumed = less access 	None
Legal deterrence for providing alcohol to underage • Keg registration laws	 A unique ID is required on each beer keg; ID number is recorded at the time of purchase along with purchaser information 	S, L	 Because law enforcement can identify who purchased the keg, adults will be deterred from buying kegs for use by underage students = less access 	Limited: General population
Shoulder tap campaigns	 Under the supervision of law enforcement, an underage person approaches an adult outside a store and asks the adult to purchase alcohol for them. If the adult provides alcohol he/she is subject to citation 		 Perceived certainty of being caught will deter adults from purchasing alcohol for an underage individual = less access 	Limited: General population, College students
Social host laws	 If an adult illegally serves alcohol to an underage person, and the underage person injures themselves or someone else, the offending adult may incur civil and/or criminal penalties. Social host laws may also require hosts to pay for enforcement costs 		 Due to legal risk, fewer people willing to provide alcohol or host a party = less access 	Yes: General population
Noisy assembly laws	Law stipulates that parties exceeding a specified noise level may be subject to search and citation by law enforcement	S, L	Restrictions on noise level may deter large parties; landlords and property owners held accountable for parties will be more strict = less access	None

Research evidence for **Policy** Policy description Policy level Policy rationale underage persons? REDUCE COMMERCIAL ACCESS TO ALCOHOL Managers/servers less likely to allow alcohol sales to **RBS** training Managers and servers of alcohol establishments are S, L, C Yes: General population required to receive training in how to check age underage individuals = less access requirements identification and refuse sales to underage customers Employees under a specified age are not permitted to Older employees are less likely to sell alcohol to an Minimum age S, L, C Yes: General population requirements to serve or deliver alcohol underage person = less access serve/sell alcohol Yes: General population Compliance checks Under the supervision of law enforcement, an underage S, L Consistent ID verification when establishments are person attempts to purchase alcohol from on- and/or routinely checked for compliance = less access off-premise serving establishments. If alcohol is sold to underage person, server and/or license holder is penalized Dram shop liability S Individuals are able to sue alcohol serving Fewer sales to underage individuals if threat of lawsuit None establishments for injuries sustained after illegal alcohol exists = less access laws sales to an underage person Prohibition of home Retailers are prohibited from delivering alcohol to S, L Reduce the likelihood of delivering alcohol to underage None deliveries individuals at their homes persons = less access Identification card State requirements that ID cards for underage persons S Alcohol sellers/servers can more clearly identify and Limited: College students have a unique design that is difficult to falsify refuse sales to underage individuals and they are less design likely to have false age identification = less access requirements

Note: Policy level: S = state; L = local; C = college.

ALCOHOL AND DRUG PREVENTION, ADOLESCENTS AND COLLEGE STUDENTS, GAMBLING

TABLE 91.2 Policies That May Help Reduce Access to Alcohol among All Students

Policy	Policy description	Policy level	Policy rationale	Research evidence?
RESTRICT WHERE, WHEN	N, HOW ALCOHOL IS SOLD			
Limitations on number/ density of alcohol establishments	Limit the number of alcohol establishments per capita, per geographic area, or in high-risk areas (e.g. around college campuses)	S, L	Fewer alcohol establishments per geographic area = less access	Yes: General population College students
State-run alcohol retail stores	In some states, certain types of alcohol (e.g. wine) are only sold in state-run stores; if privatized, these types of alcohol are moved from state-run to privately owned stores	S	State-run stores allow for better control over number of alcohol establishments in an area, reduced hours of sales, and limited advertising = less access	Yes: General population
Restrictions on days of alcohol sales	Retail alcohol sales banned on specific days (e.g. Sundays)	S, L	Reduce number of days alcohol can be sold $=$ less access	Yes: General population
Restrictions on hours of alcohol sales	Retail alcohol sales banned during specified hours of day	S, L	Fewer hours for alcohol sales = less access	Yes: General population
RBS training requirements	Managers and servers of alcohol establishments are trained how to prevent patrons from becoming overly intoxicated (e.g. cutoff service to intoxicated, slow alcohol service, promote alcohol-free drinks/food)	S, L, C	Managers/servers slow service of alcohol or cut off service = less access	Yes: General population
Dram shop liability laws	Individuals are able to sue alcohol serving establishments for injuries sustained after illegal alcohol sales	S	Fewer sales to intoxicated individuals if threat of lawsuit exists = less access	Yes: General population
Alcohol license cost increases	The cost of obtaining an alcohol license for retail establishments can be increased	S, L	Higher price of alcohol licenses may decrease number of alcohol establishments and increase price of alcohol = less physical and financial access	None
INCREASE ALCOHOL PR	ICE			
Alcohol tax increases	Tax applied on alcoholic beverages at retail level	F, S	Increased taxes on alcohol will lead to higher prices = less financial access	Yes: General population College students
Restrictions on happy hours/price promotions	Promotions that greatly reduce the price of alcohol at the retail level are prohibited or restricted	S, L, C	Eliminating price promotions for alcohol reduces incentive to drink = less use	Yes: General population College students
Limitations on free alcohol	Availability of free alcohol at campus events is restricted or prohibited	С	Less free alcohol available = less use	None

TABLE 91.2 Policies That May Help Reduce Access to Alcohol among All Students—cont'd

Policy	Policy description	Policy level	Policy rationale	Research evidence?
REDUCE ACCESS AT CAM	IPUS EVENTS			
Prohibition of alcohol sales/use in high-risk areas	Alcohol sales or use are prohibited in areas where rates of alcohol use and problems are high (e.g. areas where tailgating events occur, at sporting events)	S, L, C	Eliminating or restricting alcohol at these places and events = less access	Limited: College students
Prohibition of beer kegs	Beer kegs are not allowed on campus or for nonretail use	S, L, C	Prohibiting primary supply of large quantities of inexpensive alcohol = less access	Limited: College students
Prohibition of self-service of alcohol	Alcohol can only be served by trained servers	С	Trained servers can control the number of drinks per person and cutoff intoxicated individuals = less access	Limited: College students
Requirement of low- alcohol content drinks	Alcohol with the lowest concentration of alcohol per volume must be offered	С	Lower alcohol content = less intoxication	Limited: College students
Requirement of alcohol- free drinks and food	Offering of alcohol-free drinks and food required at campus events (e.g. at least 50% of beverages must be alcohol free)	С	Attendees may consume more alcohol-free drinks and food = less alcohol use and less intoxication	None

Note: Policy level: F = federal; S = state; L = local; C = college.

TABLE 91.3 Other Policies Used to Address College Student Drinking

Policy	Policy description	Policy level	Policy rationale	Research evidence?
Prohibition of alcohol sponsorship and advertising	Colleges ban advertising for alcoholic beverages and/or alcohol establishments that serve alcoholic beverages in student newspapers, on campus billboards and other university-controlled media	С	Decreasing advertising and promotion for alcohol = less alcohol use	Yes: General population, College students
Amnesty policies	Underage students in need of medical attention and/ or individuals/student organizations who call for help are exempt from Judicial Affairs citation — terms of exemption vary by school and are usually limited to instances occurring on University property	С	Eliminate barrier to helping behavior = more students receiving medical attention = fewer alcohol-related harms and deaths	Limited: College students
Requirement of Friday morning classes	Colleges mandate a minimum number of classes scheduled on Friday mornings	С	Mandating Friday morning classes may decrease heavy drinking on Thursday nights	Limited: College students
Requirement of alcohol- free alternatives	Colleges offer and fund social events and venues that do not serve alcohol and are open during times students commonly drink alcohol	С	Provides social alternatives to drinking for students = less access, less alcohol use	Limited: College students
Alcohol-free campuses and residence halls	Colleges prohibit alcohol on campus or alcohol is prohibited in designated residence halls	С	Fewer locations allowing alcohol consumption = less alcohol use	Yes: College students

Note: Policy level: C = college.

require alcohol retailers to place a unique identifier on a keg and collect the purchaser's name and address. This enables police to identify and hold responsible the person who bought the keg if the keg is found to be a source of alcohol for underage youth. As of January 1, 2011, 31 states have keg registration laws in the United States, although the strength of these laws may vary by state. One study showed that strict state-level keg registration laws are associated with lower alcohol consumption and drinking driving among teens.

Another set of policies that may help prevent social provision of alcohol at parties are social host laws. Social host laws may specify criminal penalties for individuals who host underage drinking parties on their property and/or provide alcohol to underage youth. Alternatively, social host laws may also provide for civil liability, which enables individuals who are injured by an underage drinker to sue a host of an underage drinking party and/or provider to recover damages for those injuries. Finally, social host laws can also provide a mechanism for local communities to recover enforcement costs resulting from law enforcement agencies responding to problems related to underage drinking parties. As of January 1, 2011, 27 states have some form of a state social host law. Research studies suggest that state-level social host laws are associated with fewer drinking and driving-related fatalities among youth and young adults.

Underage individuals may also obtain alcohol by asking people going into liquor establishments to purchase alcohol for them. This is often times referred to as "shoulder tapping." To address this type of social provision, police can conduct shoulder tapping campaigns where underage people, under the supervision of law enforcement, approach an adult outside a store that sells alcohol and asks the adult to purchase alcohol for them. If the adult purchases alcohol, the adult is given a warning or fine or is arrested. One study found that younger males are more likely to agree to purchase alcohol for underage individuals during a shoulder tap than other adults going into alcohol establishments; this suggest that shoulder tap enforcement campaigns may be most effective if they target younger male populations rather than the general adult population. Shoulder tapping to obtain alcohol may be a method used more often by younger age groups than college students.

Reduce Commercial Access to Alcohol

Several research studies show that alcohol establishments, including bars, restaurants, and retail stores, have a fairly high likelihood of selling alcohol to underage patrons. Although many colleges do not allow the sale of alcohol on campus, some colleges have bars

on campus and/or allow the sale of alcohol in stadiums and auditoriums. Many community alcohol establishments often surround college campuses and underage college students often know which bars and stores are most likely to sell to or serve underage patrons.

To help reduce illegal sales to underage students, alcohol servers, managers, and owners of retail establishments selling alcohol, whether on or near campus, can be required to attend training on how to responsibly serve alcohol. Owner and manager training should cover how to develop, communicate, and enforce policies around selling alcohol responsibly. Training of alcohol servers/sellers should focus on how to check age identification and how to refuse alcohol service to those who are underage. Establishments that have monitoring systems to observe their servers to ensure alcohol sales laws are being followed are less likely to sell alcohol to underage individuals. In addition, establishments and communities can restrict the age of those who deliver or serve alcohol. Several research studies have found that younger servers are more likely to sell alcohol to an underage person. Research suggests that responsible beverage service (RBS) training programs by themselves may not be sufficient to prevent underage alcohol sales but may be necessary to build support for more effective enforcement interventions.

One effective enforcement strategy is compliance checks where an underage person attempts to purchase alcohol under the supervision of a law enforcement agent; if alcohol is sold, the server and/or the owner may face penalties. Several studies have shown that compliance checks are effective in reducing the likelihood of sales to underage patrons – but it is important to conduct compliance checks at all establishments and to conduct the checks several times per year to maintain a reduction in likelihood of alcohol sales to underage individuals. Based on the likely effectiveness in reducing sales to underage individuals, the Centers for Disease Control and Prevention (CDC) Community Guide recommends use of compliance checks. The structure and type of penalties for selling to underage individuals are also important to consider.

One type of risky, unmonitored sale that may particularly increase the likelihood of alcohol being sold to an underage person is the home delivery of alcohol. Over half the states in the United States allow home delivery of alcohol and one study showed that 7% of 18–20 year olds reported drinking alcohol that had been delivered to the home from a retail establishment. Alcohol can also be ordered via the Internet. To prevent delivery to underage people, communities can ban or restrict home deliveries of alcohol. Law enforcement officers can also conduct compliance checks where an underage person orders alcohol to be delivered to home.

In addition to focusing on changing merchants' behaviors, campuses and communities may reduce illegal sales to underage students by implementing policies aimed at reducing the use of fake age identification (ID). Several studies have examined the prevalence of fake ID use among college students, with estimates ranging from 13 to 46%. Use of fake IDs appears to increase from freshman to sophomore year and be more prevalent among members of fraternities and sororities. Communities and states can apply strong and certain penalties to those caught using fake age identification and issue drivers' licenses or other identification cards that are difficult to duplicate (e.g. use of holograms), and that clearly identify an underage person (e.g. use of different colors for underage).

POLICIES TO REDUCE ACCESS TO ALCOHOL: ALL STUDENTS

Many policies have been identified that may help reduce access to alcohol among all students (Table 91.2). These policies may affect how easily college students can obtain alcohol as well as the cost of alcohol. Research on the need for and effectiveness of many of these policies have grown significantly; however, some of the suggested policies have no or limited research focusing on them.

Restrict Where, When, and How Alcohol Is Sold

A variety of policies can be used to place restrictions on alcohol sales to decrease the availability of alcohol among all students on campus. Research shows, in general, that increasing availability of alcohol will lead to increased alcohol use and related problems.

Policies can be implemented at the state or community level to restrict the number of or density of alcohol establishments per population size or geographic area. Many studies have found that a higher density or number of alcohol establishments is related to higher rates of alcohol-related problems, including violence, other crime, sexually transmitted diseases, and other health problems in the general population. Research also suggests that a higher density of alcohol establishments around college campuses may increase rates of heavy alcohol use and alcohol-related problems among college students, both among students on campus as well as in the surrounding community. A higher density of alcohol establishments around campuses is associated with more vandalism, noise, and disturbances among neighborhoods surrounding campuses. Based on a systematic review of the research literature, the CDC

Community Guide recommends limiting the density of alcohol establishments to prevent excessive alcohol use and related problems.

The majority of US states allow alcohol to be sold in stores run by private individuals or corporations that are licensed to sell alcohol. Eighteen states as of 2011, however, restrict the sale of some types of alcohol (e.g. liquor and wine) to state-owned stores; these are considered state monopolies. In the 1970s and 1980s, many states privatized their state monopolies, allowing privately owned stores to sell the previously restricted types of alcohol. Studies show that privatization of these state monopolies may lead to an increase in alcohol sales (a proxy for alcohol consumption) in those states. Availability of alcohol may increase following privatization in state monopolies because of a higher number of alcohol establishments, longer hours of alcohol sales, and more advertising at the privately owned stores versus publicly owned stores. Some studies have shown only short-term increases in alcohol sales following privatization, however, other studies suggest that these increases in alcohol sales may be sustained for longer periods of time. No studies have specifically assessed effects of privatization on college students. Preventing privatization of state monopolies may be important for the following reasons: (1) research shows an increase in alcohol sales following privatization of state monopolies, (2) we currently do not know the long-term effects of privatization on alcohol-related problems among the general population or on subgroups such as college students, and (3) once privatization occurs, it is unlikely that states would be able to return to a state monopoly system.

Regardless of the number of alcohol establishments in a community or around a campus, communities or states can enact other restrictions to limit the availability of alcohol. For example, communities and states can restrict the number of days alcohol can be sold. Following the revocation of prohibition, many states banned alcohol sales on Sundays; however, since that time some of these states have overturned their Sunday sales bans (as of January 1, 2011, 14 states still have Sunday bans on alcohol sales). Studies show that increasing the number of days alcohol is sold may result in an increase in alcohol-related problems such as traffic crashes among the general population. Researchers have not looked at the effects of changes in days of alcohol sales on college student behavior. Based on a systematic review of the research literature, the CDC Community Guide recommends maintaining current restrictions on days of alcohol sales. Similar to privatization, once prohibitions on days of alcohol sales are lifted, it may be difficult or impossible for those bans to be re-imposed.

Communities and states can also restrict hours of alcohol sales. Effects of changes in hours of sales may depend on the scope of the change. If communities increase the hours of alcohol sales by an hour or two, they may not see an increase in alcohol-related problems – rather they may just see a shift when these problems occur. However, an expansion of hours of alcohol sales beyond 1-2 hours appears to increase access to alcohol enough that alcohol-related problems actually increase in the general population. Again based on a systematic review of the research literature, the CDC Community Guide recommends maintaining limits on hours of alcohol sales.

Availability of alcohol can also be controlled by servers at alcohol establishments and other alcohol venues. Similar to preventing alcohol sales to underage patrons, states, communities, and colleges may require RBS training for servers and managers of alcohol establishments to prevent patrons from becoming highly intoxicated. Alcohol servers can be trained to slow service of alcohol, promote alcohol-free beverages and food, and cutoff service to patrons who are already intoxicated. To encourage responsible alcohol servers, managers need to be trained and incentivized to create an establishment environment that sets expectations for responsible alcohol service (e.g. by setting and implementing establishment policies, backing up and rewarding servers' responsible serving behavior). Managers can also set establishment policies that directly affect alcohol use – for example, policies to only serve standard size drinks (e.g. 12 oz.) rather than oversized drinks (e.g. 24 oz.) or pitchers of alcohol. The need for RBS training is clearly indicated by studies showing that alcohol servers at the majority of alcohol establishments, community festivals, and professional stadiums will serve alcohol to customers who are obviously intoxicated. Research on the effectiveness of RBS programs and policies is mixed. Some of the more intensive training programs may reduce the intoxication levels of customers; however, many programs have only changed the knowledge, attitudes, and mild interventions (e.g. offering food) of alcohol servers. Research has shown that not all RBS training programs are equal, and that the best training programs include a focus on policy development for managers and skill-building techniques for alcohol servers. Research has also shown that state RBS laws vary greatly, with stronger laws specifying the required program content (e.g. ensuring skillbuilding components), having penalties for lack of compliance with the policy, and being supported by active monitoring. Researchers have found that traffic crash deaths decreased following Oregon's enactment of a RBS law, and that Oregon has one of the strongest RBS laws in the United States.

Responsible serving policies may also be encouraged through dram shop liability laws that enable individuals to sue alcohol establishments for injuries sustained after illegal alcohol sales. Research has shown that dram shop liability laws are associated with decreased traffic crashes and fatalities and incidence of drunk driving. Owners and managers of alcohol establishments may be more motivated to reinforce RBS policies and practices in their establishments when the perceived threat of a lawsuit is relatively high.

Increase the Price of Alcohol

Many studies have shown that higher alcohol prices are associated with lower rates of alcohol use and some alcohol-related problems, such as violence, traffic crashes, and liver cirrhosis mortality. All types of drinkers, including heavy alcohol users and youth, appear to be affected by the price of alcohol; however, the effect of alcohol price will vary by type of alcohol and the category of the drinker. College students exposed to higher alcohol prices are less likely to consume alcohol. Furthermore, among college students, higher beer prices are associated with students less likely to get in trouble with police or college authorities, cause damage to property, have an argument, be in a fight, take advantage of someone sexually or be taken advantage of sexually.

Price of alcohol can be influenced through policy change. One of the recommended policy changes to increase price of alcohol is to raise taxes on alcohol. Taxes are typically set at the state or federal levels and vary by type of alcohol. Since taxes are typically not adjusted for inflation, the effect of taxes erodes over time – resulting in the real price of alcohol also decreasing over time. Research shows that as taxes are increased, alcohol use and alcohol-related problems decrease. Youth and young adults such as college students may be particularly sensitive to changes in taxes. Based on the current research, CDC's Community Guide Task Force recommends increasing the unit price of alcohol by raising taxes.

Price of alcohol may also be influenced by policies restricting happy hours or other price promotions (e.g. two drinks for the price of one, ladies' night) in licensed establishments. Researchers found that happy hours are associated with more alcohol use among light and heavy drinkers in the general population. Drink promotions are common in alcohol establishments around college campuses, with many offering drink promotions at least some days of the week. These drink promotions are associated with heavier alcohol use on college campuses. Research shows that restrictions on happy hours are related to less drinking among college students. Although most of the policy changes affecting price of alcohol are likely to occur at the local, state, or federal levels, college campuses can also implement pricerelated policies. If campuses have alcohol establishments on campus, campuses can restrict or ban price promotions.

Reduce Access at Campus Events and Parties

Many students drink heavily at certain types of campus events (e.g. tailgating and sporting events) and parties, where alcohol often flows heavily. Policies can be used to restrict the flow of alcohol at events and places where alcohol consumption and related problems are high. For example, campuses can ban alcohol use in parking lots to ensure that tailgating events on their campuses are alcohol free. Campuses can also ban alcohol sales at sporting events. One study showed that a ban of beer sales at football games at the University of Colorado at Boulder may have reduced rates of game-day arrests for assaults, ejections from the stadium, and student referrals to student affairs.

Policies also can be implemented to reduce the flow of alcohol at parties held on and off campus; however, only a few of these policy recommendations have related research. Beer kegs may provide large amounts of inexpensive alcohol to students attending parties. Beer kegs are banned on the majority of college campuses in the United States and studies suggest that these bans, in combination with other policies, may decrease alcohol-related problems. One study found that allowing the self-service of alcohol at parties may lead to more drinking among college students. Another study found that serving students low alcohol content beer may lead to lower blood alcohol content levels than serving regular alcohol content beer, even though the students consumed the same number of drinks. Although these studies suggest that policies banning beer kegs, requiring the availability of low alcohol content drinks, and banning self-service of alcohol may lead to decreased consumption and related problems, further research is needed to evaluate these policies, as well as other policies listed in Table 91.2, that were identified to reduce the flow of alcohol at parties.

OTHER PROMISING POLICIES FOR ADDRESSING COLLEGE STUDENT DRINKING

College administrators have not limited themselves to policies that reduce access to alcohol. A variety of other approaches are used, and the research base for these emerging efforts is starting to build. These efforts include advertising restrictions, amnesty policies, encouraging faculty to offer classes on Friday morning, providing social activities for students that do not involve alcohol, and banning alcohol from the entire campus or parts of the campus. The following section

reviews these efforts, their rationale, describes the state of the evidence base, and highlights some key considerations for complying with the intent of each effort. Results are also summarized in Table 91.3.

One promising area for reducing student drinking is restricting exposure to advertising. Research studies using cross-sectional designs have shown a strong positive association between marketing/promotion of alcoholic beverages and student drinking levels. However, no research has examined whether changes in marketing and promoting alcohol or policies designed to restrict alcohol advertising have been associated with changes in college student drinking patterns. Colleges may be able to exert some control over student exposure to advertising by adopting polices to ban advertising of alcoholic beverages in various forms of media on campus. These can include student newspapers, radio and television stations, sport stadiums, athletic programs, and campus billboards. Additional research is needed to examine whether such policies can reduce exposure to advertising and lead to lower levels of drinking by students.

Colleges are increasingly adopting or considering policies to provide amnesty from punishment for students who act to get appropriate medical attention for students who have consumed too much alcohol. Amnesty is usually offered to both the victim and helper and some universities also include a provision covering student organizations such as fraternities. Most amnesty policies only apply to the university's judicial affairs process and do not provide amnesty from other legal consequences in the community. The rationale behind amnesty policies is to ensure that students are not deterred from seeking medical assistance out of concern about being punished. Amnesty policies are based on the assumptions that students (1) can correctly identify the warning symptoms of alcohol poisoning; (2) can understand the risk associated with the symptoms; (3) are sober enough to judge the risk; (4) are afraid to seek help because of a fear of getting in trouble, either for themselves or their peers; and (5) are more likely to call for help if an amnesty policy exists. Medical amnesty policies are relatively new and have not yet been well evaluated enough to fully understand potential positive or negative effects. A consideration when implementing medical amnesty policies is that alcohol tends to acutely affect judgment and cognitive skills and as a result students may underestimate emergency situations. Another consideration is that, other factors being equal, heavy drinking students tend to show less concern for alcohol poisoning symptoms and have lower recognition of symptoms of alcohol poisoning than nonheavy drinking students. Finally, some research also suggests that students are less likely to intervene in a party environment due to a diffusion of responsibility and/or misinterpretation of an emergency situation. While additional research is needed to determine whether medical amnesty policies are effective in reducing harms to students, they may promote increased calls for medical care.

One aspect of college life that has received greater attention in recent years related to student drinking behavior is class scheduling. Heavy drinking among students on Thursday nights appears to be common, and speculation about the reasons for this has focused on the relative lack of classes scheduled on Friday mornings. Some course instructors may prefer to avoid scheduling class on Friday to leave time available for other academic pursuits. Bars and restaurants influence weeknight drinking by incenting students with drink specials and promotions. Some descriptive research has been done in this area, but few studies exist. The available research suggests that students who do not schedule a class on Friday morning are more likely to drink heavily on Thursday night. It is possible that students who tend to drink heavily are less likely to schedule their classes on Friday, perhaps to make an additional night available for drinking. As a result of the increased attention on the role of class schedules in student drinking behavior, some colleges have begun to institute policies that increase the offering of classes on Friday morning. Additional research is needed to determine whether these policies reduce student drinking behavior on Thursday nights.

Providing social events and venues that do not involve alcohol are popular efforts to combat heavy drinking among students and considerable college and student resources and activity funds are committed to establishing these efforts. However, there has been very little research to determine whether alcohol-free alternative activities reduce student drinking or attract simply students who do not otherwise drink alcohol. Two important concerns about the effectiveness of these efforts are the relative costs involved and the limited reach in terms of both the number of students who might attend a given event and the number of times such events might be held. Nevertheless, more research is needed to determine whether these popular efforts are effective.

Colleges have established policies that ban alcohol from the entire campus or parts of the campus. Students that attend a college with a ban on alcohol are more likely to abstain from alcohol, less likely to binge drink, and less likely to experience the secondhand effects of drinking by other students than peers attending colleges without a ban. At colleges that allow alcohol on campus, students who live in substance-free residences (i.e. a ban on alcohol and tobacco) are less likely to use alcohol and experience secondhand effects from other students'

drinking. More research is needed to determine whether instituting these polices can reduce student drinking and related harms.

IMPORTANCE OF USING MULTIPLE POLICY STRATEGIES TO TARGET COLLEGE STUDENT DRINKING

Alcohol use is a complex behavior. Changing college student rates and patterns of alcohol use to create substantial and sustained reductions in alcohol-related problems will require a multifaceted intervention. Implementing one program or policy will not be sufficient. The research assessing each of the policies listed in Tables 91.1–91.3 is important to consider in developing more comprehensive interventions. Research can help identify which policies are most likely to help change college student alcohol use and determine ways to increase their effectiveness. Policies can then be combined to decrease access to alcohol in multiple ways, increasing the likelihood of greater shifts in alcohol use and related problems. Policies that reduce access can also be complemented by other campus and community policies that help discourage heavy alcohol use by college students.

Several studies have shown that combining alcohol policies and related enforcement efforts can reduce alcohol use and related problems among underage individuals. One study showed that reducing access to alcohol from multiple sources in a community, both social and commercial, can effectively decrease alcohol use and related problems among 18- to 20-year olds. Multiple state-level policies may also help reduce underage alcohol use. Another study found that states with four or more of laws targeting underage drinking have lower rates of underage alcohol use than states with fewer such laws.

Several recent studies have also assessed effects of combined policies and enforcement efforts to reduce heavy alcohol use and related problems among all college students. The combination of strategies varies across studies. Multiple campus policy strategies have been used to address specific problems (e.g. reducing problems related to homecoming events) as well as all college student drinking in general. Sometimes multiple campus policy strategies have also been combined with policy strategies implemented in the surrounding community to address high rates of alcohol use among college students and related problems occurring on and off campus. Although the studies evaluating these combined strategies have some limitations (e.g. small sample size), taken together these studies indicate that use of multiple policy and enforcement strategies can effectively reduce heavy alcohol use and related FURTHER READING 915

problems among college students on campus and in surrounding neighborhoods.

CONCLUSION

Many policies have been identified that can be implemented on college campuses, in surrounding communities and states, or at the federal level to reduce college student drinking and related problems. Although research studies suggest that combining many of these policies may be an effective approach for addressing college student drinking, more research is needed to determine whether there are ideal combinations of policies to create sustained reductions in high-risk drinking and related problems among college students.

