Adherence to Pediatric Medical Regimens

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To Kim
Who I always love, therefore I always need

To Lindsey and Nathan
Our hope for the future and the joys of our lives

To Andrew and Shirley Rapoff
For good beginnings

To M. A. Groff
For showing me how to love and respect children

Preface

Medications don't always work like they should, transplanted organs are rejected, bacteria develop resistance to previously effective antibiotics, and physicians are hampered in their ability to judge the efficacy of treatments they have prescribed. What factors could account for these alarming trends in medicine? One significant factor is that patients and their families don't always adhere to prescribed treatments. Why this is the case and what can be done about it is the subject of this book.

Adherence has been defined as "the extent to which a person's behavior (in terms of taking medications, following diets, or executing lifestyle changes) coincides with medical or health advice" (Haynes, 1979, pp. 1–2). This is the most widely quoted definition in the literature because it specifies several important elements related to adherence:

- It brings the focus on specific behaviors that are required of a prescribed medical regimen. Patients are asked to do specific things, like take medications and follow diets. Specifying behavioral requirements of regimens is a necessary prelude to assessing and improving adherence.
- The word *extent* is an important qualifier related to adherence. It conveys that adherence is not a dichotomous, all-or-nothing phenomenon. There are qualitative and quantitative differences in adherence. For example, nonadherence to medications can take many forms, such as never filling the prescription, omitting doses, doubling up on missed doses, or even overdosing.
- This definition also focuses on the concordance between what patients are being asked to do and what they actually do (if their behavior "coincides" with advice they are given). This implies that there is a standard for judging whether adherence is acceptable or not. This "standard," however, has been rather arbitrary. More data are needed to develop standards that specify the level of adherence necessary to produce acceptable clinical outcomes for most medical regimens.

Before proceeding with this discussion of medical adherence in pediatrics, several caveats are in order:

1. *It is incumbent on medical providers that they are asking patients to adhere to regimens with demonstrated efficacy.* Providers need to remind themselves of the Hippocratic oath: "I will follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous" (as cited in Cassell, 1991, p. 145).

2. *Providers need to abandon the "blame and shame" approach to dealing with medical adherence problems.* It is tempting to blame patients for adherence failures and shame them into changing their behavior. Providers need to share the blame (or better yet omit blame) and look at their own attitudes and behaviors that impact adherence. For example, failing to simplify regimens or minimize negative side effects can adversely impact patient adherence.

3. *Patients and their families are no longer (or maybe were never) satisfied with a passive role in their health care.* In fact, the term *compliance* lost favor in the literature because it implied for some an authoritarian approach to health care that required unquestioned obedience by patients to provider recommendations (DiMatteo & DiNicola, 1982). Comprehensive and effective health care requires a cooperative relationship between providers and patients and their families. It also acknowledges the following realities, particularly for treating persons with chronic illness:

"Doctors do not treat chronic illnesses. The chronically ill treat themselves with the help of their physicians; the physician is part of the treatment. Patients are in charge of themselves. They determine their food, activity, medications, visits to their doctors—most of the details of their own treatment" (Cassell, 1991, p. 124).

4. *It is possible that nonadherence to prescribed regimens may be strategic, rational, and adaptive in certain cases* (Deaton, 1985). The "culture of medical practice" rests on the assumption that patients or their parents seek medical advice and will follow this advice with reasonable fidelity (Vandereycken & Meermann, 1988). Scientifically trained providers find it difficult to understand why people would seek advice, receive empirically validated advice, and then not follow it. Indeed, this does appear to be irrational behavior on the part of patients or their families. But medical treatments sometimes have serious side effects, do not produce anticipated outcomes, or patients find acceptable substitutes. In certain cases, nonadherence becomes rational. As Cousins (1979) observed: "The history of medicine is replete with accounts of drugs and modes of treatment that were in use for many years before it was recognized that they did more harm than good."

5. *Finally, children are not little adults.* Pediatric adherence issues are arguably more complex than with adults because of the influences of family members and peers. There are also developmental processes and constraints that uniquely affect adherence for children and adolescents. Caution is in order when theoretical and empirical work with adults is extrapolated to pediatric patients.

This volume is intended to give primary and allied health care providers, researchers, and students an overview of the topic of medical adherence in pediat-

rics. Chapter 1 reviews the prevalence and potentially serious consequences of adherence problems. There is also an overview of patient, family, disease, and regimen correlates or predictors of adherence. Chapter 2 is a review and critique of adherence theories, such as self-efficacy theory, and applications to clinical examples. Chapter 3 provides a critical overview of ways to assess adherence, including drug assays and electronic monitoring devices. There are also examples of adherence assessment formats that can be used by clinicians. Because the desired outcome of adherence interventions and research is that patients get better, feel better, and do better, Chapter 4 reviews both traditional and quality of life approaches to measuring disease and health status outcomes. Chapter 5 is an overview of educational, organizational, and behavioral strategies for improving adherence to acute and chronic disease regimens. Practical strategies are outlined and actual adherence-enhancing protocols are provided for use by clinicians. Chapter 6 concludes with a summary and critique of adherence intervention studies that focus on acute and chronic pediatric diseases. There are also recommendations for improving research and clinical approaches to assessing and enhancing adherence.

I would like to acknowledge the people who have helped shape the contents of this book and my career in pediatric psychology. I appreciate the feedback and patience of the series editors Drs. Michael Roberts and Annette La Greca, particularly their challenging me to make this book clinician-friendly. I thank my mentor, Dr. Ed Christophersen, for giving me my first opportunities and training in pediatric psychology. I thank my valued physician colleague and collaborator, Dr. Carol Lindsley, for giving me the support and setting for studying ways to help children and adolescents with rheumatic diseases adhere to medical treatments and cope with the demands of a chronic illness. I am also very grateful to the patients and families who have participated in our studies and have given me more than I could give them. Former students who made significant contributions to our research program on medical adherence include Drs. Kathryn Pieper and Mark Purviance and Ms. Joni Padur. I thank them for their efforts and for tolerating me. I am also grateful to the Arthritis Foundation and Bureau of Maternal and Child Health for funding my research on pediatric medical adherence. Finally, a special thanks to my close friend and colleague, Dr. Pat Friman, who critically reviewed parts of this manuscript. Knowing him has helped me strive to be a better thinker and a better person.

Contents

1

Medical Nonadherence Prevalence, Consequences, and Correlates

A 10-year-old boy with asthma presents in the emergency room looking pale, having extreme problems breathing, and is admitted to the intensive care unit. After several days, his asthma is stabilized and he is sent home. This pattern has been repeated several times over the past several years for this boy. He and his mother report that he "usually" takes all of his prescribed inhaled and oral medications to treat his asthma and rarely misses a dose. His pulmonary function test results, his frequent visits to the emergency room, and his repeated hospitalizations would suggest otherwise.

Sadly, the above scenario is familiar to most clinicians. Less than optimal adherence to medical regimens has been described as the "the best documented but least understood health-related behavior" (Becker & Maiman, 1975, p. 11). There is now over 20 years of accumulated evidence that speaks to the ubiquity of adherence problems in the treatment of acute and chronic diseases children and adults (Rapoff & Barnard, 1991). This chapter will review the prevalence, consequences, and correlates of nonadherence to medical regimens in pediatrics. Clinical implications will be drawn from the literature on correlates of adherence.

LEARNER OBJECTIVES

- Describe the range of prevalence estimates for nonadherence to acute and chronic disease regimens in pediatrics.
- Identify the negative consequences of nonadherence to medical regimens including health, economic, clinical decision-making, and treatment outcome research.
- Describe patient, family, disease, and regimen factors associated with adherence to medical regimens and their implications for intervention.

PREVALENCE OF NONADHERENCE TO MEDICAL REGIMENS

The prevalence of nonadherence to medical regimens varies according to the patient sample, what behavior is assessed, how adherence is assessed, and the criteria for classifying patients as adherent or nonadherent. There is general agreement that nonadherence is a much greater problem with chronic versus acute regimens. General estimates are that about one-third of patients fail to adequately adhere to acute regimens while the figure for chronic disease regimens is between 50 and 55% (Rapoff & Barnard, 1991).

Nonadherence to Acute Disease Regimens

Rates of nonadherence show considerable variability to medications for acute diseases, reflecting how and when adherence was assessed (see Table 1.1). These estimates also vary by the criterion set by the investigator for classifying patients as nonadherent (or adherent). Consider a 10-day course of antibiotics for the treatment of otitis media. In one study, 53% of patients were nonadherent based on the criterion of taking less than half of the prescribed amount (Mattar, Marklein, & Yaffe, 1975). In another study, 5 or 11% of patients (depending on the medication) were nonadherent based on the criterion of taking less than 80% of medications (McLinn, McCarty, Perrotta, Pichichero, & Reindenberg, 1995). Thus, different criteria yield different estimates. Also, these criteria are arbitrary because no biologic basis for determining optimal levels of adherence (in terms of producing acceptable therapeutic effects) has been established for most medical regimens (Gordis, 1979).

Another interesting point about acute disease regimens is that adherence tends to drop over the course of a 10-day regimen (see Table 1.1). This drop makes sense, as children usually start to feel better after the third or fourth day of a 10-day course of antibiotics, which removes a major impetus for adherence (symptom relief) for patients and their parents. It also argues for clinicians to monitor adherence over the course of a regimen to determine when adherence starts to decline and to time adherence interventions to coincide with this decline.

Nonadherence to Chronic Disease Regimens

There is also considerable variability in nonadherence rates for chronic disease regimens depending on the disease, regimen requirements, measure of adherence, and the criteria for classifying patients along adherence dimensions (see Table 1.2). The majority of studies measured adherence to medications for asthma and to diabetes regimen components, such as dietary modifications and glucose monitoring. Despite this focus on a few diseases and methodological variations between studies, several conclusions can be made.

Table 1.1. Rates of Nonadherence to Medications for Acute Diseases in Pediatrics

Reference	Sample	Disease and regimen	Adherence measure	Results
Bergman & Werner (1963)	*n*=59 *Mdn* =2.5 yr	Pharyngitis or otitis media Penicillin for 10 days	Pill Counts Urine Assay	>50% stopped taking medications by the 3rd day, 71% by the 6th day, and 82% by the 9th day
Charney et al. (1967)	*n*=459 *Mdn* =5 yr	Pharyngitis or otitis media Penicillin for 10 days	Pill counts Urine Assay	44% failed to complete the 10-day course; 19% were not taking medication on the 5th day
Daschner & Marget (1975)	*n*=105 1.5–13.5 yr	Recurrent urinary tract infections Antibiotics	Urine assay (twice weekly for 1 week)	29% were "nontakers" and 39% were "irregular"
Dickey et al. (1975)	*n*=100 1–12 yr	Otitis media Penicillin for 10 days	Pill Counts Interviews	5% completed the 10-day course; 59% took less than half of the prescribed amount
Disney et al. (1979)	*n*=75 4–16 yr	Group A streptococcal pharyngitis Penicillin V or cefaclor	Urine assay	100% of children had antibiotic present in urine on days 5–8 of treatment
Feldman et al. (1988)	*n*=221 (203 evaluated for adherence) *M* =5.1 yr	Otitis media amoxicillin or trimethoprim–sulfamethoxazole (10-day course)	Bottle measurement (volume of liquid medication) at home visit	16% of amoxicillin patients and 8% of trimethoprim–sulfamethoxazole patients received <80%
Gerber et al. (1986)	*n*=195 2–25 yr	Group A streptococcal pharyngitis Penicillin V (t.i.d.) or cefadroxil (q.d.) for 10 days	Urine assay on 9th day of therapy	12% on penicillin 4% on cefadroxil had negative test for presence of drug
Ginsburg et al. (1982)	*n*=198 2–15 yr	Group A streptococcal pharyngitis penicillin V, penicillin G, cefadroxil, or erythromycin	Urine Assay	6% of children tested negative

(*continued*)

Table 1.1. (*Continued*)

Reference	Sample	Disease and regimen	Adherence measure	Results
Goldstein & Sculerati (1994)	*n*=77 0–11 yr	Otitis media Prophylactic antibiotics	Parent report	23.4% of parents admitted nonadherence
Gordis et al. (1969)	*n*=136	Children with history of rheumatic disease Penicillin prophylaxis	Urine assay Interviews	36% of children were noncompliers, 32% were intermediate compliers, 32% were compliers
Henness (1982)	*n*=198 *M* =7 yr	Streptococcal pharyngitis Penicillin, erythromycin, or cefadroxil	Urine Assay (5th day of therapy)	6% of children tested negative
Mattar et al. (1975)	*n*=100 1–12 yr	Otitis media Antibiotics (10-day course)	Bottle measurement (volume of liquid medication)	59% took less than half of the prescribed medication; only 5% completed the full 10-day course
Mclinn et al. (1995)	*n*=296 6 mos–8 yr	Otitis media Ceftibuten or amoxicillin (10-day course)	Bottle weights	5% of ceftibuten patients and 11% of amoxicillin patients received <80% of medication
Pichichero et al. (1987)	*n*=150 4–12 yr	Streptococcal pharyngitis Cefadroxil or penicillin	Pill Count Medication Diaries	7 of 145 (5%) patients assessed did not complete the 10-day course
Rabinovich et al. (1973)	*n*=118 children (no age range given)	Streptococcal pharyngitis Penicillin G, penicillin V, or cephalexin	Urine Assay	Of the 74 patients who had an assay, 11% tested negative for presence of drug in urine
Schwartz et al. (1981)	*n*=105 2 mos–17 yr (*M*= 44 mos)	Otitis media Antibiotics (10-day course)	Urine Assay (obtained on days 4, 7, and 10 of regimen)	18% had negative tests for two of three assays

Table 1.2. Rates of Nonadherence to Regimens for Chronic Diseases in Pediatrics

Reference	Sample	Disease and regimen	Adherence measure	Results
Cluss et al. (1984)	*N*=22 7–12 yr	Asthma Theophylline	Urine assay	50% nonadherent
Coutts et al. (1992)	*N*=14 9–16 yr	Asthma Inhaled Prophylactic Medication	Automated chronolog	Underuse of medications recorded on 55% of study days; overuse on 2% of study days
Eney & Goldstein (1976)	*N*=43 3–16 yr	Asthma Theophylline	Serum assay	88% of sample had subtherapeutic levels
Miller (1982)	*N*=21 12–17 yr	Asthma Theophylline	Serum assay	90% had subtherapeutic levels
Radius et al. (1978)	*N*=80 9 mo-17 yr	Asthma Theophylline	Serum assay	34% had negative values
Sublett et al. (1979)	*N*=50 8 mo-14 yr	Asthma Theophylline	Serum assay	98% had subtherapeutic levels
Wood et al. (1985)	*N*=111 1–20 yr	Asthma Theophylline	Serum assay Caretaker report	34% nonadherent
Zora et al. (1989)	*N*=17 5–13 yr	Asthma Metaproterenol delivered via metered-dose inhaler	Canister weighing Patient/family diaries	3 of 5 children completing 2 weeks of treatment were nonadherent (60%); 11 of 12 children completing 4 weeks of treatment were nonadherent (92%)
Festa et al. (1992)	*N*=50 (2 samples with *M*=15.6 yr and *M*=19.1 yr)	Cancer Prednisone (*N*=21) for ALL Penicillin (*N*=29) for postsplenectomy prophylaxis	Serum assay for prednisone Urine assay for penicillin	52% nonadherent to prednisone 48% nonadherent to penicillin
Lansky et al. (1983)	*N*=31 2–14 yr	Cancer Prednisone	Urine assay	42% had subtherapeutic levels
Lau et al. (1998)	*N*=24 (*M*=7.3 yr)	Cancer 6-MP	Electronic monitor	17% nonadherent

(*continued*)

Table 1.2. (*Continued*)

Reference	Sample	Disease and regimen	Adherence measure	Results
Phipps & DeCuir-Whalley (1990)	*N*=54 1 mo-20 yr	Cancer Antibiotics as part of bone marrow transplant protocol	Review of patient chart and notes from psychosocial team meetings	"Significant" adherence difficulties identified in 52% of sample
Smith et al. (1979)	*N*=52 8 mo-17 yr	Cancer Prednisone	Urinary assay (17 kg/creatine ratio <18.7 defined as subtherapeutic)	33% had subtherapeutic levels
Tebbi et al. (1986)	*N*=46 2.5–23 yr (*M*=6.85 yr)	Cancer Prednisone	Patient and parent report (corroborated by serum assay)	Nonadherence rates at 2 weeks post-diagnosis=18.8%; at 20 weeks=39.5%; at 50 weeks=35%
Czajkowski & Koocher (1987)	*N*=40 13–23 yr	Cystic fibrosis Chest physiotherapy, diet, medications, recording daily input and output, and cooperation with medical tests on inpatient unit	Medical and nursing notes used to rate degree of adherence	35% of sample nonadherent
Passero et al. (1981)	*N*=58 Ages not specified	Cystic fibrosis Antibiotics, vitamins, chest physiotherapy, diet	Patient report	Incomplete adherence for antibiotics=7%; vitamins=10%; chest physiotherapy=60%; diet=80%
Hentinen & Kyngas (1992)	*N*=47 15–17 yr	Diabetes Insulin, diet, glucose monitoring	Patient report (questionnaire)	% of patients rated as having low adherence by regimen component: insulin=3%; diet=34%; glucose monitoring=38%

Jacobson et al. (1987)	*N*=57 9–15 yr	Diabetes Diet, insulin usage, blood glucose monitoring	Health care provider ratings on a 4-point scale (4=excellent, 3=good, 2=fair, 1=poor) for each regimen component and a composite index	First 9-month-interval mean adherence ratings by regimen: diet=3.2; insulin usage=3.3; blood glucose monitoring=2.8; composite index=3 Second 9-month-interval mean adherence ratings by regimen: diet=2.9; insulin usage=3; blood glucose monitoring=2.5; composite index=2.7 (second 9-month-interval significantly lower than first)
Jacobson et al. (1990)	*N*=61 9–16 yr	Diabetes Diet, glucose monitoring, insulin use	Health care provider rating (4=excellent to 1=poor adherence) Composite index calculated for the three regimen components	Means by year of follow-up: year 1=3.07; year 2=2.83; year 3=2.63; year 4=2.43
Kovacs et al. (1992)	*N*=95 8–13 yr	Diabetes Insulin use, glucose monitoring, diet	Diagnosis of medical nonadherence by clinicians based on structured interviews with patients and parents	29.5% of sample were nonadherent, with nonadherence emerging an average of 3.5 years after diabetes onset
Lorenz et al. (1985)	*N*=90 9–15 yr	Diabetes Diet	Observations unobtrusively done in camp setting Error rate calculated by summing additions and deletions to the meal plan divided by the total number of exchanges	Mean error rate=0.35 (standard deviation=.19)

(*continued*)

Table 1.2. (*Continued*)

Reference	Sample	Disease and regimen	Adherence measure	Results
Schmidt et al. (1992)	*N*=69 4–18 yr (*M*=14.2 yr)	Diabetes Diet	Patient dietary records over a 3-day period and registered dietician tallied the number of food exchanges that deviated from prescribed meal plans	Mean daily deviation from prescribed food exchanges=23.8% (i.e., patients added or deleted, on average, about 1 of 4 exchanges)
Wilson & Endres (1986)	*N*=18 12–18 yr	Diabetes Blood glucose testing	Meters with memory	30% of blood tests not performed over 6 weeks; an average of 40% of blood tests recorded by patients were not registered by the meter; an average of 18% of blood tests not recorded by patient were registered by the meter
Wing et al. (1985)	*N*=282 *M*=13.2 yr *N*=209 completed adherence measure	Diabetes Blood glucose monitoring	Patient report (frequency of monitoring in the past month)	12% not monitoring 25% monitoring <1 X/ day 37% monitoring 1–2 X/day 26% monitoring ≥ 3 ×/day
Wing et al. (1986)	*N*=62 *M*=13.5 yr	Diabetes Blood glucose monitoring	Observation of blood glucose monitoring technique by trained observers in clinic	48% estimated blood glucose within 20% of actual value; sterile technique poor, only 10% worked on a tissue or paper towel and none washed hands; 40% incorrectly timed test; 21% did not adequately wipe blood from testing strip
Litt & Cuskey (1981)	*N*=82 *M*=12.12 yr	Juvenile rheumatoid arthritis Salicylates	Serum assay	45% nonadherent
Litt et al. (1982)	*N*=38 *M*=14.2 yr	Juvenile rheumatoid arthritis Salicylates	Serum assay	45% nonadherent

Beck et al. (1980)	*N*=21 3–20 yr	Renal disease Immunosuppressive drugs, posttransplant	Pill counts	43% nonadherent (all were adolescents)
Blowey et al. (1997)	*N*=19 *M*=15 yr	Renal disease Immunosuppresive drug, posttransplant	Electronic monitor	21% nonadherent
Ettenger et al. (1991)	*N*=165 *M*=13.5 yr Adherence analyzed for subset of 70 patients	Renal Disease Immunosuppressive drugs, posttransplant	Patient report and serum assay	50% nonadherent
Kurtin et al. (1994)	*N*=23 10–19 yr	Renal disease Medications Diet	Nurse rated adherence on a 5-point scale ("very often" to "never"); nonadherence defined as those patients rated as "sometimes," "almost never," or "never" adherent	59% nonadherent
Friedman et al. (1986)	*N*=25 9–17 yr	Seizure disorders Phenobarbital	Saliva assay	21% nonadherent
Hazzard et al. (1990)	*N*=35 9–16 yr	Seizure disorders Anticonvulsant medications	Serum assay	56% nonadherent
Olivieri & Vichinsky (1998)	*N*=17 *M*=12.3 yr	Sickle cell Hydroxyurea capsules	Electronic monitor	4% nonadherent

Note: *M* = Mean

First, there is a tendency toward lower adherence to more complex and intrusive regimens, such as dietary modifications in the treatment of cystic fibrosis and dietary or glucose monitoring in the treatment of diabetes. In contrast, simpler, less intrusive regimens have greater adherence rates. Second, most studies have focused on adherence to medications. This makes some sense because the main regimen component for chronic diseases is medications. However, other components can be as important as medications (such as special diets for patients with diabetes and renal disease). Adherence to these nonmedication components also needs to be assessed and targeted for intervention as needed. Third, about one-third of the studies relied on patient or provider estimates of adherence, which may actually underestimate the degree of nonadherence to chronic disease regimens. Finally, varied and rather arbitrary criteria have been used to classify patients in a dichotomous fashion (adherent or nonadherent) based on cross-sectional and single assessments of adherence. Nevertheless, nonadherence to regimens for chronic diseases is disturbingly prevalent and not without significant consequences for the health and well-being of children and adolescents.

CONSEQUENCES OF NONADHERENCE

Nonadherence to medical regimens can adversely affect the health and well-being of patients, the cost-effectiveness of medical care, clinical decisions, and the results of clinical trials.

Health and Well-Being Effects

Potentially serious health consequences can result from adherence failures. Incomplete adherence to immunosuppressive drugs has been linked to heart, kidney, and liver transplant failures. In one study, about two-thirds of adolescents were found to be nonadherent to immunosuppressant medications, with 15% rejecting their allografts and 26% experiencing graft dysfunction attributed to nonadherence (Ettenger et al., 1991). These preventable transplant failures are especially tragic considering the number of children and adolescents who die while waiting for a transplant. Estimates are that approximately 19% of heart, 12% of liver, and 1% of kidney transplant candidates die while waiting for a suitable donor (Stuber, 1993).

Nonadherence has also been implicated in the alarming rise in mortality related to asthma in children and adolescents (Sly, 1988). African-American children with asthma are particularly vulnerable, with asthma-related death rate being at least five times higher than for Caucasian children (Goldring, James, & Anderson, 1993; Taylor & Newacheck, 1992). They are also at increased risk for morbidity related to asthma, such as compromised functional status (Goldring et al., 1993; Taylor & Newacheck, 1992).

Adherence failures have also been linked to the reemergence of infectious diseases such as tuberculosis (Bloom & Murray, 1992; Gibbons, 1992). These diseases have become more resistant to previously effective antibiotic drugs. Resistance is thought to be caused, in part, by incomplete adherence to medications, which exposes offending microbes to less than optimal levels of antimicrobial action, thus making the organism stronger or more resistant to medications. In effect, incomplete adherence can "inoculate" microbial organisms against the effects of medications. This is especially serious given that drug companies are not developing many new types of antimicrobials (Gibbons, 1992). Also, the potential for drug-resistant microbes could be especially threatening to children with compromised immunity, such as those with cancer and cystic fibrosis, who are prone to opportunistic infections.

Adherence failures can also affect the quality of life for patients and their families. For example, children who are nonadherent to their asthma medications can experience more wheezing and variability in their pulmonary function which can limit their daily activities (Cluss, Epstein, Galvis, Fireman, & Friday, 1984). Also, nonadherent patients with chronic diseases may be hospitalized or stay home for brief but repeated periods of time. They then miss school more often which can adversely impact their academic and social functioning.

Cost-Effectiveness of Medical Care

The cost-effectiveness of medical care can also be reduced by nonadherence (Smith, 1985). Money may be wasted on unused medications or other therapies that are not followed. Nonadherence may also increase unnecessary clinic appointments, emergency room visits, and hospitalizations. The cost of nonadherence in the United States (including adult and pediatric patients) is estimated to be $100 billion every year (Berg, Dischler, Wagner, Raia, & Palmer-Shevlin, 1993). The costs associated with drug-resistant infectious disease are estimated to be between $100 and $200 million a year in the United States alone (Gibbons, 1992). These potentially unnecessary expenses may add to the existing economic burden on families of chronically ill children and society in general, in the form of increased insurance costs and taxes.

Clinical Decisions

Variations in adherence can also negatively impact medical decisions. If physicians are unaware of adherence problems, they may incorrectly attribute poor outcomes to inadequacies in the treatment regimen and prescribe more potent medicines with more serious side effects. They may also order more invasive and risky procedures to determine the lack of treatment success.

The opposite pattern can also occur. Physicians may overattribute treatment failures to adherence problems, particularly when they use treatment outcome as

an indicant for adherence. They may then fail to make appropriate and necessary changes in regimens. For example, medications for adolescents (such as insulin in the treatment of diabetes) need to be adjusted in response to pubertal growth spurts (Barnard, 1986). Without these adjustments, poor treatment outcomes among adolescents may be misattributed to patient nonadherence.

Clinical Trials

Adherence (or the lack thereof) can bias clinical trials of promising therapies. Consider a randomized clinical trial comparing a promising new drug (Group A) with a placebo (Group B). Patients are matched on relevant characteristics (e.g., age, duration of disease, gender) and randomly assigned to Group A or Group B. If patients in Group A have less than optimal adherence, then the therapeutic benefits and side effects of the new drug would be underestimated (Urquhart, 1989). Also, a number of studies have shown that patients who adhere to active or placebo medications have better health outcomes than do poorly adherent patients (Horwitz & Horwitz, 1993). This has been called the *adherence main effect* (Epstein, 1984). Returning to our example, if a comparable number of patients in the placebo group are as adherent as those in the active drug group, there is less likely to be a significant difference in treatment outcomes. Thus, incomplete adherence among patients in the active drug group or adherence main effects would increase sample size requirements for demonstrating a significant difference between the two groups.

Nonadherence can also lead to overestimates of the effectiveness of a newly tested drug. In some trials, investigators discard treatment outcome results for patients who are nonadherent with the test drug or they analyze nonadherent patients' outcome results with the placebo or comparison group (the rationale being they did not really "receive" the new drug). Although this may be justified when testing a drug under "ideal" circumstances (so-called "efficacy" trials), it is not acceptable for "effectiveness" trials or the testing of a drug under ordinary circumstances (Fletcher, Fletcher, & Wagner, 1988).