The NIAAA released its recommendations for strategies to address college student drinking in 2002. A national study in 2010 examined whether colleges were implementing these recommendations and found that administrators at a substantial minority were not even aware of the NIAAA recommendations. Although about half of the colleges offered recommended intervention programs for students at high risk for alcohol problems, very few college communities had worked on implementing other recommended strategies such as compliance checks to monitor illegal alcohol sales, mandatory RBS training for alcohol servers, restrictions on the density of alcohol establishments, or increasing the price of alcohol. In contrast, nearly all colleges used educational programs to address student drinking, despite clear findings by the task force that these efforts by themselves were ineffective. These findings suggest that more can be done to address college student drinking and provide a possible explanation for why rates of alcohol use among college students remain problematic.

SEE ALSO

The Impact of Drink Driving Laws, Effects of Licensing and Supply Practices, Marketing and Advertising Control, Mobilizing Communities for Alcohol, Drug, and Tobacco prevention, Alcohol Advertising and Underage Drinking, The Impact of Price and Taxation on Drinking and Related Problems among Youth and Young Adults, History and Impact of Minimum Legal Drinking Age Laws on Alcohol Use and Consequences Among Adolescents and College Students

List of Abbreviations

CDC Centers for Disease Control and Prevention

NIAAA National Institute on Alcohol Abuse and Alcoholism

RBS responsible beverage service

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http://www.alcoholpolicy.niaaa.nih.gov/ – Alcohol Policy Information Service (APIS), National Institute on Alcohol Abuse and Alcoholism.

http://www.hsph.harvard.edu/cas/ – Harvard School of Public Health College Alcohol Study.

http://www.madd.org/underage-drinking/ – Mothers Agains
Drunk Driving.

http://www.collegedrinkingprevention.gov/ – Research about College Drinking, National Institute on Alcohol Abuse and Alcoholism.

http://www.thecommunityguide.org/alcohol/index.html – The Community Guide: Preventing Excessive Alcohol Consumption, Centers for Disease Control and Prevention.

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Alcohol Advertising and Underage Drinking

Keryn E. Pasch*, Cayley E. Velazquez\$

*University of Texas, Austin, TX, USA \$University of British Columbia, Vancouver, BC, Canada

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INTRODUCTION

Underage Drinking

Although the rate of alcohol use has declined somewhat since 1999, underage drinking is still very prevalent in the United States. Over one-fourth of youth aged 12–20 report using alcohol in the past month and almost one-fifth report binge drinking (drinking five or more drinks in one sitting at least once in the past 2 weeks). In 2008, alcohol use initiation, defined as having first used alcohol in the past year, was reported by 4.5 million youth and adults, with almost 85% (3.8 million) of these 4.5 million new alcohol initiates younger than the legal drinking age of 21-years-old at the time of initiation.

By the time adolescents reach age 18, almost 75% will have tried alcohol in their lifetime and almost half will have used alcohol in the past month. Rates of alcohol use vary by ethnicity with Hispanic youth using the most alcohol at the beginning of adolescence and White youth using the most alcohol at the end of

adolescence. Boys begin using alcohol earlier than girls, however, girls quickly catch up and even surpass the boys by 8th grade. By 12th grade, however, alcohol use rates among boys and girls are similar. While alcohol use is more common among older adolescents, use of alcohol is still prevalent among those as young as 13 years. National data suggest that 23.8% of 9th graders report drinking more than a few sips of alcohol before the age of 13 and 3.4% of 12–13-year-olds currently use alcohol. By the ages of 14–15, the percentage of youth who are currently using alcohol almost quadruples to 13.1%.

Alcohol use in early adolescence (by age 12) has been found to be associated with subsequent use of alcohol and problem behaviors in later adolescence including drinking and driving, alcohol-related violence, injuries, as well as increased risk for using other drugs. Youth who drink before age 15 are estimated to be four times more likely to develop alcohol dependence than those who begin drinking after age 18. With each year, the

onset of alcohol use is delayed, the odds of alcohol dependence decrease by 14%, and the odds of abuse decrease by 8%. Research has shown that early users of alcohol, specifically those who use alcohol by the start of 6th grade, are significantly different on nearly all socio-environmental, behavioral, and personal risk factors examined. Early users of alcohol are especially more likely to engage in delinquent and violent behaviors and to have lower self-efficacy, positive outcome expectations, and expectancies concerning alcohol use, greater access to alcohol, higher normative estimates of alcohol use, and a greater number of friends who report using alcohol than nonusers of alcohol in 6th grade. This suggests that it is important to understand and address most factors that put youth at risk for alcohol use early, before youth begin using alcohol. Advertising, specifically, alcohol advertising is one such factor.

Advertising and Youth

Marketing has been in existence for over a century, most often with the purpose of fostering consumer acceptance for the product being promoted, as well as encouraging voluntary purchases of the product. Initial efforts to advertise to children began in the 1930s, with companies placing advertisements for their products during radio show broadcasts. However, it was not until the 1950s, with the advent of television, that children truly began to attract the attention of marketers. Children were, perhaps for the first time, seen by industry professionals as being capable of purchasing products on their own. As McNeal illustrates, the focus on children as consumers has evolved from the perspective of a marketer over time, in that "the '50s provided children in large numbers, the '60s gave them increased incomes to spend, the '70s developed and produced many new products and services for children to want and buy, and the '80s gave children the legitimacy, or equality of sorts with adult consumers" (p. 6) all of which led to the commercialization of childhood that began during the 1980s.

Given the newfound legitimacy of children, the 1980s were characterized by an explosion of child-oriented media and advertising. Additionally, changes in the purchasing power of youth, in combination with an increasing number of techniques and outlets to promote products, have resulted in a highly commercialized society where youth are the major targets of marketers. Although the products advertised to children and adolescents have remained relatively constant in recent years, the power of youth to purchase products on their own has increased considerably over time. Recent estimates suggest that personal spending increases with age; for example, individuals between 8 and 12 years of age are

thought to spend \$19.1 billion annually, whereas older youth between the ages of 12 and 17 are thought to spend closer to \$112.5 billion annually. Moreover, it is thought that youth influence more than \$500 billion worth of family spending per year. Thus, when targeting youth, marketers are also making inroads to the spending of their families.

Persuasive advertising techniques, for example animated characters and branded logos, are commonly used in advertisements, and are often used as a means of attracting the attention of youth and engaging them in what is being offered. Moreover, the use of persuasive advertising techniques tends to provide visual cues which represent the attributes of the brand (i.e. fun, excitement), and are often used in an attempt to build awareness, generate product recognition, establish loyalty, and create perceived product value. Although the understanding of the persuasive intent and bias of advertising, mistrust of advertiser motives, and knowledge of advertising tactics all increase with age, youth still may not be able to evaluate messages appropriately given that their ability to access and retrieve such knowledge may not occur until mid-adolescence.

Branding, the process of using a name or symbol to identify or differentiate a product from items within the same product category, is a technique that is often used to create brand equity. Branding helps to create product recognition and helps to communicate product attributes to potential consumers. Because the goal of marketers is to create lifelong customers, establishing brand awareness at an early age is particularly important given that product awareness is thought to lead to stronger brand loyalty, particularly as children grow older. Children are highly aware of brand names and logos beginning at an early age. For example, in a study designed to examine the development of brand awareness among young children, researchers found that children as young as 2 years of age are able to recognize a number of different brand logos for products.

In fact, some of the more well-known techniques used in tobacco advertising included the use of a branded, animated character. Prior to the elimination of cartoon characters in cigarette advertisements in the United States, Joe Camel was perhaps the most prominent one of all, and his popularity was high among both children and adolescents. For example, in one study, slightly more than 90% of 6-year-old children were able to recognize the Joe Camel cartoon as being associated with cigarettes. Among older adolescents, close to 94% of youth were able to identify the Camel cigarette brand name, as opposed to only 58% of adults. Moreover, the use of Joe Camel also helped to increase Camel's sales among the adolescent market, as their market share moved from 0.5% of youth to 32.8% of youth at the height of

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his use. Alcohol products also advertised using animal characters and among 4th and 9th graders, 75 and 87% respectively, recognized the animal character used in a Budweiser advertisement, while 33% of 4th graders and 75% of 9th graders were able to name the brand that the character was used to advertise.

In addition to persuasive advertising techniques, marketers often rely on the emotions of consumers in order to influence them. Emotional marketing, specifically the messages that advertisers use to evoke positive reactions and feelings from consumers, are particularly prominent in alcohol marketing. Given that items within similar product categories are for the most part comparable, alcohol advertising tends to rely heavily on emotional forms of advertising as a way of influencing consumer choice. The effects of emotional advertising may be particularly effective among youth given that they may not possess the cognitive abilities that are necessary to actively process advertising messages. Many psychological models propose that emotional advertising alone may increase the effectiveness of persuasion as well.

Psychological models, for example those that propose that unconscious processes influence consumers, are also hypothesized to persuade youth through such things as brand inference and affect. For example, branded items are often used to create beliefs about the attributes and benefits of products, thus creating and establishing associations with the product and an individual's personal motivations. For youth, fun and excitement are particularly salient motivations that marketers recognize and target. Research suggests that associations that are formed based on inference may actually be stronger than associations that are formed from more direct methods of communication that identify product benefits.

Youth Susceptibility to Advertising

A child's developmental stage is thought to be particularly important in the type of response a child has to a particular product being marketed. A review by Pechmann and colleagues suggests that in contrast to adults, the cognitive development of children and adolescents is characterized by shifts in one's basic cognitive abilities over time. While the adolescent brain does not grow in size after about 6 years of age, it does go through tremendous structural and functional reorganization. This brain plasticity, or changes in the brain systems and structures, may result in certain vulnerabilities as these systems and structures are highly susceptible to negative environmental input. These neurobiological changes are also associated with adolescents' increased likelihood of impulsivity and self-consciousness as compared to adults. As such, adolescents may be particularly attracted to products deemed as risky (i.e. alcohol products), as well as those who provide immediate gratification and may influence social status. Additionally, due to increased plasticity of the adolescent brain, the use of these products may be especially harmful and increase the risk of future addiction.

As a result, youth may be particularly susceptible to the influence of advertising, especially given its ability to expose some of the common vulnerabilities of youth. For instance, adolescents are more likely to experience heightened self-consciousness and social anxiety during this time of their lives, which Solomon suggests may make them particularly receptive to image advertising, as well as advertisements, which include high-status brands. Given that many youth desire to appear older and more mature, advertisements that focus on achieving social status may also be particularly influential. In fact, adolescents have been found to prefer advertisements with desirable lifestyle images, lowering their ratings of advertisements, brands, and products when lifestyle images were removed from beer and cigarettes advertisements.

Additionally, advertisements, which depict risky behavior, are also thought to be influential among youth, especially given their tendency to experience high negative affect. Because this heightened negative arousal contributes to the propensity of adolescents to engage in risky and impulsive behavior, advertisements using this particular type of theme may be especially effective. Moreover, the choices that adolescents make tend to be driven by reward rather than risk, in part because youth expect to experience less harm as a result of engaging in risky behavior than would adults. As a result, adolescents may be tempted to use heavily advertised popular brands of alcohol, particularly because these brands may fulfill their need for immediate gratification and thrill seeking.

Media Exposure

Media use, including, television, music, computers, video games, print, and movies, has increased among youth as of late. Between 1999 and 2004, total media use among youth in the United States held steady at almost 6½ h day, however, by 2009, youth were consuming slightly more than 7½ h day. Youth spend most time watching television (4½ h), followed by time spent on music/audio (2½ h), computers (1½ h), video games (1¼ h), print (slightly more than ½ h), and movies (slightly less than ½ h). However, given that many youth multitask, overall media exposure has increased dramatically, from 7½ h in 1999 to 8½ h in 2004 to 10³/₄ h in 2009. Additionally, exposure to advertising is perhaps even greater than what some studies suggest, particularly

given that youth are exposed to advertising in many other forms, for example, billboards, inside or outside of stores, and at community events. In addition to these more traditional forms of media, many new forms have become increasingly popular among youth including social media, smart phones, and tablets. Given that exposure to these forms of media is not always assessed, true exposure rates are likely to be higher.

Alcohol Advertising

Alcohol advertising includes the advertising of products via a number of different media including television, movies, radio, magazines, in-stores, outdoors, and new media (e.g. Internet, video games). Alcohol advertising also includes the use of alcohol-branded merchandise, or items with an alcohol brand name (e.g. T-shirts, hats, key chains). Alcohol advertising, like other forms of advertising, seeks to develop new customer bases as well as maintain current ones. Because heavy drinking tends to peak in later adolescence and early adulthood, advertising to this demographic is important for alcohol brands to develop market shares within these cohorts.

Television and Movies

The Center on Alcohol Marketing and Youth (CAMY) found that alcohol advertising on television in the United States has increased over the past decade. From 2001 to 2009, exposure among youth aged 12–20 years increased by 71%. This increase in exposure among youth was greater than the increase among adults (21) and over). During this time, alcohol manufacturers spent more than \$8.2 billion on 2 664 919 alcohol product television advertisements. Over this same time period, alcohol advertising on cable television increased by 252.7%, while advertising on broadcast network television decreased by only 2.0%. On cable network, the only product to decrease in advertising exposure was wine (-40.6%), while distilled spirits, beer and ale, and alcopops (flavored malt beverages) all increased in exposure (+3078%, +183.3%, and +143.6%, respectively).

In a study using Nielson data, national data obtained from representative households in order to determine viewership of television programming, researchers determined that almost all of the alcohol advertisements appeared in time slots which had 30% or fewer underage adolescent viewers (95% of all time slots). However, each percentage point increase in adolescent viewership (particularly among female adolescents) resulted in an increase of beer, spirits, and alcopop advertisements (7, 15, and 22%, respectively) suggesting that adolescent viewers were exposed to more alcohol advertising than would be expected if the aim of the

advertisement placement was to target adults of legal drinking age.

Dal and colleagues analyzed the content of the top 100 major motion pictures for each year between 1998 and 2002 and found that over 80% of movies showed alcohol use, with a specific alcohol brand appearing in over half of all movies. Even in G/PG rated movies, alcohol use was shown in more than half and almost 20% contained at least one alcohol brand. On an average, movies exposed US adolescents (aged 10–14) to 5.6 h of alcohol use and nearly 250 alcohol-branded moments.

Magazines and Radio

Youth are also exposed to alcohol advertising in magazines and radio. While exposure in magazines is not as prevalent when compared to television, CAMY reports alcohol companies spent \$2.7 billion for 29 026 product advertisements from 2001 to 2008. Unlike television advertising, wine advertisements in magazines increased by 62.7% over the period from 2001 to 2008. Similarly, beer and ale, as well as alcopop advertising, also increased (157.6 and 39.3%, respectively). The only alcohol product to decrease in magazine advertising was spirits, with a 34.4% decrease. In a study of 118 magazines published between 2002 and 2006, youth readership (under age 21) increased so did the likelihood of exposure to alcohol advertising (from 1.5 to 4.6 times greater likelihood of exposure). Radio advertising of alcohol products has declined, with alcohol industry spending for radio advertising in the 25 markets for which data are available decreased from 2001 to 2006 from \$138.2 million to \$86.2 million, respectively. Despite these declines, youth are still exposed to alcohol advertising through this medium.

In-Store Advertising

In the United States, sample of stores that sold alcohol (3961 stores) almost all (94%) contained alcohol advertisements, half of which were within 3½ ft of the floor, a level previously documented to be in the straight eye-line of children. Convenience stores and smaller markets, along with liquor stores, tend to have the most alcohol advertising. Having a greater quantity of alcohol advertising in these locations is problematic because youth typically visit convenience stores and tend to stay longer than adults, thus increasing exposure.

Outdoor Advertising

Outdoor advertising of alcohol products includes billboards, signage on buildings such as product names and price information as well as other advertising on any outdoor structure. Youth exposure to outdoor advertising is common, with studies in Chicago and Boston INTRODUCTION 921

documenting increased exposure. In Chicago, students were exposed to approximately 15 outdoor alcohol advertisements, on average, around middle schools. In Boston, alcohol advertising was prevalent on public transit train systems with an average of approximately two alcohol advertisements in each of the train cars sampled. Given that nearly 10 000 youth use the transit system in Boston each day, youth exposure to alcohol advertising is tremendous.

New Media

Given that youth are heavy consumers of media, marketers have expanded to newer mediums such as the Internet, cell phones, and video games to target youth. While spending for these newer mediums is increasing, new media provides an outlet for advertising and promotion that does not require much expense and allows for very high levels of exposure. One form of new media, which may be particularly problematic among youth, is online digital marketing, especially given that advertising on this form of media is not as well understood. Many alcohol brands have their own Facebook® pages and Twitter® accounts. For example, 776 731 people "like" the Budweiser® Facebook® page, an Anheiser Busch® brand, which means that close to 800 000 people receive messages from Budweiser in their Facebook® feed. Depending on how often these companies post messages or how often other friends post about alcohol products, the rate of exposure from this type of advertising could well surpass that on other forms of advertising. What is also important to note about these Facebook® and Twitter® messages is that they are not subject to the same scrutiny as those in the mainstream media. While Facebook® does require youth to be a minimum age of 13 in order to have an account, there is no minimum age on Twitter, so youth of any age could receive these advertising messages.

Targeting of Alcohol Advertising

Despite making up less than half of the total population, Hispanic and African-American youth aged 12–20 are disproportionately exposed to more alcohol advertising in all media including magazines, radio, television, and outdoor advertising. Outdoor advertising of addictive products, such as alcohol and tobacco products, is also more prevalent in African-American and Hispanic neighborhoods as compared with non-Hispanic white neighborhoods. A study of alcohol and tobacco bill-boards and freestanding outdoor signs in the city of Chicago, for example, found these advertisements were targeted at poor neighborhoods. On an average, there were 11.8 alcohol billboards in the Hispanic majority neighborhoods as compared to 0.7 in the White majority neighborhoods. The researchers estimated that a child

walking to school in a predominantly African-American or Hispanic neighborhood was three times more likely to see an alcohol or tobacco advertisement than a child walking to school in a predominantly White neighborhood. Around middle schools in Chicago, youth attending schools with 20% or more Hispanic students were exposed to 6.5 times more alcohol advertising than students attending schools with less than 20% Hispanic students. Additionally, schools with 20% or more Hispanic students were also surrounded by more beer advertising and alcohol advertisements on bars and liquor stores.

Alcohol Advertising and Underage Drinking

Messages and Themes

Messages in alcohol advertising are particularly appealing to youth and influential in developing their intentions to drink. Exposure to alcohol advertisements lead youth to perceive that those who drink alcohol have more fun, are good looking and happy, likely as a result of the images portrayed in many alcohol advertisements. Studies have found that alcohol advertisements that are particularly appealing to youth advertise distinct themes such as sexual connotations, camaraderie, conformity, recreation, and friendship. Attractiveness cues of models in alcohol advertisements have also been found to portray sex appeal, femininity, friendliness, and sophisticated/high fashion. All of these themes and cues may be particularly appealing to youth given their stage of development and desire to fit in and engage in activities that make them appear older and more mature.

Alcohol advertising has also been found to influence positive expectancies about alcohol use, which in turn influence intention to use alcohol for under-aged youth (15–20). In a study of 5th through 12th graders, 56% reported that alcohol advertising encouraged them to drink. This encouragement to drink reported by youth likely occurs through the use of images and storylines which depict positive outcomes resulting from alcohol use, perhaps because youth are particularly motivated by benefits during adolescence. Exposure to alcohol advertising also leads children to have higher brand recall and hold more positive beliefs about the social and ritual uses of beer. Alcohol advertisements also shape knowledge, attitudes, and perceptions about alcohol use, which in turn are predictive of positive expectancies and intentions to drink.

In addition, it has been suggested that there has been an increase in the value that youth culture attaches to brand labels and symbols and that the marketing of brands has become an integral part of the everyday social lives of young people. Youth see marketing as part of the entertainment, sporting, and cultural environment that surrounds them, thereby allowing them to link brands for alcohol to normative events in society, and reinforcing the perception that alcohol use is a frequent, everyday occurrence. Through social media, youth are also exposed to messages which promote alcohol use through status updates by friends and other fan pages on Facebook®, Twitter® feeds, and other media sites. Advertising research has shown that over time, repetitive exposure to advertising can lead to low-involvement learning, or learning that occurs when a person is a passive participant. Therefore, even if adolescents do not agree with, like, or are skeptical of advertisements, they still form associations between alcohol use and important values, goals, and lifestyles.

Exposure to Alcohol Advertising and Underage Drinking

In a review of longitudinal studies which document the impact of alcohol advertising and media exposure on adolescent alcohol use, Anderson and colleagues found that across 13 studies findings provide consistent evidence that exposure to alcohol advertising and media is significantly associated with alcohol-use initiation, as well as escalation among those who already use alcohol. In another review of seven longitudinal cohort studies, Smith and Foxcroft also found that increased exposure to alcohol advertising was associated with increased risk of underage drinking.

Several forms of advertising have been linked to underage alcohol use and alcohol-use initiation. In a US national longitudinal study, which examined selfreported exposure to alcohol advertising on television, radio, magazines, and billboards, youth who reported greater exposure had higher levels of alcohol consumption. Specfically, for each additional advertisement that youth saw, the number of drinks consumed increased by 1%. In another study of exposure to alcohol advertising on television, both self-reported exposure to alcohol advertisements as well as type of programming watched were obtained. Using the measure of the type of program watched, 7th graders who watched more television shows were more likely to engage in beer drinking, wine or hard liquor drinking, or have episodes of drinking three or more drinks in a row in 8th grade, while those who watched more sports programs were more likely to engage in beer drinking. For self-reported exposure to alcohol advertising, greater exposure predicted increased beer consumption. Greater exposure to any media (including television, music video and videotapes, computer and video game use), not specifically alcohol advertisements, also predicted alcohol-use initiation among 14–15-year-olds. For every 1-h increase in music video exposure, the odds of drinking initiation risk increased by 31% while the same amount of television exposure increased the odds by 9%. Exposure to alcohol advertising in movies has also been found to predict alcohol-use initiation among 10–14-year-olds.

Exposure to alcohol advertising in stores has been associated with increased risk of alcohol use among youth in several studies. For example, middle school youth who frequently visited convenience stores, liquor stores, or small grocery stores were more likely to have ever used alcohol. In a sample of 7th graders who did not drink alcohol, exposure to in-store beer advertisements significantly predicted initiation of drinking in 9th grade. Additionally, greater exposure to objectively measured outdoor alcohol advertising, including billboards, other freestanding alcohol signage, and alcohol signage on buildings, predicted increased alcohol use intentions among middle school youth. Among youth who had not used alcohol at baseline, greater exposure to outdoor advertising also predicted increased alcohol use intentions. Interestingly, while overall signage predicted intentions, even those signs which included only brand name or product information predicted increased alcohol intentions, suggesting that even exposure to advertisements which may not be particularly appealing to youth also have an effect on alcohol use.

Alcohol-Branded Merchandise and Underage Drinking

While alcohol advertising on media channels such as television, print, radio, and outdoor media is prevalent and increases the risk of underage drinking, the expenditures of these forms of advertising may account for only one half of the company's advertising budget. Another form of promotion is merchandising, which would include things such as packaging, direct mailing, point-of-sale materials, and branded promotional merchandise or alcohol-branded merchandise.

The influence of alcohol-branded merchandise, or merchandise such as hats, shirts, or water bottles with the name and/or logo of alcohol brands, has been associated with youth alcohol use in several studies. In a nationally representative sample of United States youth aged 10-14, ownership of alcohol-branded merchandise was common, with rates ranging from 11-20%. The most common forms of alcohol-branded merchandise were clothing such as t-shirts, jackets, and headwear (88%) and over 80% of the branded merchandise was for beer brands. Most commonly, adolescents received their alcohol-branded merchandise from friends and family, however, almost one-quarter purchased these items on their own. Youth with higher levels of sensation-seeking and rebelliousness were more likely to own alcohol-branded merchandise and youth who were involved in extracurricular activities were also more likely to own alcohol-branded merchandise. African-American and Hispanic youth were less likely to own alcohol-branded merchandise than White FURTHER READING 923

youth. Alcohol-branded merchandise ownership was significantly related to an increased likelihood of becoming susceptible to alcohol (less likely to refuse peer offers of alcohol, increased intentions to use alcohol, and increased positive expectancies of alcohol use). In addition to indirectly predicting alcohol-use initiation through alcohol susceptibility, owing alcohol-branded merchandise also directly predicted the initiation of alcohol use, as well as binge drinking among those who were nondrinkers at baseline.

In another large cohort study, the Growing Up Today Study, youth aged 9–14 who owned or were willing to own alcohol-branded merchandise were more likely to initiate alcohol use at the 1-year follow-up. Among girls, owning alcohol-branded merchandise was associated with binge drinking. Similarly, students in California middle schools who owned at least one alcohol promotion item were found to be three times more likely to have ever tried drinking and 1.5 times more likely to be current drinkers than those who did not own any alcohol promotion items. In another study of northern New England adolescents, youth who own alcoholbranded merchandise were significantly more likely to have initiated alcohol use 1-2 years later as compared to youth who did not own this type of merchandise. Each of these studies, while not nationally representative, provides evidence that regardless of region of the United States, alcohol-branded merchandise does influence underage alcohol use.

CONCLUSIONS

Underage drinking is prevalent in the United States, and associated with subsequent use of alcohol and other problem behaviors in later adolescence including drinking and driving, alcohol-related violence, injuries, as well as increased risk for using other drugs. As a result of their developmental stage, youth may be particularly susceptible to the influence of advertising, especially given its ability to expose some of the common vulnerabilities of youth. Alcohol advertising, although intended for individuals of legal drinking age, uses persuasive techniques and images that are particularly attractive to youth. As a result, alcohol advertising gains youth attention and engages them in what is being offered. Several longitudinal studies have found that exposure to alcohol advertising and alcohol-branded merchandise both predict underage alcohol use as well as initiation of alcohol use among nondrinkers. Because early alcohol use is associated with alcohol dependence in later life, understanding the effects of exposure to alcohol advertising, as well as reducing exposure, is crucial.

SEE ALSO

Marketing and Advertising Control, Substance Use Prevention Approaches for School-aged Youth, Mobilizing Communities for Alcohol, Drug, and Tobacco prevention, Impact of Alcohol Policies on College Student Health (Including Alcohol Access Restrictions, Policy Enforcement, Amnesty Policies), Understanding Individual Variation in Student Alcohol Use

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The Impact of Price and Taxation on Drinking and Related Problems among Youth and Young Adults

William R. Ponicki

Prevention Research Center, Pacific Institute for Research and Evaluation, Berkeley, CA, USA

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Alcohol use by youth and young adults is very common and has been associated with a variety of serious societal problems. For example, three-fourths of 12th graders in the United States have consumed alcohol during their lifetimes, with 45% having done so in the last month and 22% having consumed at least five drinks in a single occasion. The Surgeon General's office estimates that 5000 US residents under the age of 21 die each year from injuries due to underage drinking including 1900 related to motor vehicle crashes and 1600 due to homicides. These high levels of alcohol use and problems have led to an array of policies designed to discourage youth drinking including education campaigns, minimum legal drinking age laws, enhanced regulation of driving after drinking, and higher beverage taxes or prices. The impacts of taxes

and prices on adult drinking, young adult drinking, and underage drinking have been evaluated by hundreds of studies over more than 60 years. Although the results of these studies generally indicate that greater taxes and prices are related to less drinking and fewer alcohol-related problems, there is also a fair amount of disagreement within the empirical literature.