CORRELATES OF ADHERENCE TO MEDICAL REGIMENS

By understanding why patients do or do not adhere to medical regimens, effective interventions can be designed to improve adherence. In turn, this should reduce disease-related morbidity, mortality, and unnecessary health care costs. In contrast to the adult literature, of the reported theoretical models that have been proposed and tested, few are relevant to pediatric medical adherence (Rapoff, 1996). Most studies have examined correlates or predictors of adherence through correlational/regression analyses or by analyzing between-group differences on

variables thought to impact adherence. A few of these types of correlational studies have been based on theoretical models, such as the Health Belief Model (e.g., Bond, Aiken, & Somerville, 1992; Gudas, Koocher, & Wyplj, 1991; Radius et al., 1978). But the vast majority are neither generated by nor linked to any particular theory. This can create a sort of "variance derby" where investigators correlate a myriad of variables to determine which ones account for the most variance in adherence. The result can be no clear "winners" or ostensible winners (e.g., variables such as age and gender) which are spurious or not modifiable.

There are some good reasons for examining correlates of adherence (Rapoff & Christophersen, 1982). First, negative correlates of adherence that have been identified consistently can be used to develop "risk profiles" that clinicians can use (with appropriate cautions) to identify patients likely to be nonadherent. Second, some adherence correlates that have been consistently related to adherence are modifiable (e.g., complexity of regimens) and therefore can suggest potential remedies (e.g., reducing the complexity of regimens). Third, correlates of adherence can be used as matching or control variables in clinical studies. For example, to improve the internal validity of studies, patients can be matched on relevant dimensions (e.g., age, gender, and socioeconomic status) and then randomly assigned to an adherence intervention or control group. Finally, correlates of adherence can be used to support or refute existing theories or help generate new theories.

Patient and family, disease, and regimen factors have been most frequently studied as correlates of adherence (see Fig. 1.1). The bulk of these studies have examined patient and family correlates of adherence. Each of these types of factors will now be examined, followed by a summary and implications for impacting adherence. Studies that have examined correlates from a specific theoretical position (such as the Health Belief Model) will be reviewed in the next chapter.

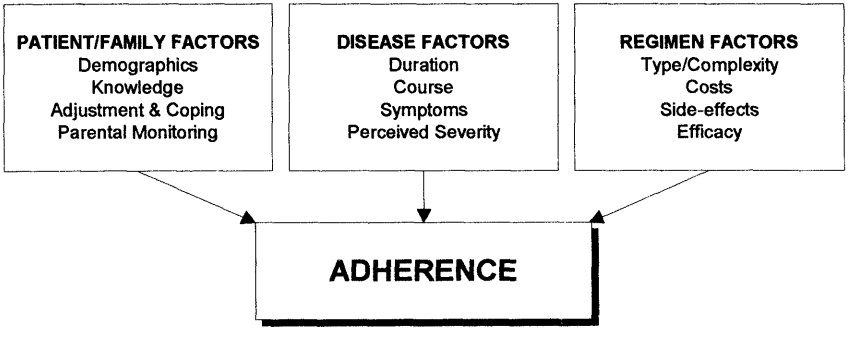


Figure 1.1. Patient/family, disease, and regimen factors correlated with adherence to pediatric medical regimens.

Patient/Family Correlates

Demographics

A number of patient and family-related demographic variables have been associated with adherence. Adolescents are more likely to be nonadherent than younger children to regimens for cancer, cystic fibrosis, diabetes, and renal disease (Anderson, Auslander, Jung, Miller, & Santiago, 1990; Beck et al., 1980; Bond et al., 1992; Brownbridge & Fielding, 1994; Gudas et al., 1991; Jacobson et al., 1987, 1990; Johnson et al., 1992; Kovacs, Goldston, Obrosky, & Iyengar, 1992; La Greca, Follansbee, & Skyler, 1990; Patterson, 1985; Smith, Rosen, Trueworthy, & Lowman, 1979; Tebbi et al., 1986). However, one study found no significant differences in adherence to medications between adolescents and children with juvenile rheumatoid arthritis (Litt & Cuskey, 1981).

A few studies have examined patient gender as a correlate of adherence. Boys have been found to be less adherent than girls to regimens for cystic fibrosis and diabetes (Lorenz, Christensen, & Pichert, 1985; Patterson, 1985). In contrast, one study found that boys were more adherent than girls to insulin and exercise regimens for diabetes (Johnson, Freund, Silverstein, Hansen, & Malone, 1990).

Socioeconomic status (SES) and family composition variables have also been studied. Lower SES, in general, and lower parental education levels, specifically, have been associated with nonadherence to regimens for asthma, cystic fibrosis, diabetes, and renal disease (Bobrow, Avruskin, & Siller, 1985; Brownbridge & Fielding, 1994; Patterson, 1985; Radius et al., 1978). Parental separation or divorce has been associated with lower adherence to regimens for asthma and renal disease (Brownbridge & Fielding, 1994; Radius et al., 1978). In addition, patients in larger families or where mothers work outside the home are less likely to be adherent to regimens for cancer and cystic fibrosis (Patterson, 1985; Tebbi et al., 1986). One study, however, found that boys with cancer from larger families were more adherent to medications (Lansky, Smith, Cairns, & Cairns, 1983).

Knowledge

Patients who are less knowledgeable about their disease and treatment tend to be less adherent to regimens for cancer, cystic fibrosis, and diabetes (Gudas et al., 1991; La Greca et al., 1990; Tebbi et al., 1986). In contrast, patient knowledge was not associated with adherence to medications for renal disease (Beck et al., 1980). A different picture emerges with parental knowledge about their child's disease and treatment. Maternal knowledge of diabetes was unrelated to adherence for adolescents but positively related to adherence for preadolescents (La Greca et al., 1990).

Adjustment and Coping

Patient adjustment and coping variables have consistently been linked with adherence. On the positive side of the adjustment and coping ledger, higher self-esteem has been associated with better adherence to regimens for diabetes, juvenile rheumatoid arthritis (JRA), and seizure disorders (Friedman et al., 1986; Jacobson et al., 1987; Litt, Cuskey, & Rosenberg, 1982). Greater perceived autonomy and personal independence has been related to higher adherence to regimens for JRA and seizures (Friedman et al., 1986; Litt et al., 1982). Higher social functioning, better disease-specific adjustment, and an internal locus of control have all been associated with higher adherence to diabetes regimens (Jacobson et al., 1987). A sense of optimism has been correlated with better adherence to regimens for cystic fibrosis (Gudas et al., 1991) and greater problem-solving skills have predicted higher adherence to diabetes regimens (McCaul, Glasgow, & Schafer, 1987).

On the negative side of the adjustment and coping ledger, patients with behavioral or emotional problems are less likely to adhere to regimens for diabetes and renal disease (Brownbridge & Fielding, 1994; Jacobson et al., 1987; Kovacs et al., 1992). The use of "denial" has been related to poorer adherence to cancer medications (Tamaroff, Festa, Adesman, & Walco, 1992) and greater pessimism has been associated with nonadherence to regimens for cystic fibrosis (Gudas et al., 1991).

Turning to the family unit, studies have examined both positive and negative aspects of family and parental adjustment and coping as correlates of adherence. On the positive side, greater family support, expressiveness, harmony, integration, cohesion, and organization have been associated with higher adherence to regimens for cystic fibrosis, diabetes, renal disease, and seizure disorders (Friedman et al., 1986; Hauser et al., 1990; Kurtin, Landgraf, & Abetz, 1994; La Greca et al., 1995; McCaul et al., 1987; Patterson, 1985). Also, mother–daughter interactions characterized by clear communication, empathy, and effective conflict resolution have been associated with higher adherence to regimens for diabetes (Bobrow et al., 1985). Surprisingly, some positive aspects of family and parental functioning have been associated with *lower* adherence to medical regimens. Increased family social and recreational activities outside the home and higher marital satisfaction have been associated with poorer adherence to regimens for cystic fibrosis (Geiss, Hobbs, Hammersley-Maercklein, Kramer, & Henley, 1992; Patterson, 1985).

On the negative side of family and parental adjustment and coping, poor parental coping has been associated with lower adherence to regimens for JRA and renal disease (Brownbridge & Fielding, 1994; Wynn & Eckel, 1986). Increased parental depression has been related to poor adherence to regimens for renal disease (Brownbridge & Fielding, 1994) and greater parental anxiety has been associated with lower adherence to seizure medications (Hazzard, Hutchinson, & Krawiecki, 1990). Also, the children of parents who are more likely to place behavioral restrictions on them tended to be less adherent to their seizure medica-

tions (Hazzard et al., 1990). Somewhat surprisingly, parental "nagging" has been associated with better adherence to regimens for diabetes (Burroughs, Pontious, & Santiago, 1993; La Greca et al., 1995).

Parental Monitoring

The lack of parental monitoring of treatment-related activities has been found to contribute to nonadherence. Family situations characterized by ambiguity about who assumes primary responsibility for regimen tasks or by low parental monitoring have been associated with lower adherence to regimens for cancer, diabetes, and renal disease (Anderson et al., 1990; Beck et al., 1980; Bobrow et al., 1985; Ingersoll, Orr, Herrold, & Golden, 1986; Tebbi, Richards, Cummings, Zevon, & Mallon, 1988). In one study, parental supervision virtually ceased by the time children were 15 years of age (Ingersoll et al., 1986).

Disease-Related Correlates

Duration

Diseases of longer duration tend to be associated with lower adherence. This is true even among chronic diseases, as longer disease duration has been associated with poorer adherence to regimens for diabetes, JRA, and renal disease (Bond et al., 1992; Brownbridge & Fielding, 1994; Litt & Cuskey, 1981). Also, adherence deteriorates significantly over time to regimens for diabetes, with nonadherence emerging an average of 3.5 years after disease onset (Jacobson et al., 1990; Kovacs et al., 1992).

Course

Adherence to acute disease regimens decreases over the course of the illness, presumably because children start to feel better after 3 or 4 days on an antibiotic regimen. With chronic diseases, symptoms wax and wane over time and adherence may be particularly difficult to sustain during periods when patients are relatively asymptomatic (Rapoff, 1989). Disease course has not been directly investigated in the literature. Most likely, this is because a longitudinal perspective is needed to assess disease course over time and its covariation with adherence.

Symptoms

It would be reasonable to assume that patients who have more frequent and severe symptoms would be more adherent in an effort to improve their plight. This has not been the case with the few studies investigating this variable. Greater num-

bers of health problems and hospitalizations has been associated with lower adherence to regimens for renal disease (Brownbridge & Fielding, 1994). Also, greater seizure activity has been related to lower adherence to anticonvulsant medications (Hazzard et al., 1990). Because these studies assess adherence and symptoms concurrently rather than longitudinally, it is just as likely that lower adherence produced worsening or increased symptoms.

Perceived Severity

Here we are speaking of patient or parental *perceptions* of severity, which appear to be more useful predictors of adherence than those of providers (Rapoff & Barnard, 1991). There is some evidence that parent and patient perceptions are differentially related to adherence. Maternal perceptions of higher severity have been associated with better adherence to medications for asthma (Radius et al., 1978). In contrast, patient perceptions of higher severity have been related to poorer adherence to chest physiotherapy in the treatment of cystic fibrosis (Gudas et al., 1991).

Regimen-Related Correlates

Type and Complexity

Adherence tends to be lower with more complex regimens, such as chest physiotherapy for cystic fibrosis, dietary regimens for diabetes, and exercise regimens for JRA (Glasgow, McCaul, & Schafer, 1986; Hayford & Ross, 1988; Passero, Remor, & Salomon, 1981; Rapoff, Lindsley, & Christophersen, 1985).

Costs

Treatment costs can be prohibitive for some families. For example, one survey of parents of patients with pediatric rheumatic diseases revealed that of those who had a physician visit and purchase of medication in the prior month, 41% reported difficulty paying physician-related charges and 25% had problems paying for medications (McCormick, Stemmler, & Athreya, 1986). Although this study did not correlate costs with adherence, the assumption is that prohibitive costs would lead to poorer adherence. Studies are needed to specifically relate the effect of out-of-pocket expenses on adherence.

Side Effects

Intuitively, regimens that produce more negative side effects should be associated with lower adherence. For example, chest physiotherapy for patients with

cystic fibrosis helps clear the lungs of excessive mucus but results in paroxysms of coughing and gagging. Surprisingly, few studies have examined this factor. One study found that bad-tasting medications correlated with lower adherence to asthma medications (Radius et al., 1978). In contrast, recent studies have shown that although children may have taste preferences for different antibiotics, these preferences are not differentially related to adherence (El-Charr, Mardy, Wehlou, & Rubin, 1996; Matsui, Barron, & Rieder, 1996).

Efficacy

Patient and parent perceptions (rather than providers') regarding the efficacy of medical treatments are most relevant to adherence. Higher levels of perceived benefits as rated by patients and parents has been associated with better adherence to regimens for asthma and diabetes (Bobrow et al., 1985; Bond et al., 1992; McCaul et al., 1987; Radius et al., 1978). A related issue is the immediacy of benefits, which are often delayed for treatments of chronic diseases. For example, an adequate trial of nonsteroidal anti-inflammatory medications in the treatment of JRA is considered to be at least 8 weeks (Lovell, Giannini, & Brewer, 1984).

Correlational Cautions and Risk Profile for Nonadherence

Cautions

Before attempting to develop a risk profile for nonadherence and drawing implications for intervention, an important cautionary note is in order: *Correlation does not imply causation*. To establish a causal relationship, a minimum of four conditions are necessary: (1) covariation between variables, (2) temporal precedence of the designated causal variable, (3) the absence of alternative explanations for covariance, and (4) a logical connection between variables (Haynes, 1992). The preceding review of adherence correlates generally demonstrates covariation and, in most cases, a logical connection between variables. However, because of the cross-sectional nature of most studies and the complete absence of experimental manipulation of variables, they *cannot* address temporal precedence or rule out alternative explanations. They can, however, suggest variables that are modifiable and can be experimentally tested for their effect on adherence.

Nonadherence Risk Profile

This review of adherence correlates suggests the following composite "risk profile" for children and adolescents (particularly with chronic disease) who are likely to be nonadherent to medical regimens. They tend to live in families that are preoccupied with dysfunctional interaction patterns, or, by contrast, with positive

social and recreational activities outside the home that consume time, energy, and resources necessary for supervising and managing treatment regimens. Their families are also likely to be larger and in the lower socioeconomic strata, possibly with only one parent living at home.

The parents of at-risk children and adolescents tend to have less education in general and/or to be less informed about their childrens' illness and treatment. Also, the parents may be preoccupied with their own adjustment and coping problems.

The children and adolescents themselves are also likely to have adjustment and coping problems and may be less knowledgeable about their disease and treatment. They are also likely to have primary responsibility for carrying out regimen tasks with little or no supervision from their parents.

At-risk children and adolescents have also had to cope with their disease and treatment over a protracted period, with fluctuations in disease symptoms. In addition, they may be prescribed regimens that are complex, intrusive, costly, have negative side effects, and are not immediately beneficial.

Clinical Implications Related to Adherence Correlates

Some correlates of adherence are static or immutable. For example, what are the clinical implications for considering male gender as a risk factor for nonadherence to chronic disease regimens (a sex change operation)? Fortunately, most adherence correlates are modifiable and suggest ways to improve adherence. Even static correlates may be useful in identifying at-risk patients or in identifying other modifiable variables that are "marked" by the static variable. For example, adolescence is a relatively static variable. Parents and providers cannot just "wait out" this developmental period with the hope that patients will be more adherent as they get older. Instead, clinicians can identify other factors associated with being an adolescent that impact adherence (e.g., how parents decrease their monitoring of regimen tasks during this period). The following clinical implications focus on modifiable variables that can be altered to improve adherence.

Patient/Family Correlates

One clear overarching implication is that the family needs to be the focus of interventions to improve adherence (La Greca, 1990). This is consistent with the general trend in pediatric psychology for promoting family-based theories and interventions (Kazak, 1997; Roberts & Wallander, 1992). Patients and their families may need varying degrees of psychosocial support and assistance, ranging from brief and restricted interventions focused on specific adherence behaviors to more comprehensive therapies for enhancing adjustment and coping.

Educational efforts also need to focus on patients and their families. This focus should also include siblings who can have a significant impact on adherence, particularly older siblings who have caretaking responsibilities for younger children with chronic illnesses.

The need for parental monitoring of regimen tasks is taken for granted for younger children who rely primarily or exclusively on their parents to consistently administer medical treatments. However, adolescents also need monitoring by their parents. One reason why adolescents tend to be at risk for nonadherence may be the lack of parental monitoring. Parents should be cautioned not to assume that their teenager is capable of independently carrying out regimen tasks. They should continue to monitor and assist their teenagers in being consistent in following prescribed regimens. Teenagers and parents should be encouraged to share responsibilities for monitoring and carrying out regimens.

Disease-Related Correlates

Patients and their families are more likely to need assistance from clinicians to address adherence issues after the first few years postdiagnosis. When first diagnosed, patients and families may be sufficiently motivated to be adherent so as to control symptoms and minimize disease impact. However, motivation is likely to decrease over time and during relatively asymptomatic periods. Adherence interventions could thus be timed to coincide with these vulnerable periods.

Because the presence of increased symptomatology has been associated with poorer adherence, clinicians should assist patients' families in simultaneously monitoring symptoms and adherence. Then, when adherence-enhancing strategies are introduced, they can be more aware of how adherence impacts symptoms and disease course. Also, if patients and families fail to see improved symptom control in spite of adequate adherence, they can negotiate with their physician about changes that can be made in the regimen to improve symptom control.

Perceptions of disease severity by parents and patients are also critical to adherence and may function differently for parents and patients. For parents, emphasizing the potential negative impact or risks of disease may enhance adherence, as they are better able to cognitively process and utilize this information. This may not be the case for children and adolescents who have less ability to process and use this information. Instead, children and adolescents may seek to avoid risk-framed instructions and those who deliver them. Thus, clinicians should exercise caution in the way severity or risk messages are communicated to patients and parents. A good compromise may be to communicate risk messages in a positive way by emphasizing the benefits of doing specific and manageable things to prevent or minimize disease severity or risk.

Regimen-Related Correlates

Implications related to regimen factors are very straightforward. Providers must be careful not to overburden families by prescribing unnecessarily complex and costly regimens. Families with ill children have a finite amount of time, energy, and resources to devote to medical regimens, if they are to maintain some semblance of a "normal" family life (Patterson, 1985). Providers must help rather than contribute to this problem of balancing regimen and other family activities. For example, newer antibiotics can be given once a day for 5 days instead of two to three times daily for 10 days to treat acute illnesses. Also, patients can be prescribed generic medications that are less costly to their families and insurance carriers.

Again, parental and patient perceptions enter into the adherence picture in terms of their judgments about the efficacy of prescribed regimens. If they do not perceive that a medical treatment is helpful, patients and families will not continue to consistently follow a regimen or they may discontinue it entirely. So how can providers influence the perceptions of patients and families? One way is to make sure that the most efficacious treatment has been prescribed. Another way is to provide patients and families clear and concise information about the efficacy of regimens that are specific to their situation. This would include traditional measures of outcome (such as disease signs and symptoms and laboratory parameters) as well as quality of life markers (such as increased participation in daily social and recreational activities). Patients and parents can also be trained to monitor some indices of outcome so as to demonstrate to themselves that their efforts to maintain optimal adherence "pays off" in ways that are meaningful to them.

2

Adherence Theories: Review, Critique, and Clinical Implications

A theory is "a set of general or abstract principles based on experimentally established relationships among events used to explain a phenomenon" (Johnston & Pennypacker, 1993, p. 371).

One reason why clinicians might be tempted to skip over this chapter is that discussions of theories often seem pedantic, argumentative, and devoid of practical applications. So, why should clinicians be concerned about theories that speculate about why children and adolescents do or do not adhere to medical regimens? There are two major reasons why clinicians might consider theories.

First, theorizing is ubiquitous and must serve some useful purpose. As soon as humans become language-able, they begin to ask "why" questions (have you spoken to a toddler lately?). In a very real way, we are driven to make sense of our world, ourselves, and others around us. All clinicians have at least implicit theories about why people think, feel, and behave as they do. By explicating and critically analyzing their theories, clinicians can clarify how they conceptualize and approach adherence issues. The other reason why clinicians should consider theories is to get them out of their "conceptual ruts" (Wicker, 1985). Examining adherence issues from different perspectives will help clinicians find new ways to assess, analyze, and solve adherence problems. It is easier to justify why researchers should critically examine theories. Like all scientific theories, those that seek to explain why patients adhere or fail to adhere to medical regimens can impact researchers in at least two ways (Johnston & Pennypacker, 1993; O'Donohue & Krasner, 1995). First, theories influence decisions made in planning and conducting studies including the experimental questions, measures, designs, and data analytic procedures. During a lecture to a group of physics students in Vienna, the philosopher Karl Popper gave them the following instructions: "Take pencil and paper; carefully observe, and write down what you have observed." Naturally the students asked what he wanted them to observe, thus making his point that theories precede

observations (Popper, 1963, p. 46). Theories also affect the way investigators react to their data in terms of interpreting and relating their results to other studies, including the body of literature in which they chose to report their findings. Finally, in a practical vein, funding agencies require that investigators present an explicit theoretical framework for their research proposals.

This chapter describes, critically appraises, and draws clinical implications relevant to the major theories in medical adherence research. A final section will summarize and integrate implications for adherence enhancement as suggested by these theories. The most common theories referred to in the literature will be examined, including the Health Belief Model, Social Cognitive Theory (especially Self-Efficacy), the Theory of Reasoned Action/Planned Behavior, the Transtheoretical Model, and Applied Behavior Analytic theory. With the exception of the Health Belief Model and Applied Behavior Analytic Theory, most of these theories have been worked out with adults. Therefore, the following discussion will, by necessity, extrapolate from the adult literature to apply these theories to children and adolescents.

LEARNER OBJECTIVES

- Describe, critique, and draw clinical implications from the Health Belief Model, Social Cognitive Theory (particularly Self-Efficacy), the Theory of Reasoned Action/Planned Behavior, the Transtheoretical Model, and Applied Behavior Analytic Theory.
- Summarize, integrate, and describe two generic clinical principles from the theories reviewed.

THE HEALTH BELIEF MODEL

Description

The Health Belief Model (HBM) has been one of the most widely used theories in health behavior research over the past four decades (Strecher & Rosenstock, 1997). Originally developed in the early 1950s to understand why people failed to take advantage of preventive health services (such as hypertension screening), the HBM was later extended to adherence to prescribed medical regimens (Janz & Becker, 1984; Rosenstock, 1974).

The HBM posits five major sets of variables that predict or explain adherence: (1) *perceived susceptibility* (including the person's perceived risk of contracting or recontracting a condition or acceptance of an existing condition), (2) *perceived severity* (the person's evaluation of the medical and social consequences of contracting an illness or not receiving treatment), (3) *perceived benefits* (the

person's judgment of the perceived benefits of taking a particular health action), (4) *perceived barriers* (the person's perception of impediments to adhere to recommended treatments, including a cost-benefit analysis where the person weighs the pros and cons of taking action), and (5) *cues to action* (internal cues, such as disease symptoms or external cues, such as prompting by others, that trigger action). In addition, recent formulations of the HBM have included Bandura's concept of self-efficacy (Strecher & Rosenstock, 1997).

The HBM has been adapted for use with pediatric populations. The Children's Health Belief Model (CHBM) is schematically represented in Fig. 2.1 (Bush & Iannotti, 1990). As can be seen, the CHBM includes similar dimensions as the classic HBM (e.g., perceived severity) but also emphasizes the role of caretaker influences on children's health beliefs and actions (e.g., caretaker's perceived benefit of the child taking medicines).

Critical Appraisal

Two comprehensive reviews found "substantial empirical support" for the HBM and concluded that perceived barriers were the most "powerful" predictor of a

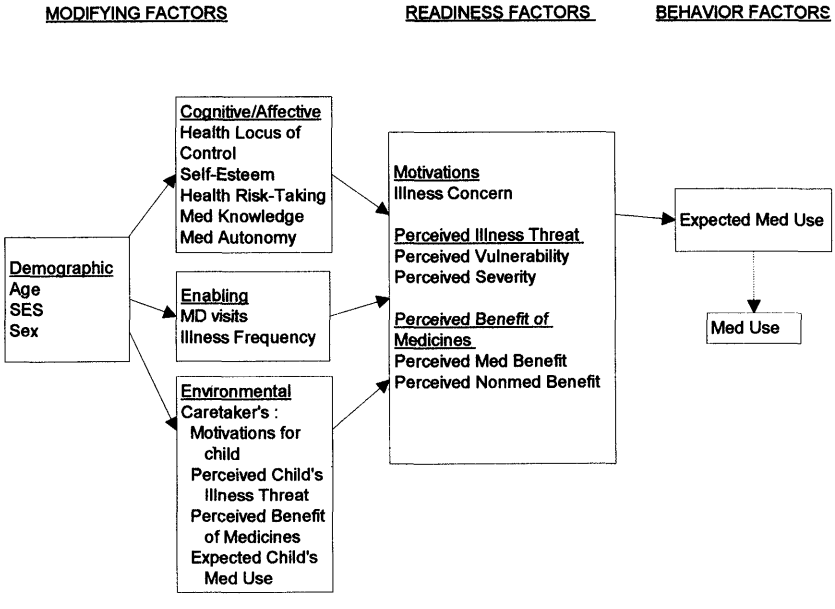


Figure 2.1. The Children's Health Belief Model. From "A children's health belief model," by P. J. Bush and R. J. Iannotti, 1990, *Medical Care, 28,* p. 71. Copyright 1990 by Lippincott-Raven Publishers. Reprinted with permission.

wide range of health practices (Becker, 1974; Janz & Becker, 1984). There is also correlational support for components of the HBM in the pediatric medical adherence literature. Higher susceptibility/vulnerability and severity, as rated by mothers, has been associated with better adherence to medications for asthma (Radius et al., 1978) and, as rated by patients, to better adherence to medications for cancer (Tamaroff et al., 1992). In contrast, higher perceived threat or severity, as rated by adolescents, has been associated with lower adherence to regimens for diabetes and cystic fibrosis (Bond et al., 1992; Gudas et al., 1991).

Higher levels of perceived benefits, as assessed by mothers, have been associated with better adherence to asthma medications (Radius et al., 1978) and, as assessed by patients, with diabetes regimens (Bobrow et al., 1985; Bond et al., 1992; McCaul et al., 1987). Consistent with general reviews of the HBM, higher perceived barriers as rated by parents and adolescents have been uniformly correlated with poorer adherence to regimens for asthma and diabetes (Glasgow et al., 1986; McCaul et al., 1987; Radius et al., 1978). The presence of relevant cues to action, as assessed by adolescents, has also been associated with better adherence to diabetes regimens (Bond et al., 1992).

To date, however, only one analogue study has been conducted with the CHBM (Bush & Iannotti, 1990). This study found that 63% of the variance in children's expected medication use was predicted by the CHBM, with two readiness factors (perceived severity and benefit) accounting for most of the variance. However, this study is limited by its analogue nature and failure to measure actual medication use.