Tax- and price-based measures have both advantages and disadvantages relative to other alcohol-control policy options. On the positive side, alcohol tax policies cost relatively little to administer, unlike drunk driving or underage purchase laws that involve considerable expense to enforce and prosecute. Higher beverage taxes can simultaneously reduce the costs that problem drinkers impose on other citizens (such as victims of

drunk driving) and help defray the governmental costs of alcohol-related law enforcement and treatment programs. The major disadvantage of alcohol taxes is that they are not as closely tied to problem drinking as other alcohol-control policies. Whereas underage-sales laws only limit access for a group whose drinking is considered particularly risky and drunk driving laws only affect those who combine alcohol and vehicle use, higher beverage taxes indiscriminately discourage both low-risk and high-risk drinking behaviors. This lack of focus on problem drinking causes beverage taxes to be more controversial than some other alcohol-control policies, and makes it important for empirical research to demonstrate that tax policies reduce the types of alcohol use that are most problematic to society. This level of controversy also encourages political partisans to emphasize studies that either support or discount the harm-reduction potential of tax or price policies, making it important to understand how these policies work and how their effectiveness can best be evaluated.

This chapter provides a general introduction to the effectiveness of tax and price policies for reducing drinking and related problems, particularly among youth and young adults. It is organized as follows: The first section explains how these policies work in theory. The second section explains the ways in which the policies are typically evaluated, stressing the strengths and weaknesses of different methodological approaches. The third section briefly reviews the broader literature estimating price and tax effects on drinking and other related problems among all ages. The fourth section looks more closely at tax and price effects on youth drinking and problems, explaining how variation in findings across studies are often explainable based on their methodological differences. The final section summarizes the strengths and weaknesses of these various parts of the literature and offers conclusions about their usefulness in formulating alcohol-control policy.

HOW TAX AND PRICE POLICIES WORK

The top panel of Fig. 93.1 presents a simplified conceptual model for using taxes or prices to control drinking and related problems.

Taxes to Prices

Although some governments set alcohol prices directly via retail monopolies, others allow market forces to determine beverage prices. These governments use tax policy to influence prices, and the plus sign above the first causal arrow in Fig. 93.1 suggests that tax increases induce alcohol sellers to raise beverage

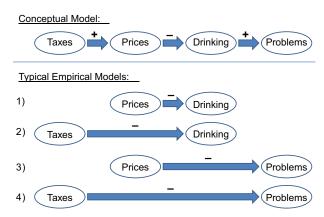


FIGURE 93.1 Conceptual and empirical models of tax or price effects.

prices. Confirming prior research, a 2005 analysis by Donald Kenkel found that a major alcohol tax increase consistently led to even larger price increases across various beverages and outlet types (i.e. the tax increase was more than 100% passed through to customers).

Prices to Drinking

The minus sign above the middle causal arrow represents a negative relationship between alcohol prices and drinking. This reflects the "law of demand" at the core of economics: when a product's price increases, people will generally choose to buy less of it. Although this assumption is quite sensible among of-age drinkers who typically purchase the beverages they consume, it is somewhat more controversial for underage individuals who are legally prohibited from buying alcohol. Although these individuals sometimes make retail purchases despite being underage, their access more often comes indirectly through social networks, availability in their families' homes, or purchases by adults on their behalf. The underage drinker may not pay the full cost of their alcohol in such instances, which weakens the logical case for price effects. However, even when young drinkers do not pay for the beverages they consume, someone is paying the retail price, and these purchasers have an incentive to buy less when prices are high. Also, research indicates that youth drinking norms are positively related to adult drinking behaviors in their communities, and these adult behaviors will be affected by prices.

Drinking to Problems

The plus sign over the last causal arrow in Fig. 93.1 reflects the fact that increased drinking is typically associated with increased risks for various problems such as motor vehicle crashes, accidental injuries, assaults (as victim or perpetrator), homicides, suicides, and chronic ailments such as liver disease and some cancers.

HOW THESE POLICIES ARE EVALUATED

Any one empirical study is very unlikely to investigate all of the causal relationships shown in the conceptual model. Instead, such studies tend to relate either taxes or prices to either drinking or problems. These two choices lead to the four typical analysis models shown in the lower panel of Fig. 93.1. Model 1 directly investigates a consumer's purchase decision: faced with a given price level for alcohol, how much does an individual buy? Model 2 directly relates tax rates to drinking while ignoring the intervening effect of prices. Model 3 directly associates prices with some measure of alcohol-related problems such as traffic crashes, disregarding the intermediating impact of drinking. Finally, model 4 relates tax rates directly to an alcohol problem indicator, ignoring the intermediate roles of both prices and drinking. Each of these four typical models can be analyzed using either individual-level or aggregatelevel data. An individual-level example for model 1 might relate college-specific price indicators to student-specific survey reports of heavy drinking. An aggregate-level example using model 4 might relate state-specific beer tax rates to state-level automobile fatality rates among youth and adults.

Each of these modeling alternatives involves advantages and disadvantages, both in terms of policy-relevance and the reliability of statistical results. An understanding of these issues is helpful for understanding why the existing empirical literature is less than unanimous in its findings regarding the effectiveness of tax and price policies.

Prices versus Taxes

One attraction of using prices rather than tax rates is that taxes may be a small and varying portion of each beverage's price. For example, wine prices may rise considerably due to poor harvests in grape-growing regions, and tax rates will not be able to explain any resulting decline in wine consumption. Another advantage of using price to predict drinking levels is the product-demand relationship that can be defined in a directly comparable way across the full array of goods and services. Economists typically express this relationship as "price elasticity," defined as the percent change in a product's consumption resulting from a 1% increase in its price. Because the price and purchase changes are both measured as proportions, price elasticities can be directly compared across product categories regardless of the units used for currency or quantity purchased. For example, Craig Gallet's 2007 literature review was able to compare the median-study's elasticity for beer (-0.36, suggesting a 0.36% drop in purchases from a 1% price increase) to those for wine and spirits

(-0.68 and -0.70, respectively) and conclude that beer demand was roughly half as responsive to price changes as was demand for spirits or wine. Elasticities calculated using taxes rather than prices will vary with each product's tax-to-price ratio, preventing direct comparisons across different consumer goods.

On the other hand, prices also have some disadvantages relative to taxes. Unlike prices, taxes are directly under the control of policymakers, so results from a tax-based model will be more relevant for policy analysis purposes. Also, any given consumer faces a wide range of possible drink prices depending on his or her choice of beverage, brand quality, container size, and purchase location. Empirical studies generally employ a single price index for each beverage type, often based on a single brand. For example, many US studies have used alcohol prices from the Council for Community and Economic Research's Cost of Living Index (C2ER COLI), formerly published by the American Chamber of Commerce Researchers Association (ACCRA). For several decades, this data system has surveyed local retail prices for one specific brand and container size each for beer, wine, and spirits. The chosen price index may not be particularly relevant for those drinking other brands, and research by Douglas Young and Agnieszka Bielinska-Kwapisz has demonstrated how this imprecision can bias estimated price effects toward zero. This is much less of an issue for models using beverage taxes, where a single rate typically applies over a broad class of beverages.

Drinking versus Problems

Studies also measure drinking in many different ways, including participation (any drinking), frequency of any drinking (e.g. occasions per month), participation in or frequency of "binge" drinking (e.g. occasions with 4+ drinks for females, 5+ for males), average drinks per occasion, or total volume consumed over a given time period. Some of these measures of drinking may be more important from a policy standpoint than are others. As discussed above, alcohol policy should ideally reduce problematic drinking with minimal disruption of low-risk (or even health-improving) alcohol use. Knowing that a price increase would reduce total alcohol consumption by 1% does not clearly imply a reduction in problem drinking. On the other hand, drinking by underage individuals is often considered problematic in and of itself, so youth drinking measures might be more meaningful from a policy perspective. Similarly, survey reports of heavy or binge drinking are typically assumed to be inherently more problematic than other consumption measures. Studies may also investigate a range of specific alcohol-involved problems such as impaired driving,

violence, accidental injuries, or chronic conditions such as liver cirrhosis.

Individual versus Aggregate-Level Data

Studies can also be differentiated by whether they investigate person-level or aggregated drinking problems. Aggregated drinking indicators are generally limited to measures of alcohol sales within a tax jurisdiction, such as barrels of beer sold in a given state and year. A major advantage of aggregated sales data is that the information is automatically and reliably recorded in the process of collecting alcohol taxes, whereas survey self-reports of drinking behaviors will likely be less accurate due to memory lapses or underreporting bias. For example, a recent US analysis by David Nelson and colleagues finds that average per capita self-reported beverage consumption in the Behavioral Risk Factor Survey tends to be roughly one-third as high as per-capita taxable alcohol sales. This finding suggests either that survey respondents greatly understate their drinking or that the heaviest drinkers often refuse to participate in the surveys. Another advantage of taxable-sales data is that they tend to be consistently collected over long time spans, increasing the statistical power to measure price effects with reasonable precision. One disadvantage of taxable-sales data is that certain types of drinking will not be counted (illegal production) or will be counted as consumption in a different jurisdiction (as when individuals cross state or national borders to purchase in a neighboring low-tax jurisdiction but transport the beverages back to their high-tax area). Another limitation of tax-based aggregate drinking measures is that there is no way to differentiate by the types of drinking (e.g. frequency of binge drinking) or groups of drinkers (e.g. youth versus adult), and it may be impossible to differentiate onpremise from off-premise sales (e.g. consuming at a bar versus at home). These specific types of drinking may be differentially related to alcohol problems, and can generally be distinguished only with individuallevel surveys.

Analyses of alcohol-related problems can also be performed at the aggregate or individual level. Governments frequently collect jurisdiction-level data on traffic crashes, hospital admissions or fatalities by diagnostic code, arrests for various offenses, and other indicators such as educational performance that may be related to drinking. Unlike for aggregated beverage-sales data, many of these problem rates can be differentiated by age group, such as counts of traffic fatalities among drivers aged 18–20. Although survey data allow more flexibility in terms of specific problems (e.g. arguing with a spouse), aggregate data sources

tend to be more reliable and complete for the limited problems for which they are available.

Aggregate-level studies of drinking or related problems require tax or price data of corresponding geographic areas. For example, state-specific cirrhosis death rates could be compared to state alcohol tax rates. In contrast, individual-level drinking or problems can be related to either aggregated or individual-level price data. Use of aggregated tax/price data has the advantage that is more independent of a person's drinking choice; for example, a student at a college in a high-tax state will likely have to pay more for alcohol regardless of which beverage brand he or she chooses to consume. Self-reported price data, on the other hand, may be heavily influenced by the product chosen (e.g. cheap or expensive brand, large or small container) and drinking location (e.g. at a party versus a bar). This "choose your price" aspect of individual reports can have advantages or disadvantages over aggregate-level price indices. If a hypothetical individual decides to attend a college party without knowing whether there will be a charge for alcohol, then the fact that the chosen party provides free drinks could be said to have an exogenous impact on how much the student drinks on that occasion. Frank Chaloupka has argued that college studies that examine only local retail prices will understate estimated price elasticities by ignoring the effect of such no-cost drinking. Conversely, an individual who intends to drink heavily on a given occasion may be more likely to choose a bar with low prices and to buy the cheapest brand. Such a study would tend to overestimate the price effect on drinking problems because part of the causation is actually going from heavy intended drinking to beverage cheapness.

EMPIRICAL EVIDENCE OF TAX AND PRICE EFFECTS ACROSS ALL AGES

Studies of Drinking

Combining results from 112 separate empirical papers, a 2009 literature review by Alexander Wagenaar and colleagues provides strong general support for the hypothesis that prices and taxes are negatively related to all-age drinking. They found that these studies were over 30 times more likely to report a statistically significant negative impact on drinking than to find a significant positive effect (although analyses with unexpected results may be less likely to appear in the published literature). Ten reviewed studies specifically estimated price or tax effects on various measures of heavy alcohol use, with seven finding a significant negative effect and only one reporting a significant positive relationship. Some authors have hypothesized that heavy alcohol

consumers should be less responsive to price changes than are lighter drinkers due to the addictive nature of alcohol, while other authors expect heavy drinkers to be more affected by prices due to alcohol being a larger part of their household budget. Empirical studies have reached no clear consensus over which group is more price-responsive, however.

Studies of Problems

Wagenaar and colleagues' 2010 literature review provides a similar summary across 50 separate studies relating prices or taxes to mortality and morbidity from various causes. Their meta-analysis procedure calculated average price/tax effect sizes within each of eight problem categories: alcohol-related disease, violence, suicide, traffic, risky sex or sexually transmitted disease, tobacco or drug use, crime or misbehavior, and nonalcohol-specific injuries. All eight of these averaged effects were negative, and all were significantly different from zero except for suicide (which was nearly significant with a *p*-value of 0.084). Although their meta-analysis combined studies of problems across all age groups, the review also itemized 40 estimates relating prices or taxes to youth-specific problems; 65% of these reported significant effects in the hypothesized negative direction, whereas none found a significant positive relationship.

EMPIRICAL EVIDENCE OF TAX AND PRICE EFFECTS AMONG YOUTH AND YOUNG ADULTS

The literature reviews and meta-analyses discussed above provide strong general support for the hypothesis that price and tax policies can reduce drinking and problems, both in the general population and young age groups. Despite this general agreement in the literature, however, there is a substantial amount of variation in results across studies. This section summarizes the strength and consistency of evidence from various sections of the literature describing youth and young adults.

College Drinking

Survey-based analyses of college drinking typically find the expected negative relationship with prices, but the results vary somewhat depending on how relevant the tax or price measure is to a given school's drinking experience. For example, a 1996 study by Frank Chaloupka and Henry Wechsler relates the city-level C2ER COLI beer-price index to student drinking in Harvard's College Alcohol Study (CAS) and found significant

negative price effects for underage female students but not males or of-age females. A 2005 CAS analysis by these authors and Jenny Williams found more consistently significant price effects by replacing the noncollege-specific C2ER COLI index with a measure of typical prices paid by survey respondents at each particular school, including "all you can drink" fees. A 2009 analysis by Ryan O'Mara and colleagues went even further in the direction of price relevance, finding that individual respondents' blood alcohol levels upon leaving a college bar district had a strong negative association with the amount that they had paid per unit alcohol on that particular day. The less-significant C2ER COLI-based results suggest that broad tax or price indices may not adequately reflect the alcohol costs faced by individual college students. At the other extreme, using prices specific to a single drinking occasion makes the direction of causation somewhat suspect, as individuals who plan to consume heavily may choose cheap brands and low-cost drinking venues.

Other Youth Drinking

Noncollege studies have used a variety of survey data sets to assess whether higher taxes or prices are associated with reductions in youth and young adult drinking. The majority of studies in this literature have confirmed the hypothesized negative relationship. However, a number of studies published since the late 1990s have found far less consistent results using more conservative statistical specifications. This methodological division arises because there is more than one logical explanation for the observation that people drink more where taxes or prices are low. The standard economic demand hypothesis assumes that high taxes and prices in a given area induce local residents to drink less. An alternative explanation suggests that some regional populations will have particularly strong anti-drinking sentiments, and these attitudes could lead to both high local beverage taxes and low levels of drinking, even if taxes or prices themselves do not influence alcohol use. Basic empirical models have generally found that jurisdictions with high taxes tend to have lower per capita drinking, but this evidence is consistent with either hypothesis above. Other statistical models test whether jurisdictions with rising (falling) taxes tend to reduce (increase) their alcohol consumption relative to other places with unchanged taxes, and this sort of study provides a more-direct test of the hypothesis that taxes influence drinking behavior. An influential 1999 paper by Thomas Dee used both types of models to analyze self-reported drinking data from 16 years of the Monitoring the Future (MTF) survey; simpler specifications confirmed earlier findings that youth consumption moves inversely with beer taxes, but models concentrating on tax changes found inconsistent results. Frank Chaloupka has argued that the latter results are not convincing evidence against the standard demand hypothesis, noting that the rarity of tax changes over the period studied implies low statistical power to identify a significant tax effect. This argument is supported by Christopher Carpenter and colleagues' 2007 analysis that used a longer 28-year sample of MTF data to find significant negative tax effects on youth drinking even using the more conservative specifications. Studies of youth drinking based on other US survey data sets (National Longitudinal Study of Youth, National Survey of Drug Use and Health) have produced a similar pattern of results, with significant negative price or tax effects in simple models but mixed results using the more conservative methods.

Youth Motor Vehicle Crashes

A large number of studies have investigated the relationship between alcohol taxes or prices and youth traffic crashes. Most of these studies have focused on aggregate-level fatal crash statistics for US states, available from the Fatal Accident Reporting System (FARS). This source provides consistently collected data for all states over several decades, with detailed reports collected for all vehicles in every crash involving a fatality. Several different state-level studies using FARS data over various time spans have found that higher prices or taxes are significantly related to lower traffic fatality rates, with the effect usually being stronger among youths than for adults. Unlike in youth drinking studies, these significant negative tax or price effects generally remained even in analyses using more conservative statistical specifications designed to avoid biases from states with antialcohol sentiments enacting higher tax rates. However, a 2001 study by Thomas Dee and William Evans found a similar negative beer tax effect on youth crash fatalities regardless of whether they occurred during the day or night, despite the fact that the daytime crashes were rarely found to have involved drinking. This fact, along with somewhat implausibly large tax elasticities, made the authors question whether these results are really due to the effects of drinking. An individual level 1997 study by Frank Chaloupka and Adit Laixuthai found a significant negative relationship between beer taxes and nonfatal youth crashes as reported in the MTF surveys.

Other Youth Problems

A series of studies by Sara Markowitz and Michael Grossman have related higher alcohol prices to reductions in several problems on college campuses including suicidal thoughts and actions (significant for males but not females), sexual assault, property damage, and trouble with police. They have also found significant price or tax impacts for youth birth control use and sexually transmitted diseases, the latter of which was confirmed for males only in a 2000 paper by Harrell Chesson and colleagues. A 2003 analysis by Bisakha Sen found that higher beer taxes were associated with fewer teen pregnancies and abortions. Although these results suggest the breadth of problems that could be affected by alcohol price or tax policies, it is hard to judge the robustness of each individual finding in their absence and other analyses investigating that particular outcome measure.

SUMMARY AND CONCLUSIONS

The great majority of empirical studies are consistent with the hypothesis that higher beverage taxes or prices lead to reductions in drinking and related problems. Yet this literature is far from unanimous regarding the size or, to a lesser extent, the direction of these effects. In part because they are not well targeted toward problem drinking, alcohol taxes tend to be controversial, and inconsistent empirical results regarding their harm-reduction effectiveness reduce the political will to raise tax rates. This helps to explain why alcohol taxes in the United States have failed to keep pace with inflation during the past 50 years, with the result that real beverage prices have declined considerably.

There are many possible reasons for the lack of agreement across these empirical studies. All statistical analyses involve some imprecision in their estimates, and this explains some of the variations. Certain measurement issues can further compromise the ability of models to provide accurate estimates of price and tax impacts. For example, single-brand price indices fail to reflect the wide array of product choices that consumers typically choose from, and it has been demonstrated that inaccurate price measures bias elasticity estimates toward zero. The use of single brand, city-level price indexes may be especially poor at capturing the prices spent on alcohol in college drinking studies, helping to explain their inconsistent effect estimates relative to price measures that account for free alcohol or all-youcan-drink fees. Unreliable self-reported drinking on surveys would also result in poorly estimated price or tax effects, and this could help to explain the less-thanconsistent results in the literature for youth drinking.

There are also several reasons that tax and price effects may truly vary depending on the situation. For example, a tax increase that applies only to spirits might cause many consumers to switch to wine or beer without any substantial impact on total drinking, whereas an equivalent tax hike across all beverages could lead to a considerably larger drop in overall consumption. The

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local impact of a tax increase may also depend on whether consumers can easily substitute locally bought beverages with purchases in neighboring jurisdictions that have not changed their tax rates. Raising taxes that are defined as a percentage of wholesale value will tend to increase prices particularly for high-quality brands, perhaps inducing some drinkers to switch to cheaper brands rather than reduce their total drinking. Raising taxes that are defined as a flat rate per unit of ethanol would most affect the prices of the lowest-cost forms of alcohol, and consumers of these products will have less ability to maintain consumption by switching to cheaper brands. Research by Gruenewald and colleagues based on Swedish price data suggests that equivalent changes in average prices may have far different effects on total alcohol consumption depending on how they are distributed across the brand-quality spectrum. A new study by Tim Stockwell and colleagues further supports this idea, finding that Canadian beverage sales are more sensitive to changes in the cheapest beverages' prices than to the average price across a broad beverage category.

The effect of a given increase in taxes might also vary with the current share of taxes in the full price of drinking. Consider the effect of a proposed 10% rise in beverage taxes. If taxes currently represent 5% of the retail price, the 10% tax hike would only raise that price by about 0.5%. If the current tax share is 50%, however, the same proportional tax hike would raise retail prices by roughly 5%, implying a far larger expected reduction in drinking. The full price of drinking also includes the time spent on obtaining beverages as well as other possible costs related to alcohol use such as penalties for drunk driving. A given proportional change in the monetary price of a beverage would represent a smaller portion of the full price in places with stronger alcohol policies other than taxes, possibly leading to smaller estimates of the price elasticity of drinking. As a result, price sensitivity of drinking may vary considerably across geographic areas or time periods. For example, some authors have noted that US studies using morerecent data tend to find smaller price effects on motor vehicle crashes, which might reflect increased penalties for drunk driving or perhaps other changes in society. A disproportionate share of tax and price studies have been conducted in the United States because of its greater variation in state tax policies but reasonably uniform drinking culture, which lets states with unchanged tax rates function like control cases in judging the effects of other states' tax changes. Although this makes the United States a convenient laboratory for testing tax effects, it does not imply that other countries will experience similar effects of tax or price changes.

In conclusion, the empirical literature provides ample evidence of the potential effectiveness of tax and price

policy for reducing youth drinking and related harms. Some portions of the literature are less conclusive than others. For example, youth drinking studies are typically based on self-reported drinking which may be seriously under-reported, and this may help explain why price effects estimates vary considerably across studies. However, weaknesses in some sections of the literature are compensated somewhat by stronger findings in other areas. Thus, even if price effects are somewhat difficult to measure for youth drinking, there are more-conclusive results for all-age drinking based on aggregate sales data, and traffic fatality studies suggest that youths may be more responsive to tax and price policy than are adults. The literature also provides limited evidence regarding the types of tax or price policies that should be most effective, and also suggest how well they might be expected to work in different social and legal environments. Such research can help individual communities formulate their optimal blend of alcohol-control policies.

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SEE ALSO

The Impact of Drink Driving Laws, Effects of Licensing and Supply Practices, Marketing and Advertising Control, International Policies to Reduce Alcohol Consumption and Related Harms, Alcohol Misuse Prevention in the Military, Individual Prevention of College Student Alcohol Misuse, Substance Use Prevention Approaches for School-aged Youth, Examining the Role of Parents in College Student Alcohol Etiology and Prevention, Mobilizing Communities for Alcohol, Drug, and Tobacco prevention, Impact of Alcohol Policies on College Student Health (Including Alcohol Access Restrictions, Policy Enforcement, Amnesty Policies), Alcohol Advertising and Underage Drinking, History and Impact of Minimum Legal Drinking Age Laws on Alcohol Use and Consequences Among Adolescents and College Students, Understanding Individual Variation in Student Alcohol Use

List of Abbreviations

CAS college alcohol study

FARS Fatal Accident Reporting System

Monitoring the Future

Glossary

MTF

Price elasticity the percent change in consumption of a product that results from a 1% change in the product's price.

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Impact of Tobacco Control Policies on Youth Smoking Rates

Annette Kaufman, Yvonne Hunt

National Cancer Institute, USA

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INTRODUCTION

Adolescence is the period of increased susceptibility for cigarette smoking uptake and progression. In the United States, approximately 90% of adults who smoke daily begin smoking before the age of 18. Accordingly, efforts to reduce smoking prevalence must include tobacco control policies aimed at preventing smoking uptake and promoting cessation among youth. Rates

of youth smoking in the United States remain unacceptably high. Every day, almost 4000 youth (aged 12–17 years), smoke their first cigarette and about 1000 become daily smokers. In 2009, 19.5% of high school students (grades 9–12) had smoked at least one cigarette in the past month. Furthermore, previously observed declines in youth smoking have stalled; smoking prevalence among youth has remained virtually unchanged since 2003.

Youth smoking behavior is influenced by a variety of intra-individual and contextual factors, including genetic/biological factors, parent/peer influences, and broader environmental influences (i.e. community characteristics, media, policy). Policies are a set of rules that guide the present and future behaviors of individuals and organizations to achieve a specific goal. Youth-centered policy approaches work at the environmental level, by altering the legal, economic, social, and physical contexts that shape tobacco-use behavior. When implemented as part of a comprehensive tobacco control program (e.g. programs involving a range of coordinated and coexisting tobacco control strategies) these policy tools can work independently and synergistically to drive down youth smoking rates.

This chapter provides a broad overview of tobacco control policies that are intended to and/or have an effect on reducing youth cigarette smoking in the United States For the purpose of this review, we consider four broad policy approaches: youth tobacco access restrictions, smokefree laws, economic approaches, and restrictions on tobacco marketing and promotion. Within each of these broad categories, we review the evidence for specific policies. The contribution of each policy tool is discussed as it relates to the reduction of youth smoking rates. Additionally, because policies can influence youth smoking behavior at multiple points along the smoking trajectory, we consider the action of these policy tools across the tobacco use continuum, from experimentation to cessation.

Youth smoking is a global problem, and a growing number of countries are implementing and enforcing tobacco control policies that influence youth. According to international data, an estimated one in seven teenagers smoke cigarettes, and almost one-quarter of those have smoked their first cigarette before age 10. The youth tobacco problem is especially pronounced in economically developing nations. It is estimated that worldwide more than 80% of youth who smoke live in low- and middle-income countries. While the focus of this chapter is on the United States, examples of global policy approaches are included throughout.

No examination of the tobacco control landscape as it pertains to youth would be complete without a look at the challenges that lie ahead. The tobacco industry is nimble; as policy tools evolve over time, so too do industry tactics designed to circumvent these policies. For example, in the face of an increasingly regulated cigarette market, tobacco companies are actively investigating alternative tobacco products that have the potential to attract young people (e.g. smokeless tobacco, little cigars, hookah). Though cigarettes are the focus of this chapter, many of the policy approaches discussed could be potentially applied to other forms of tobacco.

Youth Policy: US Perspective

A variety of tobacco control policies have been enacted over the last two decades that aim to prevent smoking initiation and reduce consumption among adolescents. Early efforts to reduce youth smoking employed key reports, litigation, and legislation passed at the local, state and federal levels. A 1994 publication by the Institute of Medicine, "Growing up Tobacco Free: Preventing Nicotine Addiction in Children and Youths," was one of the first high-profile reports to focus on youth tobacco use. The report discussed initiatives throughout the world to limit access, control/ban tobacco sales to minors, and reduce tobacco advertising, and examined price sensitivity among youth. Another prominent 1994 publication was "Preventing Tobacco Use Among Young People: A Report of the Surgeon General," which was the first Surgeon General's report to focus entirely on the problem of youth smoking.

The largest civil litigation settlement in US history was the 1998 Master Settlement Agreement (MSA) between the four major US cigarette manufacturers and 46 US states (Florida, Mississippi, Texas, and Minnesota settled separately with the manufacturers around the same time). The main purpose of the MSA was to seek reimbursement for healthcare costs incurred by the states over the decades when the tobacco companies were denying the causal relationship between smoking and disease and the addictive nature of tobacco. A secondary objective was to reduce underage tobacco use through prohibiting tobacco companies from directly or indirectly targeting youth through marketing (enforced by state attorneys general). Funds from the MSA created the American Legacy Foundation that is devoted to "building a world where young people reject tobacco and anyone can quit." Furthermore, the settlement compelled tobacco companies to release millions of internal tobacco industry documents, which revealed long-standing practices of targeting underage users and potential users. The availability of these documents would bolster future litigation efforts to hold tobacco companies accountable for their actions. The MSA represented an important step toward ending some of the tobacco industry's most egregious-youthmarketing practices and helped to set the stage for future policy efforts. However, the MSA was fairly limited in its regulatory authority, leaving many avenues for continued efforts by the tobacco industry to recruit youth smokers.