Despite its track record in the literature, primarily with adults, the HBM can be criticized on the following conceptual and methodological grounds: (1) There are variations in the way HBM constructs have been conceptualized and measured. This has resulted in lack of standardization of measures and variable performance of these constructs as predictors of adherence (Janz & Becker, 1984; Strecher & Rosenstock, 1997). (2) Perceptions of health risks (such as perceived vulnerability and severity in the HBM) are subject to an "optimistic bias," or the well-known tendency for people to underestimate their own health risks compared with others (Stroebe & Stroebe, 1995). This may be particularly true of adolescents who tend to view themselves as relatively invulnerable to health risks and behave accordingly by driving too fast, not wearing seat belts, having unprotected sex, and smoking (Coleman & Hendry, 1990; Millstein, Petersen, & Nightingale, 1993). (3) The HBM is limited to accounting for variance in adherence-related behaviors that can be predicted by attitudes and beliefs. Social psychologists have oft cited the tenuous relationship between attitudes and behavior (Stroebe & Stroebe, 1995). Supporters of the HBM acknowledge that changes in health-related behaviors are rarely achieved by direct attempts to change health-related attitudes (Strecher & Rosenstock, 1997). Other influences on adherence need to be considered such as social contingencies, physiologic factors, and perceptions of self-efficacy

(Guerin, 1994; Janz & Becker, 1984). (4) The HBM fails to suggest particular strategies for altering relevant health beliefs. Therefore, there is a dearth of studies designed to experimentally manipulate HBM-related factors to improve adherence (Janz & Becker, 1984). Supporters of the HBM have called for such studies rather than replications of previously confirmed correlational findings (Strecher & Rosenstock, 1997).

Clinical Implications of the HBM

Consider an 8-year-old boy who has moderately persistent asthma that requires daily inhaled anti-inflammatory medication and an inhaled bronchodilator medication as needed. The boy has also been asked to monitor his peak flow levels once per day and after he takes his bronchodilator medication. His parents have been asked not to smoke in the house and to take steps to minimize his exposure to other allergens in the home, such as dust and pet dander. Applying the HBM to this clinical example would suggest the following strategies for assessing and modifying factors related to adherence:

- Perceived susceptibility and severity: The clinician could assess whether the patient and his parents have accepted his condition and have a realistic view of the severity of his asthma. If they have an unrealistic view of severity, the clinician could review peak flow records and encourage the patient and parents to more closely monitor his symptoms so as to gain a more realistic perspective about severity. Information about severity should be balanced with positive information and encouragement that conveys a sense of optimism about the patient's and parents' ability to control his disease with increased monitoring and better adherence to prescribed regimens.
- Perceived benefits: The clinician could assess how confident the patient and parents are that the prescribed regimen is beneficial, especially in terms of quality of life benefits. If confidence is low, the clinician could review potential benefits of the prescribed regimen, such as increased participation in social and recreational activities. Clinicians should be alert to the possibility that prescribed treatments may not be beneficial for particular patients, in spite of optimal adherence. In these instances, the patient and parents should be encouraged to communicate this information to the physician and ask for modifications/additions to increase regimen efficacy.
- Perceived barriers: The clinician could interview the patient and parents to identify logistic barriers that prevent them from fully adhering to the regimen. For example, taking inhaled bronchodilator medications "as needed" requires the patient or parents to make judgments about "need."

They may need assistance in how to monitor symptoms and decide when bronchodilator medications are required. They may need to be instructed to monitor peak flow rates following vigorous exercise and to administer bronchodilator medications if peak flows drop significantly below the patient's baseline levels (see NAEPP, 1997, for such guidelines). The parents may also perceive multiple barriers to reducing their son's exposure to indoor allergens, such as finding the time to remove dust and pet dander on a regular basis and going outside to smoke during the winter. A good general question to ask of patients and parents would be : "What gets in the way or prevents you from doing...?" The answer to this question should lead to practical recommendations from clinicians (e.g., smoke in the garage during the winter).

- Cues to action: The clinician could assess for the presence of reliable internal and external cues to prompt adherence. If the patient is relatively asymptomatic, there may not be consistent internal cues (such as dyspnea) to prompt adherence behaviors. Therefore, external prompts may be required, such as having the patient set his watch alarm for times when medications are to be taken or encouraging the parents to monitor and prompt adherence behaviors.

SOCIAL COGNITIVE THEORY (SELF-EFFICACY)

Description

Social cognitive theory (SCT) is a comprehensive theory of human behavior originally proposed and promoted by Albert Bandura (Bandura, 1986, 1997). SCT proposes a *triadic reciprocal causation* model that focuses on the interdependence and reciprocal interactions among three major determinants of human agency: behavior, internal personal factors (cognitive, affective, and biological events), and the external environment. The central mechanism of human agency (and the one most relevant to medical adherence) is beliefs of personal efficacy or *perceived self-efficacy*.

Perceived self-efficacy refers to *"beliefs in one's capabilities to organize and execute the courses of action required to produce given attainments"* (Bandura, 1997, p. 3). Competent functioning (such as adhering to complex medical regimens) requires both skills and self-beliefs of efficacy to use skills effectively. Children and adolescents who have the necessary skills to perform adherence tasks and have a strong belief in their capabilities to perform are more likely to (1) approach difficult regimen tasks as "challenges" to be mastered rather than "threats," (2) set challenging health-enhancing goals for themselves and remain strongly committed to these goals, (3) increase and sustain efforts to achieve their goals even when they are faced with failure, (4) quickly recover from failures

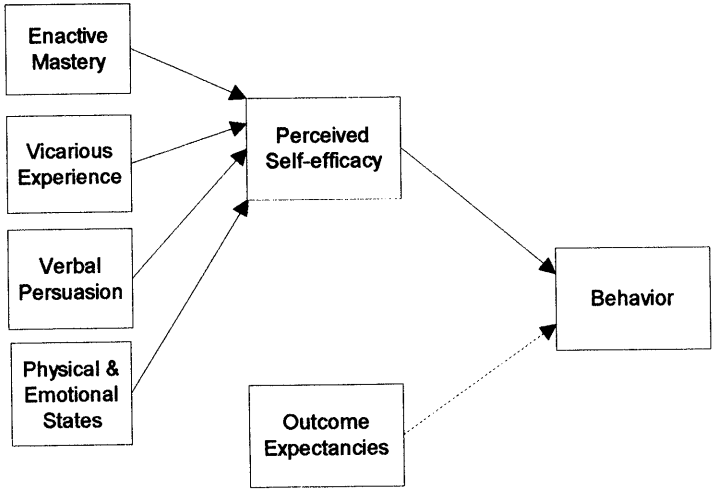


Figure 2.2. Self-efficacy theory.

or setbacks to achieve their goals, in part, by attributing these setbacks to knowledge or skill deficiencies that are remediable, and (5) realize personal accomplishments, reduce stress, and lower their vulnerability to negative affective states, such as depression (Bandura, 1996).

Two major pathways for self-efficacy influences on health have been proposed (O'Leary, 1992). One pathway involves its direct effect on adoption of health practices and adherence to medical regimens. Those high in self-efficacy are more likely to adhere to medical regimens and thereby improve or maintain their health. The other pathway concerns its effect on physiological stress responses. Those high in self-efficacy may experience less stress and negative emotional states that can exacerbate chronic diseases, such as asthma, arthritis, and diabetes in children and adolescents.

SCT also emphasizes the role of *outcome expectancies* or judgments of the likely consequences of one's actions (Bandura, 1997). Self-efficacy judgments (whether one can produce certain actions) are distinguished from outcome expectations (the anticipated consequences of producing actions) but perceived self-efficacy is considered to be the more powerful determinant of behavior (Bandura, 1986). Figure 2.2 is a schematic representation of self-efficacy theory.

Critical Appraisal

SCT and its central construct of self-efficacy has been a robust predictor of human functioning in such diverse areas as cognitive, affective, social, and organizational

domains (see Bandura, 1997, for a recent comprehensive review). Self-efficacy has also been an important predictor of a variety of health-related behaviors in adults, including breast cancer screening, smoking, physical exercise, weight control, pain management, and risky sexual behaviors (Bandura, 1997; O'Leary, 1985, 1992; Schwarzer & Fuchs, 1995; Strecher, DeVellis, Becker, & Rosenstock, 1986). The success of self-efficacy as a predictor of health-related behaviors is evident from its more recent inclusion in well-established theories such as the HBM. Although the vast majority of this work has been done with adults, there have been some attempts to develop and validate illness-specific self-efficacy scales for children and adolescents with asthma (Schlösser & Havermans, 1992) and diabetes (Grossman, Brink, & Hauser, 1987).

Even the most vocal critics of self-efficacy theory acknowledge that it is an influential and useful theory in psychology (Catania, 1995; Hawkins, 1995). However, self-efficacy theory can be criticized on the following conceptual and methodological grounds: (1) Self-efficacy is not a cause but a reflection of behavior change. It represents an index of the positive and negative outcomes of past performances, a sort of "running average" (Hawkins, 1992). Bandura (1995) counters by citing numerous studies that show self-efficacy retains its predictive power even after controlling for past performance. (2) Self-efficacy theory is also said to minimize environmental influences, including response contingencies and verbally controlled (rule-governed) behavior (Catania, 1995; Hawkins, 1992; Hayes & Wilson, 1995). Bandura has noted that "incentive inducements" or reinforcement contingencies are not sufficient causal agents, particularly as humans gain facility with language and self-referent thought assumes a more critical mediational role in person–environment interactions (Bandura, 1996, 1997). (3) A related criticism is that there is no evidence that self-efficacy (or any other) beliefs have been directly changed. So-called evidence rests on the direct manipulation of some environmental event; no one "randomly assigns" research participants to different levels of self-efficacy (Hayes & Wilson, 1995). (4) Conceptual confusion has led to variability in how self-efficacy has been operationalized and measured (Corcoran, 1995). Bandura (1996, 1997) acknowledges this criticism and notes that the predictive utility of self-efficacy is attenuated by excessively long intervals between self-efficacy and performance assessments (as self-efficacy may have changed in the interim), the limited scope of self-efficacy assessments (e.g., measuring efficacy beliefs related to dieting but not exercising when predicting weight loss), global versus domain-specific assessments of efficacy, and errors in measuring criterion performance variables.

Clinical Implications of SCT (Self-Efficacy)

Consider a 7-year-old girl with cystic fibrosis (CF). Her complex and time-consuming medical regimen included the following components: oral pancreatic

enzyme replacement to be taken with each meal and snack; increased caloric intake (especially high-protein and high-calorie foods); an inhaled bronchodilator and antibiotic to be taken three times per day; postural drainage with percussion three times per day; and DNase (to break up mucus in the lungs) delivered via a nebulizer once a day. She also had to take inhaled or oral corticosteroids and intravenous antibiotics, with exacerbations in her disease. She lives in a two-parent family with both parents working outside the home. The patient has a 6-month-old sister (who does not have CF).

Applying SCT to this clinical example would suggest the following assessment and intervention strategies:

- Although SCT primarily focuses on self-efficacy, it also emphasizes the importance of prerequisite skills for carrying out tasks. The clinician could directly observe how well the patient and parents execute regimen tasks (such as proper technique for using a metered-dose inhaler to deliver bronchodilator and antibiotic medications) and give corrective feedback, training, and practice as needed. This will ensure that the patient and parents know how to carry out regimen components.
- Self-efficacy is the most important and relevant component of SCT. Therefore, the clinician would want to assess self-efficacy perceptions of the patient and the parents. For example, the clinician could ask the parents: "How confident are you in being able to help your daughter be consistent in taking medications, doing postural drainage, and following dietary recommendations related to CF treatment?" Parents could respond using a five-point scale, ranging from "not at all sure" to "very sure" (Parcel et al., 1994). If parents (or the patient) are not very confident about managing regimen tasks, efforts can be made to enhance self-efficacy through three major processes: enactive mastery, vicarious experiences, and verbal persuasion (Bandura, 1997).
- Enactive mastery is the most powerful source of self-efficacy and refers to taking steps to ensure that the patient and parents are successful in managing the CF regimen and that they attribute their successes to their efforts. The clinician could provide the parents and patient with social reinforcement for managing regimen tasks and emphasize the importance of their efforts in achieving hard-won successes. Because of the inherent aversiveness of some regimen tasks (such as postural drainage), the patient may need more tangible positive consequences for adherence, such as tokens that can be exchanged for special privileges.
- Vicarious experiences can be promoted by having the patient and parents observe or visualize competent models. For example, the patient and parents could be paired up with other patients and their parents who have encountered and mastered similar problems with regimen tasks.

- Verbal persuasion is the route that most clinicians take to enhance self-efficacy and is most effective if the persuader is viewed as trustworthy and competent. This essentially involves "pep talks" or trying to persuade the patient and parents that they are capable of doing what they need to do. However, clinicians should be careful to avoid overemphasizing this approach and to help the patient and parents experience successes in managing the regimen. Otherwise, parents and patients may discount any attempts to boost self-efficacy just by verbal persuasion.
- Clinicians would also need to assess outcome expectancies, particularly patient and parental perceptions of the likelihood that their efforts to manage CF would reap positive benefits. If expectations of beneficial outcomes are low, the clinician may need to emphasize the purpose and potential benefits of prescribed regimens. Also, physicians and nurses can provide disease outcome data (such as pulmonary function test results) or have the patient and parents monitor disease symptoms so as to demonstrate the benefits of prescribed regimens. In some cases low outcome expectancies are accurate (patients are not benefiting from treatment) and clinicians can refer patients and parents to their medical providers for reassessment of their condition and changes in their regimen.

THE THEORY OF REASONED ACTION/PLANNED BEHAVIOR

Description

The Theory of Reasoned Action/Planned Behavior (TRA/PB) is a recent extension of the TRA and incorporates predictors from it (Montaño, Kasprzyk, & Taplin, 1997). The TRA was originally introduced in 1967 to help understand why attitudinal measures were often poor predictors of behavior and to improve the predictive utility of attitudinal measures (Ajzen & Fishbein, 1977; Fishbein, 1967). The TRA proposed that attitudinal measures were more likely to predict behavioral outcomes when measures of both specify four elements: (1) the *action* or behavior to be performed, (2) the *target* at which the action is directed, (3) the *context* or situation, and (4) the *time* frame. Thus, attitude–behavior consistency is more likely if measures of attitudes and behaviors "match" in terms of the level of specificity across these four elements. The TRA also proposed that the most proximal determinant of behavior is "intention," or the perceived likelihood of the person performing the behavior. Behavioral intentions are, in turn, influenced by a number of factors (see Fig. 2.3).

Intentions are determined by three major factors: (1) *attitude toward the behavior* (incorporating specific opinions about the behavior and the potential consequences of performing that behavior), (2) *subjective norms* (whether important

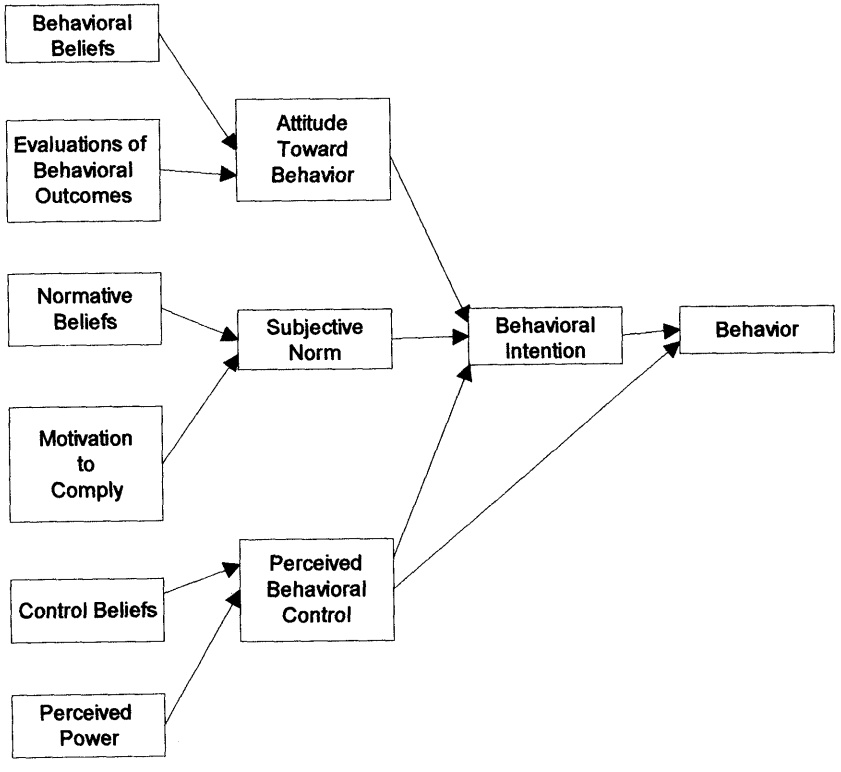


Figure 2.3. The theory of reasoned action/planned behavior.

people in the person's life approve or disapprove of the action and whether the person is motivated to meet their expectations), and (3) *perceived behavioral control* (whether the person believes she or he can perform the behavior and the expected outcome of performing). The construct of perceived behavioral control was the major variable added to the TRA to form the TRA/PB (Ajzen, 1991). Perceived behavioral control can influence behavior directly or indirectly through its effect on intentions (see Fig. 2.3).

Critical Appraisal

The TRA/PB has been applied to the prediction of a variety of behaviors, from academic performance to shoplifting (Stroebe & Stroebe, 1995). These studies tend to provide correlational support for the major components of the theory (Ajzen, 1991). The relatively few studies that have used the TRA/PB to predict health-

related behaviors have focused on adults and specific areas such as exercise and mammography screening (Montaño et al., 1997). One study with secondary education students in Holland found that attitudes toward condom use, perceived norms, and perceived control were predictive of intentions to use condoms, while AIDS-related knowledge was not predictive (cited in Stroebe & Stroebe, 1995).

Despite its promise, the TRA/PB can be criticized on several points: (1) Although verbal "intentions" may be useful (particularly when it is hard to measure behavior directly), they are not foolproof (Guerin, 1994). After all, the "road to perdition" is paved by well-meaning intentions. This criticism is particularly relevant when more direct measures of behavior are available and measures of intention are used in place of these direct measures (e.g., asking adolescents with IDDM about their intentions to test blood glucose levels rather than relying on glucometers that record and store blood glucose testing results). (2) The degree of specificity of attitudinal and behavioral measures needs to match or be contextually relevant. Mismatches have resulted in low correspondence between attitudinal and behavioral measures. (3) The construct "perceived behavioral control" appears to be conceptually similar to Bandura's construct of self-efficacy (Montaño et al., 1997). This apparent redundancy needs to be evaluated, both conceptually and empirically. (4) Like all "attitudinal" theories, the burden is on proponents of the TRA/PB to show that experimental manipulations designed to change attitudinal variables actually result in behavior change.

Clinical Implications of the TRA/PB

Consider a 15-year-old girl with systemic lupus erythematosus (SLE), which is a rheumatic disease that affects multiple organ systems, most notably the musculoskeletal system. The patient's oral medication regimen includes a once-daily antimalarial drug (Plaquenil) and a corticosteroid (prednisone) every other day. She also has to avoid exposure to sunlight. The patient lives with her mother and stepfather. The patient and her mother have frequent conflicts, which often results in the patient staying over at a friend's house, sometimes during the week and almost exclusively on the weekends.

Applying the TRA/PB to this clinical example might suggest the following strategies:

- Given the centrality of intentions as the most immediate determinant of behavior, the clinician could assess the patient's intentions relevant to her medication regimens. For example, the patient could be asked: "How likely are you to consistently take your medications?" and provided with a three-point response format ("very likely, somewhat likely, or not likely"). The clinician could further ask about intentions to adhere to medications at home or when she stays at her friend's home.

- The clinician could also ask about the patient's attitude toward taking the prescribed medications, how significant others (such as friends and parents) react to her regimen (whether they approve or disapprove), whether she believes she is capable of carrying out the regimen, and what she expects to gain by adhering to the regimen.
- If the clinician determines that the patient has weak intentions to adhere to the regimen because significant others provide little support and the patient is doubtful about her ability to be consistent and/or effectively control her disease, then a number of remedial steps can be taken. Perhaps the mother and stepfather could provide increased monitoring and support for the patient. In this example, family therapy would be needed to address ongoing conflicts so that the mother and stepfather could function as agents of support and the patient could be more motivated to meet their expectations.
- In addition (or as an alternative), the patient's friend and her parents could be enlisted as sources of support, since the patient spends many hours at her friend's house.
- To address the issue of low perceived behavioral control, the clinician could ask the patient's physician to provide further information about the purpose and benefits of therapy and disease outcome data that supports the efficacy of the prescribed regimen for this particular patient. The patient can also monitor disease symptoms and demonstrate to herself that better disease control occurs when she is more consistent in following her regimen.

TRANSTHEORETICAL MODEL

Description

The Transtheoretical Model of Change (TTM) was originally applied to systems of psychotherapy (Prochaska, 1979) and then extended to smoking and other addictive behaviors (DiClemente & Prochaska, 1982; Prochaska & DiClemente, 1983; Prochaska, DiClemente, & Norcross, 1992). The TTM focuses on intentional change and has two major dimensions. The first dimension, *stages of change*, specifies "when" shifts occur in attitudinal and behavioral change. In the process of changing a particular health-related behavior (such as quitting smoking), people are said to progress through a series of five stages (Prochaska, Redding, & Evers, 1997): (1) *precontemplation* (the person has no intention to change in the foreseeable future, usually within the next 6 months), (2) *contemplation* (the person intends to change within the next 6 months), (3) *preparation* (the person intends to change in the immediate future, usually within the next month),

(4) *action* (the person has been making overt changes in lifestyle in the past 6 months), and (5) *maintenance* (the person is working to sustain changes and avoid relapse). Progression through these stages may not be linear. People may relapse and recycle through previous stages, particularly with addictive behaviors.

The second major dimension of the TTM is *processes of change*, which is concerned with "how" people change. They include overt and covert activities people employ to progress through stages of change (Prochaska et al., 1997). These are empirically supported processes derived from various theoretical perspectives in psychotherapy (thus the term *transtheoretical*). People are said to use different processes at different stages of change. Therefore, interventions designed to help people change should "match" particular processes to particular stages of change (see Table 2.1).

Two additional constructs have been recently added to the TTM (Prochaska et al., 1997). Similar to the HBM and TRA/PB, one construct is *decisional balance*, which refers to a person's relative weighing of the pros and cons of changing. The other construct is *self-efficacy*, adapted from Bandura's self-efficacy theory, but reflecting two components: (1) the degree of confidence people have to cope with high-risk situations without relapsing to unhealthy habits and (2) temptation or the intensity of the person's urges to engage in an unhealthy habit (e.g., the degree of self-efficacy a teenager has to avoid smoking during a social event with friends who smoke).

Critical Appraisal

The TTM has been applied to a wide range of health-related behaviors with adults, including smoking, weight control, condom use, exercising, and mammography screening (Prochaska et al., 1994). In general, there has been good empirical support for the major constructs of the TTM (Prochaska et al., 1997). Particular processes of change seem to be employed at different stages of change (e.g., more action-oriented strategies such as reinforcement management employed during action and maintenance stages), consistent with the depiction in Table 2.1. Also, people in the action versus the contemplation stage tend to discount the costs or cons of changing (Prochaska et al., 1994). The construct of self-efficacy is a recent and untested addition to the TTM. Given its similarity to Bandura's conceptualization of self-efficacy, it should be a similarly robust predictor of health-related behaviors.

Despite being one of the most popular theories in health psychology, the following conceptual and methodological criticisms can be raised about the TTM (Bandura, 1997): (1) The "stage" aspect of the TTM has been questioned on grounds that human functioning is too complex to be categorized into specific stages. Also, the TTM stages of change violate the three defining properties of a stage theory: qualitative changes across stages (such as Piaget's theory, where

Table 2.1. Stages of Change in which Particular Processes of Change Are Emphasized

Precontemplation	Contemplation	Preparation	Action	Maintenance
Consciousness raising (increasing information about self and problem) **Dramatic relief** (experiencing and expressing feelings about one's problems and solutions) **Environmental reevaluation** (assessing how one's problem affects physical environment)				
	Self-reevaluation (assessing how one feels and thinks about oneself with respect to a problem)			
		Self-liberation (choosing and commitment to act or belief in ability to change)		
			Reinforcement management (rewarding one's self or being rewarded by others for making changes) **Helping relationships** (being open and trusting about problems with someone who cares) **Counterconditioning** (substituting alternatives for problem behaviors) **Stimulus control** (avoiding or countering stimuli that elicit problem behaviors)	

Note: From "In search of how people change: Applications to addictive behavors," by J. O. Prochaska, C. C. DiClemente, and J. C. Norcross, 1992, *American Psychologist, 47*, pp. 1108 and 1109. Copyright 1992 by the American Psychological Association. Adapted with permission.

preoperational thinking changes qualitatively to operational thinking), an invariant sequence of change (one does not skip stages), and nonreversibility (one does not recycle through stages; for example, an operational thinker does not recycle back to preoperational thinking, unless a catastrophic event occurs, such as brain damage). (2) The TTM stages of change are circular in that the stages are defined in terms of the very behavior to be explained. In studies using the TTM, people are categorized into stages based on their self-reports of health-related behaviors, such as smoking and exercising. For example, people might be asked to report how many days per week, how many minutes per session, and how intensely they engage in exercises and whether they intend to increase their exercise activity within the next month (Myers & Roth, 1997). They are then categorized into stages (e.g., in the "precontemplation" stage if they don't exercise and don't plan to in the next month) based on their self-reports of whether they exercise or intend to exercise. This is circular and the correlations between stages and behavior patterns would be spurious. (3) The specific temporal dimension of stages in the TTM appears to be arbitrary and contrived. In studies on addictive behaviors, people have been classified as being in various stages depending on their reported behavior patterns over a 6-month interval (DiClemente et al., 1991) or in a recent study on exercising, over a 1-month interval (Myers & Roth, 1997). The point here is that one could segment the "stream of behavior" anywhere in time. Also, 6-month or 1-month time frames seem ill-conceived when applied to chronic disease regimens. It is difficult to imagine a child recently diagnosed with IDDM and her parents "precontemplating" for 6 months about whether insulin should be given to treat hyperglycemia. (4) It remains to be seen whether the TTM is applicable to people with chronic health problems, particularly pediatric populations. TTM developers admit that empirical support for the model comes from studies with convenience or volunteer samples and focus on single, rather than multiple, health-related behaviors (Ruggiero & Prochaska, 1993). Also, the stages and processes that apply to decreasing or eliminating damaging health-related behaviors (such as smoking) are likely to be quite different than those relevant to increasing healthy behaviors (such as exercising). (5) Although a potential strength of the TTM is the matching of specific behavior change strategies to specific stages of change, there is limited support for the superiority of matched versus standard or "mismatched" interventions. Also, there is the potential for contradictory recommendations derived from a "transtheoretical" approach that draws from behavioral, psychodynamic, and existential perspectives (Bandura, 1997).

Clinical Implications of the TTM

Consider a 16-year-old boy with IDDM. His daily regimen is typical of patients with this disease and consists of insulin injections three times per day, blood glu-

cose testing four times per day, following a meal plan that avoids concentrated sweets, and exercising (while balancing diet and insulin requirements). The patient is active in sports and other extracurricular activities at school, and like other teenagers, has an active social life. The patient has been diagnosed with IDDM since he was 8 years of age and until recently his disease has been under good control. In the past year, however, control of his disease has been in the "fair to poor" range.

Applying the TTM to this example might suggest the following clinical strategies (Ruggerio & Prochaska, 1993):

- To "stage" this patient, the clinician could ask the following questions: "Do you always time your insulin injections, check your blood glucose, follow your special diet, or balance exercising with diet and insulin requirements as you were instructed to do?" The patient would then be classified in one of the TTM stages depending on his choice of one of the following response options for each regimen task: "No, and I don't intend to in the next 6 months" (precontemplation); "No, but I plan to in the next 6 months" (contemplation); "No, but I plan to in the next month" (preparation); "Yes, but for less than 6 months" (action); or "Yes, for more than the past 6 months" (maintenance). Once the patient has been "staged," behavior change strategies suited to his current stage could then be implemented.
- If the patient is in the precontemplation or contemplation stage, the clinician might provide more personalized education, opportunities for emotional expression, and supportive networks. This would allow him to increase his awareness and acceptance of IDDM and increase confidence in his ability to carry out the regimen.
- If the patient is in the preparation stage, the clinician might assist him in setting specific and achievable goals (e.g., testing his blood glucose at least before each meal) and reinforcing any progress (however small) toward meeting these goals. This is a shaping process and the clinician may have to settle for less than optimal performance as long as the patient progresses toward achieving his goals.
- If the patient is in the action stage, the clinician might provide behavioral skills training and self-management strategies, such as self-monitoring and self-reinforcement. Because the patient is trying to establish a new behavioral pattern, he would also require frequent positive reinforcement and social support.
- If the patient is in the maintenance stage, the clinician might help him anticipate and strategize about how to manage obstacles to maintaining adherence. For example, if he goes out to eat with friends, how can he handle social pressures to eat forbidden foods that his friends are eating?

Also, the clinician can help the patient cope with lapses in management by putting these into perspective (e.g., "just because I ate the wrong foods today, it doesn't mean I have to in the future") and problem solving about ways to cope with future temptations (e.g., "what can I do if I am out with my friends and they are eating what I am not supposed to eat?").

APPLIED BEHAVIOR ANALYTIC THEORY

Description

Applied behavior analytic (ABA) theory has its historical roots in the foundational work on operant conditioning by B. F. Skinner and has been explicitly related to understanding and modifying adherence to medical regimens (Rapoff, 1996; Zifferblatt, 1975). The ABA model emphasizes two general processes whereby human behavior is shaped: *contingency-shaped* and *rule-governed* behavior (Hayes, 1989; Skinner, 1974).

Contingency-shaped behavior refers to behavior directly shaped by environmental contingencies and its basic form is schematically represented by the *three-term contingency*:

$$S^D \longrightarrow R \longrightarrow S$$

For example, a discriminative stimulus (pain) sets the occasion for or prompts a response (taking pain medications) and the probability of that response is altered by a consequent stimulus (pain relief).

Four basic operant processes can be distinguished based on whether a consequence is added or subtracted contingent on a behavior and the resulting effect on behavior in terms of increasing or decreasing the probability of that behavior in the future (see Fig. 2.4). *Positive reinforcement* occurs when a response-contingent consequence increases a behavior (e.g., symptom relief increases the probability the person will take prescribed medications). In contrast, *positive punishment* occurs when a response-contingent consequence decreases a behavior (e..g, taking prescribed medications results in negative side effects, thereby "punishing" medication-taking). *Negative reinforcement* occurs when response-contingent removal of a consequence increases a behavior (e.g., taking antacids terminates or allows one to avoid gastrointestinal irritation caused by some medications). *Negative punishment* (or extinction) occurs when response-contingent removal of a consequence decreases a behavior (e.g., a child does not comply with a parental request to take medications and loses privileges).

Behavior analysts are also giving increased attention to the unique role of verbal antecedents in the control of human behavior, i.e., *rule-governed behavior*

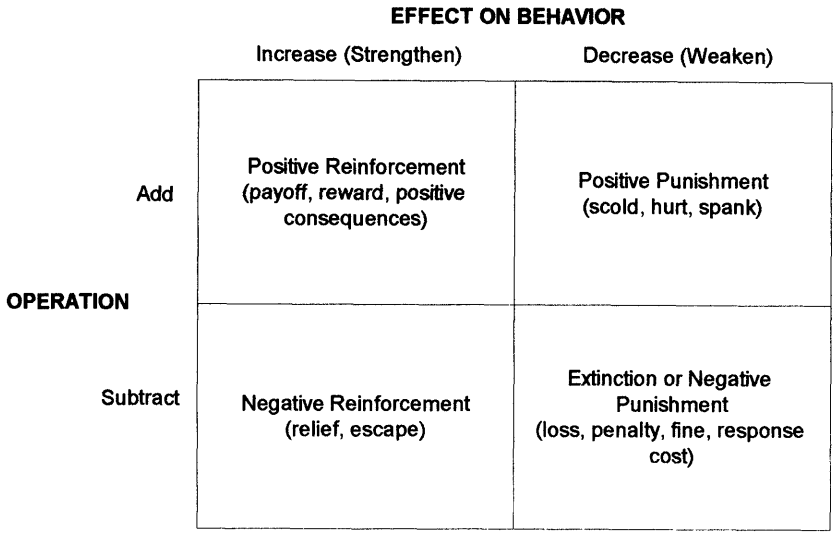


Figure 2.4. Four basic operant contingencies with technical terms and colloquial synonyms (in parentheses).

(Hayes, 1989). Rules are ubiquitous and can take many forms, such as instructions, laws, maxims, proverbs, advice, grammar, and scientific propositions (Riegler & Baer, 1989). They are valuable because people can learn them more quickly without having directly experienced (or without ever experiencing) the consequences implied or specified by the rule (Riegler & Baer, 1989; Skinner, 1974). Parents count on rules, such as "look both ways before crossing the street," to keep their children out of harm's way.

Whether rules are followed or not depends on the following factors (Hayes, 1989; Riegler & Baer, 1989): (1) a generalized history of reinforcement for following rules (or punishment for failing to follow rules), (2) immediate local consequences for following rules (often in the form of social approval or disapproval), (3) contact with the contingencies described in a rule (e.g., taking medications and experiencing symptom relief), and (4) automatic or self-given consequences (e.g., positive or negative feelings and thoughts).

There are, however, problems and limitations of rule-governed behavior. Children may not be able to follow rules because they lack the prerequisite skills (Poppen, 1989). Also, following rules may result in negative consequences, such as taking medications and experiencing aversive side effects. Children may also fail to generate rules when its advantageous to do so or they may form inaccurate or unrealistic rules (Hayes, Kohlenberg, & Melancon, 1989). For example, a teenager

with lupus in one of our studies said she took steroid medication more often or less often than prescribed, depending on how she felt (Pieper, Rapoff, Purviance, & Lindsley, 1989). This rule was unhelpful because by following it she did not adequately control the symptoms of her disease.

A critical dimension of the ABA approach is doing a functional analysis, which involves identifying "important, controllable, causal functional relationships applicable to a specified set of target behaviors for an individual client" (Haynes & O'Brien, 1990, p. 654). Relating this approach to medical adherence would involve the following steps: (1) operationally defining adherence behaviors, (2) identifying antecedent events that set the occasion for or predict adherence behaviors, (3) generating hypotheses about consequences that maintain adherence behaviors, and (4) collecting observational data (when feasible) to provide at least correlational confirmation of the hypothesized associations of antecedent and consequent events with adherence behaviors (see Horner, 1994). Once the functional analysis is completed, a treatment plan can be formulated, implemented, and tested.

Critical Appraisal

There is strong empirical support for interventions based on the ABA model in improving adherence to pediatric medical regimens, particularly those for chronic diseases (Meichenbaum & Turk, 1987; Rapoff & Barnard, 1991; Varni & Wallander, 1984). Interventions generated from an ABA perspective have primarily involved contingency management procedures, such as token systems. There do not appear to be any studies that have explicitly examined medical adherence from a rule-governed behavioral perspective, though this would seem feasible. For example, older children and adolescents with chronic diseases could be taught to identify unrealistic or unhelpful "rules" about medications (e.g., "Medications can be taken depending on how one feels") and challenge these rules by verbal and experiential means (as with traditional cognitive therapy methods).

Despite strong empirical support, ABA approaches have been criticized on the following grounds: (1) The ABA model is too simplistic to account for the richness and complexity of human behavior. It is based on studies that modify the "rate of trivial responses emitted by animals in barren controlled settings" (Bandura, 1995, p. 185) or what has been referred to as the "behavior of small animals in boxes" (Todd & Morris, 1992, p.1441). This criticism underlies many that follow here and partly reflects the foundational work on operant conditioning with simpler organisms in highly controlled experimental settings. Not surprisingly, behaviorists have countered that research with simpler organisms can reveal basic processes (as in medical research) but acknowledge that elaborations and extensions are needed when moving to the study of more complex organisms (Skinner, 1974; Todd & Morris, 1992). They would also point to an extensive and diverse

body of applied literature that speaks to the utility of ABA approaches in addressing socially significant problems in medicine, education, business, family life, and community settings (see Kazdin, 1994, and representative issues of the *Journal of Applied Behavior Analysis*). (2) Concerns have been raised that "external" or "extrinsic" rewards may undermine "intrinsic" motivation (Deci & Ryan, 1985). For example, highly adherent patients may become nonadherent when offered external rewards for adhering to medical treatments. A variant of this criticism is voiced by parents who sometimes object to providing external rewards for something their child "should do" without being explicitly rewarded. Behavior analysts have addressed this issue and concluded that detrimental effects of rewards are rare, easily avoided, and they agree that more "natural" reinforcers are preferable (Eisenberger & Cameron, 1996). (3) The "cognitivist challenge" to the ABA model contends that human beings respond to "cognitive representations" of the environment and not the environment per se (Mahoney, 1974). ABA theory is criticized for minimizing or rejecting the causal role of cognitions and other "private events" (such as feelings and sensations) in human functioning (Bandura, 1996). ABA adherents counter with an oft-quoted remark by Skinner (1974): "What is inside the skin, and how do we know about it? The answer is, I believe, the heart of radical behaviorism" (pp. 211–212). Though they recognize that behavior analysts have traditionally ignored the study of private events, they also cite recent theoretical and empirical developments that seek to rectify this situation (Anderson, Hawkins, & Scotti, 1997; Wilson, Hayes, & Gifford, 1997). (4) ABA approaches have been characterized as manipulative, totalitarian, and punitive (Todd & Morris, 1992). Some have even argued that it denigrates freedom and undermines personal agency (Bandura, 1997). The counter to this criticism is that controlling influences are omnipresent and need to be delineated so people can understand and counter these influences (Skinner, 1974). Also, behavior analysts have argued for greater use of positive reinforcement-based procedures and have actively worked to reduce aversive control and to safeguard the rights of vulnerable groups, such as children and individuals with disabilities (Kazdin, 1994; Todd & Morris, 1992).

Clinical Implications of ABA Theory

Consider a 14-year-old boy who was diagnosed with polyarticular JRA 2 years ago. His disease has been under poor control as evidenced by multiple active joints, extended joint stiffness in the morning, severe limitations in daily activities, and moderate to severe joint pain reported by the patient. His regimen consists of an oral anti-inflammatory medication (tolmetin sodium) four times a day, range-of-motion exercises once per day, and wearing joint splints on his wrists at night. The referring rheumatologist suspected that nonadherence to this regimen contrib-

uted significantly to the patient's poor disease control. The patient lived with both parents, who worked outside the home, and an older sister.

Applying an ABA perspective to this case might suggest the following strategies:

- Focusing on the complexity of the regimen (response costs), the clinician might discuss with the patient's physician and occupational therapist ways to simplify the regimen. For example, the patient may be able to take the anti-inflammatory medication three rather than four times per day and reduce the number of range-of-motion exercises.
- The clinician's assessment might reveal that the patient tends to be more adherent to his regimen on days when he has increased joint pain and stiffness. On these days, his symptoms "remind him" to take his medications, do his exercises, and wear his splints. The clinician might need to help the patient and parents find specific and reliable cues or prompts for adherence on days when his disease symptoms are not as severe. For example, the patient may be asked to monitor and record adherence tasks as he completes them using a calendar chart posted in a prominent place.
- Considering potential negative regimen effects, the clinician may need to provide advice about how to reduce aversive consequences of adhering to the regimen. For example, anti-inflammatory drugs often cause gastric irritation and pain. The patient could be reminded to take medications with foods and along with his parents, to consult with his physician about the use of antacid medications to reduce gastric irritation and pain.
- Attending to potential positive consequences for adherence, sometimes these occur for this patient when he is symptomatic and adherence results in relief of disease symptoms, such as pain. During relatively asymptomatic periods, positive consequences may need to be specifically programmed to reinforce adherence behaviors. For example, the patient could be exposed to a token system program, whereby he earns points for adhering to regimen tasks and exchanges points for routine and special activities. The token system might also need to include point fines for nonadherence.
- Taking a rule-governed perspective, the patient may operate on unrealistic or unhelpful rules about his disease and regimen. For example, he may think he needs to be vigilant about following his regimen only when he is symptomatic. The clinician would need to help him challenge the utility of this rule and to formulate more helpful rules to advance his health status (e.g., "I need to take my medications, do my exercises, and wear my splints at night, even when I feel OK, in order to control my arthritis and to prevent flareups").

SUMMARY AND IMPLICATIONS OF ADHERENCE THEORIES

At the theoretical and philosophical level, there may be little hope (or need) for agreement between proponents of different theories about why people do or do not follow prescribed medical regimens. Proponents of competing theories "practice their trades in different worlds" and communication across the theoretical divide is "inevitably partial" (Kuhn, 1970, pp. 149–150).

Agreement can be reached about the content and behavior change processes addressed by various theories. The content refers to the focus on adherence behaviors or what people actually do in relation to a prescribed regimen (even within the TRA/PB the intermediary step of "intentions" leads to adherence-related behavioral requirements). Behavior change processes can be summarized as two basic types: (1) cognitive or self-mediated thought processes (e.g., self-efficacy in Bandura's theory and rule-governed behavior in ABA) and (2) environmental contingencies (e.g., cues to action in the HBM and consequences in ABA). What clinicians do to activate these processes are similar despite differing theoretical frameworks and constructs. That is, clinicians can promote adherence to medical regimens by

- Verbally persuading patients and their families of the value of prescribed regimens
- Providing competent role models who demonstrate how to successfully manage regimens
- Helping patients and families set specific goals and monitor progress to these goals
- Teaching patients and families the necessary skills for carrying out regimen tasks
- Helping patients and their families arrange more reinforcing consequences for adherence, be they direct, vicarious, or self-generated

Those of different theoretical persuasions may have more in common then they thought. Clinicians and researchers should direct their energies and talents to applying generic principles and strategies, while retaining their unique perspectives and cherished theoretical constructs. Patients and their families would be better served by taking this integrative approach.

3

Assessing Adherence

Why assess adherence? It is vital to assess adherence because adherence failure is a ubiquitous problem that directly impacts the health and well-being of children. This chapter will expand on reasons *why* to assess adherence, as well as *what* is to be assessed, *who* should be assessed (and who should do the assessment), and *how* to assess. Because there is no ideal measure of adherence, the most common methodological limitations and problems (such as measurement reactivity) will be reviewed and strategies for minimizing their impact will be offered. Medical outcomes (such as glycosylated hemoglobin levels in patients with IDDM) are often treated as indirect measures of adherence, even though they are separate phenomena with a variable and conditional relationship to adherence. Measures of disease or health status outcomes relevant to the more common acute and chronic illnesses require a separate discussion (see Chapter 4).

LEARNER OBJECTIVES

- Identify reasons for assessing adherence, such as screening, prediction, and evaluation.
- Identify adherence behaviors common to pediatric medical regimens.
- Describe and give rationales for who is to be assessed and who should do assessments.
- Describe adherence assessment strategies and evaluate their relative advantages and disadvantages, including the comparative performance of these strategies.
- Describe generic methodological limitations of adherence measures and offer recommendations for addressing these problems.

WHY ASSESS ADHERENCE?

The aims or functions of adherence assessment are consistent with those applicable to assessing any behavioral phenomenon: (1) screening or diagnosis, (2) pre-

diction, (3) selection of intervention strategies, and (4) evaluation of intervention efforts (Barrios, 1988; Johnston & Pennypacker, 1993; Mash & Terdal, 1988).

Screening and Diagnosis

Not all patients are candidates for interventions to improve medical adherence. Clinicians may do more harm than good if they intervene with those patients who are maintaining an acceptable level of adherence (Finney, Hook, Friman, Rapoff, & Christophersen, 1993). Patients may require varying degrees of assistance to elevate their adherence levels. Screening is helpful in determining who would benefit from efforts to modify adherence and to limit the time and expense of monitoring and intervening with patients who do not require assistance. This could be done by monitoring adherence in a group of patients, setting a minimum criterion for nonadherence (e.g., <80% of medications taken), and offering interventions to those classified as nonadherent.

In some cases a specific "diagnosis" of nonadherence is required. The most recent edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV) contains a supplementary (or "V") code labeled "Noncompliance with Treatment" (American Psychiatric Association, 1994) . To make this diagnosis requires the clinician to identify adherence problems that are severe enough to require independent clinical intervention. This, in turn, requires some measure of adherence and specific criteria to determine the severity of adherence problems (neither of which are specified in the code description). If this code could be further defined and standardized, clinicians who provide adherence interventions could be reimbursed by third-party payers for their efforts. Also, patients and their families who do not warrant other (possibly more stigmatizing) psychiatric diagnoses could avoid unnecessary out-of-pocket expenses to receive assistance in improving adherence.

Prediction

Isolating predictors of adherence requires an adequate measure of adherence. The best predictor of future adherence to a specific regimen is current or past adherence to that same regimen (confirming the old maxim that the best predictor of future behavior is past behavior). Adherence has also served as a predictor of disease and health status outcomes. Thus, adequate assessments of adherence, along with disease status information, measures of psychosocial adjustment, and properties of the prescribed regimen, can facilitate better predictions about the outcomes of various medical treatments.

Intervention Selection

Adherence assessment can aid in the selection of intervention strategies for improving adherence. In designing adherence interventions, clinicians need to know

the extent and nature of adherence problems. Those patients with less severe adherence problems would require less complex efforts to improve adherence. For example, patients who occasionally forget to take medications may be provided with simple strategies to prompt adherence (such as setting a watch alarm). In contrast, those patients who frequently miss doses and actively resist their parents' attempts to prompt adherence might need a more complex intervention, involving prompting, shaping, reinforcement, and even mild punishment (e.g., time-out) strategies.

The nature of adherence problems may dictate the type of intervention needed. Patients who underdose (the most common medication adherence error) may require a different intervention (e.g., instructing them about the importance of maintaining a therapeutic drug level to optimize treatment benefits) than those who overdose (e.g., instructing them to avoid trying to make up missed doses by taking extra doses). Expanding assessments to include a functional analysis of variables that impact adherence (such as antecedent and consequent events) would greatly enhance the ability of clinicians to select individualized interventions that match the unique history and life circumstances of their patients.

Evaluation of Intervention Efforts

Adequate assessments of adherence are necessary to evaluate efforts to improve adherence to medical treatments. The relative efficacy of different approaches to improving adherence can be evaluated, such as educational versus behavioral strategies. Clinicians can also determine whether adherence interventions can be successfully faded out or modified if they fail to address adherence problems. Adherence assessments are also needed to evaluate the efficacy or effectiveness of medical treatments. If adequate adherence can be demonstrated, then the relative merits of various medical treatments can be more accurately determined in clinical and research contexts.

WHAT IS TO BE ASSESSED? SELECTION OF TARGET BEHAVIORS

Adherence is about behavior. But which behaviors are selected for assessment depends on the type of illnesses and their associated treatments. For acute illnesses (such as otitis media), "medication taking" is the primary behavior of interest, such as the ingestion of antibiotics on a specific schedule (from one to four times a day) over a limited period of time (5 to 14 consecutive days). The situation is more complex for chronic disease regimens (see Table 3.1). These regimens require multiple and more complex classes of behaviors over an extended or indefinite period of time. Therefore, they require more complex and long-term assessments of adherence.

Table 3.1. Regimen Requirements for Chronic Pediatric Diseases

Disease	Medications	Diet	Exercise	Symptom monitoring
Asthma	Oral and inhaled	Avoid certain foods if allergic	General	Peak flow
Cancer	Oral and parenteral (chemotherapy)	Supplements	General	None
Cystic fibrosis	Oral and inhaled	Pancreatic enzyme replacement and boosted intake	General	Peak flow
Diabetes	Parenteral (insulin self-injections)	Avoidance of concentrated sugars Intake coordinated with insulin requirements	General	Blood glucose
JRA	Oral	PRN supplemental intake	General Specific range of motion	None
Seizures	Oral	General	General	Seizure episodes

Note: These are basic requirements that may be altered depending on the course of the illness. Also, symptom monitoring could (or should) become central to adequate management of all chronic diseases.

Given these multicomponent regimens, which behaviors in a complex regimen should be selected for assessment? Guidelines for target behavior selection from the behavioral assessment literature offer some clues (Barrios, 1988; Kratochwill, 1985; Mash & Terdal, 1988; Sturmey, 1996).

Guidelines for Selecting Target Regimen Behaviors

1. Select Them All (or at Least Baseline Them All)

This means selecting all behaviors relevant to adhering to a particular treatment regimen (such as those in Table 3.1). The rationale for this strategy is that there is currently no empirical basis for selecting one behavior over another in terms of its importance in achieving medical treatment goals. In theory, they are all considered equally important and need to be assessed.

Although in theory all regimen behaviors should be given equal weight, this does not seem to be the case in clinical practice. Providers seem to emphasize certain regimen components over others (e.g., medications), possibly because they consider these components more critical to treatment success or because they have more expertise in and responsibility for certain components (e.g., medication management for physicians). The choice of which regimen behaviors to select for

measurement may depend on providers' judgments of which regimen behaviors are critical to the health of their patients.

A variant of this approach would be to conduct baseline or screening assessments of all relevant regimen behaviors and then target low-rate behaviors or ones that fail to meet some minimum standard (e.g., <80% adherence) for further assessment and intervention. This would establish some empirical basis for selecting target behaviors, but minimum standards of adherence (other than arbitrary ones) have not been determined for most pediatric medical regimens.

2. Select Behaviors that Are Identified as Most Problematic or Disturbing to Others

With reference to medical adherence issues, these "others" are most often parents and providers. The patients themselves may not acknowledge problems with adherence. Interviewing parents or providers can reveal which behaviors need to be the focus of assessment. Most likely, these will be behaviors perceived as critical to the patient's health and those that have been difficult to establish or maintain for a particular patient. This guideline would appear to be the most socially or ecologically valid as it addresses the specific concerns of patients and other key people (family members and providers).

3. Select Critical or "Keystone" Behaviors

Originally, "keystone" behaviors were described as those behaviors that produce response generalization, i.e., altering the keystone behavior would produce desirable changes in other target behaviors (Sturmey, 1996). Some behaviors are chained together or may be part of the same functional class, such as insulin injections in relation to eating and exercise for patients with IDDM. Altering one behavioral requirement may produce changes in other behaviors. However, adherence to different behavioral requirements (such as diet, exercise, and medication taking) within the same treatment regimen may not be highly correlated (Johnson, 1993). Thus, altering one behavior may fail to produce changes in other relevant behaviors.

The general concept of keystone or critical behaviors, however, might prove useful. Providers who treat patients with chronic diseases prescribe a myriad of behaviors that (hopefully) to the best of their knowledge and experience are likely to improve the health and well-being of their patients. The key in selecting keystone behaviors is to identify which of these behaviors are critical to optimal medical treatment outcomes. These critical regimen behaviors can be gleaned from medical textbooks, surveys of relevant providers, and consensus treatment guidelines from governmental and medical associations that set empirically validated criteria for standard medical practice (Johnson, 1993). For example, consistency in taking

inhaled corticosteroids in the treatment of moderate to severe asthma may be more critical for reducing morbidity and mortality for large numbers of patients than environmental control measures, such as minimizing indoor allergens. Even if critical behaviors can be identified for groups of patients with a particular disease, they may not be relevant for a particular patient.

4. Select Behaviors that Are the Easiest to Change

The rationale for this guideline is that behaviors that are more easily changed can create momentum to change other, more difficult behaviors. This approach would help patients be more successful in managing their illness and should enhance their self-efficacy.

WHO SHOULD BE ASSESSED AND WHO SHOULD ASSESS?

Adherence assessment in pediatrics is arguably more complex than in adult medicine, in that others (particularly parents) have varying degrees of responsibility in helping children carry out medical regimens. In fact, for younger children, parents are primarily or exclusively responsible for ensuring that treatments are consistently maintained. Therefore, the focus needs to be on assessing patient and parent regimen-related behaviors. For school-aged children, this might also involve assessing the behaviors of school nurses who supervise and/or sometimes administer treatments at school. A student and I are currently working with sisters who receive both doses of their asthma medications at school. The school nurse is responsible for making sure these girls receive their medications. Therefore, it was important to assess how well the nurse prompts and supervises the medication regimen.

A variety of informants or assessors can be employed to monitor adherence. These include parents, physicians, nurses, and therapists. There are obvious advantages to employing these significant others. They are often a major source of data on adherence because of their unique and regular access to patients in their homes, schools, clinics, and in the community. In research contexts, data obtained from participant observers or raters need to meet rigorous criteria of validity, reliability, and accuracy, as with data from other sources (Johnston & Pennypacker, 1993). This requires proper training and quality controls. For example, in some of our clinical studies on improving adherence to medication regimens for pediatric rheumatic diseases, my colleagues and I trained parents to conduct observations or pill counts and the parents obtained acceptable levels of agreement with independent observers (Pieper et al., 1989; Rapoff, Lindsley, & Christophersen, 1984; Rapoff, Purviance, & Lindsley, 1988a,b).

HOW TO ASSESS ADHERENCE? A CRITICAL REVIEW OF ASSESSMENT STRATEGIES

A variety of strategies exist for assessing adherence, including assays, observations, mechanical devices, pill counts, provider estimates, and patient/parental reports. Each of these strategies has associated assets and liabilities, including relative costs and clinical applicability or feasibility (see Table 3.2). Some liabilities are common to all of these measures and will be discussed later in this chapter. Also, some of these strategies are only applicable to certain types of regimens, such as assays to assess medication adherence.

Drug Assays

Description

Laboratory assays can measure drug levels, metabolic products of drugs, or markers (pharmacologically inert substances or low-dose medications) added to

Table 3.2. Assets and Liabilities of Adherence Measures

Measure	Assets	Liabilities
Assays	Verify drug ingestion	Pharmacokinetic variations
	Adjust drug levels	Short-term measure
	Quantifiable	Invasive and expensive
Observation	Direct measure of nonmedication regimens	Obtrusive and reactive
		Clinically impractical
	Repeated measurements	Difficult to obtain representative samples
	Necessary to functional assessment	
Automated	Precision (reveals dosing and dosing interval data)	Does not measure consumption
		Reactive
	Continuous and long-term assessments	Mechanical failures
	Helps identify drug reactions	
Pill counts	Feasible	Relies on patients to return unused medications
	Inexpensive	
	Validate provider or patient estimates	Overestimates adherence
		Does not measure consumption
Provider estimates	Feasible	Overestimates adherence
	More accurate than global patient reports	Accuracy not a function of provider training or experience
	Correctly identifies adherent patients	Global estimate
Patient report	Feasible	Overestimates adherence
	Accurate if patient is asked in nonjudgmental fashion	Subject to reporting bias ("faking good")
	Patient has continuous access to own behavior	Not feasible for younger children

Note: Adapted from Rapoff & Christophersen (1982).

target drugs in bodily fluids, such as serum, urine, and saliva (Roth, 1987). To properly interpret assays requires some basic knowledge of clinical pharmacokinetics, which is concerned with the absorption, distribution, and elimination of drugs in the body (for general and relatively nontechnical overviews, see Benet, Mitchell, & Sheiner, 1990; Johanson, 1992; Winter, 1994). The following is a simplified version of these processes and a description of other important terms relevant to interpreting drug assays.