In addition to the advances achieved through the states' litigation, the 1990s also saw the first serious efforts to pass youth-focused tobacco control legislation. The Synar Amendment, passed in 1992, requires states to enact and enforce laws prohibiting the sale and distribution of tobacco products to individuals less than

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18 years of age. In 1996, under US Food and Drug Administration (FDA) Commissioner David Kessler, the FDA issued a groundbreaking rule to restrict the sale, distribution, and advertisement of tobacco products, arguing that smoking is "a pediatric disease," as the vast majority of smokers smoke their first cigarette before 18 years of age. The tobacco industry challenged these efforts in the courts. Ultimately, the only provisions of that rule that went into effect were a series of youth access restrictions. Though the 1996 final rule was struck down by the US Supreme Court, it laid the groundwork for a 13-year effort that would ultimately result in the passage of even stronger Federal legislation in 2009, which incorporates provisions of the 1996 rule.

2009 United States Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act)

On June 22, 2009, US President Obama signed the legislation granting the FDA broad regulatory authority over the manufacture, distribution, and marketing of tobacco products to protect public health. One of the main objectives of this legislation is to reduce youth tobacco use. The US Congressional Budget Office estimated that the new law would reduce youth smoking by 11% over 10 years. The FDA Center for Tobacco Products (FDA-CTP) was created to oversee the implementation of the Tobacco Control Act. A priority emphasis of the FDA-CTP is to prevent and reduce tobacco use among young people through provisions that target this population. The different components of the law will be implemented over many years. A ban on the manufacture and distribution of flavored cigarettes (with the exception of menthol) went into effect on September 22, 2009. On June 22, 2010, the FDA issued a final rule containing a broad set of federal requirements restricting the sale, distribution, and marketing of tobacco products to make them less accessible and less attractive to kids. This rule builds on the youth access and marketing restrictions that were introduced in the 1990s through the MSA and the 1996 final rule. Table 94.1 shows the provisions contained in the final rule.

The FDA has many other regulatory authorities that, when implemented, could help reduce youth smoking rates. For example, the Tobacco Control Act directs the FDA to require larger text warning labels on smokeless tobacco and larger graphic warning labels on cigarette packages and advertisements, which will help reduce tobacco rates and prevent smoking initiation among youth. Larger smokeless tobacco text warnings went into effect from June 2010, and the FDA issued a final rule in June 2011 mandating graphic health warnings on 50% of the front and back of all cigarette packs. However, the tobacco industry has since sued the US government, alleging that the mandated graphic warning labels on cigarette packages and advertising

TABLE 94.1 FDA Final Rule Restricting the Sale and Distribution and Marketing of Cigarettes and Smokeless Tobacco (Title 21 CFR Part 1140) (June 22, 2010)

Sale and Distribution

Prohibits the sale of cigarettes or smokeless to bacco to people younger than 18

Prohibits the sale of cigarette packages with less than 20 cigarettes

Prohibits the sale of cigarettes and smokeless tobacco in vending machines, self-service displays, or other impersonal modes of sales, except in very limited situations

Prohibits distribution of free samples of cigarettes and restricts distribution of free samples of smokeless tobacco

Marketing (Labeling, Advertising, and Promotion)

Prohibits tobacco brand name sponsorship of any athletic, musical, or other social or cultural events, or any team or entry in those events

Prohibits gifts or other items in exchange for buying cigarettes or smokeless tobacco products

Requires that audio advertisements use only words with no music or sound effects

Prohibits the sale or distribution of items, such as hats and t-shirts, with cigarette and smokeless tobacco brands or logos

 $\label{lem:http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/RegsRestrictingSale/ucm205020.htm.$

unconstitutionally infringe on the companies' First Amendment rights. On November 7, 2011, a Federal Judge issued a preliminary injunction staying the FDA from implementing and enforcing its rule. On August 24, 2012 the US Court of Appeals for the D.C. Circuit voted 2–1 against the US FDA graphic warning labels. The case is currently working its way through the courts. The legislation also allows the FDA to set standards for tobacco products appropriate for public health such as reducing nicotine levels (but not to zero), and reducing or eliminating harmful tobacco constituents and components including smoke constituents. Any product standards set by FDA would likely influence youth tobacco use given FDA's mandate to consider the risk and benefits to the population as a whole, including users and nonusers of tobacco products when setting a product standard. A Tobacco Products Scientific Advisory Committee has established to provide advice, information, and recommendations to the Commissioner of Food and Drugs on health and issues relating to tobacco products.

Youth Policy: International Perspective

The World Health Organization (WHO) reports that important contributing factors increasing the risk of youth smoking include tobacco industry advertising and promotion, easy access to tobacco products, and low prices. A variety of global policy efforts have been undertaken with the goal of influencing these factors. The most significant of these was the WHO's Framework Convention on Tobacco Control (FCTC), which introduced a legal instrument to enable global cooperation around a variety of tobacco control concerns.

Adopted by the World Health Assembly on May 21, 2003 and entered into force on February 27, 2005, the WHO FCTC is the first international public health treaty promulgated by the WHO. This convention is one of the most widely embraced, with 174 parties having ratified the treaty as of June 2011. The main provisions of the FCTC aim to reduce population-level tobacco consumption and protect youth from the tobacco epidemic. Demand reduction provisions include price and tax measures and nonprice measures to reduce demand for tobacco including protection from secondhand smoke exposure; regulation of the contents of tobacco products; regulation of product disclosures, packaging, and labeling; education, communication, training, and public awareness; restrictions on tobacco advertising, promotion, and sponsorship; and tobacco cessation measures. Core supply reduction provisions include addressing the illicit trade of tobacco products, reducing sales to and by minors, and providing support for economically viable alternative activities.

RESTRICTIONS ON SALES AND DISTRIBUTION

Easy access to tobacco products is an important environmental risk factor for tobacco use among youth. Reducing youth access to tobacco products has been advocated as one strategy to address the problem of youth tobacco use. There are a variety of approaches that can be used to reduce youth access, including regulation of tobacco retailing and sales, as well as civil penalties for youth consumers who purchase or possess tobacco products (PUP laws).

Sales to Minors Laws

It is now unlawful for tobacco retailers to sell tobacco products to minors in all 50 US states. In 1992, the Synar amendment was enacted by the US Congress requiring all states to adopt laws prohibiting the sale of tobacco to any individual under the age of 18. In 2009, the Tobacco Control Act strengthened this standard by setting forth a sweeping set of federal provisions designed to limit young people's access to tobacco products. The Tobacco Control Act prohibits tobacco sales to those under 18, requires photo identification checks for over-the-counter sales to anyone appearing under

27 years of age, and imposes substantial penalties for vendors who violate these provisions. Importantly, this new federal standard does not preempt states or localities from enacting laws relating to access to tobacco products that are more stringent than the access provisions set forth in the Tobacco Control Act. As of March 1, 2010, four states (Alabama, Alaska, New Jersey, and Utah) had established 19 years of age as the minimum legal age for purchasing tobacco products.

Limiting the supply of tobacco to minors can influence youth smoking behavior by deterring smoking uptake, reducing smoking consumption, curtailing the social exchange of cigarettes among youth, and strengthening antismoking social norms. However, controlled intervention studies have suggested that a very high level of retailer compliance, coupled with community involvement, may be necessary before youth access laws can effectively decrease youth smoking rates. This is because despite existing laws, some tobacco retailers persist in selling tobacco products to youth and a large proportion of adolescents are still able to obtain tobacco from commercial and social sources.

Theoretically, illegal tobacco sales can be reduced through active enforcement of tobacco-sales laws whereby merchants' compliance with the law is tested and consequences for noncompliance are administered. Until recently, the primary Federal enforcement oversight mechanism was the Synar Amendment, which requires states to meet annual targets for reducing youth access to tobacco. States measure their compliance by conducting annual, random, unannounced inspections of tobacco retail outlets. The current federal standard requires states to document that no more than 20% of their tobacco retailers are selling tobacco products to minors, or face the loss of millions of dollars of federal aid. All states successfully met this target in 2010. However, the Synar compliance checks have been criticized for underestimating the actual rate of underage tobacco sales and for allowing too high a proportion of noncompliant retailers. Under the Tobacco Control Act, a separate and complementary mechanism for enforcement oversight was introduced that allows FDA to contract with states to conduct compliance check inspections of retailers and take enforcement action when appropriate.

Active enforcement of tobacco sales laws has been shown to change retailer behavior, but whether this extends to reducing young people's access to tobacco or their tobacco-use behaviors is less clear. A number of studies have failed to demonstrate an influence of active enforcement of sales to minor laws on youth smoking behavior. However, experts have argued that rather than this being evidence that such laws are ineffective, these studies are simply evidence that the current compliance standards are not stringent enough to meaningfully curtail the supply of tobacco to youth

and thereby produce the expected reductions in consumption. It remains to be seen whether the new FDA enforcement provisions, along with State and Jurisdictional Synar efforts, will succeed in further reducing underage tobacco sales to youth and youth prevalence.

Sales to minors' laws represent an important tool for combating youth smoking. Unfortunately, the ability of these laws to influence youth demand for tobacco is largely dependent on consistent and stringent enforcement, which has historically been lacking. There is some evidence indicating a stronger effect of these laws on younger adolescents versus older teens. Aggressive approaches to measure retailer compliance with youth access laws and consistent enforcement of penalties are needed if such laws are to influence youths' ability to purchase and use tobacco.

Purchase, Use, and Possession Laws

Enactment and enforcement of laws prohibiting the possession, use, and/or purchase (PUP) of tobacco by minors represents another approach to restrict youth tobacco access. Currently, 45 states have laws that penalize youth for PUP of tobacco. Penalties for youth found in violation of PUP laws include civil fines, loss of driver's license, and/or diversion to tobacco prevention/educational programs, depending on the state. However, controversy exists regarding the appropriateness of continuing to direct tobacco control resources toward enforcing these laws. Although many community members and law enforcement officials endorse the use of PUP laws as a method for decreasing smoking in public places by youth, some anti-tobacco advocates are opposed to this public health policy tool arguing that the laws are conceptually flawed, difficult to enforce, and punish youth rather than the retailers who violate the law and tobacco companies who market these products to youth.

Compared to other youth policy approaches, relatively little is known about the effect of PUP laws on youth smoking behavior. Several studies from schoolbased samples have suggested that PUP laws may have a deterrence effect and reduce the prevalence of youth smoking, when enforced strictly with a meaningful penalty. But in the United States, PUP laws are rarely enforced. Community-level interventions have successfully increased enforcement of PUP laws within their target communities, suggesting that communities can improve their implementation of PUP laws when provided with targeted assistance.

PUP laws, when enforced strictly, may have the secondary effect of decreasing the visibility of youth smoking in public. This reduced visibility may decrease the effects of smoking behavior modeled by peers and minimize the perception of teenage smoking as normal

and acceptable behavior within the community. To the extent that PUP laws are successful in reducing smoking in public places by youth, they can be a tool for reinforcing community norms against smoking.

Internet Sales

Cigarette sales on the Internet first appeared in the late 1990s and this market continues to grow. The Internet poses serious challenges for tobacco control, including unrestricted sales of low-cost cigarettes to minors. In response to the growing problem of Internet cigarette sales, Congress passed the Prevent All Cigarette Trafficking (PACT) Act. Effective June 29, 2010, the PACT Act requires Internet and other mail-order sellers to check the age and ID of customers both at the point-of-sale and at delivery to stop Internet tobacco product sales to underage buyers. In addition, it bans shipment of cigarettes and smokeless tobacco products via the US postal service. Enforcement tools attached to the law enable federal and state officials to intercept deliveries of illegally sold tobacco products before they reach youth consumers.

Retailer Licensing

The availability of tobacco retail outlets near homes and schools may influence youth tobacco use by making cigarettes easier for youth to obtain. Tobacco retailer licensing laws are a tool that can be used by state and local officials to restrict and control the location and density of tobacco retailers. In ecological studies, the density of tobacco retail outlets near schools has been associated with increased experimental smoking and current smoking by youth. The Institute of Medicine has called for states to place limits on the number of tobacco retail outlets for the express purpose of reducing youth access to tobacco. Despite its potential, few communities have utilized this policy tool and little evidence on the effects of these laws exists. However, tobacco control advocates are encouraged by evidence for similar state and local policies limiting alcohol outlet density, which have been shown to reduce underage alcohol use.

International Perspective

There is substantial international variation in the extent to which youth access policies protect young people from tobacco. Age restrictions on the purchase of tobacco products vary around the world, with most high-income countries having a minimum age policy of 18 or 19 years old. Youth access policies are less common in low- and middle-income countries, such that few legal barriers exist to prevent minors from

purchasing tobacco products. Where youth access policies do exist, there is even greater variation in their enforcement. Even among high-income countries, only a handful of nations enforce youth access laws to the extent necessary to ensure their success. In low-income countries, the necessary infrastructure and resources for implementing and enforcing these restrictions is often lacking entirely.

Summary

When enforced consistently, public policies that aim to restrict young people's access to tobacco may effectively reduce youth demand for cigarettes. However, as currently implemented, these policy tools have generally not succeeded in meaningfully reducing youth access to tobacco, in the United States or internationally. A large proportion of adolescents are still able to obtain tobacco from commercial and social sources. Aggressive enforcement of youth tobacco access laws would likely strengthen the ability of these policies to influence youth's willingness and ability to use tobacco.

SMOKEFREE LAWS

Tobacco control policies that restrict smoking in workplaces and enclosed public places (e.g. restaurants and bars) are primarily intended to protect nonsmokers from exposure to secondhand smoke. However, they also represent an important policy tool for reducing smoking prevalence among youth.

Public Bans

Policy efforts to restrict smoking in public places occur at the state and local level. All 50 states and the District of Columbia restrict or prohibit smoking in certain places, but there is wide variation in the extent of coverage and the stringency of these restrictions leading to variation in youth exposure to smoking restrictions. The most stringent type of restriction is a comprehensive law requiring all public places (i.e. all non-hospitality workplaces, restaurants, and bars) to be 100% smokefree. As of 2011, comprehensive smokefree laws protect approximately 48% of the US population. Many other states and municipalities have enacted partial smokefree laws that limit smoking in at least one of these settings.

In addition to reducing nonsmoker's exposure to secondhand smoke, smokefree laws have also been shown to reduce the prevalence of cigarette smoking among adults. Less is known about the impact of smokefree laws on youth smoking behavior. However, a

growing body of evidence suggests that smoking bans in public places significantly decrease overall youth smoking prevalence. Smokefree laws seem to have their greatest influence on youth cigarette consumption. States and communities with comprehensive smokefree laws consistently have a lower proportion of youth who report daily smoking. Studies have estimated that comprehensive smokefree laws may reduce per capita cigarette consumption among youth by as much as half.

Smokefree laws not only influence consumption but also appear to reduce progression from experimental use to established smoking. There is less evidence to suggest that smokefree laws are effective in deterring smoking initiation, however some studies have found evidence that they are. Teens employed in workplaces with a comprehensive smokefree policy were 32% less likely to ever smoke, compared to teens in workplaces with less restrictive policies. Furthermore, ecological studies have shown that states with more stringent smokefree laws have a lower proportion of ever-smoking youth. The precise mechanisms by which smokefree laws reduce youth smoking are largely unknown, although there are likely a number of contributing factors; smokefree laws reduce opportunities to smoke, raise awareness of the hazards of exposure to tobacco smoke, and contribute to a cultural norm in which smoking is socially unacceptable.

Home Bans

Voluntary bans on smoking at home, even when parents smoke, significantly reduce youth smoking behavior. Home smoking bans are becoming increasingly common in the United States. In 2003, the latest year for which nationally representative data were available, approximately 74% of US households had a complete home smoking ban (i.e. no smoking allowed anywhere inside the home). A growing proportion of youth are also being protected by smokefree policies in multiunit housing complexes. Home smoking bans are more common in households with higher income and education levels. Moreover, emerging evidence suggests that voluntary bans are more likely to be adopted in localities with comprehensive public smokefree laws. Regarding reducing youth smoking, household smoking bans appear to be at least as influential as smokefree laws. Young people living in households with strong rules against smoking in the home are less likely to report smoking themselves, even when one or both parents are smokers. They are also significantly less likely to progress from experimental smoking to established smoking. It is believed that household smoking bans work to reduce youth initiation and smoking uptake by modeling positive behavior and creating a strong norm about the unacceptability of smoking.

Other Smoking Bans

Policies that ban smoking in and around schools are another common type of smokefree policy. The Pro-Children's Act of 1994 requires all schools and daycare facilities receiving federal funding prohibit indoor smoking. However, school smoking bans are often poorly complied with. Comprehensive smokefree school policies have been found to significantly lower rates of student smoking, but only if the bans are strongly enforced. Increasingly, private vehicles are becoming a focus for smokefree policies. Several states and territories have taken steps to prohibit smoking in privately owned vehicles while children are present. These efforts have brought significant attention to the risks of secondhand smoke exposure in vehicles. However, the impact of such policies on youth smoking rates has not yet been evaluated.

International Perspective

The vast majority of countries restrict smoking in public places to some degree, but there is considerable variation in the comprehensiveness of these smokefree laws worldwide. The United States lags behind many other high-income countries in terms of national smokefree protections. Worldwide, a growing number of countries have passed national comprehensive smoking bans (e.g. Ireland, Italy, Finland, Norway, New Zealand, Hong Kong), and more are poised to do so. In highincome countries smokefree laws tend to be largely self-enforcing, but typically have fairly comprehensive restrictions covering work-sites and sometimes restaurants and bars. In this regard, they successfully reduce nonsmokers exposure to secondhand smoke, reduce the visibility of smoking in public places, and contribute to establishing smokefree norms. In contrast, low- and middle-income countries are still in the early stages of developing such policies. Low- and middle-income countries are less likely to have smokefree laws; if they do, they are often largely ignored. As a result, smokefree laws are currently less able to influence smoking behavior among youth living in low- and middleincome countries.

Summary

Taken together, the evidence suggests that implementing stringent smoking prohibitions, both in public places and at home, is an essential component of a comprehensive tobacco control strategy to reduce youth tobacco use. School nonsmoking policies can significantly lower rates of student smoking, but only if they are strongly enforced.

ECONOMIC APPROACHES

Keeping the price of tobacco products high is viewed as a key component of comprehensive tobacco control strategies. Cost is a major public policy tool that influences both adult and youth smoking behavior. The influence of price on population-level tobacco use is often described in terms of "price elasticity," which refers to the overall change in aggregate cigarette consumption that is be expected to occur in response to a price increase. Changes in aggregate cigarette consumption following a price increase are produced by a combination of factors. These include individuals who do not start smoking (who might have otherwise), smokers who quit, and smokers who cut back on their smoking. Thus, price can influence both smoking prevalence (the number of people who smoke) and consumption (the amount that is smoked).

A strong dose–response relationship exists between cigarette price and cigarette consumption, for both youth and adults. It has been estimated that a 10% increase in the price of cigarettes would result in a 4% reduction in overall cigarette consumption in the short-term, and 8% in the long-term, due to compounding effects over time. Among adolescents, this relationship is even more pronounced. A 10% increase in price is estimated to reduce the number of youth who smoke by 7%. Youth may be influenced by cigarette price both directly (reductions in purchasing) and indirectly (changing smoking norms). Economists contend that adolescents are particularly "price sensitive" (i.e. their purchasing behavior is strongly influenced by cost). One reason for greater price sensitivity is that adolescent smokers have a smaller proportion of disposable income compared to adult smokers, making cost increase more difficult to absorb. In addition, many adolescents who smoke are still experimenting with smoking and have not yet become addicted. Thus, they may be less motivated to continue purchasing cigarettes in the face of rising prices. Evidence has shown that more addicted smokers are less responsive to price than their less addicted counterparts.

The smoking uptake continuum may be interrupted through price policies. Cigarette price influences smoking initiation and escalation of smoking behavior among adolescents. Among youth, it is estimated that a 10% increase in the price of cigarette would reduce the probability of smoking initiation by about 3%, of daily smoking by nearly 9%, and of heavy daily smoking by over 10%. Youth who experiment with smoking, or smoke infrequently and at low levels, may get their cigarettes from social sources, including friends, rather than purchasing cigarettes themselves. Thus, experimenters may not be as responsive to higher cigarette prices

compared to youth who have moved to more regular smoking behavior. In contrast, price can be expected to have a larger influence as cigarette consumption increases and is associated with reduced probability that youth will become daily, addicted smokers. This is an important and a key strategy for tobacco control because preventing youth from becoming heavy smokers will reduce the public health burden of tobacco. In addition to preventing escalation, price has also been associated with cessation behaviors. Evidence suggests that a 10% increase in the price of cigarettes would increase the probability of smoking cessation by about 12% for young males and 19% for young females.

Sociodemographic differences have been noted regarding the influence of price on youth and young adults. For instance, differences have been found by ethnicity, socioeconomic status, and education level. It is important to consider that the price of tobacco products may affect subpopulations differently.

Increasing Cigarette Prices

Excise Taxes

There are many ways in which public policy can influence the price of tobacco. Excise taxes are the most common route of increasing price within the United States and are considered to be the most effective government intervention for increasing the price of cigarettes. Excise taxes are additional prices put on the sales of goods or services. These prices are typically based on the quantity of the good that is sold. Tobacco excise taxes are set at both the federal and state level. The Federal Excise Tax on cigarettes was established in 1864. Effective from April 1, 2009, the federal cigarette excise tax increased to \$1.01 per pack from 39 cents per pack. States and many localities also impose excise taxes on tobacco; in 2011 the average combined state-local excise tax rate was \$1.46 per pack; New York City's, at \$5.85 per pack, was the highest.

Minimum Price Laws

Originally designed to ensure fair competition among tobacco retailers, states initiated cigarette minimum price laws in the 1940s. These laws require a minimum percentage markup added to the wholesale/retail price of tobacco products. Minimum price laws can counteract the discounting practices of tobacco companies, and thus represent a potentially important policy tool for keeping tobacco prices high. Unfortunately, minimum price laws are underutilized; they do not exist in every state, and many states have very weak laws. In 2009, the Centers for Disease Control and Prevention (CDC) reported that 25 states had statutory minimum wholesale price markups for cigarettes ranging from

2.0 to 6.5%; however, these markups are likely too low to meaningfully raise prices. Policy efforts to strengthen minimum price laws may help reduce youth smoking prevalence.

Tobacco Industry Efforts to Lower Price

The tobacco industry has recognized the influence that price can have on discouraging teenage smoking and has manipulated price in order to counteract the effects of tax hikes and other economic regulations. Tobacco companies use retail loyalty programs and aggressive promotional pricing strategies such as coupons, multipack specials, and other special discounts to lower the price for consumers. Industry has targeted younger smokers with these price-related promotions, because they are known to be more price-sensitive than adults. When tobacco companies lower tobacco product prices, more people, especially young and new users, tend to purchase cigarettes. Industry efforts to reduce the price of tobacco are often more heavily concentrated in low-income and minority areas, evidence that tobacco companies are selectively targeting the most vulnerable populations.

Much of the literature to date has focused specifically on cigarette excise taxes. However, other products, such as smokeless tobacco and little cigars, can be expected to show price elasticity similar to cigarettes. Use of other tobacco products may also be influenced by any price differential with cigarettes. In recent years, with the release of novel smokeless tobacco products, experts have noted these products are less expensive and frequency of their use among youth is rising. For example, it has been estimated that smokeless tobacco use among males between 16 and 24 years of age would rise by approximately 12% if a state excise tax rate on cigarettes rose by 10%, due in part to the differential excise tax rates. Recent epidemiological trends also show a rise in the use of little cigars (e.g. Black and Mild) among youth, especially black females. Price differential between products plays an important role in tobacco use.

International Perspective

Among industrialized countries, the United States has one of the lowest tax rates on cigarettes. The World Bank recommends setting tobacco taxes between two-thirds to four-fifths of the retail price of cigarettes. Countries receiving the highest percentage of tobacco tax include China, Greece, Nepal, Brazil, and Argentina. The influence of price increases on reducing consumption is stronger in low- and middle-income countries, where an increase in tobacco taxes by 10% is estimated to decrease tobacco consumption by about 8%. Few low-

and middle-income countries achieve this level of taxation, but can significantly increase their tax levels. Youth, minorities, and low-income smokers are two to three times more likely to quit or cut back on their smoking than other smokers in response to price increases.

Summary

A large body of evidence documents that higher prices are effective in reducing youth smoking rates. However, the tobacco industry engages in systematic efforts to drive prices down. As a result, policy tools that keep the price of tobacco high are a critical component of youth tobacco control efforts. There is little evidence on how the price of other types of tobacco products influences their use by youth, however, these products tend to cost less than cigarettes and therefore may have particular appeal for youth.

MARKETING AND PROMOTION

The tobacco industry systematically and aggressively targets youth through advertising and promotion. In a landmark court case, the US Department of Justice successfully prosecuted several major tobacco companies for engaging in a conspiracy to defraud the public about the dangers of smoking, including the practice of purposely targeting youth in their marketing campaigns. The final decision, issued by US District Judge Gladys Kessler in 2006, held that the United States' major tobacco companies had engaged in fraud and violated the Racketeer Influenced and Corrupt Organizations Act statute by falsely denying that they advertised, marketed, and promoted cigarettes to youth. The Federal Trade Commission reports that in 2008 the largest cigarette companies in the United States spent \$9.94 billion on advertising and promotion. The majority of this money (approximately 72%) was spent on price discounts to retailers or wholesalers to reduce the price of cigarettes. Advertising and promotion has been shown to causally influence the decisions of young people to begin and continue smoking. The 2008 National Cancer Institute monograph, "The Role of the Media in Promoting and Reducing Tobacco Use," concluded "the evidence base indicates a causal relationship between tobacco advertising and increased levels of tobacco initiation and continued consumption." Not surprisingly, youth smokers prefer the most heavily advertised brands – Marlboro, Camel, and Newport.

Youth are exposed to pro-cigarette messages through both direct and indirect advertising. Direct advertisements, those that are explicitly meant to market a specific product to consumers, include print (e.g. magazine), point-of-sale (POS) displays, mail, coupons and promotions, distribution of specialty items (e.g. hats with logos), and sponsorship of sporting events and public entertainment (e.g. placement of brand logos in bars and nightclubs). Indirect advertising refers to marketing a product that is not explicit. An example of indirect advertising includes depictions of smoking in the movies. The Internet is a unique medium for tobacco advertising, as it includes both direct advertisements (e.g. paid advertisements, tobacco industry webpages) and indirect advertisements (e.g. promotion through YouTube videos and social media).

A comprehensive ban on direct and indirect forms of tobacco advertising, promotion, and sponsorship can be expected to have the largest impact on smoking rates. Partial bans (e.g. limiting only some advertising, promotion, or sponsorship options) or voluntary agreements have little or no effect on tobacco consumption. It is estimated that comprehensive bans, those banning tobacco advertising in five or more mediums (television, radio, print, outdoor, point-of-sale, movies, and sponsorship), would result in an overall 7.4% reduction in cigarette use and a 5.4% reduction in tobacco use.

Point-of-Sale Advertising

Point-of-sale (POS) advertising refers to advertising at the place where a product is sold and tobacco companies spend a significant amount of money every year to market products in convenience stores, grocery stores, and pharmacies. The retail environment provides important opportunities for the tobacco industry to communicate with current, former, and potential smokers providing cues to promote smoking consumption, discourage quitting, and encourage smoking uptake. Retail POS advertising is the dominant channel for tobacco advertising in the United States in 2011. Spending on POS promotional materials accounted for \$163.7 million of the tobacco industry's \$9.94 billion marketing budget in 2008. Weekly or more exposure to retail tobacco marketing is associated with a 50% increase in the odds that adolescents will smoke. Tobacco companies provide more advertising and shelf space for cigarettes in stores where adolescents shop frequently. National marketing data have shown that 75% of adolescents shop in a convenience store at least once a week and 63.7% of adolescents report seeing cigarettes advertisements all or most of the time when they visit convenience stores, supermarkets, and gas stations. Teens may be more likely than adults to be influenced by advertising and promotion in convenience stores and other retail outlets and exposure to POS advertising is associated with initiation of cigarette smoking. There is a patchwork of state laws with regards to the display of tobacco products, however, the tobacco industry has been known to place advertisements and displays at children's eye-level and within children's reach. There are numerous provisions in the Tobacco Control Act that aim to regulate the POS environment and the act is expected to dramatically change how tobacco products are sold and marketed in stores. "Power Wall" displays (prominent display of a particular brand), interior and exterior advertising, and other POS advertisements build brand recognition and loyalty, attract youths' attention, and undermine smokers' motivations to quit.