Absorption of drugs depends initially on the dose administered and route of administration. Drugs can be delivered orally, parenterally (intravenous, intramuscular, or subcutaneous), by inhalation into the lungs, transdermally (skin patches), and via mucosal routes (the nose, mouth, or rectum). There are relative advantages and disadvantages of these various routes, such as immediate onset of action for intravenous versus slow onset for oral routes (see Johanson, 1992, Table 2, p.19 for a more thorough delineation). Because oral routes are most the common and relevant to assessing adherence, this discussion will focus on what happens when a drug has been administered orally.

Once a drug is administered, it enters the gastrointestinal tract where absorption takes place. At this point, absorption can be affected by the acidity in the stomach, contents of the stomach (such as food, which is why medications are often taken prior to meals), and the formulation of the drug (generic versus brand versions). Metabolism of the drug primarily occurs in the liver as a result of enzymatic reactions. The rate or extent of metabolism can be affected by individual differences in the structure of liver enzymes (reflecting genetic differences), and the functioning of liver enzymes (which can be altered by a number of factors, including disease, age, and present or past administration of other drugs).

Once the drug has been absorbed and metabolized by the liver (so-called "first-pass"), it reaches the circulatory system where rapid distribution occurs to bodily tissues. Rapid distribution occurs because the blood circulates throughout the body every minute. Again, the liver comes into play, as there is a second pass through the liver after it is distributed throughout the body.

The next phase is elimination or excretion of the drug, which occurs primarily by the kidneys. Fluid is forced into the kidneys and contains the drug, its metabolites, other waste products (natural metabolites of bodily function) as well as electrolytes (such as potassium and sodium). That which is not needed or wanted by the body is transported out through the ureters to the bladder and eliminated through urination.

There are important concepts to consider when interpreting assays. The *bioavailability* of a drug is that percentage or fraction of the administered dose that enters the patient's systemic circulation (Winter, 1994). Several factors can affect bioavailability, including the intrinsic dissolution and absorption properties of a drug, the route of administration, the dosage form (tablet or capsule), the stability of the active ingredient of the drug in the gastrointestinal tract, and the extent of

drug metabolism before reaching the circulatory system. The rate of elimination is directly related to plasma drug concentrations or the *half-life* of a drug, which is "the amount of time required for the total amount of a drug in the body or the plasma drug concentration to decrease by one-half" (Winter, 1994, p. 43). For most drugs in clinical situations, it can be assumed that all of the drug has been effectively eliminated after three to four half-lives (Winter, 1994).

Another important concept is *steady state* or when drug concentrations plateau, which is determined by the half-life of the drug. In general it takes one half-life to reach 50% steady state, two half-lives to reach 75%, three half-lives to reach 87.5%, and four half-lives to reach 93.75%. It is also important to know maximum (*peak*) and minimum (*trough*) plasma levels for a given drug at steady state during a particular dosing interval. Plasma samples for drug assays are often drawn just before the next dose because trough levels are the most reproducible. Some drugs have a narrow therapeutic range and it is useful to identify fluctuations in plasma drug levels between doses. This is particularly true when the dosing interval is longer than the half-life, which results in large fluctuations in plasma drug levels (Winter, 1994).

Assets

Assays confer several advantages. They are quantifiable, clinically useful for determining subtherapeutic, therapeutic, and toxic levels of drugs, and they provide information on dose-response relationships (Rand & Wise, 1994). Also, they do not rely on potentially biased or inaccurate reports or estimates provided by patients, family members, or providers. Most importantly, assays confirm that drugs have been ingested. Chemical markers or tracers share these same advantages and can used with drugs for which there are no standard assays. Ideal markers should be chemically inert, nontoxic, nonradioactive, and undetectable by patients (Insull, 1984). Several types of chemical markers have been safely used for medication adherence assessments in pediatrics, such as riboflavin (Cluss & Epstein, 1984) and deuterium oxide (Rodewald, Maiman, Foye, Borch, & Forbes, 1989).

Liabilities

Assays have some serious limitations. They measure adherence over relatively short time intervals and thus fail to provide information about consistency in medication adherence over extended periods of time. Most assays reflect medication ingestion that has occurred (at best) no further back than five half-lives (Rudd, 1993). Consider phenobarbital, which is a barbiturate used to treat seizure disorders. The plasma half-life of phenobarbital in children may be as short as 2 to 3 days (Winter, 1994). Assuming the half-life is 3 days (a more forgiving estimate than 2 days) and an assay reflects adherence no further back than five half-lives, a

particular assay for phenobarbital would (at best) quantify adherence over the 15-day period prior to the assay assessment.

Assays can also be expensive and invasive, which makes them less feasible for use in pediatric settings (especially for chronically ill children who do not want another, and from their perspective, an unnecessary painful procedure like having their blood drawn). When assays are obtained in relation to dosing is also a complicating factor. Samples for assays are usually drawn just before the next medication dose (at trough levels), which requires knowledge of when the last dose was taken, which in turn depends on the accuracy of patient reports of when they took their most recent dose (Backes & Schentag, 1991). Laboratory errors can also be made in transporting, analyzing, and reporting results to providers, although these are considered to be minimal.

Low drug levels can also reflect inadequacies in the prescribed regimen. This may be particularly true for adolescents when medication doses are not adjusted for rapid growth (especially increased body fat for females and muscle mass for males) and hormonal changes that occur during puberty (Brooks-Gunn & Graber, 1994; Cary, Hein, & Dell, 1991).

Finally, pharmacokinetic variations in the way drugs are absorbed, metabolized, and excreted can account for variability in drug levels unrelated to or in addition to adherence. Such factors include, the route of administration, the type of preparation (enteric coated, uncoated, or liquid forms), contents of the stomach, drug interactions, smoking, gastric pH levels, age, gender, puberty, body fat, and disease states, particularly compromised liver or renal functioning (Backes & Schentag, 1991; Johanson, 1992; Winter, 1994). This is further complicated by the paucity of quantitative data in pediatrics (relative to adult medicine) on the relationship between pharmacokinetics and drug treatment effects (Boreus, 1989).

Markers share some of the same disadvantages as standard assays, in terms of being affected by pharmacokinetic variations. In addition, adding markers to existing drugs may require approval by the FDA as a "new" drug and patients may consume foods that contain markers, such as riboflavin (Rudd, 1993).

Observation

Description

Direct observation of patient adherence is rare (Rapoff & Barnard, 1991). This may be because most studies examine adherence to medications and other measures, such as assays, are firmly entrenched as the optimal way to assess medication ingestion. Observation measures, in the form of behavioral checklists, have been used to evaluate patient technique in performing skills necessary for adherence. Behavioral checklists have been developed for assessing blood or urine glucose testing (Epstein, Figueroa, Farkas, & Beck, 1981; Wing, Koeske, New,

Form 3.1. Checklist for Monitoring Proper Use of a Metered-Dose Inhaler

Metered-Dose Inhaler (MDI) Checklist

Critical skills

1. Spacer is correctly assembled (assembly criterion is specific to each spacer) (O,A,I)*
2. Patient opens InspirEase bag (I)
3. Canister is placed into actuator (O,A,I)
4. Patient closes mouth around mouthpiece (O,A,I)
5. Patient positions hand with index fingers on top of canister and thumb on bottom of spacer/mouthpiece (if child is physically unable to perform this skill, the parent can actuate the canister or another adaptation can be made) (O,A,I)
6. Patient presses canister once (O,A,I)
7. Patient actuates canister just before or at beginning of inhalation (O,A)
8. Patient continues to hold canister down through the entire inhalation (O)

Additional skills

9. Patient shakes canister at least 3 times (prior to actuation) (O,A,I)
10. Patient exhales before inhalation (O,A)
11a. Patient inhales slowly and deeply through the mouth (O,A)
11b. Patient breathes in slowly (so that whistling does not sound), causing bag to deflate completely (I)
12. Patient holds breath to count of five (O,A,I)
13. Patient breathes back into bag, then breathes in slowly (so that whistling does not sound), causing bag to deflate completely (I)
14. Patient holds breath again to count of five (I)

*Letters in parentheses indicate items that are appropriate for different types of inhalers, with O=Optihaler, A=Azmacort, and I=InspirEase. Items are not weighted equally. Failure to perform any of the critical skills (the number of these skills varies by type of inhaler) results in a total score of zero.

Note: From "Development of a scale to measure children's metered-dose inhaler and spacer technique," by L. Boccuti, M. Celano, R. J. Geller, and K. M. Phillips, 1996, *Annals of Allergy, Asthma, & Immunology, 77*, p. 219. Copyright 1996 by Annals of Allergy, Asthma, & Immunology. Adapted with permission.

Lamparski, & Becker, 1986), insulin administration (Gilbert et al., 1982), factor replacement therapy (Sergis-Davenport & Varni, 1983), and metered-dose inhaler (MDI) use (Boccuti, Celano, Geller, & Phillips, 1996). Form 3.1 provides an example of a behavioral checklist to monitor MDI technique for children with asthma. Of course, observing and evaluating how patients execute these skills says nothing about how often or consistently they accurately perform them.

Some studies have utilized parent or sibling observations as a primary data source, with acceptable levels of agreement with independent observers (Lowe & Lutzker, 1979; Rapoff et al., 1984). Direct and unobtrusive observations in camp settings have also been used to measure dietary adherence (Lorenz et al., 1985) and

to demonstrate concurrent validity of 24-hr recall interviews (Reynolds, Johnson, & Silverstein, 1990).

Assets

Unlike other strategies, observational measures are direct measures of regimen-related behaviors. They are automatically valid, in the sense that they measure what they intend to measure (Johnston & Pennypacker, 1993). By directly measuring behavior, observational measures avoid subjective and potentially misleading judgments about behavior inherent in patient, family, and provider ratings of adherence. Observational measures also assess important dimensions of adherence behaviors, such as frequency (e.g., how often patients exercise), duration (e.g., the amount of time that patients exercise), interresponse time (e.g., the schedule or time between medication doses taken), and how well the behavior was performed (e.g., the way exercises were done or medications delivered relative to performance standards). Finally, by focusing on public behaviors, observational measures can also reveal contemporaneous controlling variables (antecedents and consequences) related to adherence that may be amenable to intervention (Mash & Terdal, 1988). But if observational measures have so much to offer, why are they so infrequently used in medical adherence research and even less, in clinical practice?

Liabilities

The major problem with observational measures is accessibility. Clinicians or researchers simply do not have sufficient access to patients to measure their behavior in any consistent or representative way. At best, they have limited samples of behavior that may not reflect how patients typically behave in relation to prescribed regimens. Also, observational measures can be labor-intensive, as they require extensive training, monitoring, and recalibration or retraining of observers (Mash & Terdal, 1988).

An oft-cited disadvantage of observational measures is their potential for reactivity (Wildman & Erickson, 1977). That is, when patients are being observed, they may behave in ways that are not typical and usually in a socially desired direction (e.g., they may be more adherent). Compared with other assessment strategies, it is conceivable that directly watching patients has the potential of being more reactive than taking a blood sample, electronically monitoring their adherence, or asking them about adherence behaviors. However, reactivity is a potential problem with all measures of adherence.

Another type of reactivity is relevant to those conducting observations. When observers are being monitored, the quality of their observations may be higher than when they are not being monitored (Wildman & Erickson, 1977). Ob-

server reactivity may be particularly critical when using participant observers (such as parents) who have a direct interest in what is going on.

Another concern with observational measures for researchers is observer "drift" or variations in how paired observers record behavior over time. Over time, paired observers tend to develop a consensus about how behaviors are defined and recorded, which may substantially change or drift from the original coding definitions (Wildman & Erickson, 1977). Checking interobserver agreement between pairs of observers will not detect this problem because drift produces adequate agreement but with a corresponding decline in accuracy over time (Foster, Bell-Dolan, & Burge, 1988). Fortunately, there are many ways to minimize drift, including rotating pairs of observers, videotaping observation sessions and scoring them in random sequences, and retraining (Foster et al., 1988; Kazdin, 1977). There are a host of other observer, instrument, and subject variables to consider when conducting behavioral observations (see Bellack & Hersen, 1988; Kazdin, 1977; Mash & Terdal, 1988).

Microelectronic Monitors

Description

Technological advances in microprocessors have led to the development of automated measures of adherence. Microelectronic monitors are now available to record and store information on the date and time of tablet or liquid medication removal from standard vials, removal of pills from blister packages, actuation of metered-dose inhalers, blood glucose test results, and patient diary notations on adherence or other clinical events, such as pain levels (Cramer, 1991; Urquhart, 1994). These monitors can store information in real time for up to several months and can be downloaded into data files for analysis. This is one of the most exciting developments in adherence measurement, with some even calling electronic monitors the new "gold standard" (Cramer, 1995). Electronic monitors have been used to measure adherence to oral or inhaled medications in pediatrics (Coutts, Gibson, & Paton, 1992; Kruse & Weber, 1990; Matsui et al., 1992; Olivieri, Matsui, Hermann, & Koren, 1991).

One such device for measuring removal of pills is the Medication Event Monitoring System (MEMS®) available from the Aprex Corporation (Menlo Park, CA). The hardware consists of two components: the monitor and communicator module. The monitor is a cap with self-enclosed electronic circuitry that fits on a standard pill vial. One current version is the MEMS® TrackCap™ (with or without a child-resistant cap), which stores up to 1800 dose events and has a battery life of approximately 18 months. Another version is the MEMS® SmartCap™ (also available with or without a child-resistant cap), which stores up to 1500 dose events, also has a battery life of about 18 months, but has two additional features: a visual

display showing how many times the vial has been opened each day and how long (in hours) since the vial was last opened, as well as an optional audible signal programmed for when medications are to be taken. The communicator module is attached to a serial port of a computer and allows data from the cap to be downloaded into a software program that reads, displays, and prints out dosing records. Form 3.2 shows a typical printout from an earlier version of the MEMS® for a child with JRA who participated in one of our studies on improving adherence to nonsteroidal anti-inflammatory drugs (NSAIDs). The top portion of Form 3.2 shows the printout of her daily medication removal for a 1 week period and the bottom portion shows the calendar plot. This patient was prescribed Voltaren (an NSAID) on a twice-daily schedule and the half-life of the drug was set at 14 h, in consultation with the treating rheumatologist. The printout shows the month (mm), day (dd), year (yy), hour (hh), minutes (mm), and seconds (ss) the cap was removed and the days, hours, and minutes that elapsed between openings. The calendar plot shows the number of times the cap was removed each day.

Several parameters can be obtained from the MEMS® (using data from Form 3.2): number and percentage of doses removed (10 of 14; 71%); number and percentage of optimal daily dosings (3 of 7 days where two doses were taken; 43%); an estimate of therapeutic coverage over the 7-day time course based on the half-life (76.3%); and the average and range of interdose intervals (based on 10 doses taken over 7 days, in this example, yields a mean interdose interval of 16.66 h and a range of 8.73 to 27.67 h, versus the ideal interval of 14 h). As can be seen, different results are obtained depending on the parameter used to reflect adherence. For example, using "percentage of doses removed" (which is analogous to pill counts) yields a 71% adherence rate, in contrast to using "percentage of optimal daily dosings," which yields a much lower adherence rate of 43%.

Assets

Electronic monitors provide a continuous and long-term measure of medication adherence in real time, which is not available with any other measure. Monitors can reveal a spectrum of adherence problems, including (1) underdosing (the most common dosing error), (2) overdosing (which can contribute to toxic effects), (3) delayed dosing (dosing that exceeds recommended dosing intervals, which can reduce therapeutic coverage), (4) drug "holidays" (omitting doses for several days in succession without provider authorization), and (5) "white-coat" adherence or giving the appearance of adequate adherence by dumping medications or taking medications consistently several days before clinic visits (Urquhart, 1994).

The close monitoring conferred by electronic devices can also help distinguish probable from improbable drug reactions or side effects. For example, a drug reaction reported by a patient (such as dizziness) can be correlated in real time by

Form 3.2. Printout of Adherence Data Obtained by Electronic Monitoring

Aprex MEMS® Medication Event Listing

Physician:	Lindsley	Medication:	Voltaren
Patient name:		Prescribed regimen:	BID
Medical record number:	004	Drug duration action:	14 hr
Observation period:	Start: 10/10/92 00:01:00		
	Stop: 10/16/92 23:59:00		
Total recorded events:	10	Events listed for time zone:	Central

Dose Time (Cap removed)		Dose Interval (Elapsed time)	
mm/dd/yy	hh:mm:ss	dd:hh:mm	Notes
10/10/92	07:22:40	0:13:58	
10/10/92	17:10:24	0:09:47	
10/11/92	20:50:40	1:03:40	E
10/12/92	05:34:56	0:08:44	
10/12/92	17:13:36	0:11:38	
10/13/92	05:57:20	0:12:43	
10/14/92	05:41:52	0:23:44	E
10/14/92	20:10:08	0:14:28	E
10/15/92	21:14:40	1:01:04	E
10/16/92	16:04:48	0:18:50	E

Notes legend:
E—Dose Interval EXCEEDS Drug Duration of Action
F—Dose Time FILTERED due to less than 15 minutes separation from previous Dose Time
I—Dose Time INSERTED at end of Cap Open Length greater than 2 hours

October 1992

Date	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
				—	—	—	—
5	—	—	—	—	—	2	1
12	2	1	2	1	1	—	—
19	—	—	—	—	—	—	—
26	—	—	—	—	—	—	—

Therapeutic coverage: 76.3%

an electronic monitor with inappropriate medication dosing, such as shortened intervals between doses or taking extra doses. Conversely, improbable drug reactions can be revealed if the patient reports a side effect when the monitor indicates low adherence (Rudd, 1993).

Monitors can also help identify "actual" drug resistance (low efficacy in spite of high adherence to an adequate dosing regimen) versus "pseudo" resistance caused by delayed or underdosing (Rudd, 1993). Combined with plasma assays, monitors can also help identify within-patient variation in plasma concentrations, as they provide information about the timing of drug administration (Rubio, Cox, & Weintraub, 1992).

Finally, the detailed information on adherence patterns provided by electronic monitors can be used clinically to provide feedback and counseling to patients and their families during brief clinic visits or by telephone (Cramer, 1995).

Liabilities

When referring to the capability of electronic monitors, it is more precise to say that they measure "presumptive" dosing. The presupposition here is that patients ingest what they dispense. Thus, the major drawback of electronic monitors is that they do not confirm ingestion or proper inhalation of medications and may overestimate actual adherence. Assays are needed to help confirm ingestion (Roth, 1987). Although deliberate falsification can occur if patients dispense but fail to ingest medications, this seems highly unlikely as patients must do this at the precise time when medications are to be taken (Urquhart, 1994). Thus, the degree of effort needed to falsify adherence would seem to present adherence problems in its own right. Monitors could also underestimate adherence if patients take out several doses at once to carry with them when they are away from home or to load pill reminder boxes.

Electronic monitors, like any mechanical device, can malfunction. They may record events that did not occur, fail to record events that did occur, or simply stop working because batteries expired. However, most of these mechanical failures occurred with prototypes (Averbuch, Weintraub, & Pollock, 1990). Sometimes failures occur when devices are used in ways not designed by the manufacturers. For example, in our JRA adherence study we attempted to use the MEMS® for younger children who received liquid NSAIDs (although this was not recommended by the manufacturer). When patients or parents shook the medication vigorously prior to administration (as instructed), the liquid seeped into the microelectronic processor and destroyed the circuitry (most likely because of the corrosive nature of NSAIDs).

The clinical utility or feasibility of monitors is limited by the relatively high costs for the rental or purchasing of monitors, communicators, and proprietary software. There have also been unexpected mechanical failures of monitors

(Matsuyama, Mason, & Jue, 1993). Some of these failures may be patient-induced, such as in our JRA adherence study when a 9-year-old female patient returned a completely demolished monitor with the explanation that an "entertainment center fell on it" (we suspected something more deliberate, such as a hammer wielded by the patient).

There are also practical problems regarding the convenience and portability of the monitors. The monitors are somewhat oversized and heavier relative to standard vial caps, which may make them cumbersome, particularly for patients on t.i.d. or q.i.d. dosing schedules who have to transport them outside the home. Also, to download data from the monitors, they have to be retrieved, and in some cases, patients have lost the monitors or have not returned them.

Ethical objections can also be made to using electronic monitoring ("big brother is watching"), particularly if patients are not informed about the capabilities of monitoring devices. This is particularly critical for children who are not afforded the same degree of legal or ethical protection as adults.

Pill Counts

Description

Pill counts have a long tradition in adherence assessment and are relatively straightforward. For example, consider the data from Form 3.2 on the patient prescribed Voltaren twice a day assessed over a 1 week period. Pill counts would involve counting medications at two points in time, separated by 1 week. The number of pills counted at time 2 (4 pills on 10/16/92) is subtracted from that counted at time 1 (14 pills on 10/10/92) and this result (10 pills) is then divided by the total number of pills prescribed (14 pills) over the 1-week counting interval, to determine a fraction or proportion (0.71), which is then multiplied by 100 to obtain a percentage of doses taken (thus, No. of pills removed ÷ No. of pills prescribed × 100, would be 10 ÷ 14 × 100 = 71%). Liquid medications can be similarly "counted" by measuring the volumes of medications at times 1 and 2. Another variation for inhaled medications is to weigh canisters at times 1 and 2 (Rand & Wise, 1994). Relative weights correlated with the number of actuations of the inhaler can be pretested with different types of canisters (e.g., to determine the initial weight of a full canister and progressive decreases in weight correlated with the frequency of actuations).

Assets

Pill counts are uncomplicated and relatively feasible for use in clinical settings. Their feasibility has been enhanced by obtaining pill counts from patients or family members by telephone (e.g., Pieper et al., 1989). Because pill counts have been widely used in research, they can also be used to summarize and compare ad-

herence rates over a wide variety of medication regimens and patient samples. Pill counts or measurements can also be used to validate other adherence assessment methods, such as patient, parent, or provider estimates.

Liabilities

Pill counts, like electronic monitors, cannot confirm ingestion. Most often, they overestimate adherence rates, which can occur if patients "dump" medications. Medications (particularly antibiotics) may also be shared with other family members. Pill counts reveal very little about variations in drug administration, such as overdosing, underdosing, drug holidays, and the white-coat effect. Sometimes pill counts are not possible because patients do not bring medication containers to clinic visits, even when reminded by telephone calls prior to the visit. Patients may also dispense medications from more than one container or load them in pill reminder containers ahead of time, thus precluding an accurate count (Rudd, 1993). Because of converging evidence that pill counts overestimate adherence relative to other methods (such as assays), some have recommended that investigators cease using this as a measure of adherence (Bond & Hussar, 1991).

Provider Estimates

Description

Provider estimates generally involve global ratings by physicians or nurses of the degree to which their patients are adherent to a particular regimen. For example, in one study, physicians were asked to rate adherence to medications, chest physiotherapy, and diet for children with cystic fibrosis using a five-point Likert-type scale, with 4 being "almost always (95% of the time)" and 0 being "rarely (5% or less of the time)" (Gudas et al., 1991). Providers are sometimes asked to make dichotomous judgments (yes or no) about whether patients will be adherent.

Assets

Provider estimates are fast, simple, and inexpensive, which makes them very feasible for use in clinical practice. If providers assess adherence at all, they probably prefer this method. There is some evidence that provider estimates are better than global estimates obtained from patients or family members (Rapoff & Christophersen, 1982).

Liabilities

Provider estimates are not very accurate compared with other measures, such as assays (Rudd, 1993). Furthermore, providers are inaccurate in a specific

way. Although they are generally accurate in identifying adherent patients, they often fail to identify nonadherent patients. This is nicely illustrated by one study in which pediatric providers (nurses, resident and staff pediatricians) were asked to predict which of their patients would be adherent to an antibiotic regimen for otitis media (Finney et al., 1993). In response to the question "Do you think this family will administer most of the prescribed medication?" providers' estimates were dichotomized as "will adhere" or "will not adhere." The "objective" measure of adherence was a pill count/liquid measurement conducted by the investigators in the patients' homes on the 7th to 10th day of the prescribed regimen and the criterion for classifying patients as nonadherent was <80% of medicine removed. In this study, providers' predictions were treated as a diagnostic or screening test (like a laboratory test) and nonadherence the condition to be diagnosed (like a disease). Viewing the findings this way, yielded the following results: The *sensitivity* of provider predictions (the proportion of patients predicted to be nonadherent who ended up being nonadherent) was quite low (28%); the *specificity* of provider predictions (the proportion of patients predicted to be adherent who ended up being adherent) was perfect (100%); and the overall *accuracy* of provider predictions (proportion of all predictions, both positive and negative, that were correct) was moderate (65%). These results confirm previous studies showing that providers fail to identify patients who are nonadherent, and illustrate that overall accuracy does not capture the type of prediction errors made by providers. Most importantly, a fair number of patients who could benefit from interventions to improve adherence would not be identified by their providers.

The inaccuracy of predictions or clinical judgment should come as no surprise to behavioral scientists and clinicians. There is good evidence that even among such "experts" in human behavior, clinical judgments are often biased and may be inferior to actuarial or statistical methods (Dawes, Faust, & Meehl, 1989).

Clinical judgments can be biased in a number of ways (see Rock, Bransford, Maisto, & Morey, 1987, for a review). Clinicians may hold onto or become "anchored" to their initial judgments even when faced with new and disconfirmatory evidence (the "anchoring" bias). Clinicians may also base judgments on the apparent correlation of two events (e.g., adherence and patient characteristics, like intelligence) when there is no direct correlation, the correlation is less than expected, or is the opposite of what is expected (the "illusory correlation" bias). Clinicians may also believe that judgment accuracy increases as they gain more clinical experience (the "overconfidence" bias). Finally, there is the "correspondence" bias, which is the generalized tendency for people to attribute others' behavior (but not their own behavior) to unique dispositional determinants (e.g., "laziness," "stupidity," or "lack of motivation"), while ignoring important situational determinants (see Gilbert & Malone, 1995, for an excellent review). All of these biases have the potential of reducing the accuracy of clinical judgments and experienced clinicians may actually be more vulnerable to their effects (Rock et al., 1987).

An additional question concerns the basis on which providers make predictions or judgments about adherence. I recently queried several experienced pediatricians in private practice and pediatric residents and staff at our medical center as to whether they make judgments about patient adherence and on what basis they did so. They all agreed that they made such judgments (not surprisingly, given the focus of my inquiry). They based their judgments on several factors: (1) health or disease status (such as the presence of wheezing in a child with asthma or resolution of otitis media after treatment, although one pediatrician said, "Some will get better, no matter what you do"), (2) patient or family characteristics (intelligence or "brightness," socioeconomic status, "willfulness" of the child, and age, particularly adolescence), (3) the parents' or patient's level of "interest" as determined by their attention to the doctor's advice and whether they had a list of questions or sought out information on their child's symptoms, (4) direct questioning of patients and/or parents about adherence, (5) checking to determine if prescriptions were refilled and how often, and (6) an in-office demonstration of treatment efficacy to rule out this as a cause of treatment failure and, by default, to rule-in the likelihood of nonadherence (e.g., pre- and postassessments of pulmonary function to evaluate the efficacy of inhaled bronchodilators for children with asthma).

Hall of Fame catcher Yogi Berra once said, "A guy ought to be very careful in making predictions, especially about the future." As clinicians and researchers, we should acknowledge the monumental task of trying to predict adherence behaviors and try to critically analyze the basis for our predictions.

Patient/Parental Reports

Description

Consistent with the emphasis on history taking in clinical practice, it is not surprising that patient and/or family reports are often used to assess adherence. Reporting formats include *global ratings*, *diaries* or self-monitoring of adherence behaviors, and *structured interviews*.

Global ratings, like provider estimates, require that patients or parents rate adherence over unspecified or varying (and sometimes lengthy) time intervals. For example, parents might be asked, "In the last two months, was there any time he missed taking his pills for more than one day?" (Gordis, Markowitz, & Lilienfeld, 1969). Parents might also be asked to rate their children's adherence on a weekly basis using a five-part Likert-type scale, with 1 being "very nonadherent" and 5 being "very adherent" (Rapoff et al., 1988b).

Diaries or other monitoring formats require patients or parents to record specific adherence behaviors over varying lengths of time using standard forms (such as Fig. 5.4). Consistent with developments in microelectronic processors, there are

now portable hand-held computers that patients can use to record adherence events or other clinical parameters, such as pain levels (Dahlström & Eckernäs, 1991).

Over the past decade, significant progress has been made in the development of structured interviews for assessing adherence. An excellent example of this progress is the extension and validation of the 24-h recall interview (a standard dietary assessment technique), which has been refined and extended to assess adherence to IDDM regimens by Suzanne Bennett Johnson and her colleagues (see Johnson, 1995, for a review). This method involves assessing and quantifying adherence to 13 standard components of regimens for IDDM, as shown in abbreviated form in Table 3.3. Telephone interviews are conducted separately with patients and parents. They report the day's events in temporal sequence, from the time the child awakens in the morning until retiring to bed, but the interviewer re-

Table 3.3. Brief Description of 13 Adherence Measures Quantified from 24-h Recall Interview Data

Injection behaviors	
Injection regularity	Degree to which injections are given at the same time every day
Injection interval	Degree to which time between injections approaches ideal
Injection–meal timing	Degree to which injections are given 30-60 minutes before eating
Regularity of injection–meal timing	Degree to which time between injection and eating is consistent across days.
Exercise behaviors	
Exercise frequency	How often a youngster exercises on a daily basis
Exercise duration	How long a youngster exercises on any exercise occasion
Exercise type	Strenuousness of the youngster's exercise
Dietary behaviors	
% calories: carbohydrate	Percentage of total calories consumed consisting of carbohydrates, in relationship to the 60% ideal recommended by the American Diabetes Association
% calories: fat	Percentage of total calories consumed consisting of fats, in relationship to the 25% ideal recommended by the American Diabetes Association
Calories consumed	Youngster's ideal total number of daily calories (based on age, sex, and height) subtracted from youngster's reported daily calorie consumption
Concentrated sweets	Average number of concentrated sweet exchange units eaten on a daily basis (40 calories of any concentrated sweet equal to one concentrated sweet exchange unit)
Eating frequency	How often a youngster eats, on a daily basis
Glucose testing	
Testing frequency	How often a youngster conducts a glucose test on a daily basis

Note: From "Managing insulin-dependent diabetes mellitus in adolescence: A developmental perspective," by S. B. Johnson, in *Adolescent health problems: Behavioral perspectives* (p. 273), by J. L. Wallander and L. J. Siegel, 1995, New York: Guilford Press. Copyright 1995 by Guilford Press. Adapted with permission.

cords only diabetes-related activities. To ensure representativeness, three separate interviews (two on weekdays and one a weekend) are conducted over a 2-week interval. Interviews are restricted to the previous 24 h to minimize recall errors. Each interview takes about 20 minutes to complete (Freund, Johnson, Silverstein, & Thomas, 1991).

Each of the 13 adherence measures is constructed to yield a range of scores, with higher scores indicating relative nonadherence and scores close to zero indicating relative adherence. For example, *glucose testing frequency* is calculated based on an ideal frequency of four times per day, for a total possible frequency of 12 over the three interview days. The number of glucose testings reported is divided by the ideal and multiplied by 100 (e.g., $4 \div 12 \times 100 = 33$). This product is then subtracted from 100 (e.g., $100 - 33 = 67$), so that high scores indicate few glucose tests and low scores indicate frequent tests (e.g., a score of 67 indicates the patient reported four glucose tests being conducted over 3 days).

A similar structured interview format for assessing diabetes-related adherence, the Self-Care Adherence Inventory (SCAI), has been reported by Cindy Hanson and her colleagues (Hanson et al., 1996). In addition, a new semistructured interview, the Family Asthma Management System Scale (FAMSS), has been developed for use with parents of children with asthma (Klinnert, McQuaid, & Gavin, 1997). The FAMSS assesses a variety of family-centered asthma management constructs, including adherence to medications and environmental control recommendations.

Assets

In general, patient or proxy (such as parents) reports are relatively simple, convenient, inexpensive, and clinically feasible (Bond & Hussar, 1991). They also address the problem of accessibility to patient behaviors over time and in ecologically relevant contexts (such as home and community).

How patients or family members are questioned about adherence may be critical in the quality of data obtained by reports. Questions that are nonjudgmental, specific, and time limited are likely to yield more accurate information about adherence, as they are less likely to generate evasive and defensive reactions and are less subject to recall errors or misunderstanding (Kaplan & Simon, 1990; Klinnert et al., 1997). For example, contrast the following formats for questioning a parent about the child's adherence during a return clinic visit after a 10-day antibiotic course for otitis media:

Type A [*not recommended*]: "Mrs. Johnson, Nathan doesn't seem to be any better. Did you give him ALL of that medicine I prescribed?" (said with a disapproving facial expression).

Type B [*recommended*]: "Mrs. Johnson, Nathan doesn't seem to be feeling any better. This can happen for many reasons. Sometimes a different or stronger medicine is needed. Sometimes a child doesn't get enough of the medicine. Many parents have problems giving medicines to their children; my husband and I sometimes forget to give our son his medicine when he's sick. I wonder if you have had any problems giving Nathan his medicine for one reason or another?" (said in an empathetic, but not patronizing manner).

Although these two formats are admittedly characterizations, Type A is an invitation for parental defensiveness and incomplete or inaccurate disclosures about adherence, while Type B is more likely to elicit complete and accurate reports and lead to a dialogue about obstacles to adherence.

Diary and structured interviews offer additional advantages of providing detailed information on adherence patterns, the types of problems or obstacles encountered, and can be correlated with disease symptoms or outcomes. They can also be integrated into disease management programs, which facilitates patient and family involvement in health care (Rand & Wise, 1994). Computerized diary or interview methods can also facilitate the disclosing of more sensitive information, such as adherence to safe-sex practices.

Structured interviews may be the best of the patient or family report measures because they are less labor-intensive for patients and families and more comprehensive. Also, the 24-h recall interview, by Johnson and her colleagues, has shown adequate stability, parent–child agreement, factor structure, agreement with independent observations of behavior, and predictive validity (Johnson, 1995). Similarly, adequate reliability and validity data have been reported for the SCAI (Hanson et al., 1996) and the FAMSS (Klinnert et al., 1997).

Liabilities

Patient or family reports tend to overestimate adherence, most notably, by minimizing doses that have been missed. This is likely to be more true of global estimates and diaries than structured interviews. Global estimates can also tax the person's memory for adherence events. Unless they are actively rehearsed, memories fade within a short period of time. The "outer limits" of recall for events are generally less than 2 weeks (Rudd, 1993). Also, people tend to remember unique events (ones that are stimulating or emotionally laden) and remember events in chronological order for up to 10 days and thereafter, in relation to other major events, such as holidays and birthdays. Diary methods can obviate the need for remembering events if patients complete them close in time to the behavior being monitored. However, about 50% of patients keep complete records (Johnson,

1993). Even if diaries are complete, one cannot ascertain when and where they were completed.

Report measures are also sensitive to demand or social desirability effects. That is, patients or families may tell providers what they want to hear, which could lead to overestimates or outright deception about adherence (Johnson, 1993). In this way the patient or family "protects" their relationship with the provider or at least avoids their disapproval.

Proxy informants (such as parents) do not always have access to relevant behaviors, especially during adolescence. For example, only about 50% of diabetes-related activities are observed by parents (Johnson, 1995). Obviously, parents can only report on that which they see.

Structured interview methods appear to be the most promising of all the patient and family report measures. Parents and patients are interviewed separately to obtain more representative samples of adherence behaviors and psychometric data on reliability and validity seem to meet minimal standards. However, further work is needed to corroborate interview methods by more direct measures such as observations, assays, or electronic monitoring.

Comparative Performance of Adherence Measures

Compared with the adult literature, relatively few studies have directly compared adherence measures with pediatric patients. The "classic" comparative assessment study in the pediatric literature was reported almost 30 years ago by Gordis et al. (1969). They compared patients' and their mothers' reports of adherence to penicillin prophylaxis for rheumatic fever with urine assays obtained during clinic visits, at least every 2 months for a 6-month period. Children were classified as *compliers* if they or their mothers reported on at least 75% of the visits that medication had been taken the day they were reporting. By urine assay, children were classified as *compliers* if at least 75% or more of urine specimens were positive for penicillin, as *noncompliers* if no more than 25% of specimens were positive, and as *intermediate compliers* if 26–74% of specimens were positive. Using these criteria, 69–73% were classified as compliers by patient/parental report, in contrast to 33–42% by urine assays. The major conclusion of this study was that patient or parental reports of adherence are "grossly inaccurate."

In a recent update, Smyth and Judd (1993) compared parent reports with urine assays to assess adherence to antibiotic prophylaxis for pediatric patients with urinary tract infections. Although 97% of parents reported their children took antibiotics every day, only 69% of urine assays were positive. Another study on adherence to antibiotics for otitis media found significant correlations between parent interviews, parent diaries, volume measurements, and urine assays. However, correlations between urine assays and the other adherence measures were not sig-

nificant for an antihistamine–decongestant medication (Devries & Hoekelman, 1988).

Although done with healthy children, one study compared direct observations of dietary intake with daily diaries kept by children in grades three to six (Baranowski et al., 1986). Trained personnel conducted observations in the home for two continuous 12-h days. Percentage agreement between the children and observers was 82.9% across all foods.

A recent study compared electronic monitoring (MEMS®) with pill counts and daily diaries kept by patients who were prescribed a chelating medication to prevent iron overload secondary to transfusion-dependent β homozygous thalassemia (Olivieri et al., 1991). Adherence was monitored during the first 4 months of treatment. There were no significant differences between the monitor and pill counts, but patient diaries significantly overestimated adherence relative to the monitor. Moreover, the monitors revealed that patients often delayed taking their medications.

Collectively, these studies and previous reviews of the literature suggest that assays or electronic monitors are superior measures of medication adherence compared with patient, parental, or provider reports and pill counts (Bond & Hussar, 1991; Rand & Wise, 1994; Rapoff & Barnard, 1991; Rudd, 1993). However, there is no error-free way to assess adherence. All adherence measures share some common methodological problems that clinicians and researchers need to address.

GENERIC METHODOLOGICAL ISSUES AND RECOMMENDATIONS

Reactivity

All adherence measures are potentially subject to reactivity effects. If patients are informed about why someone is drawing their blood, watching them, asking them to use a special container with microelectronics, counting their pills, or asking them direct questions about adherence, they are more likely to behave in a socially sanctioned manner (we call this "being careful"). Although reactivity can contribute to measurement error, it turns out to be useful in helping patients change their behavior, as with self-monitoring strategies to increase adherence. Fortunately, the behavioral observation literature would suggest that reactivity effects are either nonexistent or short-lived and can be minimized (Johnston & Pennypacker, 1993; Wildman & Erickson, 1977). Clinicians and researchers can try to

- Make measurements as unobtrusive as possible. Observers should minimize discussions and eye contact with patients while conducting observations. Alternatively, participant observers, such as parents or older siblings, can be asked to make observations.

- Allow patients time to adapt to measurement conditions, just as a physician has a patient rest for 5 minutes before obtaining the blood pressure. This might involve disregarding information collected during the initial assessment period.

Representativeness

Obtaining representative samples of behavior is also a problem shared by all adherence measures, particularly when assessing adherence to chronic disease regimens. Regimen-related behaviors are required at specific times or opportunities and one may miss many of these opportunities to record what the person is doing. To obtain more representative samples, clinicians and researchers should

- Measure as long and often as possible (Johnston & Pennypacker, 1993).
- Use methods that are more likely to yield representative samples of behavior. For example, electronic monitors are better at this than periodic drug assays.
- Compare continuous and discontinuous methods to determine if much is lost by using the more feasible, discontinuous method. For example, one could do six structured interviews and compare the results obtained with three interviews.

Directness

A direct measure is one that measures a phenomenon in a way that captures the essence of that phenomenon. Because the focus of adherence assessment is behavior, this means directly observing behavior at the time and place of its natural occurrence (Barrios, 1988). As this is not usually feasible, all methods for assessing adherence will vary in their degree of directness. Asking patients to report retrospectively and globally about their adherence is much more indirect than electronic monitoring or directly observing them. The issue of directness can be addressed in several ways by clinicians and researchers:

- When possible, use the most direct method available. For example, one could ask patients or family members to monitor adherence behaviors as they occur versus asking them to rate adherence retrospectively.
- Define and refine, as needed, behavioral response classes so they are more easily understood and used by observers, including patients and families. This requires that medical providers be very specific about the nature of their recommendations. For example, recommendations such as "exercise regularly" or "let your body tell you what you can do" are too vague and need some operational work.

- Compare different methods that vary in directness and empirically determine if the more indirect method converges with the more direct one (e.g., correlate pill counts with assays).

Measurement Standards

All measures of adherence vary in terms of how well they meet minimal scientific standards of measurement, including reliability, validity, and accuracy. *Reliability* refers to the consistency or reproducibility of measures (Crocker & Algina, 1986). *Validity* refers to the extent that a measure represents the phenomenon of interest or measures what it purports to measure (Anastasi, 1988). *Accuracy* (though often confused with reliability) refers to the extent that a measure reveals the "true" state of nature (Johnston & Pennypacker, 1993). The way these standards are addressed depends on the type of measure. For example, the reliability of interview measures is often tested by correlating data obtained at two points in time (test–retest reliability) while the reliability of observational measures is tested by determining agreement between two independent observers watching the same person (interobserver agreement). Accuracy is a much more difficult standard because it assumes that there is a way or an "incontrovertible" standard for judging the true state of nature (Barrios, 1988). In a very important sense, we cannot know what is "really there" because what is "really there" changes and by measuring it, the phenomenon is changed. So what should be done? Clinicians and researchers should

- Obtain consensus among experts about the "best" measure or combination of measures for a particular type of regimen-related behavior (for example, assays plus electronic monitoring appears to be the best way to assess medication adherence). The chosen measure then becomes the "nearly incontrovertible" standard by which all measures are compared.
- Depending on the measure, obtain appropriate reliability indices, such as test–retest and internal consistency for interview measures and interobserver agreement for behavioral observations.
- Depending on the measure, obtain appropriate validity indices, such as criterion- or construct-related validity. For example, predictive validity can be demonstrated by correlating adherence with disease or health status or construct validity can be demonstrated by correlating one measure of adherence with another (more established) measure.

Interpretation or What's in a Number?

The data obtained from assessments have "no voice meaning" (Barrios, 1988). They do not speak for themselves. Data are interpreted, in part, by assigning num-

bers or specifying the unit of analysis. There are a number of dimensions to adherence behaviors that may be of interest, including frequency (e.g., number of pills consumed), duration (e.g., time spent exercising), rate or the frequency per unit of time (e.g., frequency of exercising per week), and percentage of opportunities to engage in the behavior (e.g., percentage of times that PRN medications were taken when it was apparent by symptom monitoring that it was appropriate to do so). Because taking medications is the most common regimen-related behavior in the management of acute and chronic diseases, the following units of analysis and formulas are recommended (Kastrissios, Flowers, & Blaschke, 1996):

- *Fraction of doses* (Fr), where Fr = the number of doses taken ÷ the number of doses prescribed. This is the metric derived from pill counts and the product is multiplied by 100 to obtain a percentage.
- *Daily count index* (DCI), where DCI = the number of days on which the prescribed number of doses were taken ÷ the number of days of monitoring. The product is multiplied by 100 to obtain a percentage. This can be derived from electronic monitoring but not usually pill counts (unless they are done on a daily basis, which is unlikely).
- *Prescribed intervals method* (PI), where PI = the number of prescribed dosing intervals (± some "forgiveness" interval, such as 2 hours) ÷ the total number of possible intervals. This can be derived from electronic monitoring and the product is multiplied by 100 to obtain a percentage.
- *Exact daily adherence* (EAC), where EAC = the number of days when doses were taken as prescribed (including at the recommended dosing interval ± a forgiveness interval) ÷ the total number of days of monitoring. This can be derived from electronic monitoring and the product is multiplied by 100 to obtain a percentage. This index is derived from the DCI and PI methods and is the most stringent of all the indices.
- *Therapeutic coverage* (TC), where TC = the number of hours of therapeutic coverage ÷ the total number of hours monitored. The product is multiplied by 100 to obtain a percentage. TC can only be approximated by electronic monitoring (with knowledge of a drug's half-life). Direct assessment of TC requires pharmacokinetic studies using assays.

Once a number is assigned to the data, clinicians and researchers have to make sense of these numbers or compare them to some standard. The ideal standard would be "biological" or the level of adherence necessary to achieve a therapeutic response (Gordis, 1979). Typically, however, standards have been arbitrary, such as ≥80% of medications taken as defining adequate adherence. Other approaches could include within-subject comparisons (where the patient serves as his or her own comparative yardstick) and between-subject comparisons (comparing a patient with an appropriate reference or normative group).

Clinical and Treatment Utility

Measures of adherence vary in terms of cost and feasibility for use in clinical settings. The measures that are considered more "objective," such as electronic monitoring or direct observation, are also the most expensive and the least practical for use by clinicians. Another neglected dimension of assessment is *treatment utility* or the degree to which assessments contribute to beneficial treatment outcomes (Hayes, Nelson, & Jarrett, 1987). For the most part, this has not been investigated for any of the adherence measures. For example, it is conceivable that self-monitoring by patients would demonstrate greater treatment utility than pill counts, in the sense that self-monitoring data are more likely to reveal adherence patterns and obstacles that would be useful in planning and executing interventions to improve adherence. Clinical and treatment utility issues can be addressed by

- Reducing the complexity and cost of measurement procedures to increase their clinical utility. For example, structured interviews could be simplified and tested in clinical settings.
- Improve on what clinicians already do to informally assess adherence, such as testing different approaches to questioning patients (e.g., judgmental versus empathetic) and determining the predictive validity of disease or health status measures as proxy adherence measures.
- Address treatment utility by empirically comparing different adherence measures in terms of their relative ability to produce beneficial effects, such as improved adherence and better medical outcomes. From a clinical perspective, treatment utility may be the most important dimension of assessment.

4

Assessing Disease and Health Status

Jana is a 7-year-old girl with cystic fibrosis. She lives with both parents, who work full time outside the home, and her 6-month-old sister. Jana was diagnosed with cystic fibrosis at 3-months of age and her regimen includes (1) pancreatic supplements to be taken with meals and snacks, (2) an inhaled bronchodilator medication t.i.d., (3) an inhaled antibiotic medication t.i.d., (4) chest physiotherapy t.i.d., (5) an inhaled medication to break up mucus in the lungs (DNase) q.d., and (6) increased caloric intake. This regimen is very time consuming and demanding. The parents have reported difficulties in gaining Jana's cooperation with this regimen and major problems fitting in family social and recreational activities. However, Jana's pulmonary status has improved on this regimen and she has been gaining weight.

There is a growing recognition in medicine that assessment of medical outcomes needs to expand beyond traditional methods, such as assessing disease signs and symptoms. Medical providers and researchers are beginning to appreciate that patients and their families have a unique perspective on how diseases affect important aspects of their lives, so-called "quality of life" (QOL) (Blue & Colburn, 1996; Johnson, 1994). In his 1993 presidential address to the Division of Health Psychology of the American Psychological Association, Robert Kaplan referred to this perspective as the "Ziggy Theorem" (Kaplan, 1994). In one of the Ziggy cartoon strips, Ziggy asks a wise old man about the meaning of life and the wise man replies "doin stuff." Kaplan argued that the purpose of health care is to help people live longer *and* better and that QOL is defined primarily by behavioral functioning or being able to "do stuff." The above case example illustrates how traditional measures of outcome, such as pulmonary function, do not address QOL-related issues, such as decreased time for social and recreational activities when patients and families are adherent to time-consuming regimens.

A significant impediment to incorporating patient-oriented measures of disease and health status has been the lack of validated measures acceptable to the scientific and medical community (Blue & Colburn, 1996). This situation is

improving as evidenced by the validation and proliferation of QOL instruments in adult and pediatric medicine and their inclusion in clinical trials and health care policy evaluations (Aaronson, 1989; Gill & Feinstein, 1994; Marra, Levine, McKerrow, & Carleton, 1996; Spieth & Harris, 1996; Spilker, 1990).

Perhaps QOL measures have only recently been accepted in medicine because of a fundamental bias instilled during medical training that reifies traditional "objective" measures (Johnson, 1994). In their primer on medical interviewing, Coulehan and Block (1987) state this bias cogently and concisely: "Physicians address what they believe *causes* all this suffering and pain: altered physiology, abnormal biochemical findings, disease. If you correct the bad numbers, the suffering will go away. The person and the illness are subjective; the disease and the numbers generated by machines are objective" (p. 2). I recently observed this bias in action. A physician colleague asked for my assistance in evaluating a training program for medical students to teach them to master a joint physical examination taught to them by specially trained "patient-partners" with arthritis. We developed an observation checklist to evaluate the medical students' physical examination skills but my colleague also wanted to evaluate more subjective elements of the training experience, such as changes in students' empathy. My colleague was particularly interested in my input on assessing these subjective dimensions because he said rheumatologists have not been particularly interested in these "soft" measures.

This chapter will address why and how medical outcomes should be assessed. Traditional measures of disease and health status, including clinical signs and symptoms, laboratory tests, and diagnostic procedures, will be reviewed separately from QOL measures. Also, methodological issues relevant to traditional and QOL measures will be raised and recommendations will be offered for addressing these issues. Given the complexity in diagnosing and monitoring various diseases, this can only be a cursory review and more extensive reviews cited in the reference section need to be consulted. Behavioral scientists and clinicians are particularly encouraged to consult with their medical colleagues about traditional outcome measures relevant to specific diseases.

LEARNER OBJECTIVES

- Identify reasons for assessing medical outcomes, particularly in relation to adherence.
- Describe traditional outcomes including clinical signs and symptoms, laboratory tests, and diagnostic procedures.
- Contrast "hard" (objective) versus "soft" (subjective) medical outcomes and their relative strengths and weaknesses.
- Describe generic and disease-specific QOL measures.

- Identify methodological issues related to assessing disease and health status (e.g., representativeness) and offer recommendations for addressing these issues.

WHY ASSESS OUTCOMES?

Disease and health status parameters are initially monitored to establish a medical diagnosis. Once a diagnosis is made and a treatment plan implemented, these parameters are useful for monitoring changes in patients' status over time and informing physicians about when and how to alter the initial treatment plan. In clinical trials, outcomes are needed to demonstrate the relative efficacy of various treatments and for monitoring unintended (iatrogenic) effects of medical treatments.

Outcome assessments, particularly QOL measures, can help identify the psychosocial as well as physical consequences of chronic diseases. These can help in identifying subgroups of patient populations at risk for psychosocial adjustment problems (Spieth & Harris, 1996). They can also help evaluate the quality of medical care and inform health care policy (Kaplan, 1994). Decisions about allocation of medical resources and services can be better made when evaluated in light of outcomes that reflect both the quantity and quality of life.

Disease and health status indicators also need to be assessed to determine the relationship between adherence and outcome, which is either imperfect or unknown (Johnson, 1994). The whole enterprise of assessing, predicting, and improving adherence is predicated on developing reliable and valid measures of adherence *and* treatment outcome. QOL measures may be particularly useful in determining if higher adherence has positive or negative consequences for patients and their families. The case example opening this chapter illustrates how adherence to time-consuming treatments can have positive effects as assessed by traditional outcome measures (e.g., better pulmonary function) but at the expense of compromised QOL (e.g., less time available for family social and recreational activities).

TRADITIONAL OUTCOME MEASURES

Traditional outcome measures include clinical signs (e.g., limited joint range of motion) and symptoms (e.g., pain), laboratory tests (e.g., blood chemistry profile), and diagnostic studies (e.g., radiographic imaging). These types of outcomes are often called *disease activity* parameters because they are more direct measures of biological states attendant to specific diseases (Liang & Jette, 1981). They can be identified by consulting general and subspecialty medical texts, consensus treat-

ment guidelines developed by governmental and medical agencies, and in collaboration with physician colleagues. Medical outcomes vary by the type of disease and the affected body system.

Clinical Signs and Symptoms

In medical parlance, *signs* refer to disease or health status indicators that are obtained during direct physical examination or observation of the patient by a provider, with instrumentation (e.g., blood pressure) or without instrumentation (e.g., palpation of lymph nodes). *Symptoms* are disease or health status indicators that are obtained from patient (and/or proxy) reports (e.g., pain or fatigue).

Signs

Clinical signs are obtained by specially trained providers (physicians, nurses, or physician assistants) and have traditionally been described as objective or "hard" measures of disease or health status, in contrast to patient report of symptoms, which are designated as "soft" or subjective indicators. Two decades ago, medical researchers began exposing the "soft underbelly" of so-called "hard" measures of disease and health status. They found evidence for the unreliability of clinical judgments formed on the basis of physical examinations, laboratory tests, and diagnostic procedures (Feinstein, 1977). Consider, for example, one of the basic "vital" signs, blood pressure (BP).

BP in pediatric patients (as with adults) is typically measured with a standard sphygmomanometer, using a stethoscope placed over the brachial artery pulse (Reeves, 1995). New normative BP tables for children and adolescents have recently been released that are adjusted for height percentiles, age, and gender (National High Blood Pressure Education Program Working Group on Hypertension Control in Children and Adolescents [NHBPEP], 1996). There are also detailed guidelines on how to measure BP, including placement of the cuff, the size of the cuff used, and the need to average two readings obtained at least 30 seconds apart (Reeves, 1995). However, there can be extensive within- and between-patient variability in BP readings reflecting patient, equipment, examiner, and procedural factors (Reeves, 1995). For example, BP can vary in children because of normal diurnal fluctuations in physical activity, stress, and the tendency for BP to be higher in the day versus the evening. Another well-known factor is "white-coat hypertension" or the tendency for BP to be elevated during clinic visits, particularly in the presence of a physician. Thus, relatively "objective" signs can be fraught with measurement and interpretation problems.

One way to reduce examiner errors is to use automated measures of clinical signs, such as oscillometric devices for measuring BP (NHBPEP, 1996). However, these type of instruments need frequent calibration and they currently lack

established pediatric reference standards, which limits their use for routine clinical assessments. Portable automated devices can also be used to monitor BP over a specified period (usually 24 h) but their use is limited by patient tolerance, lack of published data on children, and questionable cost-effectiveness (NHBPEP, 1996; Reeves, 1995). Patients can also be asked to monitor BP at home but this has been of questionable benefit for adults with hypertension (Reeves, 1995).

Symptoms

Symptoms are often obtained from patient and/or parent reports during routine medical interviews. They can also be obtained from diaries kept by patients and/or parents over longer time periods. For example, Form 4.1 shows the JRA Symptom Rating Scale, which my colleagues and I developed to be completed by parents on a daily basis. In one study, all three indices and a summary score correlated significantly with active joint counts as determined by physical examinations by pediatric rheumatologists. Internal consistency was moderately high and 1-week test–retest was moderate for the summary score (Rapoff, Lindsley, & Purviance, 1991).