Depictions of Smoking in the Movies

The 2008 NCI monograph, "The role of the media in promoting and reducing tobacco use," concluded that exposure to depictions of smoking in the movies is causally related to youth smoking initiation. Product placement in movies and television is an indirect advertising form that glamorizes smoking, making it more appealing to youth. Under the MSA, tobacco companies are prohibited from paying for brand placement in movies, however, there is no mechanism to ensure that payoffs are not occurring. Three of the Motion Picture Association of America's six member studios currently have voluntary policies, adopted between 2004 and 2009 that limit or restrict depictions of smoking in movies. For these studios, depictions of tobacco in youth-related films declined 95.8% between 2005 and 2010. For the three member studios with no policies, the decline was only 41.7%, over the same period.

Several studies have shown a dose–response relationship between exposure to smoking in movies and smoking uptake among youth. Currently, efforts are underway to encourage the movie industry to assign an R-rating (for more mature audiences) to movies that depict smoking. The movie industry is also being encouraged to show antismoking messages (Public Service Announcements) before films that include smoking. Limiting smoking to R-rated movies would substantially limit youth exposure to smoking in movies, since youth-rated movies are seen by three times as many teens as R-rated movies. Reducing or eliminating depictions of smoking in the movies is an important avenue for tobacco control policy, especially because many movies have global reach.

Counteradvertising and Anti-tobacco Media Campaigns

Counteradvertising and anti-tobacco media campaigns can help to educate the public and change social norms. However, the financial resources available to the public health community are dwarfed by those available to the tobacco industry. The MSA created a nonprofit organization, the American Legacy Foundation, which has developed some of the most effective youth-focused

anti-tobacco media campaigns to date. Antismoking messages that have large impact on reducing cigarette consumption and denormalizing smoking among youth are those that are aggressive, focus on industry manipulation to recruit young smokers, and focus on the adverse health effects of secondhand smoke exposure. Campaigns that show individuals are not acting autonomously or of their own free will also appear to be very effective in deterring smoking. Pursuant to its new regulatory authority over tobacco, the FDA-CTP will be involved in public education efforts to provide youth and adults with accurate information about tobacco ingredients and the consequences of tobacco use.

Cigarette Warning Labels

The Federal Cigarette Labeling and Advertising Act, enacted in 1965 and amended in 1969, required cigarette packages and print advertisements to contain a textual health warning. In 1984 this act was amended to require that one of four warning labels appear on cigarette packages and advertising. The warning labels have remained unchanged since that time and there is no evidence to suggest that these warning labels had a meaningful impact on youth tobacco use. As required by the Tobacco Control Act, FDA has now mandated nine graphic health warnings to cover 50% of the front and back of cigarette packages and 20% of advertisements. This policy tool is currently the target of litigation by the tobacco industry.

A large body of scientific evidence indicates that graphic warning labels increase public knowledge about the health risks of using tobacco and help to reduce their consumption. Nonsmokers, particularly adolescents, are likely to be influenced by the new graphic warning labels. Evidence from population-based surveys and empirical studies indicates that large graphic warnings on cigarette packages increase adolescents' attention to and cognitive processing of the warning, increase thoughts of quitting and forgoing of cigarettes, and lower intentions to smoke. Additionally, graphic warning labels have been shown to reduce the social appeal of smoking among adolescents.

Other Tobacco Industry Activities

The tobacco industry engages in other activities to promote youth tobacco use and provide an impression of responsibility by building positive public perceptions. These include corporate sponsorship (e.g. sporting and entertainment events), social responsibility efforts (e.g. donations), and public relations advertising (e.g. youth antismoking campaigns) in order to be perceived as ethical and good corporate citizens. Tobacco companies have engaged and sponsored youth antismoking campaigns. The campaigns have been used to conduct

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extensive market research on adolescents' attitudes toward smoking. Tobacco companies' youth-targeted smoking prevention advertising campaigns (e.g. "Think. Don't Smoke") have been shown to lower youth's perceived harm of smoking, increase smoking approval, increase intentions to smoke in the future, and increase the likelihood of having smoked in the last 30 days. Other industry sponsored campaigns have focused on such topics as how much money is spent on smoking and placing responsibility on parents, youth, and retailers: these may undermine or compete with more effective campaigns sponsored by government agencies or nongovernment organizations.

International Perspective

In light of the overwhelming evidence that advertising influences youth smoking behavior, the FCTC requires parties to implement and enforce a comprehensive ban on all tobacco advertising, promotion, sponsorship, and corporate social responsibility efforts (or to apply restrictions where a ban is not possible). Currently, 18 countries have total bans on tobacco advertising. In other countries (e.g. Canada and New Zealand) advertising bans are part of comprehensive tobacco control efforts, including tax increases and pictorial warning labels. Large declines in tobacco use after implementation were noted in both these countries; however, it is unclear whether smoking declines were mostly attributable to the advertising ban or the comprehensive strategies.

Summary

The tobacco industry engages in aggressive direct and indirect marketing, advertising, and promotion of their products and has challenged FDA's efforts to regulate in these areas. Future efforts must be made to understand how the tobacco industry responds as FDA works to implement the provisions of the Tobacco Control Act that influence tobacco marketing and promotion.

CONCLUSIONS

Effective tobacco control policies are essential in reducing the burden of tobacco use on public health and have important ramifications for adolescent tobacco use. Tobacco control policies do not work in isolation, but rather may influence each other or work synergistically to influence tobacco use. These policies, in different strengths and combinations, have been implemented both in the United States and abroad, resulting in significant reductions in youth smoking rates. Policies may also target different stages along the smoking continuum, from experimentation to cessation, among

youth. Some policy tools, such as large graphic warning labels, advertising bans, and youth access laws, appear to exert their strongest influence on youth smoking initiation. Other tools, such as smokefree laws and tobacco excise taxes, appear to be most effective at reducing consumption and interrupting adolescents' progression along the smoking trajectory. Though initiation is the classic target for youth smoking prevention efforts, disrupting the transition from experimentation to regular (or daily) smoking is equally important.

In the ongoing public health effort to protect youth from tobacco, the passage of the Tobacco Control Act represents a key milestone, and the culmination of decades of policy progress. This historic legislation ushered in a new era of tobacco control in the United States, one that promises to have particular significance for youth. Under the new authority granted by the Tobacco Control Act, the FDA-CTP has a number of new tools at its disposal with the potential to dramatically change the policy environment in which youth initiate and continue to use tobacco products (e.g. flavoring bans, youth access laws, sales and marketing restrictions, graphic warning labels, etc.). Going forward, it will be important to understand how these new policy tools influence patterns of youth tobacco use over time. It will also be important to monitor how the tobacco industry responds to FDA-CTP tobacco regulation.

International efforts for the implementation of effective tobacco control policies are diverse and face distinct obstacles. The WHO FCTC is a landmark policy instrument that contains many provisions aimed at protecting youth from tobacco; however, implementation and enforcement of these provisions currently varies widely across participating parties. It is essential that tobacco policies including youth access laws, smokefree laws, price increases, and restricted advertising are quantified in order to assess the effectiveness of such policies across various populations.

Tobacco control policies targeting youth are important, but tobacco control interventions that reduce consumption and encourage cessation among adults are also imperative. These policies have the effect of reducing youth exposure to tobacco and to tobacco role models. One of the best means of discouraging adolescents from smoking is to reduce tobacco consumption at the population level. Numerous strategies are needed in order to end the global pediatric epidemic of tobacco use. The broad influence, relatively low cost, and notable effectiveness of well-implemented comprehensive tobacco control policies makes these one of the most important components of tobacco control efforts. Such policies, when implemented and enforced, are an effective means of deterring youth smoking and serve to protect future generations from the dangers of tobacco-related disease and death.

Acknowledgments

We would like to thank Michele Bloch, Mitch Zeller, and Cathy Backinger for their comments on this manuscript.

SEE ALSO

International Policies to Reduce Tobacco Use, Behavioral Treatments for Smoking, Substance Use Prevention Approaches for School-aged Youth, Mobilizing Communities for Alcohol, Drug, and Tobacco prevention,

List of Abbreviations

CTP Center for Tobacco Products

FCTC Framework Convention on Tobacco Control

FDA Food and Drug Administration

MSA Master Settlement Agreement

PACT Prevent All Cigarette Trafficking

POS point-of-sale

PUP possession, use, and/or purchase

WHO World Health Organization

Glossary

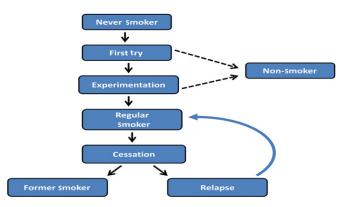
Cigarette smoking the act of drawing in or inhaling smoke of burning tobacco in a cigarette and exhaling it.

Consumption the overall amount of cigarettes consumed among smokers.

Low- and middle-income countries the World Bank's main criterion for classifying economies is gross national income (GNI) per capita. These categories are based on the Bank's operational lending categories. Also referred to as economically developing countries.

Youth smoking rates refers to both the prevalence and the incidence of youth cigarette use. *Prevalence Rate* refers to the total number of existing smokers (e.g. current smoking) in a given population at a particular point of time. *Incidence Rate* refers to the number of new cases of smoking (e.g. initiation) over a given period of time.

Smoking continuum smoking behavior ranges and moves between seven stages. These include never smoker, trying cigarettes or initiation (has had even a puff of a cigarette), experimentation (has had more than a puff of a cigarette, but fewer than 100 cigarettes in lifetime), non-smoker (has tried or experimented, but does not progress to regular smoking), regular smoker (reports smoking at least 100 cigarettes in lifetime and has smoked in the last 30 days), relapse (quits smoking, but reverts back to regular smoking), and former smokers (those who report quitting smoking). The diagram below depicts the smoking continuum.



Tobacco Products Any products containing, made, or derived from tobacco that is intended for human consumption, whether chewed, smoked, absorbed, dissolved, inhaled, snorted, sniffed, or ingested by any other means, or any component, part, or accessory of a tobacco product, including, but not limited to, cigarettes; cigars; little cigars; cheroots; stogies; periques; granulated, plug cut, crimp cut, ready rubbed, and other smoking tobacco; snuff; snuff flour; cavendish; plug and twist tobacco; fine-cut and other chewing tobacco; shorts; refuse scraps, clippings, cuttings and sweepings of tobacco, and other kinds and forms of tobacco. Tobacco products excludes any tobacco product that has been approved by the U.S. Food and Drug Administration for sale as a tobacco cessation product, as a tobacco dependence product, or for other medical purposes, and is being marketed and sold solely for such an approved purpose. (adopted from the Tobacco Modernization and Compliance! Act of 2010, Minn Stat Section 297F.01, subdivision 19).

Youth typically a person between the ages of about 12 and 19. Also known as teen or adolescent.

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Relevant Websites

http://www.no-smoke.org/ – Americans for Nonsmokers' Rights (ANR).

http://www.tobaccofreekids.org/ – Campaign for Tobacco-Free Kids. http://www.cdc.gov/tobacco/youth/index.htm – CDC – Youth Tobacco prevention – Smoking and Tobacco Use.

http://www.fda.gov/TobaccoProducts/default.htm - Center for Tobacco Products - Food and Drug Administration.

http://www.ftc.gov/os/2011/07/110729cigarettereport.pdf – Federal Trade Commission Cigarette Report.

http://www.legacyforhealth.org/ – LEGACY – For Longer Healthier Lives.

http://www.impacteen.org/ – Research Informing Practice and Policy for Healthy Youth.

www.teen.smokefree.gov cancercontrol.cancer.gov/tcrb/monographs/ – Smoking and Tobacco Control Monographs.

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History and Impact of Minimum Legal Drinking Age Laws on Alcohol Use and Consequences among Adolescents and College Students

James C. Fell

Pacific Institute for Research and Evaluation, Calverton, MD, USA

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MINIMUM LEGAL DRINKING AGE

When consumed in moderation, alcohol has been shown to have modest health benefits for some people aged 40 years or older. However, alcohol is an addictive intoxicant and, when abused, can cause numerous public health problems, not only for the drinker but also for the people around the drinker and in society at large. The harmful use of alcohol is the third leading risk factor for premature deaths and disabilities around the world and responsible for an estimated 3.8% of worldwide deaths. Approximately 2500 000 people die

annually of alcohol-related causes around the world, including 320 000 young people aged 15–29 years. Alcohol abuse is associated with unintentional and intentional injuries, including traffic crashes, assaults, homicides, and suicides, especially with young people. Harmful alcohol use is also associated with several infectious diseases, including HIV/AIDS, tuberculosis, and pneumonia. The degree of risk for the harmful effects of alcohol varies with age, gender, and some biological factors, as well as the setting and the context in which the drinking occurs. Some vulnerable at-risk groups, such as young people, are especially susceptible

to the toxic, psychoactive, and addictive properties of ethanol (alcohol) (see Impulsivity, Disinhibition, and Risk Taking in Addiction, Adolescent Substance Use: Symptoms and Course, Addiction and the Human Adolescent Brain, Epidemiology of Adolescent and Young Adult Alcohol, Tobacco, and Drug Use and Misuse in the United States). For these reasons, most countries around the world attempt to control the production, marketing, distribution, and sales of alcohol, at least to some extent.

The harmful use of alcohol is influenced by the general level of alcohol consumption in the population, various drinking patterns, local contexts, and alcohol policies and laws. Populations particularly at risk from harmful alcohol use include children; adolescents; pregnant, breastfeeding, and child-bearing women; and indigenous or other minority low-socioeconomic groups (see Behavioral Economic Factors in Addictive Processes, Prenatal Exposure to Alcohol and Illicit Substances, Minority Groups and Addictions). Most countries around the world have established laws concerning the earliest age at which individuals can legally purchase, possess, and/or consume alcoholic beverages. The main reason for MLDAs is to protect young people from the harms caused by alcohol and to protect the public from the potential consequences of youthful drinking.

DRINKING AGES AROUND THE WORLD

There are a variety of sources for MLDAs around the world. The International Center for Alcohol Policies (ICAP), a not-for-profit organization supported by major producers of beverage alcohol, appears to have the most comprehensive and most up-to-date list (http://www. icap.org/Table/MinimumAgeLimitsWorldwide). ICAP has collected information on the MLDA in 119 countries. Seventy-nine countries have established an MLDA of 18 years old. Eleven countries have an MLDA of 16 years old; one country, 17 years old (Cyprus); two countries, 19 years old; and three countries, 20 years old. Only eight countries on the ICAP list use 21 years old as the MLDA, including the United States. Twelve countries have no MLDA, and alcohol is illegal in two countries. In India, the MLDA ranges from 18 to 25, depending upon the state.

In some countries, the MLDA is different depending upon the beverage type (beer, wine, or spirits). In other countries, the minimum purchasing age is different than the drinking (consumption) age, and in still others, the MLDA is different for on-premise sales (e.g. bars, pubs, and restaurants) compared to off-premise sales (e.g. liquor stores, supermarkets, petrol stations).

The general public assumes that MLDA laws are embodied in a single law, but in actuality, most MLDA

laws have multiple provisions. Some MLDA law provisions target outlets that sell alcohol to underage individuals and persons who provide alcohol to the underage individuals. Other provisions target underage persons who purchase or attempt to purchase, possess, or consume alcohol.

HARMFUL USE OF ALCOHOL

The World Health Organization (WHO), a specialized agency of the United Nations that acts as a coordinating authority on international public health, issued a report in March 2010 documenting strategies that can reduce the harmful use and effects of alcohol. Among other strategies, the WHO report describes evidence demonstrating the importance of a legal framework for reducing, or at least controlling, the availability of alcohol. The implementation and enforcement of laws that set a minimum age for the purchase or the consumption of alcohol or both show clear reductions in alcohol-related harm to youth according to the WHO report. Other strategies described in that report include reducing the hours of sale of alcohol, controlling the marketing and advertising of alcohol, increasing the price of alcohol via taxation, and enforcing existing alcohol legislation.

The policy options and interventions available for national action have been categorized by the WHO into 10 target areas:

- 1. Leadership, awareness, and commitment
- 2. Health services' response
- 3. Community action
- 4. Drink-driving policies and countermeasures
- 5. Availability of alcohol
- **6.** Marketing of alcoholic beverages
- 7. Pricing (taxation) policies
- Reducing the negative consequences of drinking and alcohol intoxication
- **9.** Reducing the public health impact of illicit alcohol and informally produced alcohol
- 10. Monitoring and surveillance

MLDA laws are an important component of these policies.

HISTORY OF MINIMUM DRINKING AGE LAWS IN THE UNITED STATES

With the exception of one or two countries, MLDA laws have been established for decades and have not changed at all in most countries around the world. The United States is one of those exceptions. Much is known about the history of MLDA laws in the United States and their effectiveness. MLDA laws were

established in the United States after the repeal of Prohibition in 1933. Most states set the MLDA at age 21 during that time. When the voting age was lowered from 21 to 18 in 1971, many states lowered their drinking age to 18 or 19. Several scientists found significant increases in alcohol-related crashes involving youth aged 18–20 in states that lowered their drinking age. As a result, some states returned to an MLDA of 21. Later, other researchers supported the earlier findings that raising the drinking age was associated with decreased traffic crashes and crash fatalities (see The Impact of Drink Driving Laws, The Effects of Substances on Driving). Consequently, the US Congress adopted the National Uniform Drinking Age 21 Act, which provided a substantial financial incentive for states to adopt an MLDA of 21, and the US President Reagan signed the bill into law in 1984. Since 1988, the MLDA has applied to age 21 for both the purchase and possession of alcohol in all 50 states and the District of Columbia. Between 1982 and 1998, the populationadjusted rate involving 16- to 20-year-old drinking drivers in fatal crashes in the United States decreased by 59%. MLDA-21 laws have been independently associated with about half of this decline. According to the US Department of Transportation, MLDA laws save approximately 800–900 lives a year in traffic fatalities alone. Other researchers found a 13% decline in alcohol use by youth aged 20 and younger associated with the older drinking age of 21.

Despite the federal incentive and the state laws raising the drinking age to 21, underage drinking is still prevalent in the United States. Underage drinking causes an estimated 5000 deaths and 2.6 million injuries and other harm annually. The cost to US society of the harm associated with underage drinking is approximately \$62 billion each year. To strengthen drinking age laws and reduce the injuries and deaths associated with youthful drinking, many US states have also enacted other legislation to address the availability of alcohol to youth, the use of fake identification by youth to purchase alcohol, and the minimum server/seller age to make it more difficult for youth to obtain alcohol from retail sources. States are also adopting social host laws that target the hosts of parties who allow underage drinking and that focus on preventing the illegal provision of alcohol to youth. Other expanded laws in the United States focus on preventing or deterring youth from drinking and driving; for example, the zero-tolerance law makes it an offense for drivers aged 20 and younger to operate a vehicle with any amount of alcohol in their systems (blood alcohol concentration (BAC) > .00). Some provisions of recent graduated driver licensing (GDL) laws in the United States have night restrictions on driving by youth to reduce the risk of drinking and driving, most of which occurs at night. So-called "use and lose"

laws that authorize the suspension of the driver's license for underage alcohol violations (i.e. purchase, possession, or consumption of alcohol) aim to provide meaningful sanctions for youth who violate the MLDA laws. At least 14 expanded laws strengthen the two core MLDA-21 laws (prohibiting possession and purchase) and increase the alcohol prevention efforts targeting US youth. However, states vary substantially in the comprehensiveness of such legislation. For example, although it is illegal in all states and the District of Columbia for underage youth to possess alcohol in public, it is still legal in 20 states for youth to consume alcohol in public. Not all states have GDL laws, and some states' GDL laws do not restrict unsupervised driving at night when alcohol is most likely to be a factor. No state has all 16 law components or regulations that have been documented. Of the 16 underage drinking laws that states could adopt, only Utah has adopted as many as 15 of the components, and Kentucky has only 7 of the 16 components. Laws that provide for a driver's license sanction (suspension or revocation) if a youth is cited for underage drinking have been shown to be effective, yet only 37 states have such "use and lose" laws. Although it is illegal in all US states and the District of Columbia for an underage youth to use a fake identification, it is illegal in only half the states (25) to transfer or produce fake identifications. Thus, the current US effort to control the drinking of alcohol by youth aged 20 and younger involves a variable package of legislative policies, and the level and intensity of enforcement of these policies at the national, state, and local levels is relatively unknown.

Despite the current variability in underage drinking laws and their enforcement across the US states, the two core laws (purchase and possession) have shown significant effects in reducing underage drinking consequences. These laws potentially can be even more effective if all the US states were to adopt all 16 components and if the exceptions to the laws were limited.

EVIDENCE IN SUPPORT OF THE EFFECTIVENESS OF MLDA-21 IN THE UNITED STATES

When the MLDA-21 restriction was initiated across all US states, driver alcohol involvement in fatal traffic crashes declined more significantly among the 16- to 20-year-old population than among drivers aged 21 and older. Although drinking drivers aged 21 and older involved in fatal crashes declined 33% from 1982 to 2004 (Fig. 95.1), drinking drivers aged 20 and younger involved in fatal crashes declined 62% during that period (Fig. 95.2). Tougher legislation, better enforcement, and greater public awareness of the drink-driving problem contributed to the overall decline in drinking-

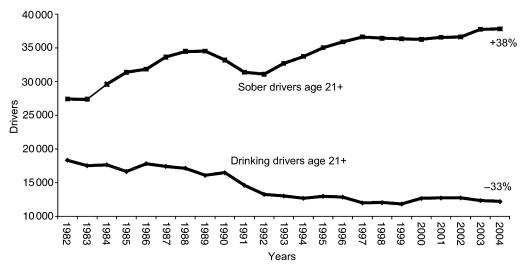


FIGURE 95.1 Drivers over age 21 involved in fatal crashes, 1982–2004, United States. Adapted from Hibell, B., Guttormsson, U., Ashlstrom, S., et al. (2009). The 2007 ESPAD Report: Substance Use Among Students in 35 European Countries. Stockholm: Swedish Council for Information on Alcohol and Other Drugs.

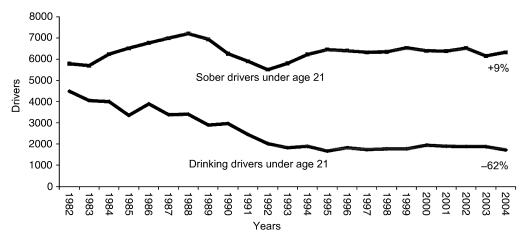


FIGURE 95.2 Drivers under age 21 involved in fatal crashes, 1982–2004. Adapted from Johnston, L. D., O'Malley, P. M., Bachman, J. G., and Schulenberg, J. E. (2007). College students and adults ages 19–45. In Monitoring the Future: National Survey Results on Drug Use, 1975–2005 (Vol. II). Bethesda, MD: National Institute on Drug Abuse.

driver fatalities, but the MLDA-21 law had an additional effect on drivers aged 20 and younger.

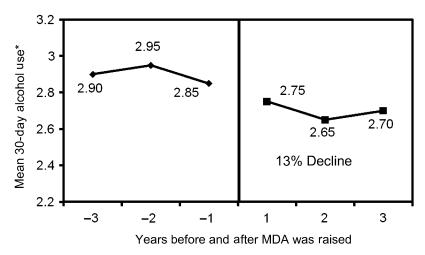
Since adoption of the National Uniform Drinking Age Act, numerous studies have confirmed the association between raising the MLDA to 21 and reducing underage alcohol consumption, youthful traffic fatalities, and other harms. Six types of fatal injuries – car crashes, suicides, homicides, falls, drowning, and alcohol poisoning – decreased for 15- to 24-year-olds following implementation of the MLDA-21 law.

In the United States, the laws making it illegal for youth to possess or purchase alcohol if they are younger than age 21 have reduced the rate of underage drinking drivers in fatal crashes by 16%. That analysis controlled or accounted for numerous other factors – other drunk-driving laws, alcohol consumption, the economy, the culture of the state,

and vehicle miles driven in the state – that could have affected underage drinking and driving. Even when accounting for all those factors, the core laws raising the minimum drinking age to 21 still resulted in a substantial reduction in youth traffic fatalities. This reduction has remained at a low level for many years, indicating that the MLDA-21 laws have maintained their initial impact.

REDUCTIONS IN HOMICIDES AND SUICIDES ASSOCIATED WITH MLDA-21 LAWS

The effects of minimum drinking age laws on alcohol consumption indicate that, as the legal age is lowered, drinking increases. Conversely, as the legal drinking



*Number of days in which youth under aged 21 drank alcohol in the last 30 days.

FIGURE 95.3 30-Day alcohol use and minimum drinking age. Source: O'Malley and Wagenaar (1991).

age is raised, it reduces the consumption of alcohol (see Fig. 95.3).

MLDA-21 laws are associated with reductions in homicides, suicides, and unintentional injuries by 18- to 20-year-olds. Alcohol use interacts with conditions such as depression and stress that contribute to suicide, the third leading cause of death among people aged 14–25. In one study, 37% of eighth grade females who drank heavily reported attempting suicide compared with 11% who did not drink. Individuals younger than aged 21 commit 45% of rapes, 44% of robberies, and 37% of other assaults. Further, an estimated 50% of violent crimes involving all ages is alcohol-related. Researchers have found that as the legal drinking age was lowered in the United States, social problems increased, but as the legal age was raised, alcohol-related problems decreased.

CONSEQUENCES OF ALCOHOL MISUSE AMONG ADOLESCENTS

Alcohol affects adolescents differently than adults, and the higher MLDAs protect them from some of the harmful effects of alcohol. An adolescent (generally considered to be ages 13–19) may look like an adult physically and may even appear more physically fit, but the adolescent's body and brain are still developing. It actually takes less alcohol for adolescents to be intoxicated than it does for adults in their 20s. A normal adult's liver can safely process an estimated 50 alcohol calories per hour (one ounce of 40% alcohol). However, an adolescent's liver can only process half of that amount. To ingest only 25 alcohol calories per hour, an adolescent could drink no more than one-fourth of a "light" beer in 1 hour. Although adolescence is often characterized by increased independence and a desire

for knowledge and exploration, it is also a time when brain changes can result in high-risk behaviors, addiction vulnerability, and mental illness, as different parts of the brain mature at different rates. There is mounting evidence that repeated exposure to alcohol during adolescence leads to long-lasting deficits in cognitive abilities, including learning and memory in humans. In one study of adolescents recruited from treatment programs (aged 13–19), researchers observed that teens who returned to drinking after the treatment program suffered further declines in cognitive abilities, particularly in tests of attention, over the next 4 years. New evidence also indicates that the brain is not fully developed until about age 25, providing further justification for higher drinking ages (see The Role of Brain Development in Drug Effect and Drug Response and Alcohol Neuroimaging in Humans).

EARLY ONSET OF DRINKING

In general, the lower the MLDA, the earlier youth begin drinking alcohol. Early onset of drinking by youth has also been shown to significantly increase the risk of future alcohol-related problems (e.g. alcohol dependence as well as getting into fights, experiencing traffic crashes, and other unintentional injuries after drinking), controlling for a variety of personal demographic characteristics as well as a history of smoking and drug use and a family history of alcoholism. Further, early drinking onset has been linked to suicide attempts. In addition, the consequences appear to be more severe for those who start drinking at a younger age. Youth who start drinking before age 15, compared to those who wait until they are age 21, are 12 times more likely to be unintentionally injured while under the influence

of alcohol, 7 times more likely to be in a motor-vehicle crash after drinking, and 10 times more likely to be in a physical fight after drinking. After analytically controlling for history of alcohol dependence, frequency of heavy drinking, years of drinking, age, gender, race/ethnicity, history of cigarette smoking, and illicit drug use, those who start drinking at age 18 are nearly twice as likely to be unintentionally injured, to be in motor-vehicle crashes, and to be in physical fights while under the influence of alcohol compared to those who start drinking alcohol at age 21.

MLDA-18 VERSUS MLDA-21

In most countries, the MLDA is 18. Youth who start drinking at age 18 have twice the odds of drinking to intoxication than youth who start drinking at age 21. Youth who start drinking at age 18 has a 33–52% greater chance of being injured while under the influence of alcohol in their lifetime compared to youth who start drinking at age 21. Fifteen percent of youth who start drinking at age 18 become alcohol dependent at some point in their lives compared to only 9% of youth who wait until age 21 before drinking. Youth who started drinking at age 18 have a 2.4-fold increase in risk of being involved in a motor-vehicle crash because of drinking too much in the past year compared to youth who started drinking at age 21. Youth who started drinking at age 18 have a 50–60% greater chance of being in a physical fight while drinking or after drinking compared to youth who started drinking at age 21.

When the drinking age is 21, those younger than 21 drink less and continue to drink less through their early 20s. The lower rates of drinking before age 21 are not compensated for by a higher rate of drinking after reaching 21, as some have conjectured. In fact, the opposite is true. Early legal access (at age 18) is associated with higher rates of drinking later in life. A full 40% of those who start drinking before the age of 15 meet the criteria for alcohol dependence at some point in their lives. This is four times greater than those who begin drinking at age 21. Twenty-eight percent who start drinking at age 17 and 15% who start drinking at age 18 develop a dependence on alcohol. Youth who start drinking at age 18 are 1.4 times more likely to become alcohol dependent than those who start at age 21 or older, even after controlling for age, gender, race/ethnicity, education, marital status, family history of alcoholism, childhood depression, antisocial behavior, and history of smoking and drug use. No evidence exists to indicate that young people will learn to drink responsibly simply because they can consume alcohol legally at a younger age. Countries with lower drinking ages suffer from alcohol-related problems similar to or greater than those in the United States.

Another country recently changed its drinking age: New Zealand lowered their MLDA from 20 to 18. After the drinking age was lowered to 18, there was a significant increase in traffic crashes among youth affected by the law change. Comparing 4 years before and after New Zealand lowered the MLDA to 18, the rate of traffic crashes and injuries to 18- and 19-year-old males increased 12% and increased 14% for males aged 15–17. For females, the effect was even greater – rates increased 51% for 18- and 19-year-olds and 24% for 15- to 17-year-olds. There was also a "trickle down" effect, as youth even younger than the MLDA increased their alcohol consumption. It is estimated that 400 serious injuries and 12 deaths could be prevented each year among 15- to 19-year-olds if New Zealand were to raise the MLDA back to age 20. The outcomes in New Zealand are similar to the evidence in the United States after the drinking ages were lowered in the 1970s.

LOWER DRINKING AGES IN EUROPE

It is often asserted that alcohol is more integrated into European culture (especially in southern Europe) and that its young people learn to drink moderately at earlier ages within the context of the family. Consequently, it is said that young Europeans learn to drink more responsibly than do young people in the United States. This may be so in a handful of countries, but in reality, a greater percentage of 15- and 16-year-olds in most European countries reported being intoxicated in the past year than in the United States (see Fig. 95.4). Evidence also indicates that some European youth have higher rates of alcohol-related problems because of their heavy drinking.

BINGE DRINKING BY YOUTH

The MLDA is associated with rates of binge drinking by youth. Binge drinking by youth in the United States declined after drinking ages were raised to age 21 nationwide and has been stable at levels lower than the early 1980s. Binge drinking (i.e. reaching a BAC \geq .08; typically having five or more drinks for males and four or more drinks for females at a drinking session) is a major problem at many colleges. Binge drinking among US college students has been fairly steady for the past 10 years. Between 1997 and 2006, the proportion of college students reporting binge drinking ranged from a high of 41.7% in 2004 to a low of 38.5% in 2003. The percentage of college students who reported being drunk in the past 30 days shows similar fluctuations and results between 1991 and 2006, with several ups and downs during that period (see

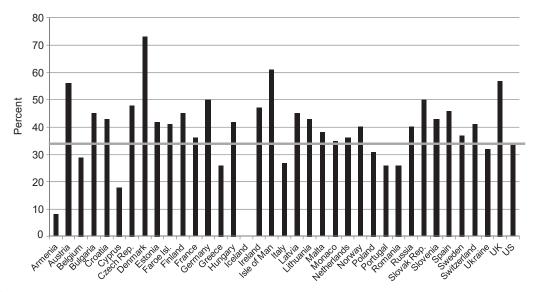


FIGURE 95.4 Prevalence of intoxication in the past year (2007) by adolescents aged 15–16: United States and Europe. Adapted from Johnston, L. D., O'Malley, P. M., Bachman, J. G., and Schulenberg, J. E. (2008b). Survey Results on Drug Use. In Monitoring the Future (Vol. I). Bethesda, MD: National Institute on Drug Abuse.

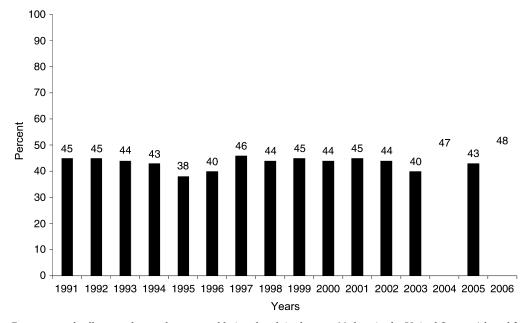


FIGURE 95.5 Percentage of college students who reported being drunk in the past 30 days in the United States. Adapted from National Center for Statistics and Analysis. (2005). Traffic safety facts: 2005 data - young drivers (No. DOT HS 810 630). Washington, DC: National Highway Traffic Safety Administration.

Fig. 95.5). Overall, the proportion of 19- and 20-year-olds (college and no college) reporting binge drinking has fluctuated from a low of 31.7% in 1995 to a high of 37.0% in 1991 (see Fig. 95.6). The proportion of 12th graders reporting binge drinking in the last 2 weeks actually declined recently, ranging from 29.8% in 1991 to a high of 31.5% in 1998 to a low of 25.9% in 2007. Thus, though the MLDA-21 in the United States has not eliminated harmful drinking by those aged 20 and younger, it has reduced the problem and sustained

a much lower rate than when the MLDA was lower (see Binge Drinking and Binge Drinking and Withdrawal: Neural Mechanisms in Humans).

COLLEGE BINGE DRINKING

The tradition of drinking and especially excessive drinking on and around college campuses is prevalent in the United States (Fig. 95.5) and in many other

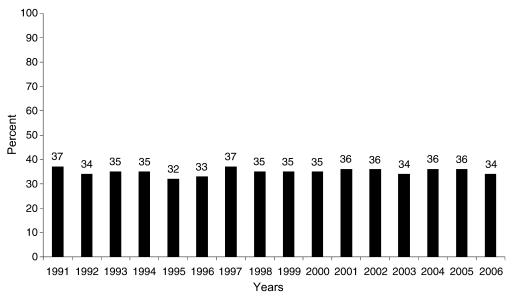


FIGURE 95.6 Percentage of 19- and 20-year-olds binge drinking (5+ drinks in past 2 weeks) in the United States. *Adapted from O'Malley, P. M., and Wagenaar, A. C.* (1991). Effects of minimum drinking age laws on alcohol use, related behaviors and traffic crash involvement among American youth: 1976–1987. Journal of Studies on Alcohol, 52(5), 478–491.

industrialized nations. This occurs despite efforts to curtail the behavior and the MLDA in those countries. The negative consequences of alcohol consumption by college students include academic problems, assaults, rapes, and deaths from unintentional and intentional injuries and alcohol poisonings. In the United States, 83% of college students report drinking and 41% report binge drinking (five or more drinks on an occasion) in the past 2 weeks. This heavy episodic, high-risk, or binge drinking is a particularly dangerous pattern of alcohol consumption.

The prevalence of alcohol dependence is highest among US youth, aged 18-24 years, whether they are in college, military, or workforce. College students may start out with lower rates of binge drinking compared to their noncollege peers, but they quickly catch up. Addressing harmful college student drinking is complicated because half or more students on a typical US campus are younger than the MLDA of 21. College officials face serious questions about how to and whether to enforce MLDA-21 on their campuses. They must balance safety, liability, and law enforcement with the colleges' historic role as havens for experimentation, personal freedom, self-expression, and individual responsibility. Beyond the harm to college drinkers themselves, 67% of all property damage, 64% of violent behavior, 42% of physical injury, 37% of emotional difficulty, 38% of poor academic performance, and 28% of all dropouts could be attributed to alcohol abuse in US colleges.

A variety of individual, campus, community, and environmental measures can work in conjunction with

enforcement of the MLDA-21 law to reduce college students' binge drinking. The effectiveness of countermeasures depends upon the culture and context of a particular college campus. In general, strategies that involve multiple aspects of campus life that include the surrounding community and that are sustained over time have a greater chance for success. Some US colleges are pursuing a range of policies and practices aimed at discouraging underage drinking and reducing its appeal:

- Aggressively enforcing the MLDA-21 law in residence halls and throughout the campus
- Offering substance-free housing and/or agesegregated housing
- Restricting or prohibiting alcohol at social activities on campus
- Prohibiting alcohol advertising on campus
- Providing alcohol-free late-night attractive social options, especially for students aged 20 and younger
- Providing information to parents and students of alcohol policies and penalties for violations

Countries with more stringent alcohol control policies tend to have lower adult and college binge-drinking rates.

ENFORCEMENT OF MLDA LAWS

Despite the establishment of MLDA laws in most countries, they are not strictly enforced. The US Centers for Disease Control (CDC) and Prevention, a United States federal agency under the Department of Health FURTHER READING 953

and Human Services that works to protect public health and safety by providing information to enhance health decisions, conducted a systematic review of the evidence on enhanced enforcement of laws prohibiting sales to minors. Enhanced programs to enforce MLDA laws include, for example, retailer compliance checks, or "sting operations," conducted or coordinated with local law enforcement or alcohol beverage control agencies with violators receiving legal or administrative sanctions (e.g. fines, store closings). These compliance checks typically involve sending a youth (called a minor decoy who looked younger than age 21) into an alcohol establishment to purchase alcohol. If proof of age was asked, the youth did not produce it. If the alcohol was sold to the youth without the proof of age, this was considered not in "compliance" with the law.

Enhanced enforcement of MLDA laws reduce or limit underage purchases of alcohol. Enhanced enforcement programs are effective in reducing retail sales of alcohol to minors. As an example, the median decrease in sales to minor decoys after an enforcement program was implemented was 42% with interquartile intervals of -57% to -17%. Enhanced enforcement programs have been found to be effective in on-premises (e.g. bars and restaurants) and off-premises (e.g. liquor stores, grocery stores) establishments, as well as among different ethnic and socioeconomic groups and in both urban and rural areas. There is little evidence, however, that these changes in retailer behavior actually affect underage drinking. Many experts believe that if MLDA laws were seriously enforced, both the laws aimed at the underage and the providers, the effects of these laws will be substantially enhanced.

SUMMARY

Most countries around the world have adopted MLDA laws for the purchase and/or possession of alcohol as a protective policy for youth. Scientific evidence indicates that the lower the drinking age, the earlier the youth begin to drink and the greater the prevalence of alcohol harm. The raising of the drinking age appears to decrease alcohol consumption for youth and is associated with declines in deaths and injuries caused by the harmful use of alcohol (at least in the United States). MLDA laws are an important component of any effort to control the production, marketing, distribution, and sale of alcoholic beverages.

SEE ALSO

The Impact of Drink Driving Laws

List of Abbreviations

BAC blood alcohol concentration GDL graduated driver licensing

ICAP International Center for Alcohol Policies

MLDA minimum legal drinking age WHO World Health Organization

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Understanding Individual Variation in Student Alcohol Use

Hong V. Nguyen, Kelly H. Koo, Hollie F. Granato, William H. George University of Washington, Seattle, WA, USA

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OVERVIEW

Alcohol problems have been shown to be prevalent among college students, with approximately 56% of students meeting DSM-IV criteria for alcohol abuse or dependence. Although substantial alcohol problems exist in this population, alcohol consumption is not uniformly excessive and there is substantial individual variation. The current chapter explores social, cultural, environmental, biological, and personality factors contributing to this variability. Topics covered include family and parental influences, genetic mechanisms, personality variables, alcohol expectancies, drinking motives, and drinking norms.

FAMILY HISTORY AND GENETIC INFLUENCES ON ALCOHOL-USE DISORDERS

Family, twin, and adoption studies have shown that a family history of alcohol-use disorders is a consistent risk factor for the development of alcohol problems. Although a strong association between family history and alcohol-use disorders has been found in the general population, research on college students has revealed mixed findings. A number of studies assessing large samples of college students have demonstrated that children of alcoholics (COAs) reported higher rates of alcohol-use disorders and alcohol problems compared

to nonCOAs. However, other studies have shown no differences in the level of alcohol consumption between the two groups. These findings indicate that COAs may experience more negative consequences from alcohol than nonCOAs at the same level of alcohol consumption. However, these results may be a function of sampling bias such that college samples of COAs may only include more functional and successful COAs who are drinking at lower levels. It is also possible that COAs are more familiar with alcohol problems due to their family history and thus are more likely to acknowledge their behaviors as problematic, thereby accounting for the higher reports of alcohol-use disorders in COAs. The current findings indicate that having a family history of alcohol-use disorders may be a significant risk factor for the development of alcohol problems, and that both genetic and environmental factors influence the intergenerational transference of alcohol-use disorders.

Research suggests that the genetic etiology of alcoholuse disorders does not involve simple Mendelian dominant or recessive genetic processes, but more complex processes involving multiple genes that reflect multiple characteristics. Further, genetic processes only account for about 50% of the risk for alcohol-use disorders. Thus, cultural and environmental factors, such as parental influence, family environment, and family history of psychopathology, have been shown to be associated with the development of problematic drinking. Moreover, studies have shown that many COAs do not develop alcohol-use disorders whereas many nonCOAs do. This indicates that other mechanisms – besides genetic inheritance – play important roles in the development of alcohol-use disorders.

Genetic Influence

Genetic Factors Predicting Alcohol-Use Disorders

Twin and adoption studies have been used to disentangle the impact of genes versus environment. Twin studies comparing monozygotic twins (one-egg twins who share 100% of genetic material) and dizygotic twins (two-egg twins who share 50% of genetic material) have consistently shown that dizygotic twins of alcoholics have approximately the same alcohol risk as full-siblings whereas monozygotic twins have significantly higher risk. Further, studies of halfsiblings of alcoholic parents raised in the same household revealed that half-siblings have a lower risk for alcohol-use disorders than full-siblings. This indicates that despite shared family environment, siblings who are more genetically similar to their alcoholic parents are more at risk for alcohol-use disorders. Adoption studies have also attested to genetic etiology. Children of alcoholics who were adopted into another family have been shown to exhibit similar drinking patterns as their biological parents and full-siblings. Overall, these studies indicate that genetics play an important role in the intergenerational transference of alcohol-use disorders, with heritability estimates between 50 and 60%.

Although there are strong gender differences in the prevalence of alcohol-use disorders, research indicates that a gender-linked mechanism is unlikely to be a major contributor toward these disorders. This is because the risk for alcohol problems has been shown to be high in both sons and daughters of alcoholics. Consequently, the higher risk for alcohol-use disorders found in men as compared to women appears to reflect cultural rather than genetic mechanisms.

Genes Involved in the Level of Response to Alcohol

The level of response (LR) to alcohol is a genetically influenced characteristic that has been associated with increased risk for alcohol-use disorders. Individuals with a low LR will consume more alcohol than individuals with a high LR to achieve the same physiological effects. Thus, compared to high LR individuals, low LR individuals are more likely to consume larger amounts of alcohol per occasion, associate with heavy-drinking peers, have positive alcohol expectancies, and develop higher tolerance for alcohol, which puts them at increased risk for alcohol-use disorders. The heritability of LR is between 40% and 60%.

The gamma-aminobutyric acid (GABA) gene cluster on chromosome 5, particularly GABRA6 and GABRA1, has been associated with LR to alcohol. GABA receptors are sensitive to alcohol, and their activation can result in sedation, motor impairment, and other responses to alcohol. Polymorphisms in the GABRA6 and GABRA1 genes are associated with a lower LR due to the receptors having less sensitivity to alcohol and to a more rapid development of tolerance as the receptors adapt during a drinking session. The lower LR produced by these mutations increases risk for heavy drinking and alcohol-use disorders. Research has shown that populations that are at risk for alcohol problems, such as COAs, Native Americans, and Koreans, have lower LR than other populations.

Genes Involved in Alcohol Metabolism

Genes involved in alcohol metabolism have also been associated with alcohol-use disorders. When alcohol is consumed, the enzyme alcohol dehydrogenase (ADH) converts ethanol into an active metabolite called acetal-dehyde. Acetaldehyde is then oxidized by the mitochondrial enzyme aldehyde dehydrogenase (ALDH2) into acetate, which eventually metabolizes into carbon dioxide and water. About 40–50% of Asian individuals have mutation of the ALDH2 gene (ALDH2*2). This mutation encodes an enzyme that is functionally inactive and is therefore unable to metabolize acetaldehyde.

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This results in an accumulation of this toxic substrate, which can lead to physiological responses such as flushing, headache, nausea, tachycardia, and hypotension. Individuals who have two ALDH2*2 alleles (approximately 10% of Asians) accumulate high levels of acetaldehyde in the blood when drinking moderate amounts, which produces intense LR to alcohol that can be aversive. Individuals who have only one ALDH2*2 allele (30-40% of Asians) also demonstrate more intense LR to alcohol than individuals without this variant; however, their response may not be more aversive. It is hypothesized that the high sensitivity to alcohol decreases the amount of alcohol consumption thereby protecting these individuals from alcohol-use disorders. A substantial number of studies have supported this hypothesis showing that those who have the ALDH2*2 mutation reported greater sensitivity to alcohol, lower rates of alcohol use, and fewer drinking consequences.

Similar, but less consistent data has been shown for genetic variations regarding ADH. Two polymorphisms, the ADH1B*2 and the ADH1C*1, have been shown to produce enzymes capable of faster metabolism of alcohol, resulting in a slight increase in acetaldehyde levels and an enhanced LR to alcohol. These genetic mutations have been shown to be protective against alcohol-use disorders in Asian, African American, and Jewish populations.

Parental Influence

Parental drinking has been shown to be an important environmental factor that directly and indirectly increases children's risk for alcohol problems. Research has found that observation of parental drinking habits, drinking refusal self-efficacy, and beliefs about alcohol's effects influence children's perceptions of alcohol and their subsequent drinking behavior. Further, parents' alcohol abuse has been shown to adversely affect global family interactions and the psychological well-being of the children. A number of studies have demonstrated that COAs are at an increased risk for alcohol abuse, either directly by using alcohol as a means to cope with the negative family environment or indirectly by their association with substance using peers due to low parental monitoring. A family history of psychopathology has also been associated with college students' alcohol use. Psychopathology has been found to adversely influence family environment and interaction, which may lead to alcohol use by both parents and children as a coping mechanism.

It should be noted that some studies have found a negative relationship between parents' alcohol use and children's alcohol use. A study assessing Russian family alcohol use found that fathers' alcohol-related violence was associated with lower drinking levels in children. This effect was termed the "aversive transmission" effect in which children of alcoholics moderate their own drinking due to their perceptions of their parents' problematic drinking behavior. In general, it appears that parental influence and family environment operate as partial mechanisms for the intergenerational transfer of alcohol problems. However, more research is needed to examine the relative significance of the direct and indirect effects of parental influence and family environment on the development of problematic drinking.

DRINKING MOTIVES

Drinking motives refer to the psychological function that drinking alcohol fulfills, or more plainly, reasons to drink. Motives are understood, both theoretically and empirically, to be potent determinants of drinking and alcohol-related problems. In fact, some theorists consider motives to be the final common psychological pathway that is most proximal to drinking and alcohol-related problems. That is, motives can be construed as the mediating mechanisms linking more distal determinants – such as family history, genetic influences, personality factors, alcohol expectancies, etc. – to drinking.

The most widely used model of drinking motives is based on the "motivational model of alcohol use," and posits that there are two motivational dimensions at play: valence (positive versus negative reinforcement motives) and source (internal versus external reinforcement motives). These two dimensions intersect to generate four specific types of drinking motives: coping (negative, internal), conformity (negative, external), enhancement (positive, internal), and social (positive, external) motives. Among college students, drinking motives have been found to be established predictors of heavy drinking and alcohol-related problems.

Also known as "drinking-to-cope," avoidance drinking, or self-medication, coping motives entail drinking to avoid experiencing negative affect, primarily anxiety and depression. Coping motives significantly predict drinking frequency and alcohol-related problems as well as increased psychological distress for college students. Of all the drinking motives, only coping motives have been found to be associated with solitary heavy drinking. When distinguishing the types of coping motives, researchers have found that college students with stronger coping motives for depression consumed more alcohol to cope with their depression, and those with stronger coping motives for anxiety consumed more alcohol to cope with their anxious mood. Coping motives have also been found to be differentially related to levels of social anxiety. Among college students who have high or moderate social anxiety, coping motives are related to greater alcohol use and problems. However, this relationship was not found for those low in social anxiety.

General associations between coping motives and drinking among college students tend to be stronger for women than men. Some researchers speculate that this gender difference may be due to women being diagnosed with depression more so than men, and thus, women may exhibit higher coping motives for drinking to decrease symptoms. Coping motives have also been shown to account for increased drinking in women with higher sensitivity to anxiety. Additionally, college students who endorse coping motives lack other coping skills and thus drink to cope with their aversive internal states, and this pattern continues to be stronger among women than men.

Driven by the desire to attain peer acceptance, conformity motives involve drinking to avoid the experience of social disapproval. Conformity motives are related to alcohol-related problems and drinking during social contexts in which there are pressures to conform. Conformity-motivated heavy college drinkers tend to have greater self-consciousness and greater anxiety, and are more likely to be men. In one recent study, freshman students and students of color had higher scores on the conformity motives than senior students and Caucasian students, respectively. For students of color, this may be due to the pressure and stress surrounding their adjustment to the largely Caucasian environment of many college campuses. Given that this study is unique, follow-up studies replicating this pattern are necessary before making conclusions. Furthermore, future studies that consider cultural constructs, such as acculturation and loss of face, and ethnicity are necessary to further elucidate these patterns.

According to the "motivational model of alcohol use," coping and conformity motives are understood to influence drinking behavior through negative reinforcement. Research in this area is somewhat mixed. Perhaps counter intuitively, some studies find that students higher in social anxiety consumed less alcohol. This may be due to the fact that these students are in less contact with social environments where alcohol is involved. However, these students experience more negative consequences from alcohol use. Other studies have found that coping and conformity motives mediate the relationship between social anxiety and negative consequences such that students who experience more social anxiety also exhibit more coping and conformity motives, leading to increased drinking and consequences. Regardless of the mixed findings, this research demonstrates the importance of addressing the negative reinforcement motives behind unwanted consequences of drinking.

The remaining two drinking motives, enhancement and social motives, have received relatively less research attention than conformity and coping motives. Enhancement motives involve drinking to increase positive affect. They have been found to predict alcohol-related problems and to be the best predictor of heavy social drinking over other motives. Drinking to achieve social affiliation is known as social motives. Although social motives are related to alcohol consumption (these students tend to socialize more and attend social situations where alcohol is present), social motives are not necessarily related to alcohol-related problems.

Taken together, research findings appear to indicate that coping, conformity, enhancement, and social motives are related to alcohol use and problematic drinking. Further, coping motives have been shown to be particularly hazardous, and drinking motives generally have been shown to play an important role in delineating the effects of personality factors on drinking.

PERSONALITY FACTORS

Within psychology and psychiatry generally and within addictions theory specifically, a long-standing tradition advances the assertion that personality exerts a determinative role in explaining behavior. Personality theorists define personality as an organized set of characteristics possessed by an individual that influences his or her thoughts, feelings, motivations, and behaviors in a systematic fashion across various situations. Personality factors are understood to represent intrinsic and unchanging dispositional tendencies that are biologically based and established early in life. In keeping with the tradition of personality theory, researchers have examined several personality factors thought to influence drinking and drinking-related outcomes among college students.

The Five-Factor Model and Related Constructs

Several decades of research by multiple investigative teams generated an empirically driven multidimensional model of personality thought to encompass the broadest array of personality attributes. The model offers a valuable heuristic frame for discussing the link between personality and college drinking.

The Five-Factor Model (FFM) identifies five distinct dimensions or higher-order factors – neuroticism, extraversion, openness to experience, agreeableness, and conscientious, each of which subsumes a set of specific facets or lower-order factors. For instance, impulsivity, anxiety, and depression are facets of neuroticism; whereas, gregariousness and excitement seeking are

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facets of extraversion. While these selected facets would – at a glance – seem intuitively relevant to drinking, researchers have examined all five dimensions and many of the subsidiary facets to evaluate their predictive value and explanatory relevance to college drinking outcomes. Overall, current trends seem to indicate that, while personality factors can be demonstrated to have a direct impact on drinking, these influences are increasingly understood to operate indirectly via drinking motives. That is, personality factors seem to fuel motives to drink and these motives, in turn, fuel drinking and related outcomes.

Neuroticism

Neuroticism refers to a person's tendency to be emotionally labile, susceptible to anxiety, hypersensitive to criticism, self-doubting, and inclined to dwell on the negative. The distinction between direct (personality trait → drinking) versus indirect pathways (personality trait \rightarrow drinking motive \rightarrow drinking) is especially striking with neuroticism. In this case, evidence suggests that the two pathways manifest opposite effects. The direct pathway appears protective, thereby lowering drinking risk, whereas the indirect pathway appears to heighten risks. Research examining direct linkages from this broad higher-order conceptualization of neuroticism to drinking variables indicates reduced drinking risks. That is, being high in neuroticism may serve a protective function against drinking and associated negative outcomes. The logic seems to be that more neurotic individuals have a lower likelihood of encountering social factors that might otherwise foster drinking activities. Presumably, their tendencies toward anxiety and negativism may curtail their socializing, thereby limiting opportunities for engaging in alcohol-involved social situations. However, evidence of an indirect pathway suggests that more neurotic individuals are motivated to drink as a way to alleviate their negative affect (particularly anxiety and depression) and that this drinking-to-cope pathway fuels greater drinking and more problematic drinking outcomes. Thus, neuroticism seems to have intriguingly paradoxical effects on drinking and this pattern warrants further study.

Impulsivity and Related Constructs

Recall that the FFM posits that neuroticism subsumes distinct subfactors or facets. Among them, impulsivity has received considerable research attention with respect to drinking, as have other related constructs. Impulsivity is generally defined as the tendency to act based on immediate urges without regard for rules, regulations, and consequences. This tendency toward rash action is considered a complex

construct, with scientists speculating a range of interrelated yet distinct aspects including urgency (a tendency to act rashly), lack of premeditation (inability to anticipate consequences), lack of perseverance or boredom susceptibility (inability to follow through on task completion), lack of inhibitory control (inability to refrain from or delay responding), and excitement or thrill seeking (which is often also considered an aspect of extraversion and refers to one's attraction to risky events and actions).