An exciting development in symptom monitoring is what has been termed *ecological momentary assessment* or EMA (Stone & Shiffman, 1994). EMA involves assessing patients as they go about their normal routines by prompting them periodically throughout the day (by pagers or programmable wrist watches) to record particular symptoms (such as pain). Compared with questionnaires or ratings made in the office, EMA can better detect symptom variability, cyclicity, and covariation of symptoms with other events, such as stressors (Stone, Broderick,

Form 4.1. The JRA Symptom Rating Scale

Juvenile Rheumatoid Arthritis Symptom Rating Scale (rated by parents)

Symptom	Rating scale
Morning stiffness	0 = No stiffness
	1 = Mild stiffness
	2 = Moderate stiffness, dressing and moving with difficulty
	3 = Severe stiffness, dressing and moving with great difficulty
Activity limitations	0 = Normal activity
	1 = Activity somewhat limited
	2 = Very little activity, resting often
Pain complaints	0 = No complaints
	1 = Occasional complaints
	2 = Complaints frequent and throughout the day

Note: Overall summary score ranges from 0 to 7. Time frame for ratings can be varied depending on the purpose of assessment (e.g., over the past week, since the last clinic visit, or today).

Porter, & Kaell, 1997). EMA also avoids recall biases associated with symptom reporting (Stone & Shiffman, 1994). Relatedly, hand-held computers have been used to record and store patient symptom ratings. For example, Swedish investigators have reported on the use of the "MiniDoc," which is a small, lightweight computer that can be programmed for patients to record symptoms such as pain (Dahlström & Eckernäs, 1991). This device is also equipped with an alarm to signal patients when to provide symptom ratings and has a port that can be connected to external devices, such as BP or heart rate monitors. EMA and automated systems for recording symptoms have been studied primarily with adults. An important contribution to the literature would be to extend these assessments to children and adolescents.

Information on clinical symptoms obtained by medical history is limited by examiner skill, time constraints, and the ability of patients and/or parents to recall and accurately describe symptoms (Coulehan & Block, 1987). Patient and/or parental diaries are often incomplete, nonexistent, or fabricated (Johnson, 1993). Automated symptom ratings would seem to be feasible for use with older children but they have not been tested with pediatric patients. Because symptoms are often internal or "private" events (pain and fatigue being prime examples), the gold standard for assessing them has to be patient reports. The way patients perceive, monitor, and report symptoms, however, can be quite complex and variable.

There is a voluminous literature (mainly with adults) that has questioned the traditional biomedical view of physical symptoms (see Cioffi, 1991, and Pennebaker, 1982, for extensive and critical reviews). The biomedical view assumes a direct, one-to-one relationship between an illness and its symptoms. This view has been challenged on grounds that it underestimates psychosocial influences and is not as relevant to contemporary health problems, such as heart disease or cancer (Cioffi, 1991).

Physical symptoms are now being viewed as "cognitive–perceptual" phenomena or stimuli that are subject to psychosocial as well as biosensory mechanisms (Cioffi, 1991). There is ample support for this view with regard to how children and adolescents perceive and report pain (McGrath, 1990). Pain is a function of the interplay between nociceptive, affective, cognitive, and behavioral dimensions, which affect children's reports of the frequency, duration, intensity, and impact of pain. Similarly, children and adolescents with asthma vary in how well their subjective reports of asthma symptoms (such as dyspnea or difficulty breathing) correlate with objective lung function and their reports can be influenced by false feedback (Fritz, Klein, & Overholser, 1990; Rietveld, Kolk, & Prins, 1996). Blood glucose estimates by adolescents with diabetes can also be quite variable in their accuracy compared with blood glucose tests (Ruggiero, Kairys, Fritz, & Wood, 1991). Clearly, much work is needed to understand how children and adolescents perceive and communicate their symptoms and how they can improve their accuracy. In most cases, direct methods are preferable , such as pulmonary

function tests to monitor asthma symptoms and glucometers to monitor blood glucose levels.

Laboratory and Diagnostic Studies

Laboratory and diagnostic studies can be essential for diagnosing diseases and monitoring the course of illness. Laboratory tests can be nonspecific (e.g., sedimentation rate as an indicator of infection or inflammation) or specific (e.g., glycosylated hemoglobin as an indicator of average blood glucose over the previous 2 to 3 months). As with drug assays, they are influenced by how and when samples are obtained, how they are processed, and the availability of appropriate norms for interpretation. Diagnostic studies, such as magnetic resonance imaging (MRI) and bone marrow aspirations (BMA), can also be useful but are limited by availability, costs, and invasiveness for pediatric patients. Also, false positives may occur with diagnostic studies, such as abnormal EEG findings in patients with no clinical evidence of seizure activity (Ferry, Banner, & Wolf, 1986).

Some diagnostic procedures are also useful for ongoing monitoring of disease and health status. A good example is pulmonary function testing for children and adolescents with asthma. Office-based spirometry assessments are recommended to establish a diagnosis of asthma, assess changes in airway function after treatment, and at least every 1 to 2 years to assess maintenance of airway function (National Asthma Education & Prevention Program [NAEPP], 1997). Spirometry typically measures forced vital capacity (FVC), the maximal volume of air forcibly exhaled from the point of maximal inhalation, and forced expiratory volume in 1 second (FEV_1), the volume of air exhaled during the first second of the FVC (NAEPP, 1997). To ensure accuracy, spirometry equipment and personnel technique need to meet standards developed by the American Thoracic Society (1995). Also, pulmonary function tests require maximal effort on the part of patients, which may be difficult for younger children (NAEPP, 1997). For patients with moderate or severe asthma, home monitoring of peak expiratory flow (PEF; the most rapid rate of airflow during a forced expiratory maneuver) using a portable peak flow meter is recommended to document exacerbations, make treatment decisions, and evaluate treatment outcome. Limitations include poor adherence to monitoring, improper technique, misinterpretation of results, and device failure (NAEPP, 1997).

Summary of Traditional Outcome Measures

Technological advances in medicine, such as MRI and sophisticated laboratory tests, have greatly aided in the diagnosis, management, and monitoring of acute and chronic diseases. They also contribute to understanding the etiology of diseases and discovering new and more effective treatments. But to fully appreciate

the impact of diseases and treatments, there is a need to incorporate the views of those who are affected by disease and their families. When our son was more severely affected by asthma, he did not seem to be particularly impressed by positive changes in the results of his pulmonary function tests. With proper treatment and monitoring, he *was* impressed that he could run and play with the other kids in the neighborhood. He just wanted to "do stuff" like other kids.

QUALITY OF LIFE MEASURES

QOL measures are often subdivided into *overall QOL* and health-related QOL types. Overall QOL refers to "the way that patients perceive and react to their health status and to other, non-medical aspects of their lives" (Gill & Feinstein, 1994, p. 619) while health-related QOL (HRQOL) refers to "the subjective and objective impact of dysfunction associated with an illness or injury, medical treatment, and health care policy" (Spieth & Harris, 1996, p. 176). For purposes of this discussion, the term QOL will be used because it incorporates HRQOL and is more commonly used. The term *functional status* is often subsumed under the construct of QOL and refers to the ability to perform developmentally-appropriate activities of daily living (ADLs), such as ambulating and self-care tasks (Liang & Jette, 1981).

There is consensus in the literature that QOL is a multidimensional construct that should include four *core domains* (Aaronson, 1989; Spieth & Harris, 1996):

- *Physical symptoms* (pain and fatigue)
- *Functional status* (ability to perform age-appropriate daily activities)
- *Psychological functioning* (affective states, adjustment indices, and self-esteem)
- *Social functioning* (the number, type, and quality of social contacts and relationships)

Another significant domain includes cognitive functioning and school-related performance (Spieth & Harris, 1996). This domain is relevant for certain diseases (e.g., epilepsy) and treatments (e.g., cranial radiation) that affect the central nervous system. Also, chronically ill children and adolescents often have brief but frequent absences from school that can adversely affect academic performance. QOL measures vary in terms of the number of these domains they assess.

QOL measures also vary in terms of whether they are *generic* or *disease-specific*. Generic measures are intended for patients who have a variety of acute or chronic health problems whereas disease-specific measures are restricted to particular diagnoses or patient groups (Aaronson, 1989). In the following selective review of pediatric QOL measures, generic and disease-specific measures are reviewed separately. For more complete summaries and critiques, the reader is re-

ferred to general reviews of pediatric QOL measures (Marra et al., 1996; Rosenbaum, Cadman, & Kirpalani, 1990; Spieth & Harris, 1996) and reviews of disease-specific measures for pediatric patients with asthma (Creer, 1992), cancer (Hinds, 1990), and rheumatic diseases (Murray & Passo, 1995).

Generic QOL Measures

A number of generic QOL instruments have been developed for pediatric patients (see Table 4.1). With the exception of the Play-Performance Scale for Children, these instruments assess various domains, including physical, functional, psychological, social, and cognitive functioning. Structured interviews, questionnaires, or both are employed and parents are the respondents in most cases. A majority of the instruments target a wide age range from infancy through adolescence, though some are limited to a specific population, such as the adolescent version of the Child Health and Illness Profile. The number of items varies from a single item (Play-Performance Scale) to over 100 items. The time frame for ratings (if reported) can vary from 5 days to 2 years. The administration time (if reported) is 30 minutes or less, which indicates they may be feasible for use in clinical and research endeavors. These instruments are in varying stages of development, which is reflected by the psychometric data. Most studies on these measures report reasonable test–retest, interrater, and internal consistency reliabilities and construct and discriminant validity (Marra et al., 1996; Spieth & Harris, 1996). Two of these generic QOL measures will be reviewed in more detail to capture the qualitative and quantitative dimensions of these types of instruments.

Play-Performance Scale for Children (PPSC)

The PPSC was originally developed as a measure of activity restrictions for children with cancer (Lansky, List, Lansky, Ritter-Sterr, & Miller, 1987). The PPSC is a one-item, parent-rated scale with 11 gradations of activity from 0 ("unresponsive") to 100 ("fully active") with a specified time frame of the past week (see Form 4.2). It was designed to have no age restrictions or developmental qualifications. The original study obtained parent ratings on children with cancer, siblings of patients, and healthy children. Interrater reliability between mothers and fathers was acceptable. The PPSC also demonstrated discriminant validity as supported by significant differences in mean scores between inpatient cancer patients and healthy children and outpatient cancer patients (but outpatients were not significantly different from healthy children). There were also significant mean differences between patients and their siblings. Construct validity was demonstrated by significant and positive correlations between nurses'and interviewers' global ratings with parent ratings. The PPSC is feasible for clinical and research purposes because it requires less than 5 minutes to complete. My colleagues and I have used

Table 4.1. Generic Pediatric Quality of Life Instruments

Measure (reference)	Domains assessed	Format and respondent	Targeted age group	No. of items and time frame	Administration time	Psychometric standards
Dimensional Health-Related Quality of Life Measure (Apajasalo et al., 1996a,b)	Physical Mental Social Functional Affect	Questionnaire Structured interview Child	12–15 yr 8–11 yr	16 17 Not given	5–10 min 20–30 min	Repeatability coefficient Discriminant validity
Health Status Measure for Children (Eisen et al., 1979)	Physical Mental Social General health Developmental milestones	Questionnaires Parent	0–4, 5–13 yr	38, 59 Varies by item, from past 2 yr to past 5 days	Not given	Internal consistency Construct and discriminant validity
Pediatric Evaluation of Disability Inventory (Feldman et al., 1990)	Self-care Mobility Social function	Interview or questionnaire Parent	6 mo–7 yr	No. of items and time frame not given	Not given	No reliability data Construct and discriminant validity
Quality of Well-Being Scale (Kaplan et al., 1978)	Physical symptoms Mobility Physical activity Functional status	Structured interview Parent	All ages	23–38 6 days	12 min	Test–retest reliability Construct validity
Play-Performance Scale for Children (Lansky et al., 1987).	Functional status	Rating scale Parent	1–16 yr	1 1 week	≤ 5 min	Interrater reliability Construct and discriminant validity

Child Health and Illness Profile-Adolescent Edition (Starfield et al., 1995).	Discomfort Disorders Satisfaction with health Achievement Risks Resilience	Questionnaire Adolescent	11–17 yr	107 items and 46 disease- or injury-specific items Not given	30 min	Internal consistency and test–retest reliability Construct and discriminant validity
Functional Status II(R) (Stein & Jessop, 1990).	General health Stage-specific scales (responsiveness, activity, and interprersonal functioning)	Structured interview Parent	<1 yr 2–3 yrs ≥ 4 yrs	43 14 (short form) Not given	< 30 min	Internal consistency Content, construct, and discriminant validity
Personal Adjustment and Role Skills Scale (Walker et al., 1990)	Peer relations Dependency Hostility Productivity Anxiety–depression Withdrawal	Interview or questionnaire Parent or other adult proxies	5–18 yrs	28 Past month	<10 min	Internal consistency Factor analysis Concurrent validity

Form 4.2. The Play-Performance Scale for Children

PLAY-PERFORMANCE SCALE FOR CHILDREN

Directions for clinicians

The play-performance scale for children is designed to provide a standardized measure of the performance status of the child with cancer.
Appropriate for use with children

- With any type of malignancy
- Ages 1 to 16 years
- In active treatment and long-term follow-up

Procedures

The play-performance scale is

- rated by parent according to directions on form
- rated on the basis of the past week
- to be readministered to assess change over time or following treatment

PLAY-PERFORMANCE SCALE FOR CHILDREN

Parent form

Child's name:
Date of birth: _____/ _____/ _____
mo day yr
Your name: _____
Relationship: Mother ____
Father ____
Other ____
Today's date: _____

Directions for parents: On this form are a series of descriptions. Each description has a number beside it. Think about your child's play and activity over the past week. Think about both good days and bad days. Average out this period. Now read the descriptions and pick the one that best describes your child's play during the past week. Circle the number beside that *one* description.

100 — fully active
90 — minor restrictions in physically strenuous activity
80 — active, but tires more quickly
70 — both greater restriction of, and less time spent in, active play
60 — up and around, but minimal active play; keeps busy with quieter activities
50 — gets dressed, but lies around much of the day; no active play; able to participate in all quiet play and activities
40 — mostly in bed; participates in quiet activities
30 — in bed; needs assistance even for quiet play
20 — often sleeping; play entirely limited to very passive activities
10 — no play; does not get out of bed
0 — unresponsive

Note: From "The measurement of performance in childhood cancer patients," by S. B. Lansky, M. A. List, L. L. Lansky, C. Ritter-Sterr, and D. R. Miller, 1987, *Cancer, 60,* p. 1656. Copyright 1987 by John Wiley & Sons Publishers. Reprinted with permission.

the PPSC in one study with children diagnosed with asthma, cancer, and diabetes (Padur et al., 1995). We found evidence for greater functional impairment (lower scores on the PPSC) for children with asthma and that functional status (as measured by the PPSC) mediated affective adjustment. We concluded that the PPSC seemed to be a useful index of functional status that is simple to use and may be applicable to children with a variety of chronic illnesses, not just cancer as originally intended by the developers. However, the major strength of the PPSC (its brevity) is also its major weakness. It only measures global functional status, like the well-known Karnofsky scale for adults from which it was derived.

Health Status Measure for Children (HSMC)

Unlike the PPSC, the HSMC is a multidimensional measure that assesses physical, mental, social, and general health domains (Eisen, Ware, Donald, & Brook, 1979). It was originally developed for the Rand Corporation Health Insurance study to evaluate the impact of different health care financing arrangements. Sample items for each domain from the version for 5- to 13-year-olds are shown in Form 4.3. Like the PPSC, it utilizes parents as respondents but the developers suggest that children 8 years and older could provide their own ratings (Eisen et al., 1979). There are two versions of the HSMC: one for children 0–4 years and one for children 5–13 years, with 38 and 59 items, respectively. The time frame varies widely across items (5 days to 2 years). In the original study, 679 children aged 0–4 years and 1473 children aged 5–13 years were rated by their parents at five different sites. Internal consistency reliabilities were all generally acceptable. Construct validity was demonstrated by higher correlations between conceptually linked versus distinct scales (e.g., higher correlations among the mental health scales versus correlations between the mental health and general health ratings). Discriminant validity was supported by significantly worse health status scores as measured by the HSMC for children rated as functional limited versus those without limitations.

Like other multidimensional scales, the HSMC shows promise as a generic QOL measure for children. Its primary weakness, shared by other measures, is the lack of pediatric normative data (Spieth & Harris, 1996). Like all generic measures, the HSMC may miss important health and disease status dimensions that are unique to specific conditions. Disease-specific QOL measures will now be considered.

Disease-Specific QOL Measures

Disease-specific QOL measures have been developed for children with asthma, cancer, diabetes, and JRA (see Table 4.2). With the exception of the JRA-related measures, each assesses multiple dimensions, such as physical, functional, and

psychological impact. Questionnaire formats are the norm and patients are more often the primary respondents in contrast to generic measures. The Juvenile Arthritis Functional Assessment Scale is unique in that therapists directly observe and rate the functional abilities of patients with JRA (Lovell et al., 1989). Age ranges of these disease-specific QOL measures are quite variable (1 to 21 years) as are the number of items per scale (from 10 to 52). For three of the measures, investigators do not report a time frame for scale ratings and the majority do not specify how long it takes to administer the measure. Psychometric standards are promising for disease-specific QOL measures as evidenced by adequate internal consistency, interrater, and test–retest reliability indices and predictive, construct, convergent, and discriminant validity indices (Marra et al., 1996; Spieth & Harris, 1996). Two disease-specific QOL measures will now be reviewed in detail for illustrative purposes.

Pediatric Cancer Quality of Life Inventory-32 (PCQL-32)

The PCQL-32 is a recently developed measure of health-related QOL for children and adolescents with cancer (Varni, Katz, Seid, Quiggins, & Friedman-

Form 4.3. Sample Items from the Version of the Health Status Measure for Children Aged 5 to 13

HEALTH STATUS MEASURE FOR CHILDREN

Domain assessed Subscales	Sample items
Physical health	
Mobility	Does this child have to stay indoors most or all of the day because of health?
Physical activity	Does this child have trouble bending, lifting, or stooping because of health?
Role activity	Does this child's health keep him or her from going to school?
Self-care activity	Because of health, does this child need help with eating, dressing, bathing, or using the toilet?
Mental health	
Anxiety	How much of the time during the *past month* did this child seem to: feel relaxed and free of tension? be able to relax without difficulty? be bothered by nervousness or "nerves"? be anxious or worried? be restless, fidgety or impatient?

Form 4.3. (*Continued*)

Depression	How much of the time during the *past month* did this child seem to: feel lonely? be depressed (downhearted or blue)? be moody or to brood about things?
Positive well-being	During the *past month* how much of the time did this child: generally seem to enjoy the things he or she did? seem to wake up feeling fresh and rested? seem to be cheerful and lighthearted? seem to be a happy person?
Social health	
Social relations	During the *past three months* how well has this child gotten along with: other children? the family? teacher and classmates?
General health	
Current health	In general, would you say this child's health is excellent, good, fair, or poor?
Resistance	This child seems to resist illness very well?
Prior health	This child was so sick once I thought he or she might die?
Developmental milestones	
Satisfaction with development	How do you feel about this child's growth/development? eating habits? sleeping habits? bowel habits?

Note: From "Measuring components of children's health status," by M. Eisen, J. E. Ware, C. A. Donald, and R. H. Brook, 1979, *Medical Care, 17,* pp. 905 and 907. Copyright 1979 by Lippincott-Raven Publishers. Adapted with permission.

Bender, 1998a; Varni et al., 1998b). There are parent- and patient-rated versions of the PCQL-32 with separate forms for children (ages 8–12 years) and adolescents (ages 13–18 years). The PCQL-32 yields a total score and scale scores that assess five functional domains: physical, psychological, social, cognitive, and disease/treatment-related symptoms. For each item, parents or patients are asked to rate the intensity of problems on a four-point Likert-type scale, ranging from 0 ("never a problem") to 3 ("always a problem"). Initial validation studies of the PCQL-32 have been promising, as evidenced by acceptable internal consistency reliability, clinical validity, and construct validity for both patient-report and parent-report forms (Varni et al., 1998a,b). The physical functioning and psychological functioning subscales of the child report version of the PCQL-32 are reproduced in Form 4.4.

Table 4.2. Disease-Specific Pediatric Quality of Life Measures

Measure (reference)	Domains assessed	Format and respondent	Targeted disease and ages	No. of items and time frame	Administration time	Psychometric standards
Childhood Asthma Questionnaires (Christie et al., 1993)	Severity Passive QOL Distressed Active QOL	Questionnaire Child	Asthma 8–11 yr	48 Not given	Not given	Internal consistency and test–re-test reliability Factor analysis
Multiattribute Health Status Classification (Feeny et al., 1992)	Sensation Mobility Emotion Cognition Self-care Pain Fertility	Structured interview Child	Cancer Not given	Not given	Not given	Interrater reliability Predicitive validity
Pediatric Oncology Quality of Life Scale (Goodwin et al., 1994)	Physical functioning Emotional distress Response to medical treatment	Questionnaire Parent	Cancer ≤ 7 and ≥ 13 yr	21 2 wks	Not given	Internal consistency and interrater reliability Factor analysis
Pediatric Cancer Quality of Life Inventory-32 (Varni et al., 1998a,b)	Disease and treatment-related symptoms/ problems Physical Psychological Social Cognitive	Questionnaire Parent Child Adolescent	Cancer 8–12 yr 13–18 yr	32 Past month	Not given	Internal consistency Clinical validity Construct validity

Diabetes Quality of Life (Ingersoll & Marrero, 1990)	Life satisfaction Disease impact Disease-related worries Global overall health rating	Questionnaire Child	Diabetes 10–21 yr	52 (plus one global rating of overall health) Not given	Not given	Internal consistency Concurrent validity
Juvenile Arthritis Functional Assessment Scale (Lovell et al., 1989)	Functional activities	Direct testing and observation Physical or occupational therapist	JRA 7–16 yr	10 Concurrent	10 min	Internal consistency Convergent and discriminant validity
Juvenile Arthritis Functional Assessment Report (Howe et al., 1991)	Functional activities	Questionnaire Parent and patient versions	JRA 7–18 yr	23 1 week	Not given	Internal consistency and Interrater reliability Convergent and Discriminant validity
Childhood Health Assessment Questionnaire (Singh et al., 1994)	Functional activities	Questionnaire Parent	JRA 1–19 yr	30 1 week	<10 min	Internal consistency and Interrater reliability Factor analysis Construct validity

Form 4.4. The Physical Functioning and Psychological Functioning Subscales of the Child Report Version of the Pediatric Cancer Quality of Life Inventory-32

PCQL-32©
Pediatric Cancer Quality of Life Inventory
Version 1.0
Child Report (ages 8–12)
DIRECTIONS

Here is a list of things that might be a problem to you. Please tell us how much of a problem each one has been to you **this past month** by circling:

0 if it is **never** a problem
1 if it is **sometimes** a problem
2 if it is **often** a problem
3 if it is **always** a problem

Please circle how much of a problem each one has been to you **this past month**

Physical functioning	Never	Sometimes	Often	Always
1. It is hard for me to play sports	0	1	2	3
2. It is hard for me to do chores around the house (for example, taking out the garbage, doing the dishes)	0	1	2	3
3. It is hard for me to walk or move around	0	1	2	3
4. It is hard for me to lift things up	0	1	2	3
5. It is hard for me to run	0	1	2	3
Please circle how much of a problem each one has been to you **this past month**				
Psychological functioning	Never	Sometimes	Often	Always
1. I feel afraid	0	1	2	3
2. I feel sad	0	1	2	3
3. I worry about what will happen to me	0	1	2	3
4. I worry about side effects from medical treatments	0	1	2	3
5. I worry that my cancer will come back or relapse	0	1	2	3
6. I worry about whether or not my medical treatments are working	0	1	2	3

Note: From "Pediatric Quality of Life Inventory-32, Version 1.0, Child Report (ages 8–12)," by James W. Varni. Copyright 1998 by James W. Varni. Reprinted with permission. Copies of the PCQL-32 forms can be obtained from James W. Varni, Ph.D., Psychosocial Research Program, Children's Hospital and Health Center, 3030 Children's Way, Suite 103, San Diego, CA 92123.

Juvenile Arthritis Functional Assessment Report (JAFAR)

The JAFAR is a 23-item questionnaire designed to measure the functional abilities of children with JRA. There are parent and patient versions of the JAFAR. Form 4.5 shows Part I of the version rated by patients (JAFAR-C). The patients' ability to perform a variety of functional activities is rated over the time period of the past week. The JAFAR also has sections that inquire about the use of assistive devices (e.g., wheelchair), assistance from parents (e.g., receiving help in getting dressed), and a 10 cm visual analogue pain scale (anchored with the descriptors of "NO PAIN" and "VERY BAD PAIN"). Although administration time was not specifically reported, based on an earlier, therapist-rated version, patients or parents should be able to complete the JAFAR in 10 minutes or less. The original validation study showed acceptable internal consistency for both the patient and parent versions (Howe et al., 1991). Significant and positive correlations were also obtained between patient and parent versions, which can be construed as evidence for interrater reliability (given that items were identical) or convergent validity. Both the patient and parent versions of the JAFAR were significantly and positively correlated with the therapist-rated version (Juvenile Arthritis Functional Assessment Scale), which provides evidence of construct validity. In addition, the JAFAR was significantly and positively correlated with physician-rated indices of disease status, including functional class, disease activity, and number of involved joints, thus lending further support to construct validity. The JAFAR appears to be a psychometrically promising and feasible measure of the functional abilities of children with JRA that could be used for research and clinical purposes. The developers caution that the three versions of this scale (therapist, patient, and parent) not be used interchangeably (Howe et al., 1991). In fact, its strength is that multiple perspectives are obtained with the three versions. A limitation of the JAFAR is that it measures only one major dimension of QOL, namely, functional activities. It would have to be supplemented by other measures to assess the social and psychological impact of JRA on children and their families.

METHODOLOGICAL ISSUES AND RECOMMENDATIONS

Both traditional and QOL measures are required to conduct a comprehensive assessment of disease and health status. They are complementary and help determine the impact of adherence to medical regimens on the physical, social, and psychological functioning of children with acute and chronic health problems. As with all measures, there are a number of methodological issues that need to be addressed.

Choice of Informants

The choice of informants varies according to the type of disease and health status measure chosen. Laboratory and diagnostic procedures require highly trained and

Form 4.5. Part I of the Juvenile Arthritis Functional Assessment Report Rated by Patients

THE JUVENILE ARTHRITIS FUNCTIONAL ASSESSMENT REPORT FOR CHILDREN

Patient name: _____ Current date: _____
Date of birth: _____

PART I. ABILITY SCALE

"I'd like to ask you some questions about some things that have to be done to eat, get dressed, and go to school. I want to know how well you've been able to do these things during the past week. Over the past week, have you been able to...by yourself all of the time, just some of the time, or almost none of the time?"