Research shows that impulsivity is a clear risk factor for drinking. A recent review of relevant studies indicated that impulsivity increases the likelihood of initiating alcohol use, continuing drinking over the college years, and developing alcohol-use disorders. Impulsivity has also been linked to greater hazardous drinking. Moreover, particular impulsivity subconstructs - for instance, motor impulsivity and boredom susceptibility - have been shown to predict heavy episodic drinking (more than four (women) or five (men) drinks in 2 h). As with neuroticism, the influence of impulsivity on drinking outcomes can be mediated by drinking motives. In one recent study, impulsivity increased alcohol problems via a direct pathway and an indirect pathway via the drinking-to-cope motive. This suggests that impulsive individuals may overly rely on quick, easy ways to cope with distress, such as drinking alcohol. They may also drink in riskier environments, thus increasing the likelihood of alcohol-related problems. It has been noted that impulsivity can have a reciprocal relationship with drinking, such that drinking induces greater impulsivity, which in turn, fuels greater drinking.

Urgency

Two emotion-based personality factors have been identified as related to impulsivity: Positive urgency is the tendency to act rashly when experiencing extremely positive emotion and negative urgency is the tendency to act rashly when experiencing extremely negative emotion. Both these urgency constructs have been shown to be related to college drinking. In an extensive series of cross-sectional surveys, a team of researchers showed that urgency (unspecified) predicted drinking and alcohol-related problems. In subsequent studies, this team showed that positive versus negative urgency exhibited differential predictive value. Positive urgency was positively related with problem drinking and other risky behaviors. In a longitudinal study, these investigators showed that positive urgency predicted increases in the amount of alcohol consumed and negative drinking outcomes. Further, in another longitudinal study, they found that positive urgency predicted drinking quantity at the end of the first year of college. Laboratory studies also showed that positive urgency predicted risk-taking and beer consumption, but only after a positive mood had been induced.

The association between positive urgency and problem drinking has been shown to be moderated by drinking motives. Positive urgency was associated with problem drinking more strongly for students who scored higher on the enhancement-drinking motive. Thus consistent with the theory, the tendency to act rashly in a positive mood state was related to problem drinking, but only for students who drink for positive internal reasons. This pattern was unique for positive urgency and did not occur with negative urgency. Alcohol expectancies also played a moderating role, such that associations were stronger for students higher in the belief that alcohol makes one social, attractive, or sexually excited. In one of the longitudinal studies mentioned earlier, negative urgency also predicted drinking quantity and the effect was mediated by the drink-to-cope motive. Thus, it appears that urgency - one's tendency to act rashly - is an important element of impulsivity with regard to college drinking. Moreover, the role played by this trait seems specific to the valence of the associated mood states; and, like other personality factors, can exert its effects on drinking outcomes either directly or indirectly via drinking motives.

Extraversion, Excitement Seeking, and Sensation Seeking

Extraversion refers to the tendency to focus on gratification obtained from outside the self. Extroverts are characterized by warmth, positivity, gregariousness, and excitement seeking. Among college students, extraversion has been consistently associated with drinking and with a host of drinking outcomes such as hangover symptoms, risky drinking, and alcohol-related problems. Extraversion is positively related to enhancement motives, and the association between extraversion and alcohol use can be mediated by enhancement motives. Additionally, social motives have also been found to mediate the relation between extraversion and alcohol use.

The FFM posits that extraversion subsumes distinct subfactors. Among them, excitement seeking has received research attention with respect to college drinking, as have other related constructs. Sensation seeking, a personality construct identified with both excitement seeking and impulsivity, has also received considerable attention. Sensation seeking has been defined by the need for "varied, novel, and complex sensations and experience and the willingness to take physical and social risks for the sake of such experience." These more specific components of extraversion tend to be more strongly related to college drinking than the broader construct.

Conscientiousness

Conscientiousness refers to tendencies that adhere to socially prescribed norms and rules regarding impulse control, to be orderly, to be achievement striving and goal-directed, and to be deliberative about planning ahead. As such, being high in conscientiousness is largely antithetical to drinking excessively and manifesting derivative problems. Accordingly, research shows that students low in conscientiousness are most likely to exhibit drinking, excessive drinking, and drinkingrelated negative consequences. In one study looking at the role of drinking motives, conscientiousness was negatively related to both enhancement and coping motives, and the negative association between conscientiousness and alcohol use was partially mediated by both enhancement and coping motives. Furthermore, the influence of conscientiousness has been shown to be mediated by use of protective behavioral strategies. These strategies are defined as "behaviors that individuals can engage in while drinking alcohol in order to limit negative alcohol-related problems" and include strategies such as adhering to a predetermined drink limit, avoiding drinking games, and resisting social pressure to drink more. Students who are high in conscientiousness use more of these protective strategies and as a result exhibit less drinking and alcohol-related problems.

Agreeableness

Agreeableness reflects the individual's tendency to develop and maintain prosocial relationships. Individuals high in this trait are more trustworthy, straightforward, altruistic, compliant, modest, and tender-minded. Conversely, individuals low in agreeableness are less concerned about social approval and less concerned about protecting others and themselves from harm. Research shows that agreeableness tends to be negatively related to excessive drinking and alcohol-related problems, especially alcohol-related aggression. Regarding drinking motives, one study showed that agreeableness was predicted by both positive reinforcement motives (drinking to attain positive outcomes). It has not been determined whether the relationship between agreeableness and drinking is mediated by motives.

Despite a seemingly protective effect, high agreeableness also carries a risk: individuals who are high in this trait are more susceptible to peer-drinking influences. Apparently, in their concern for complying with others and their efforts to meet group expectations, more agreeable individuals tend to drink less around light drinking peers, but drink more around heavy drinking peers. In a laboratory experiment, individuals high in

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agreeableness were more likely to match their drinking during a taste-rating task to that of a stranger, compared to individuals low in agreeableness. Thus, the relationship between agreeableness and college drinking is not always straightforward depending on social context.

Openness to Experience

Openness, which includes intellectual curiosity and preference for variety, appears to be the personality trait that is least reliably related to college drinking among the FFM traits. Although, a recent study reported evidence that curiosity relates to drinking outcomes. Two aspects of curiosity had opposite associations with problem drinking. Higher scores on exploration, the desire to seek out novel information and experiences, were negatively related to alcohol-related problems. Higher scores on absorption, the tendency to become deeply involved in such activities, were positively related to alcohol-related problems. This observation that curiosity factors could alternately serve protective and risk functions among college drinkers is intriguing and warrants further study. Also, the links between curiosity and drinking motives will be important to investigate.

PRECOLLEGE DRINKING AND MATURING OUT OF COLLEGE DRINKING

It has become increasingly well established that college drinking patterns do not necessarily typify lifetime drinking patterns. Precollege drinking variables such as age at first intoxication and high school drinking quantity and frequency do tend to foreshadow and predict college-drinking variables. A more delayed debut of drinking and intoxication prior to college and lesser high school consumption are protective against excessive drinking and development of alcohol problems and abuse during college. Conversely, college drinking may not foreshadow later drinking. After college, drinking patterns characterized by excessiveness and alcohol-related problems tend to subside as students transition to more demanding adult statuses such as career employment, marriage, and children, which are largely incompatible with heavy drinking. Further, changes in personality may be an important mechanism in this so-called "maturing out" of college drinking. In longitudinal studies, students who exhibited a pattern of maturing out of college drinking showed decreases in neuroticism and impulsivity and increases in conscientiousness. These findings suggest that individual variation factors seemingly as stable as

personality can operate more dynamically within individuals as a function of significant life transitions.

ALCOHOL EXPECTANCIES

Alcohol expectancies refer to beliefs people hold about the "positive" and "negative" consequences of drinking alcohol. According to Expectancy Theory, high positive and low negative expectations about the effects of drinking alcohol lead to elevated alcohol consumption. Decades of research have consistently demonstrated that positive alcohol expectancies are associated with increased drinking behavior (including number of drinks and binge episodes) among college students in both cross-sectional and longitudinal studies. Domains of positive alcohol expectancies include tension reduction, sexual enhancement, enhanced sociability, and social assertion. Alcohol expectancies have been shown to be better predictors of problem drinking than background demographic variables such as gender, class, ethnicity, marital status, religiosity, and family history of alcohol problems.

A number of factors, such as gender, family history, and anxiety, have been shown to moderate the relationship between positive alcohol expectancies and drinking behavior. Different types of drinkers tend to endorse different types of alcohol expectancies. Problem drinkers, individuals who abuse alcohol, are more likely to expect tension reduction whereas social drinkers expect social enhancement from alcohol. Further, heavier drinkers expect more positive effects than lighter drinkers. When examining different types of drinkers over the course of the freshmen college year, those who consistently consume low levels of alcohol endorsed lower alcohol expectancies than all other groups of freshman drinkers.

Anxiety among college students is another factor that has been proposed to moderate the relationship between alcohol expectancies and problematic drinking. Among college student populations, beliefs regarding increased sociability and assertiveness from drinking were positively correlated with alcohol use. College student problem drinkers had greater expectancies for improvements in social behavior than nonproblem drinkers. Alcohol expectancies of social anxiety reduction predicted quantity of alcohol consumed per occasion but not frequency of consumption in the past month, such that alcohol consumed per occasion was increased but not the overall frequency in consumption. Furthermore, socially anxious college students with low self-efficacy for avoiding heavy drinking in social situations and high positive expectancies for social facilitation reported more alcohol consumption than other socially anxious college students. These findings demonstrate that college student problem drinking may vary depending on alcohol expectancies surrounding sociability.

Negative alcohol expectancies, which can include cognitive and behavioral impairment, depressant effects, risk and aggression, and negative self-perception, are also meaningful when examining college student alcohol use. However, the relationship between negative alcohol expectancies and drinking is less straightforward than positive expectancies and drinking. More recently, the categorization of alcohol expectancies as "positive" or "negative" has been debated, as well as the inclusion of individual valuation of alcohol expectancies (the extent to which an individual desires these outcomes when drinking). It may be that the negative expectancies individuals report are not necessarily desired, but can influence drinking and drinking-related consequences regardless of their individual valuation. Theoretically, college students endorsing negative alcohol expectancies will drink at lower levels. However, the evidence is mixed.

The relationship between negative alcohol expectancies and drinking varies depending on the type of expectancy. Expectations of depressive symptoms such as feeling sad or sleepy has not been found to be associated with alcohol consumption among college students, but has been found to be associated with alcohol problems. This suggests that students who report these expectancies tend to experience more consequences, but do not similarly report that these expectancies lead them to consume more alcohol. Alcohol expectancies of greater physiological impairment (e.g. becoming dizzy and getting a headache) have been found to be a significant predictor for elevated alcohol use and alcohol problems. Perhaps negative alcohol expectancies are related to alcohol-related problems such that individuals who report these expectancies experience consequences related to these expectancies more frequently. Among female college athletes, favorable valuations of negative expectancies were associated with heavy drinking. When controlling for age, athletic membership and peer use, more negative expectancies and favorable valuations of negative and positive expectancies were predictive of increased hazardous alcohol use. Valuations of alcohol expectancies accounted for additional variance of hazardous alcohol use beyond that of expectancies. It appears that the level that individuals desire expectancy is just as meaningful as the expectancy itself. Additionally, college problem drinkers had greater expectancies of improvements in cognitive and motor abilities than nonproblem drinkers, demonstrating that expectancies are not necessarily universal across college students. Indeed, negative alcohol expectancies seem to have a complicated relationship with alcohol use and alcohol-related problems among college students.

Researchers theorize that alcohol expectancies are developed within college students' social/cultural surroundings. Given the cultural foundation of alcohol expectancies, one would venture to guess cultural differences in alcohol expectancies. Evidence suggests ethnic differences among college students in the endorsement of alcohol expectancies. Asian Americans have been found to increase their positive alcohol expectancies over the course of 3 years of college. In Australia, Asian college students expected cognitive enhancement and negative consequences from alcohol more so than their Caucasian counterparts. African-American women reported less positive alcohol expectancies than other groups of women. Among Mexican American college students, those who endorsed expectancies of physical and social pleasure and increased social assertiveness were more likely to engage in frequent heavy drinking. Longitudinal studies show that gay men increase their alcohol use at greater rates than heterosexual men during the transition into college from high school, and this relationship was mediated by positive alcohol expectancies. It is clear that the relationship between alcohol expectancies and alcohol use may differ depending on the population. However, alcohol expectancy research incorporating cultural factors is limited and thus, overall conclusions cannot yet be made.

Does addressing alcohol expectancies reduce drinking on college campuses? Overall, evidence suggests that interventions aimed at challenging alcohol expectancies are effective in decreasing alcohol use, including heavy episodic drinking, in college students. Research has shown that single-session interventions that challenge alcohol expectancies among college students can lead to significant decreases in alcohol consumptions at a 1-month follow-up, when compared to controls. However, there are some studies that suggest challenging alcohol expectancies alone may not be as effective as other interventions. For example, compared to brief motivational interventions, interventions that challenge alcohol expectancies have been shown to produce similar decreases in heavy episodic drinking and alcohol use overall, however, brief motivational interventions additionally produced decreases in alcohol problems. It has also been found that readiness to change is associated with stronger effects on challenging alcohol expectancies and more reduction in alcohol use.

DRINKING NORMS

Research has repeatedly shown the influence that peers can have on predicting alcohol use during college. Therefore, it follows logically that students' perceptions DRINKING NORMS 963

about how frequently other students are drinking should also impact their use of alcohol. A large amount of research has been dedicated to examining the role that these drinking norms can play in alcohol use, and has repeatedly suggested that the perceptions students hold about the alcohol use of their peers can be an independent risk factor for drinking. Research on the impact of these perceptions on alcohol use during college has defined two different categories of perceptions. These two categories include injunctive norms, or perceptions that students hold about others' approval of alcohol use, and descriptive norms, or the estimated rate of drinking that students make about their peer groups. Both descriptive and injunctive norms have been linked to alcohol use and the approval of alcohol use.

It has been suggested that students have limited knowledge about how other students think and act. Therefore, the development of inaccurate, descriptive norms about alcohol use among college students may stem in part from readily available images and information about heavy college drinking in the media and from peers. Additionally, these descriptive norms may be further developed and perpetuated by students' desire to see themselves or their own alcohol use in a favorable way. Injunctive norms may also be informed by public behavior and attitudes exhibited by students in the media regarding alcohol use. Furthermore, students tend to report their own attitudes toward drinking as being more conservative than the attitudes of their peers. This phenomenon is referred to as pluralistic ignorance and can result in a student's inaccurate perceptions about the attitudes toward drinking on campus.

In general, students have been found to overestimate the frequency and quantity of how much other students drink. Similarly, it has also been found that students tend to overestimate the drinking approval rates of their classmates. Even when students hold moderate views about their own drinking behavior, this overestimation persists. Additionally, students have been found to not only overestimate how much their peers drink in relation to their own alcohol use but they also overestimate the rates of student drinking when these rates are measured independently. Furthermore, students tend to estimate higher amount of negative consequences from drinking for other students than for themselves.

Inaccurate drinking norms have been frequently associated with heavier drinking rates among college students. This link has been the most strongly identified for descriptive norms. This may be because injunctive norms can vary depending on the population that the student is being asked about, thereby making injunctive norms more difficult to study. Injunctive norms have been found to be the most strongly linked to heavier drinking rates when the perception of approval is from

proximal referents such as friends and family. There has also been some evidence to support that students who express higher drinking norms, both descriptive and injunctive, experience more alcohol-related problems. However, injunctive norms surrounding perceived approval from parents and close friends have been found to most strongly predict alcohol-related problems. Therefore, it seems that there may be a complex relationship between how descriptive and injunctive norms influence a student's drinking behavior.

Students may also have unique perceptions about the drinking behavior of different groups, and this may influence their personal alcohol use depending on their affiliation with these groups. It has been suggested that a higher identification with same-sex students is associated with a stronger relationship between drinking norms for this group and the student's personal drinking. This same relationship has also been found with students having stronger identification to samerace and same-Greek-affiliation students. However, research has indicated that overall, male students express higher drinking norms than female students, in addition to consuming more alcohol on average than female students. Males may be more susceptible to peer influence, and this could have an indirect impact on distortions in injunctive norms or increases in the perceived acceptance of alcohol use.

Studies have further suggested that there may be differences in the relationship between drinking norms and alcohol use for ethnic minorities. The limited research in this area has indicated that certain ethnic groups, such as Asian Pacific Islanders and African-Americans, may express less exaggerated drinking norms than Caucasians. Further, some studies have shown that even when drinking norms are similar between ethnic minority women and Caucasian women, these norms appear to be less associated with drinking behavior for ethnic minority women than for Caucasian women. Furthermore, Caucasian women have been found to drink more similarly to Caucasian men regardless of drinking norms. This suggests that culture may serve as a protective factor against heavy alcohol use for some ethnic groups despite drinking norm misperceptions. It is important for future research to more closely examine how this may be operating for different ethnic minority groups, as well as how social norms may impact alcohol use for these groups.

Intervention programs have frequently targeted drinking norms in order to address problematic drinking on college campuses. Research has consistently found that correcting inaccurate descriptive norms decreases drinking for college students. Addressing injunctive norms has produced more conflicting results in terms of its impact on reducing alcohol use. This may be because injunctive norms are harder to address

and vary depending on which group attitude is the most salient for a student. Despite these complexities, numerous studies have shown that providing accurate data on drinking rates to college students reduce heavy drinking. Addressing drinking norms has become a key component for intervention programs that target alcohol use during college.

SUMMARY

"Danger: College life ahead!" This is not the typical farewell tiding or welcome greeting heard when starting college. College is a time of growth spurts in independence, autonomy, scholastics, social maturation, sexual exploration, and personal growth. However, warnings about dangers in college life are not misplaced because of the high prevalence of alcohol use, alcohol abuse, alcohol dependence, and alcohol-related problems. In the absence of uniformity in college drinking patterns, an understanding of the determinants of individual variation in alcohol variables is important for discerning, navigating, and potentially mitigating the risks associated with college drinking. We reviewed the roles played by family and parental influences, genetic mechanisms, personality variables, alcohol expectancies, drinking motives, and drinking norms in shaping individual variation in college drinking. All these factors can influence drinking and often exert their influence interactively. Notably, static factors such as genetic makeup, stable factors such as personality, and dynamic factors such as alcohol expectancies have been shown to have effects on drinking outcomes that are mediated or moderated by motives. The nexus posed by these interactions potentially provide important junctures for prevention and therapeutic interventions. Also, the tendency for students to mature out of excessive drinking after college suggests that modifications in structure role responsibilities in college could foster protective effects.

List of Abbreviations

COA children of alcoholics LR level of response

Glossary

- **Alcohol dehydrogenase (ADH)** enzyme that converts ethanol into an active metabolite called acetaldehyde; the first step in the metabolism of alcohol by the liver.
- ADH1B*2 and ADH1C*1 mutation of the ADH gene; this mutation produces enzymes capable of faster metabolism of alcohol, resulting in a slight increase in acetaldehyde levels and an enhanced level of response to alcohol.
- **Alcohol expectancies** beliefs regarding the positive and negative consequences of drinking alcohol.

- **Aldehyde dehydrogenase (ALDH2)** mitochondrial enzyme that oxidizes acetaldehyde into acetate, which eventually metabolizes into carbon dioxide and water; the second step in the metabolism of alcohol by the liver.
- ALDH2*2 mutation of the ALDH2 gene; this mutation encodes an enzyme that is functionally inactive and is therefore unable to metabolize acetaldehyde. This results in physiological responses such as flushing, headache, nausea, tachycardia, and hypotension.
- **Agreeableness** tendency to develop and maintain prosocial relationships characterized by trustworthiness, altruism, compliance, modesty, and tender-mindedness.
- Conformity motive drinking to avoid the experience of social disapproval.
- **Coping motive or drinking-to-cope motive** drinking alcohol to cope with distress; drinking to avoid experiencing negative affect.
- **Conscientiousness** a tendency to adhere to socially prescribed norms and rules regarding impulse control, to be orderly, to be achievement striving and goal-directed, and to be deliberative about planning ahead.
- **Descriptive norms** estimated rate of drinking that students make about their peer groups.
- **Dizygotic twins** two-egg twins who share 50% of their genes; nonidentical twins.
- **Drinking motive** the psychological function that drinking alcohol fulfills; reasons to drink.
- Enhancement motive drinking alcohol to increase positive affect.
- **Extraversion** the tendency to focus on gratification obtained from outside the self; characterized by warmth, positivity, gregariousness, and excitement seeking.
- **Five-Factor Model (FFM)** multidimensional model of personality that identifies five distinct higher-order personality attributes: neuroticism, extraversion, openness to experience, agreeableness, and conscientiousness.
- **Gamma-aminobutyric acid (GABA)** gene cluster on chromosome 5 that has been associated with level of response to alcohol. GABA receptors are sensitive to alcohol, and their activation can result in sedation and motor impairment.
- **Heavy episodic drinking** consuming four or more drinks for women or five or more drinks for men in a 2-h period.
- Impulsivity a facet of neuroticism; the tendency to act based on immediate urges without regard for rules, regulations, and consequences.
- **Injunctive norms** perceptions that students hold about others' approval of alcohol.
- **Level of response to alcohol** the degree to which an individual experience the physiological effects of alcohol after consumption.
- **Monozygotic twins** one-egg twins who share 100% of their genes; identical twins.
- Negative alcohol expectancies beliefs that alcohol consumption will lead to cognitive and behavioral impairment, depressant effects, risk-taking and aggression, and negative self-perception.
- **Neuroticism** a person's tendency to be emotionally labile, susceptible to anxiety, hypersensitive to criticism, self-doubting, and inclined to dwell on the negative.
- **Openness to experience** tendency for intellectual curiosity and preference for variety.
- **Positive alcohol expectancies** beliefs that alcohol consumption will lead to tension reduction, sexual enhancement, enhanced sociability, and social assertion.
- **Social motive** drinking to achieve social affiliation.
- **Urgency** emotion-based personality factor related to impulsivity; a tendency to act rashly; positive urgency is the tendency to act rashly when experiencing extremely positive emotion and negative urgency is the tendency to act rashly when experiencing extremely negative emotion.

FURTHER READING 965

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INTERVENTIONS FOR ADDICTION

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Editor-in-Chief

Peter M. Miller

Psychiatry and Behavioral Sciences, Medical University of South Carolina, Charleston, SC, USA





List of Contributors

- Amanda J. Abraham University of South Carolina, Columbia, SC, USA
- Nassima Ait-Daoud University of Virginia, Charlottesville, VA, USA
- Sheila M. Alessi Calhoun Cardiology Center Behavioral Health, University of Connecticut Health Center, Farmington, CT, USA
- James F. Alexander Functional Family Therapy, Salt Lake City, UT, USA
- Susan L. Ames Claremont Graduate University, Claremont, CA, USA
- Peter Anderson Apartat de Correus, Girona, Spain
- Gillinder Bedi Division on Substance Abuse, New York State Psychiatric Institute, College of Physicians and Surgeons of Columbia University, New York, NY, USA
- **Katherine E. Belon** University of New Mexico, Albuquerque, NM, USA
- Preben Bendtsen Linköping University, Linköping, Sweden
- **Junaid Bhatti** Research Centre of the Douglas Mental Health University Institute, Verdun, QC, Canada
- **Warren K. Bickel** Addiction Recovery Research Center, Virginia Tech Carilion Research Institute, Roanoke, VA, USA
- **Joyce N. Bittinger** Center for the Study of Health and Risk Behaviors, University of Washington, Department of Psychiatry, Seattle, WA, USA
- Nadine Blanchette-Martin Centre de réadaptation en dépendance de Chaudière-Appalaches, Lévis, QC, Canada
- **Arthur W. Blume** Washington State University, Vancouver, WA, USA
- **Brian Borsari** Mental Health and Behavioral Sciences Service, Providence, RI, USA; Center for Alcohol and Addiction Studies, Brown University, Providence, RI, USA
- Robert M. Bray RTI International, NC, USA
- Matthew Brensilver David Geffen School of Medicine, UCLA, Los Angeles, CA, USA
- Colin Brewer The Stapleford Centre, London, UK
- **Janet L. Brody** Center for Family and Adolescent Research, Albuquerque, NM, USA
- **Barry S. Brown** University of North Carolina at Wilmington, NC, USA
- Janice M. Brown RTI International, NC, USA
- **Thomas G. Brown** Research Centre of the Douglas Mental Health University Institute, Verdun, QC, Canada

- **Edson Sherwood Brown** The University of Texas Southwestern Medical Center at Dallas, Dallas, TX, USA
- **Alan J. Budney** Geisel School of Medicine at Dartmouth, Lebanon, NH, USA
- Douglas M. Burgess University of Missouri, MO, USA
- E. Cabrina Campbell University of Pennsylvania School of Medicine, Philadelphia, PA, USA; Philadelphia Veterans Medical Center, Philadelphia, PA, USA
- **Stanley N. Caroff** University of Pennsylvania School of Medicine, Philadelphia, PA, USA; Philadelphia Veterans Medical Center, Philadelphia, PA, USA
- Kathleen M. Carroll Yale University, West Haven, CT, USA
- **Adrian Carter** University of Queensland Centre for Clinical Research, Brisbane, QLD, Australia
- María José Casares López University of Oviedo, Asturias, Spain
- **Richard F. Catalano** University of Washington School of Social Work, Seattle, WA, USA
- **Subhajit Chakravorty** Philadelphia Veterans Affairs Medical Center, Philadelphia, PA, USA
- Martin D. Cheatle Center for Studies of Addiction, University of Pennsylvania, Philadelphia, PA, USA
- **Luke Clancy** TobaccoFree Research Institute Ireland (TFRI), The Digital Depot, Dublin, Ireland
- Jason Cohen Private Practice, San Luis Obispo, CA, USA
- Rick Collins Collins, McDonald & Gann, PC, Mineola, NY, USA
- **Ziva D. Cooper** Division on Substance Abuse, New York State Psychiatric Institute, College of Physicians and Surgeons of Columbia University, New York, NY, USA
- Jack R. Cornelius Western Psychiatric Institute and Clinic, University of Pittsburgh Medical Center, Pittsburgh, PA, USA; Pittsburgh VA Healthcare System, Pittsburgh, PA, USA
- **Jessica M. Cronce** Center for the Study of Health and Risk Behaviors, University of Washington, Seattle, WA, USA
- Elizabeth J. D'Amico RAND Corporation, Santa Monica, CA, USA
- Ann Dadich University of Western Sydney, Sydney, NSW, Australia
- Jack Darkes University of South Florida, Tampa, FL, USA
- Sharon Dawe Griffith University, Nathan, QLD, Australia
- **Menno D.T. de Jong** Institute for Behavioral Research, University of Twente, Enschede, The Netherlands

- George De Leon National Development and Research Institutes (NDRI), New York, USA; NYU School of Medicine, New York, USA
- Frank P. Deane Illawarra Institute for Mental Health, University of Wollongong, Wollongong, NSW, Australia
- Michael L. Dennis Chestnut Health Systems, Chicago, IL, USA
- Ivana Di Leo Research Centre of the Douglas Mental Health University Institute, Verdun, QC, Canada
- **Genevieve Dingle** University of Queensland, St Lucia, QLD, Australia
- Robert E. Drake Dartmouth Psychiatric Research Center, Rivermill Commercial Center, Lebanon, NH, USA
- Sarah Q. Duffy National Institute on Drug Abuse, Bethesda, MD, USA
- William D. Dundon Center for the Studies of Addiction, Philadelphia, PA, USA
- **Alex Z. Esposito** University of Pennsylvania School of Medicine, Philadelphia, PA, USA; Philadelphia Veterans Medical Center, Philadelphia, PA, USA
- **Abigail A. Fagan** Florida State University, Tallahassee, FL, USA
- Ayman Fareed Emory University, Decatur, GA, USA
- James C. Fell Pacific Institute for Research and Evaluation, Calverton, MD, USA
- **Francine Ferland** Centre de réadaptation en dépendance de Québec, Québec, QC, Canada
- **Patrick M. Flynn** Institute of Behavioral Research, Texas Christian University, Fort Worth, TX, USA
- Julian D. Ford University of Connecticut Health Center, Farmington, CT, USA
- William H. George University of Washington, Seattle, WA, USA
- **Tony P. George** Centre for Addiction and Mental Health (CAMH), Toronto, ON, Canada; University of Toronto, Toronto, ON, Canada
- Susan H. Godley Chestnut Health Systems, Chicago, IL, USA
- Mark D. Godley Chestnut Health Systems, Chicago, IL, USA
- Mark S. Gold University of Florida, Gainesville, FL, USA
- **Adam J. Gordon** University of Pittsburgh School of Medicine, Pittsburgh, PA, USA
- **Jordy F. Gosselt** Institute for Behavioral Research, University of Twente, Enschede, The Netherlands
- Michele Gould Institute of Behavioral Research, Texas Christian University, Fort Worth, TX, USA
- **John Grabowski** University of Minnesota, Minneapolis, MN, USA
- **Hollie F. Granato** University of Washington, Seattle, WA, USA
- Jon E. Grant Department of Psychiatry & Behavioral Neuroscience, University of Chicago, Chicago, IL, USA

- Christine Grella University of California, Los Angeles, CA, USA
- Joel R. Grossbard University of Washington, Seattle, WA, USA
- **Kelly Guttman** The Pennsylvania State University, University Park, PA, USA
- Daniel Gwartney Private Practice, Columbia, MO, USA
- **Catherine A. Haighton** Institute of Health and Society, Newcastle University, Newcastle upon Tyne, UK
- **Bahar Haji-Khamneh** Centre for Addiction and Mental Health (CAMH), Toronto, ON, Canada
- Wayne Hall Queensland Brain Institute, Brisbane, QLD, Australia; University of Queensland, UQ Centre for Clinical Research, St Lucia, QLD, Australia
- Margaret Haney Division on Substance Abuse, New York State Psychiatric Institute, College of Physicians and Surgeons of Columbia University, New York, NY, USA
- J. David Hawkins University of Washington School of Social Work, Seattle, WA, USA
- Annemarie Heberlein Medical School Hannover, Clinic of Psychiatry, Socialpsychiatry and Psychotherapy, Center of Addiction Research (CARe), Hannover, Germany
- **Keith Heinzerling** UCLA Substance Abuse Pharmacotherapy Unit, Los Angeles, CA, USA
- **David Herin** University of Minnesota, Minneapolis, MN, USA
- **Michael J. Herkov** University of Florida, Gainesville, FL, USA
- **Aryeh I. Herman** Yale University, VA Connecticut Healthcare System, West Haven, CT, USA
- **Leanne Hides** Queensland University of Technology (QUT), Brisbane, QLD, Australia
- **Amanda E. Higley** The Scripps Research Institute, La Jolla, CA, USA
- **Thomas Hillemacher** Medical School Hannover, Clinic of Psychiatry, Socialpsychiatry and Psychotherapy, Center of Addiction Research (CARe), Hannover, Germany
- Kim A. Hoffman Oregon Health & Science University, Portland, OR, USA
- **Jacqueline K. Holmes** University of Washington, Seattle, WA, USA
- **Max Hopwood** The University of New South Wales, Sydney, NSW, Australia
- Jaime L. Houston Hempfield Behavioral Health, Inc., Harrisburg, PA, USA
- Yvonne Hunt National Cancer Institute, USA
- Sarah B. Hunter RAND Corporation, Santa Monica, CA, USA
- **Irene M. Hurford** University of Pennsylvania School of Medicine, Philadelphia, PA, USA; Philadelphia Veterans Medical Center, Philadelphia, PA, USA
- Bianca Jardin Hollings Cancer Center, Charleston, SC, USA; Medical University of South Carolina, Charleston, SC, USA

- Kent Johnsson Malmoe University, Malmoe, Sweden
- **Alexis M. Jones** University of Minnesota, Division of Epidemiology and Community Health, Minneapolis, MN, USA
- **Eileen F.S. Kaner** Institute of Health and Society, Newcastle University, Newcastle upon Tyne, UK
- Annette Kaufman National Cancer Institute, USA
- **David J. Kavanagh** Institute of Health & Biomedical Innovation, Queensland University of Technology, Brisbane, QLD, Australia
- **Peter J. Kelly** Illawarra Institute for Mental Health, University of Wollongong, Wollongong, NSW, Australia
- Karin E. Kerfoot Yale University, New Haven, CT, USA
- Jason R. Kilmer University of Washington, Seattle, WA, USA
- **Jeffrey B. Kingree** Clemson University, Clemson, SC, USA
- Berma M. Kinsey Veterans Affairs Medical Center, Houston, TX, USA; Baylor College of Medicine, Houston, TX, USA
- Kelly H. Koo University of Washington, Seattle, WA, USA
- **Thomas R. Kosten** Veterans Affairs Medical Center, Houston, TX, USA; Baylor College of Medicine, Houston, TX, USA
- **Margaret M. Krumm** University of Pittsburgh School of Medicine, Pittsburgh, PA, USA
- **Evgeny Krupitsky** St. Petersburg Bekheterv Research Psychoneurological Institute, St. Petersburg, Russia
- Marian E. Lane RTI International, NC, USA
- Mary E. Larimer Center for the Study of Health and Risk Behaviors, University of Washington, Seattle, WA, USA
- **Sandra E. Larios** University of California, San Francisco, CA, USA
- Nerida L. Leal Queensland University of Technology, Brisbane, QLD, Australia
- **David M. Ledgerwood** Wayne State University School of Medicine, Detroit, MI, USA
- **Jonathan C. Lee** Farley Center at Williamsburg Place, Williamsburg, VA, USA
- Christine M. Lee University of Washington, Seattle, WA, USA
- **Wayne E.K. Lehman** Institute of Behavioral Research, Texas Christian University, Fort Worth, TX, USA
- **Kathleen M. Lenk** University of Minnesota, Division of Epidemiology and Community Health, Minneapolis, MN, USA
- **Yue Liao** University of Southern California, Los Angeles, CA, USA
- **Howard A. Liddle** Center for Treatment Research on Adolescent Drug Abuse, University of Miami Miller School of Medicine, FL, USA
- Mark D. Litt University of Connecticut Health Center, Farmington, CT, USA

- **Diane Logan** University of Washington, Seattle, WA, USA
- **Ty W. Lostutter** University of Washington, Seattle, WA, USA
- Natalie J. Loxton University of Queensland, St Lucia, QLD, Australia
- Jayne Lucke University of Queensland, UQ Centre for Clinical Research, St Lucia, QLD, Australia
- Janice Lybrand Philadelphia Veterans Medical Center, Philadelphia, PA, USA
- Geoffrey C.B. Lyons Illawarra Institute for Mental Health, University of Wollongong, Wollongong, NSW, Australia
- Kimberly Mallett The Pennsylvania State University, University Park, PA, USA
- **Stephan C. Mann** Central Montgomery MH/MR Center, Norristown, PA, USA
- **Jennifer K. Manuel** University of California, San Francisco, CA, USA
- **Douglas B. Marlowe** University of Pennsylvania, Chadds Ford, PA, USA
- Lisa A. Marsch Center for Technology and Behavioral Health, Dartmouth Psychiatric Research Center, Department of Psychiatry, Geisel School of Medicine at Dartmouth, Lebanon, NH, USA
- Steve Martino Yale University School of Medicine and VA Connecticut Healthcare System, West Haven, CT, USA
- **Barbara J. Mason** The Scripps Research Institute, La Jolla, CA, USA
- **Nadine R. Mastroleo** Center for Alcohol and Addiction Studies, Brown University, Providence, RI, USA
- **Bradley Mathers** The Kirby Institute, University of New South Wales, Sydney, NSW, Australia
- **Dennis McCarty** Oregon Health & Science University, Portland, OR, USA
- **Delinda Mercer** Behavioral Health Unit, Scottsbluff, NE, USA
- **Robert J. Meyers** University of New Mexico, Albuquerque, NM, USA
- **Jeremy N.V. Miles** RAND Corporation, Santa Monica, CA, USA
- **Marc Mooney** University of Minnesota, Minneapolis, MN, USA
- Benjamin J. Morasco Mental Health and Clinical Neurosciences Division, Portland VA Medical Center, OR, USA; Department of Psychiatry, Oregon Health & Science University, OR, USA
- **Kim T. Mueser** Center for Psychiatric Rehabilitation, Boston, MA, USA
- Joan A. Muir University of Miami, Miami, FL, USA
- **Toben F. Nelson** University of Minnesota, Division of Epidemiology and Community Health, Minneapolis, MN, USA

- **Dorothy Newbury-Birch** Institute of Health and Society, Newcastle University, Newcastle upon Tyne, UK
- **Howard Newville** University of California, San Francisco, CA, USA
- **Hong V. Nguyen** University of Washington, Seattle, WA, USA
- Lisa Nicholson Chestnut Health Systems, Chicago, IL, USA
- **Douglas L. Noordsy** Dartmouth Medical School, Lebanon, NH, USA
- **Timothy J. O'Farrell** Harvard Medical School, Brockton, MA, USA
- **Brian L. Odlaug** Department of Public Health, University of Copenhagen, Copenhagen, Denmark
- Frank M. Orson Veterans Affairs Medical Center, Houston, TX, USA; Baylor College of Medicine, Houston, TX, USA
- Susan M. Paddock RAND Corporation, Santa Monica, CA, USA
- Keryn E. Pasch University of Texas, Austin, TX, USA
- **Ashwin A. Patkar** Duke University Medical Center, Durham, NC, USA
- Eric R. Pedersen RAND Corporation, Santa Monica, CA, USA
- Ismene L. Petrakis Yale University, New Haven, CT, USA
- **Helen M. Pettinati** Center for the Studies of Addiction, Philadelphia, PA, USA
- **Guillermo Ponce** Hospital Universitario 12 de Octubre, Madrid, Spain
- William R. Ponicki Prevention Research Center, Pacific Institute for Research and Evaluation, Berkeley, CA, USA
- **Muthu Ramakrishnan** Veterans Affairs Medical Center, Houston, TX, USA; Baylor College of Medicine, Houston, TX, USA
- **Heleen Riper** VU University Amsterdam, Amsterdam, the Netherlands and Leuphana University, Luneburg, Germany
- **Michael S. Robbins** Oregon Research Institute, Eugene, OR, USA
- Damaris J. Rohsenow Brown University, Providence, RI, USA
- Paul M. Roman Owens Institute for Behavioral Research, University of Georgia, Athens, GA, USA
- **Gabriel Rubio** Hospital Universitario 12 de Octubre, Madrid, Spain
- Elizabeth J. Santa Ana Charleston VA Medical Center, Charleston, SC, USA; Medical University of South Carolina, Charleston, SC, USA
- **Liana R.N. Schreiber** University of Minnesota Medical Center, Minneapolis, MN, USA
- **Jeremiah A. Schumm** Cincinnati VA Medical Center and University of Cincinnati, Fort Thomas, KY, USA
- Seth J. Schwartz University of Miami, Miami, FL, USA

- Christy K. Scott Chestnut Health Systems, Chicago, IL, USA
- Brian Serna Isleta Behavioral Health Services, Isleta, NM, USA
- **Ashli J. Sheidow** Family Services Research Center, Medical University of South Carolina, Charleston, SC, USA
- **Steven Shoptaw** David Geffen School of Medicine, UCLA, Los Angeles, CA, USA
- Jane Ellen Smith University of New Mexico, Albuquerque, NM, USA
- **Mehmet Sofuoglu** Yale University, VA Connecticut Healthcare System, West Haven, CT, USA
- **David W. Soole** Queensland University of Technology, Brisbane, QLD, Australia
- **James L. Sorensen** University of California, San Francisco, CA, USA
- Michael Soyka Ludwig Maximilian University Munich, Munich, Germany; Private Hospital Meiringen, Meiringen, Switzerland
- **Tim Stockwell** Centre for Addictions Research of British Columbia, University of Victoria, BC, Canada
- **Steve Sussman** University of Southern California, Los Angeles, CA, USA
- José Szapocznik University of Miami, Miami, FL, USA
- Robert Tait The Australian National University (ANU), Centre for Mental Health Research, Canberra, ACT, Australia
- Tony Toneatto University of Toronto, Toronto, ON, Canada
- **Traci L. Toomey** University of Minnesota, Division of Epidemiology and Community Health, Minneapolis, MN, USA
- Carla Treloar The University of New South Wales, Sydney, NSW, Australia
- **Rob Turrisi** The Pennsylvania State University, University Park, PA, USA
- **Joris J. van Hoof** Institute for Behavioral Research, University of Twente, Enschede, The Netherlands
- **Lindsey Varvil-Weld** The Pennsylvania State University, University Park, PA, USA
- **Cayley E. Velazquez** University of British Columbia, Vancouver, BC, Canada
- **Holly Barrett Waldron** Oregon Research Institute, Eugene, OR, USA
- **Denise D. Walker** Innovative Programs Research Group, University of Mexico, Mexico City, Mexico
- **Barry C. Watson** Queensland University of Technology, Brisbane, QLD, Australia
- **Ursula Whiteside** Group Health Research Institute, Seattle, WA, USA
- Belinda Willis Chestnut Health Systems, Chicago, IL, USA
- **Briana A. Woods** University of North Carolina, Chapel Hill, NC, USA

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Preface

Principles of Addiction is one of three volumes encompassing the 2500 page series.

Comprehensive addictive behaviors and disorders: In both print and online formats, this series provides the most comprehensive compilation of current knowledge on addictive behaviors and disorders to date. In short, it is the definitive reference work on addictions.

The significance of this series stems from the fact that addictive behaviors and disorders represent major personal, social, and public health problems throughout the world. While research on addictions has grown exponentially over the past 20 years, the primary literature in this field is widely dispersed. For researchers and clinicians, staying abreast of this vast and expanding knowledge is a challenging, if not impossible, task. Researchers specializing in one addiction subspecialty (e.g. clinical research, neuroscience, health services, public policy, treatment, pharmacology, genetics) are unable to keep apprised of the big picture. In addition, research findings on one type of addiction (e.g. alcohol dependence, excessive gambling, methamphetamine dependence) may have relevance to other types (e.g. cocaine or opiate dependence) but such findings are not readily available to all addiction scientists since they are dispersed among so many specialty journals, books and web sites. Until now, there has been no allencompassing resource that could serve as the "go-to" compendium for information on any and all addictions.

Comprehensive addictive behaviors and disorders fills this void by providing a unique and valuable storehouse of interdisciplinary scientific information for researchers, clinicians, and policy makers that comprehensively summarizes state-of-the-art knowledge. The terms "behavior" as well as "disorder" are used purposefully in the title since the work includes both excessive use (what is often called "at risk" or "harmful" use) as well as true physiological dependence. In addition, there is lack of evidence and some controversy over the issue of whether or not some behavioral excesses (e.g. texting or video gaming) can be classified as true addictions. Finally a number of the more basic, translational chapters cover addictive brain or behavioral processes rather than focusing on "disorders" per se.

Conceptually, the three volumes that make up this series, *Principles of Addiction*, *Biological Research on Addiction*, and *Interventions for Addictions*, cover an extensive

range of topics including, but not limited to, the nature of addiction, cravings, comorbidities, types of addictions, behavioral biology, neuroscience, neuroimaging, genetics, neuropharmacology, psychosocial treatments, addiction medications, application of addiction science to practice, public policy, and prevention. With the growing emphasis on translational research, the goal has been to integrate diverse findings into a meaningful conceptualization of all aspects of use and abuse.

The audience for the series includes advanced undergraduates, graduates and postdoctoral students, professors, researchers, clinicians and policy makers. The series can also serve as a valuable aid to instructors and students in the hundreds of university-level addiction degree programs throughout the world. As an encyclopedic series, the mass media as well as the general public will find this work to be a comprehensive source of evidence-based, scientific information on addictions. This is especially important since the field of addiction is continually plagued by anecdotal and misleading information found both in print and online.

SCOPE AND FORMAT

The development and compilation of this series has been a truly collaborative effort. Nine internationally recognized addiction experts have served on the editorial board for this project. The board is composed of Peter Miller, PhD, Medical University of South Carolina; Mary Larimer, PhD, University of Washington; Kyle Kampman, MD, University of Pennsylvania School of Medicine; David Kavanagh, PhD, Queensland University of Technology; Samuel Ball, PhD., Yale University School of Medicine; Phillipe DeWitte, MD, Université Catholique de Louvain (Belgium); Marsha Bates, PhD, Rutgers University; Nancy Petry, PhD, University of Connecticut Health Center; and Arthur Blume, PhD, Washington State University. The board members were chosen to provide a wide range of interdisciplinary expertise.

The board members were responsible for selecting and inviting authors for chapters in their specialty areas and to provide editorial guidance. Chapters are authored by reputable, well-recognized authorities in the addictions field. Authors were selected for their **viii** Preface

expertise and experience, with particular emphasis placed on selecting an international group with diverse philosophies and research backgrounds.

Each chapter is approximately 6500 words in length. Chapters consist of approximately 10 printed pages each, ranging from 5 to 15 pages depending on the topic. Many chapters include tables and figures to better illustrate data. Authors were asked to summarize current knowledge in their areas without providing references within the text. Thus, the work reads like an encyclopedia, providing the reader with an overview of the state-of-the-art rather than an in-depth research report. A further reading and web site list are provided at the end of each chapter for those who require research references and more detailed information. In addition, an outline, glossary, list of keywords, and list of cross-references are provided for each chapter.

The hope is that this compendium will provide a universal platform for a more science-based approach to the study, prevention and treatment of addictions. The ultimate goal is to improve the lives of addicted individuals and their families throughout the world through a more comprehensive and detailed understanding of the addictive process.

VOLUME 3: INTERVENTIONS FOR ADDICTIONS

This third volume, *Intervention for Addictions*, provides chapters on psychosocial treatments, pharmacological treatments, provision of health care to addicted individuals, prevention, and public policy issues. Basically, this volume contains the practical application of the information in Volumes 1 and 2.

Historically, because of the lack of scientific studies at the time, treatment of addiction was based almost exclusively on personal familiarity (especially by counselors who were recovering addicts) and clinical experience. While this was standard care at the time such intuitive treatment has become increasingly unacceptable. The current emphasis on cost-effectiveness and accountability has led to a shift toward science-based treatments, i.e. treatments for which there is significant research evidence of effectiveness. Chapters in this volume describe each of these treatments, together with details of their use and evidence of their efficacy.

Chapters focus on both psychosocial treatments as well as pharmacological ones. Psychosocial chapters cover a wide range of treatment methods, ranging from traditional ones such as self-help/12-step programs to newer, innovative treatments such as contingency management. Chapters include a variety

of treatments from simple, time-efficient ones such as brief feedback (used primarily with nondependent heavy drinkers or binge drinkers) to more involved treatments including cognitive behavior therapy and multidimensional family therapy. The list of chapters on psychosocial treatments is extensive and includes not only widely used methods but also such specialized treatments as internet-based therapies, faith-based methods, criminal justice interventions, and mindfulness treatments. More challenging treatments such as those involving addicted individuals with psychiatric comorbidities are also included.

More recently, pharmacological treatments have been combined with psychosocial methods in an attempt to improve therapeutic efficacy. The explosion of neurobiological research on addictions (as provided in Volume 2) has led to the development and evaluation of new compounds that have shown great promise with some substances of abuse. For example, naltrexone, acamprosate, and topiramate have been used successfully to decrease cravings and relapse in individuals with alcohol dependence. Nicotine replacement preparations as well as sustained-release bupropion and varenicline are available for the treatment of tobacco use and, recently, buprenorphine has dramatically improved the treatment of opiate abuse. Chapters on pharmacotherapies for each of the major substances of abuse as well as for behavioral addictions are included in this volume.

Another important issue that is addressed in this volume is the time gap between the development of both psychosocial and pharmacological treatments and their use in everyday practice by clinicians. Many are examining the barriers to practical implementation and, based on this information, are developing strategies to overcome them.

In addition to science-based treatments and their routine use in clinical practice, public policy and prevention are also important issues. Countries throughout the world, often with the help of the World Health Organization (WHO), are trying to prevent or slow the progress of addictions by focusing on legislative action, price controls, and limitations on advertising. In Europe, ALICE RAP, Addictions and Lifestyles in Contemporary Europe – Reframing Addictions Project, is an innovative and dynamic transdisciplinary European Union project that aims to help policy makers rethink and reshape current and future approaches to the human and economic costs of addictions and lifestyles in Europe. Receiving input from over 126 researchers (many of whom are authors of chapters in this volume) and 73 major research institutions representing 31 countries, this project will analyze a wide range of multidisciplinary PREFACE ix

factors related to addiction to improve its prevention and treatment. This project is truly a prototype for advancing public policy interventions aimed at addictive behaviors and disorders.

Overall, this volume provides a detailed picture of the myriad of science-based interventions available for the treatment of addiction. With the expanding growth of neurobiological research, newer and more effective pharmacological treatments should be available on the near horizon. Public policy interventions are increasingly being based on the scientific literature rather than political ideologies, leading to more effective prevention interventions throughout the world.

Peter M. Miller

Editors: Biographies

Peter Miller

Peter M. Miller, PhD, is a professor of psychiatry and behavioral sciences in the Center for Drug and Alcohol Programs at the Medical University of South Carolina. He also holds a faculty appointment in the College of Dental Medicine. He is a clinical psychologist and is board certified by the American Board of Professional Psychology. He specializes in research on alcohol and substance abuse screening and intervention in medical and dental settings, with particular reference to alcohol-sensitive diseases such as hypertension and oral cancer. He has published over 100 scientific articles, has authored 11 books and has served as editor on major addictions textbooks and reference works. He is editor in chief of two international research journals, Addictive Behaviors and Eating Behaviors, and serves on several editorial boards. He is past president of the International Society of Addiction Journal Editors (ISAJE).

Samuel Ball

Samuel A. Ball, PhD, is a professor and assistant chair for education and career development in the Department of Psychiatry at Yale University School of Medicine. He also serves as research director for the NIDA-funded Psychotherapy Development Research Center, NIH-funded BIRCWH Women's Health and Addictive Behaviors program, and The APT Foundation in New Haven, CT. His research focuses on the assessment and treatment implications of personality dimensions, personality disorders, and multidimensional subtypes in substance abuse.

Arthur Blume

Arthur W. Blume is a professor of psychology at Washington State University. Before joining the faculty at Washington State University, Dr Blume was on the faculty at the University of North Carolina at Charlotte and before that at the University of Texas at El Paso. He currently serves as a section editor for this volume, and as an associate editor of the journals *Addictive Behaviors* and *Cultural Diversity and Ethnic Minority Psychology*. From 2007 to 2009, he was an American Indian representative on the National Committee on Ethnic Minority Affairs of the American Psychological Association in the United States. His program of research has focused on addictive behaviors among high-risk populations, especially those from ethnic minority groups in the United States. His extramurally funded research and

publications reflect his keen interests in ethnic minority health and well-being.

David Kavanagh

David Kavanagh, PhD, is a research capacity-building professor in the Institute and Health & Biomedical Innovation and School of Psychology & Counselling at Queensland University of Technology, and has adjunct posts at the University of Queensland and Griffith University. He was educated at Sydney and Stanford Universities and led a community mental health service before becoming an academic. He has researched and written widely on addiction, comorbidity and dissemination of evidence-based treatments and is currently researching the elicitation and maintenance of functional motivation. He has been on the editorial boards of several journals, including *Addiction and Addictive Behaviors*, and has served on several state and national expert committees on comorbidity and addiction.

Kyle Kampman

A board-certified psychiatrist specializing in addiction psychiatry, Dr Kyle M. Kampman, MD, received his medical degree from Tulane University School of Medicine. He completed his residency in psychiatry and fellowship in addiction psychiatry at the University of Pennsylvania. Currently, he is a medical director of the Charles O'Brien Center for the Treatment of Addictions, professor of psychiatry, and medical director of the Treatment Research Center at the University of Pennsylvania in Philadelphia. His research interests include pharmacotherapy for cocaine dependence and the cocaine withdrawal syndrome. He is an associate editor of Drug and Alcohol Dependence. He serves on the editorial board of the Journal of Addiction Medicine and is an active member of the American Society of Addiction Medicine, College on Problems of Drug Dependence, and the Pennsylvania Society of Addiction Medicine. His contributions to the field have been acknowledged by the Scott Mackler Award for Excellence in Substance Abuse Teaching presented by the University of Pennsylvania School of Medicine and the Caron Foundation's Medical Professional-Physician Award.

Marsha E. Bates

Marsha E. Bates, PhD (Rutgers – the State University of New Jersey), is a research professor of psychology at the Center of Alcohol Studies (CAS) at Rutgers

University and an associate professor of psychiatry at UMDNI/Robert Wood Johnson Medical School. She directs the Cognitive Neuroscience Laboratory that promotes translation between basic human experimental and clinical science. Her current multiinstitution research project is a component of the NIAAA Mechanism of Behavior Change Interdisciplinary Research Consortium (MIRC) which seeks to build novel approaches to alcohol-related problems via mechanism-based strategies. Dr Bates is vice-chair of the Rutgers Institutional Review Board for the Protection of Human Subjects involved in research. She is a member of the Behavioral and Social Advisory Council of ABMRF/The Foundation for Alcohol Research and vice-chair of the Board of Trustees of Alcohol Research Documentation, Inc. She is an editorial board member of the Journal of Studies on Alcohol and Drugs and a past associate editor of Psychology of Addictive Behaviors and Alcoholism: Clinical and Experimental Research. She is a fellow of the American Psychological Association (APA), previously served as president of APA Division 50 (Society of Addiction Psychologists), and received their 2011 Distinguished Scientific Contribution Award. Address: Center of Alcohol Studies, Rutgers the State University of New Jersey, 607 Allison Road, Piscataway, NJ 08854, USA; E-mail: mebates@rutgers. edu.

Mary Larimer

Mary E. Larimer is a professor of psychiatry and behavioral sciences, an adjunct professor of psychology, associate director of the Addictive Behaviors Research Center, and director of the Center for the Study of Health and Risk Behaviors at the University of Washington. She received her PhD in clinical psychology from the University of Washington and has been a member of the faculty since 1995. Dr Larimer's research and clinical interests include (1) prevention and treatment of alcohol and drug problems among adolescents and young adults (with a particular focus on college drinking prevention), (2) cross-cultural research regarding prediction of initiation of drinking and trajectories of alcohol and substance use during emerging adulthood, (3) comorbidity of substance use with depression, suicide, trauma, PTSD, disordered eating, and gambling problems, (4) evaluation of housing and treatment programs for chronically homeless and incarcerated individuals, and (5) dissemination of evidence-based prevention and treatment approaches into clinical-, school-, and work-site settings. She has published more than 100 articles and book chapters on these topics.

Nancy M. Petry Nancy Petry is a professor of medicine at the Univer-

sity of Connecticut Health Center, and she earned her PhD in psychology from Harvard University. She developed the prize reinforcement system that has been widely disseminated in the context of treating substance use disorders and is now being applied to address other conditions including overweight/obesity, exercise, medication adherence, and diabetes. She also conducts research related to pathological gambling and its treatment.

Philippe De Witte

Professor De Witte heads the Laboratory of Behavioural Biology at the Université Catholique de Louvain. In 1987, he received a Fulbright grant to complete a specialization in brain research at the NIH. He has also worked as invited professor in Washington State University and the University of Colorado.

He is the editor in chief of Alcohol and Alcoholism and on the editorial advisory board of a number of leading journals. He was president of the European Society for Biomedical Research on Alcoholism (ESBRA) for two terms from 1993 to 2001 and was the president of the International Society for Biomedical Research on Alcoholism (ISBRA, 1998-2002). He joined the ERAB Advisory Board in 2003 and became chairman on 1 January 2007.

His research interests include pharmacology and neurobiology of addiction including therapeutics and treatments. He is a member of a number of professional bodies including ESBRA, ISBRA, RSA, The Belgian College of Neuropsychopharmacology and Biological Psychiatry (BCNBP) and the Société française d'Alcoologie (SFA) and has published over 200 articles in scientific journals, twice as many abstracts and book chapters.

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