Responses are scored 0 for "All the time,"
1 for "Sometimes," and
2 for "Almost never"

1. Take shirt off hanger
2. Button shirt
3. Pull on sweater over head
4. Turn on water faucet
5. Sit on floor, then stand up
6. Dry back with towel
7. Wash face with washcloth
8. Tie shoelaces
9. Pull on socks
10. Brush teeth
11. Stand up from chair without using arms
12. Get into bed
13. Cut food with knife and fork
14. Lift empty glass to mouth
15. Reopen previously opened food jar
16. Walk 50 feet without help
17. Walk up 5 steps
18. Stand up on tiptoes
19. Reach above head
20. Get out of bed
21. Pick up something from floor from standing position
22. Push open door after turning knob
23. Turn head and look over shoulder

Note: From "Development of a disability measurement tool for juvenile rheumatoid arthritis: The juvenile arthritis functional assessment report for children and their parents," by S. Howe, J. Levinson, E. Shear, S. Hartner, G. McGirr, M. Schulte, & D. Lovell, 1991, *Arthritis and Rheumatism, 34,* p. 878. Copyright 1991 by Lippincott-Raven Publishers. Reprinted with permission.

skilled health care professionals. Some traditional measures require taking a history or obtaining reports of symptoms from patients, their parents, or both. QOL measures are almost exclusively based on ratings obtained from patients or their parents. The perspectives of patients and their parents may differ from providers, which is the major justification for obtaining QOL measures. Patients may also offer different perspectives than their parents (Rosenbaum et al., 1990). The term for this in the psychological assessment literature is *cross-informant variance* (Achenbach, McConaughy, & Howell, 1987). Because of this variance, reports should be obtained from multiple informants as they have unique and nonoverlapping perspectives. Clinicians and researcher should

- Utilize multiple informants including health care providers, patients, parents, teachers, and other significant people in the lives of children to obtain a comprehensive assessment of disease and health status.
- Develop and validate traditional and QOL measures that can be rated by patients (Rosenbaum et al., 1990). The pediatric pain assessment literature shows that when children are given the opportunity and a developmentally appropriate instrument, they can rate their own symptoms in a psychometrically sound way as adults (McGrath, 1990).

Representativeness

This issue concerns when and how often disease and health status assessments are obtained. Ideally, patients would be assessed frequently enough to determine their current disease and health status and to document clinically significant changes in their status from previous assessments. However, for children with chronic health problems, there are limited opportunities for obtaining measures of disease and health status, unless patients are hospitalized or seen frequently in outpatient clinics. This can create a "severity bias" in studies designed to assess the overall impact of chronic diseases. That is, patients available for assessment are those who have the most contact with the health care system because their disease is less well controlled. The upside of this bias would be that those patients in poor disease control might also be poorly adherent and could be offered interventions to improve their adherence. Clinicians and researchers should

- Assess patients as often as possible to adequately characterize disease and health status.
- Continue to develop and validate patient and/or parental measures of disease symptoms (such as EMA formats) and QOL, which can be completed by phone or in home, school, or community settings.
- When feasible, use automated instruments to record symptoms and physiological indices, such as glucometers to record blood glucose levels and

peak flow meters to record pulmonary function. Patients and their parents will need specific training and recalibration to obtain reliable and valid data for clinical and research purposes.

- The 24-hour recall interview methodology for assessing adherence could be adapted to assess disease and health status. These interviews are clinically feasible as they can be done briefly by phone.

Generic versus Disease-Specific Measures

This issue is most relevant to QOL measures. Both generic and disease-specific measures have their place in assessing disease and health status. Generic measures are most useful for documenting health-related disability and limitations for patients with a variety of chronic diseases. Disease-specific measures have greater clinical sensitivity and utility as they capture unique physical and psychosocial sequelae of specific diseases. Clinicians and researchers should

- Utilize both generic and disease-specific QOL measures, as they complement each other and provide a more comprehensive approach to assessing outcomes.
- Although specific traditional outcome measures can be used with different patient groups (e.g., pulmonary function testing being useful for patients with asthma and CF), there is a need for a global and generic disease severity index that can be used for children and adolescents with various health problems. For example, the global severity scheme (mild intermittent, mild persistent, moderate persistent, and severe persistent) applied to patients with asthma (NAEPP, 1997) is similar to other global severity indices (e.g., mild, moderate, and severe categories applied to patients with rheumatic diseases). Clinicians and researchers could agree on such a global rating format and develop unique criteria (based on traditional measures of disease activity) to operationalize severity categories for specific diseases.

Psychometric Standards

Measures of disease and health status must be scientific standards for reliability, validity, sensitivity, and specificity. Therefore, clinicians and researchers should

- Obtain interobserver or interrater reliability indices for measures generated by providers through direct physical examination, observation of the patient, or interpretation of laboratory and diagnostic studies. Interrater reliability of adult proxy reports of patients' symptoms and QOL also needs to be assessed. Internal consistency reliability would be important

to assess for questionnaires and rating scales that tap specific constructs or dimensions (such as functional status). Test–retest reliability may or may not be useful depending on the interval between assessments and whether the symptom or construct would be expected to be stable over a particular interval. Many symptoms of chronic disease (such as pain or fatigue) are variable or episodic and one may not expect consistency between assessment occasions.

- Obtain appropriate validity indices. Construct validity would be particularly important for QOL measures that seek to assess multidimensional constructs such as physical, social, and psychological functioning. Newly developed measures need to demonstrate concurrent validity with existing or standard instruments. Discriminant validity is relevant to demonstrating differences in disease and health status between healthy and ill children and among chronically ill children who are at different stages of treatment and have different disease courses.
- Ensure that traditional and QOL measures of disease and health status meet standards for sensitivity and specificity (Fletcher et al., 1988). This is particularly crucial for diagnostic or screening tests. Sensitivity is demonstrated when false positives are low and specificity is demonstrated when false negatives are low. Test results can be either positive or negative for the presence of a disease state, for abnormal versus normal test results, or for different levels of disease severity. For example, a QOL screening instrument should correctly classify patients as having lower or higher QOL based on more extensive traditional or QOL measures.

Limiting "Physiogenic Bias"

In assessing QOL, investigators sometimes employ a "battery" approach, i.e., a variety of psychological tests and scales are used to assess various psychosocial domains, such as affective distress and behavior problems (Spieth & Harris, 1996). These instruments were not specifically designed to assess QOL and they have not been normed on children and adolescents with chronic disease. Of particular concern is what has been termed *physiogenic bias* (Wells & Strickland, 1982). This means that items on psychological instruments may be tapping disease- or treatment-related symptoms rather than psychological symptoms. For example, the Child Behavior Checklist (Achenbach & Edelbrock, 1983) is one of the most commonly used questionnaires to document internalizing (e.g., depression) and externalizing (e.g., aggression) disorders in children with chronic disease (Lavigne & Faier-Routman, 1992). Cautions have been raised about using the Child Behavior Checklist with chronically ill children because some of the items may reflect physical rather than psychological symptoms (Perrin, Stein, & Drotar, 1991). Examples include "stares blankly" (which may indicate seizure activity), "consti-

pated" (which accompanies spina bifida), and "feels dizzy" (which may be a symptom of hypoglycemia). Though respondents are cautioned that these items are to be considered "physical symptoms without known medical cause," they may not be rated consistent with this caveat or the opposite pattern can occur when respondents may erroneously attribute psychological symptoms to a child's illness (Perrin et al., 1991). To minimize physiogenic bias, clinicians and researchers could

- Delete somatically loaded items. Although this creates problems in scoring and interpreting standardized scales.
- Make sure that respondents understand that they are being asked to rate symptoms that do not correspond to disease or treatment-related symptoms.
- Develop separate norms for children and adolescents with various chronic diseases.
- Conduct studies to assess whether physiogenic bias affects standardized measures of psychological functioning for children and adolescents with chronic illness. This has been done with chronically ill adults and would be an important contribution to the pediatric literature.

Clinical Feasibility, Utility, and Relevance

Measures of disease and health status may be reliable, valid, and yield clinically useful information but may be underutilized because they are not feasible. Clinical feasibility, utility, and relevance can be enhanced by

- Making instruments and scales understandable and easy to use for providers, patients, and parents. Because there is a limited amount of time during routine clinic visits, instruments should not overburden respondents or assessors. In outpatient subspecialty clinics, routine follow-up visits are often limited to 15 minutes are less and priority is given to essential and traditional measures of disease activity (e.g., physical examination and laboratory tests). This means that administration time for QOL measures needs to be 10 minutes or less. Unfortunately, most QOL measures do not meet this standard. Research is needed to shorten and revalidate current QOL measures.
- Specifying a time interval (e.g., the past week) when asking patients or proxies about symptoms and QOL dimensions. The time interval should be short enough to limit distortion and bias related to memory, which usually means over the past month or less.
- Providing patients or proxies a comparative reference point for symptom and QOL ratings, such as how they are functioning relative to before diagnosis, treatment, or since their last visit (Aaronson, 1989).

- Allowing patients or proxies to assess the importance, as well as the severity of problems in various QOL domains (Gill & Feinstein, 1994). For example, chronic illness may limit children's participation in organized sports, but depending on their pre-illness history this dimension may or may not be important to a particular child.
- Augmenting standard or supplied items on QOL instruments with open-ended supplemental items that allow patients or proxies to add unique opinions and reactions. In short, clinicians need to give patients and their parents the opportunity to communicate information they did not think to ask about.

5

Strategies for Improving Adherence to Pediatric Medical Regimens

Adherence improvement strategies can be broadly classified as *educational*, *organizational*, and *behavioral* (Dunbar, Marshall, & Hovell, 1979). Educational strategies primarily rely on verbal and written instructions designed to inform patients and their families about diseases, treatment regimens, potential negative side effects of treatment, and the importance of consistent adherence. Organizational strategies target ways in which health care is delivered, including increasing access to health care services, simplifying regimens, and increasing provider supervision of regimens. Behavioral strategies refer to behavior-change techniques to alter specific adherence behaviors such as, patient and parental monitoring of regimens, problem-solving, contracting, and token reinforcement programs.

Before describing these strategies, an important caveat is in order. *Efforts to alter adherence to medical regimens should only be considered when there is good evidence that adherence problems are compromising the health and well-being of the patient.* The corollary of this is: *if a patient is doing well, then leave well enough alone.*

LEARNER OBJECTIVES

- Describe educational strategies for improving adherence to pediatric medical regimens, including the goals, content, and methods of education.
- Describe organizational strategies for improving adherence to pediatric medical regimens, including reducing the complexity and negative side effects of regimens, increasing provider supervision, and improving provider–patient communication and relationships.
- Describe specific behavior-change strategies for improving adherence to pediatric medical regimens, including monitoring, prompting, reinforcement, and discipline techniques.

- Justify and describe an individualized adherence improvement program using unique barriers or a functional analysis approach that targets factors that are likely to be important for improving the adherence of a particular patient.

EDUCATIONAL STRATEGIES FOR IMPROVING ADHERENCE

The "Why?" or Goals of Education

Clinicians need to be clear about why they educate. The overall goal of education is to increase patient and family knowledge about diseases, treatments, and the importance of consistent adherence. In short, clinicians want patients and their families to "know" stuff. British philosopher Gilbert Ryle made an important distinction between two types of "knowing": *knowing that* and *knowing how* (Ryle, 1949). *Knowing that* means patients and their families are able to convey in verbal and/or written form that they understand information presented to them. Providers often ask patients and their families or give them questionnaires to determine what they know about diseases, treatments that have been prescribed, and the rationale for such treatments. For example, providers would want a patient with insulin-dependent diabetes (among other things) to describe how diabetes involves failure of her pancreas to produce insulin, how she should check her blood glucose and perform insulin injections, and the importance of adjusting insulin doses based on diet, blood glucose levels, exercise, and stress. The patient may demonstrate that she "knows" this information by responding correctly to verbal or written questions and prompts. However, another type of "knowing" is essential. *Knowing how* means patients and families are able to actually do something according to specific standards. Regarding the patient with diabetes, providers would want some behavioral evidence that she can correctly test her blood glucose and properly prepare, time, and inject insulin based on her specific dietary, blood glucose, exercise, and stress levels. Providers need to make sure that patients and their families have a specific knowledge base relative to diseases and treatments and the necessary behavioral repertoire to carry out prescribed regimens.

The "What?" or Specific Objectives and Content of Education

Educational content and objectives are determined by the type of disease and recommended treatments. For acute conditions, such as otitis media, the treatment is relatively straightforward in that patients are required to take antibiotic medications over relatively short periods of time (5 to 14 days). The situation is more complex for chronic conditions as patients have to adhere to multiple regimen tasks, such as taking medications, following special diets, doing general and/or specific exercises, and monitoring symptoms.

The provider who prescribes a particular regimen is responsible for determining the specific treatment plan based on the empirical literature and resulting consensus practice guidelines. Once a specific treatment plan has been developed, patients and families would generally need to be provided the following core information (JRA is used here as an example).

What the Patient Has

Information needs to be given about the disease, including its diagnostic label (e.g., JRA), possible causes (e.g., unknown, but autoimmunity implicated along with some viral or other type of trigger), course (e.g., the subtype of JRA determines the extent and severity of joint involvement and associated symptoms), and prognosis (e.g., with most children, JRA is controlled but not cured and the prognosis for a normal and functional life span is generally good).

What Needs to Be Done to Control the Disease

Patients and families need to know what they are to do (e.g., take anti-inflammatory medications, do special exercises, and wear protective splints on involved joints at night) and why (e.g., to reduce joint inflammation, control pain, increase joint range of motion, and avoid joint deformities).

Potential Negative Side Effects of Treatment and How to Reduce These

A list of possible side effects should be given and how likely they are to be experienced (e.g., gastrointestinal irritation with medications for treating JRA are common). Also, specific ways to reduce side effects should be suggested (e.g., take medications with food to reduce irritation and warm affected joints before exercising or do exercises in a hot tub).

The Benefits of Consistent Adherence and Strategies for Enhancing Adherence

Patients and their families need to be informed about how consistent adherence could be beneficial (e.g., following JRA treatment recommendations consistently can reduce inflammation and pain, increase functional activities, and reduce the need for additional diagnostic and treatment procedures). The strategies discussed in this chapter can be described verbally and in written form to patients and families (e.g., how to monitor, prompt, and reinforce children's adherence to treatment recommendations). For example, I wrote a booklet for parents of children with rheumatic diseases that describes ways they can help their children be more consistent in following treatment recommendations (Rapoff, 1997).

The "How?" or Educational Strategies

How patients and families are educated is critical and is often inadequate or infrequent. A number of general principles and strategies can be recommended.

Education as an Ongoing Process

Particularly with chronic diseases, patient and family education is not accomplished in a single session when patients are newly diagnosed. Patients and their families are often distressed when a chronic condition is first diagnosed and this distress may interfere with retention of information about the condition and its treatment. Also, chronic conditions are complex and have a variable course, which necessitates modifications in treatment plans and the need to reeducate. Thus, education continues over time and involves repetition and rewording of information as needed.

Effective Verbal Communication

Verbal instructions to patients and families must be clear, concise, and relevant to educational objectives. To facilitate patient or parent understanding and recall of information presented, clinicians should

- Be friendly rather than businesslike.
- Provide instructions clearly and concisely and early in the presentation.
- Stress the importance of the instructions.
- Use short words and sentences, avoiding jargon.
- Use explicit categorization (e.g., "I am going to tell you what is wrong, what tests need to be done, and how to treat your child's illness").
- Repeat information as needed, particularly when children are first diagnosed because patients and parents may experience emotional distress which interferes with recall.
- Check for understanding of the information and openly encourage questions, including any barriers to adherence anticipated by the patient or family.
- Determine if patient and family expectations and/or concerns have been addressed and secure a verbal commitment to attempt to follow the prescribed regimen.

Written Communication and Other Media

Clinicians should use written materials (pamphlets, brochures, or instruction sheets) and other media (videos, computer programs, and websites) to rein-

force and enhance verbal instructions. However, most clinicians are not well trained in how to develop these educational materials. This situation often results in health education reading material that exceeds the eighth grade reading level, which is the average level needed for people (such as parents) to be considered literate in our society (Singh, 1995). This situation is more complex for patients. Written and other educational materials must be designed to address normal developmental variations in cognitive development for children at various ages.

In the case of written material, readability is one critical dimension. There are a number of formulas for calculating readability, including Dale-Chall, Fry, Flesch, and SMOG (Meade & Smith, 1991). These formulas consider the average number of syllables per word, average number of words per sentence, and/or word length in characters to calculate a standard reading score or approximate reading grade level from samples of a text. There are specific computer programs (Meade & Smith, 1991) and options within word processing programs that will rapidly calculate different readability formulas. However, there are variables, other than readability level that should be considered in developing educational materials. These are summarized in Table 5.1.

Clinicians may not need to develop educational materials from scratch. There are well-developed educational materials available for patients with a variety of chronic health problems and their families. Also, national organizations provide pamphlets and information on websites for patients and their families (see Appendix for educational resources). Clinicians need to carefully review generic educational materials to determine their appropriateness for their specific population of patients and families. Also, families need to be cautioned that not all infor-

Table 5.1. Factors (in Addition to Readability) to Consider When Developing Health Education Materials

Factor	Recommendations
Organization	Use abstracts, headings, subheadings, and questions at the beginning, end, and/or interspersed throughout the text. Make sure paragraphs/sections address a single purpose or idea.
Writing style	Use active rather than passive voice (e.g., "take this medicine right after breakfast" rather than "this medicine should be taken after breakfast").
Illustrations	Use pictures, drawings, diagrams, tables, graphs, or charts to illustrate concepts and summarize material. Make sure these are relevant to the content of the text and appropriate for the target audience.
Typography	Use legible and attractive type fonts, sizes, formats, and colors.
Tailoring	Tailor material to target audience. Consider age, gender, cultural and experiential factors, and attention level. Use "focus groups" or small groups of persons from the intended audience to preview material and make changes prior to final version.

Note: Adapted from Meade & Smith, 1991, and Singh, 1995.

Treating Otitis Media: Parent Information Handout

What your child has:

Your doctor has found that your child has otitis media, an infection in the middle ear. It is very important to treat this infection because it could affect your child's hearing.

Your child's doctor has recommended:

Your child's doctor has prescribed [insert name of medication]. Your child needs to take this medication [insert dosage schedule; e.g., Zithromax®, once a day for 5 days].

Why it is important for your child to take all medication prescribed:

Your child should take all medications prescribed to totally get rid of infection. If your child misses doses or stops taking the medications when he or she feels better, the infection may not be eliminated or can come back. Also, your doctor will not be able to tell if the medication is helping your child or not.

Side effects to watch for:

A small number of children experience side effects such as loose stools, stomach pain, vomiting, or rash. If any of these side effects occur, please contact your child's doctor immediately. Also, talk to your child's doctor if your child doesn't like the taste of the medication or has difficulty swallowing pills.

Figure 5.1. Generic educational handout for parents on medications for treating otitis media in children.

mation available on websites is correct. They should access websites sanctioned by governmental agencies (e.g., Maternal and Child Health) or national foundations with professional oversight (e.g., the Arthritis Foundation).

There is good evidence that educational approaches alone are effective in improving adherence to regimens for acute diseases (Rapoff & Christophersen, 1982). When patients are diagnosed with an acute illness, such as otitis media, a standard written handout can be given to parents (see Fig. 5.1). Drug companies often supply these types of handouts, along with calendars or other types of monitoring forms to help patients and/or parents keep track of medication doses. Other strategies need to be added for more complex, chronic disease regimens.

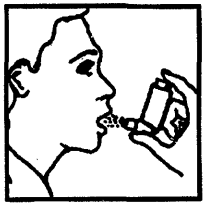
Modeling and Behavioral Rehearsal

Clinicians need to be certain that patients and their families know how to carry out regimen tasks. It is often not sufficient to provide verbal and written instructions, particularly for complex regimens. The clinician needs to model how to execute more complex regimen tasks, give the patient and parent opportunities to

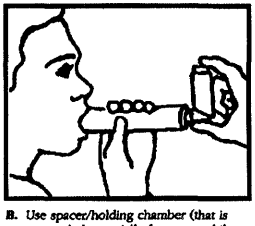
Steps for Using Your Inhaler

Please demonstrate your inhaler technique at every visit.

1. Remove the cap and hold inhaler upright.
2. Shake the inhaler.
3. Tilt your head back slightly and breathe out slowly.
4. Position the inhaler in one of the following ways (A or B is optimal, but C is acceptable for those who have difficulty with A or B. C is required for breath-activated inhalers):



A. Open mouth with inhaler 1 to 2 inches away.



B. Use spacer/holding chamber (that is recommended especially for young children and for people using corticosteroids).

C. In the mouth. Do not use for corticosteroids.

D. NOTE: Inhaled dry powder capsules require a different inhalation technique. To use a dry powder inhaler, it is important to close the mouth tightly around the mouthpiece of the inhaler and to inhale rapidly.

5. Press down on the inhaler to release medication as you start to breathe in slowly.
6. Breathe in slowly (3 to 5 seconds).
7. Hold your breath for 10 seconds to allow the medicine to reach deeply into your lungs.
8. Repeat puff as directed. Waiting 1 minute between puffs may permit second puff to penetrate your lungs better.
9. Spacers/holding chambers are useful for all patients. They are particularly recommended for young children and older adults and for use with inhaled corticosteroids.

Avoid common inhaler mistakes. Follow these inhaler tips:

- Breathe out ***before*** pressing your inhaler.
- Inhale *slowly*.
- Breathe in through your mouth, not your nose.
- Press down on your inhaler at the ***start*** of inhalation (or within the first second of inhalation).
- Keep inhaling as you press down on inhaler.
- Press your inhaler only *once* while you are inhaling (one breath for each puff).
- Make sure you breathe in evenly and deeply.

NOTE: Other inhalers are becoming available in addition to those illustrated above. Different types of inhalers may require different techniques.

Figure 5.2. An educational handout illustrating and describing how to use a metered-dose inhaler. From *Expert Panel Report 2: Guidelines for the diagnosis and managment of asthma* (p. 73), by NAEPP, 1997, Washington, D.C.: NIH, Publication No. 97–4051, in the public domain.

practice the tasks, and provide corrective feedback as needed. For example, children with asthma often have difficulty with proper administration of inhaled medications using a metered-dose inhaler (MDI). This is critical as improper use of a MDI will result in medication being deposited into the mouth or throat and not into the lungs. Patients and their parents can be provided with specific written instructions with illustrations (see Fig. 5.2). However, in most cases, proper MDI technique will need to be modeled by the clinician and patients or parents will need opportunities to practice and receive corrective feedback from the clinician.

Summary of Educational Strategies

Clinicians need to take seriously their role as educators. Patients and their families deserve a high-quality education that fosters knowledge about diseases and their

treatments and the necessary behavioral skills to be able to carry out regimens. Clinicians should remember that the desired outcome of educational efforts is to affect behavior change and not just improve scores on standard tests of knowledge. Also, there is good evidence that educational strategies are *necessary but not sufficient* to sustain adherence, particularly to complex chronic disease regimens (Rapoff & Barnard, 1991). Other strategies will often be needed.

ORGANIZATIONAL STRATEGIES FOR IMPROVING ADHERENCE

Increasing Accessibility to Health Care

Some patients do not regularly contact the health care system. Accessibility to health care can be limited because of financial reasons, transportation problems, and inconveniences inherent to health care settings. Accessibility can be increased by putting patients and their families in contact with social service agencies that can assist them in finding transportation and medical coverage. Also, health care can be brought to the patient, through outreach clinics in schools, churches, or even in the patient's home. These types of outreach clinics may be cost-effective, if they reduce morbidity, mortality, and overuse of expensive medical services, such as emergency room visits.

Consumer-Friendly Clinical Settings

Consider the following scenario. A mother brings her sick child to an outpatient acute care clinic, where she is confronted with harried and terse personnel who take 30 minutes to check her child in to see a doctor. She takes her child to the waiting room, which is full of other parents with sick and crying children. The waiting area is sparse, devoid of proper play materials for children. After waiting another 15 to 30 minutes (by which time her child is quite irritable and crying), she is then ushered into a clinic room, which is sparse and devoid of any books or play materials for her child. Her child is finally seen by a staff doctor or resident, after seeing a nurse and medical student. Because her child been has never seen by this doctor before, the mother has to catch the doctor up on her child's relevant medical history. She is briefly told what is wrong with her child and given a prescription, with little time to ask questions or receive assurance that her child is not gravely ill. Sound familiar? Although this scenario may be embellished,something like it can be observed in teaching hospital clinics around the country. This hypothetical mother may likely leave the clinic in no mood to cooperate or return to the clinic any time soon, unless her child continues to be acutely ill, in which case she may

elect to take her child to the emergency room. The message here is that clinical settings need to be consumer-friendly.

A consumer-friendly setting would yield a very different scenario. Pleasant and helpful personnel would greet the mother and child and the child would be checked into the clinic in a timely fashion. The waiting area would be full of a variety of interesting and developmental appropriate play materials. There may even be volunteers who would play with and read to children. The child would only stay in the waiting area for 10 to 15 minutes and then be escorted to a clinic room, which also has appropriate play and reading materials. A doctor, very familiar to the mother and child, would then enter the room, sometimes accompanied by a medical student. After the child was examined, the mother would be given a thorough explanation of what is wrong with her child and what the doctor is recommending to treat the illness. The mother would also be given ample opportunity to have her questions and concerns addressed. She would then leave the clinic with specific and understandable instructions on how to treat her child and what to do if the child is not better after a specified period of time. The mother in this consumer-friendly scenario is likely to leave the clinic more satisfied and more favorably inclined to carry out the doctor's treatment recommendations.

Perhaps providers would do well to consider health care as a competitive business (in the good sense of this) where they have to outdo their competitors in delivering the best and most satisfying service to their customers. Taking this position would most likely result in having more attractive and responsive clinical settings. There would also be continuity of care, where the same physician sees a child at each clinic visit. This is likely to enhance patient and family satisfaction and improve adherence. Continuity of care would also reduce the likelihood of conflicting and incongruent advice being offered, which can occur when different providers are involved with the same child.

Increasing Provider Supervision

Provider supervision can take many forms. The most basic form is asking about adherence-related issues during clinic visits. This needs to be done in a nonjudgmental and specific way, which is more likely to foster open communication and effective problem solving. If the patient and family have agreed to follow a particular regimen and still experience difficulty with being consistent, the provider can ask: "What gets in the way or keeps you from being consistent?" This type of questioning can lead to effective problem solving about how to reduce identified barriers.

Providers can increase supervision of regimens in other ways. Patients can be brought back to clinic for more frequent follow-up visits. This allows for more opportunities to monitor progress and address any problems. Also, patients and families can call a "report line" or phone number staffed during the day and re-

Form 5.1. A Form For Patients, Families, and Medical Providers to Record Regimen Requirements and Changes

Regimen record form

Regimen component	Clinic date:	Clinic date:	Clinic date:	Clinic date:
Medications: Record name and dose schedule.				
Exercise: Record the types, amount, and how often to be done.				
Diet: Record the types and amounts of food recommended.				
Other: Assistive devices, changes in activities, modifications for school, etc.				

corded after hours by an answering machine. Staff can then respond quickly to parental or patient concerns and address barriers to adherence (Rapoff & Barnard, 1991). Clinic personnel could also call patients and families at critical times when adherence is likely to be a problem. For example, many patients do not continue with 10-day courses of antibiotics after the 4th or 5th day. Clinic personnel could phone parents to remind them to give antibiotics to their children for the full 10 or 14 days to eradicate infections.

To properly monitor regimen adherence, providers must be aware of what they have prescribed. Sometimes there is confusion between patients and providers as to what has been prescribed. This most often occurs with chronic disease regimens for which multiple regimen components have been prescribed. To minimize confusion, providers, patients, or parents can keep track of regimen requirements and changes that are made over time, using a standard form (see Form 5.1).

Simplifying and Minimizing Negative Side Effects of Regimens

Patients and their families have a finite amount of time, energy, and resources to devote to medical regimens, if they are to maintain some semblance of a normal

family life (Patterson, 1985). Providers need to help them strike this balance by minimizing the complexity, costs, and negative side effects of regimens.

Reducing complexity might involve prescribing once-a-day dosing versus multiple dosing of antibiotics per day and for shorter periods of time (5 days versus 10–14 days). Also, multicomponent regimens can sometimes be introduced in a gradual and step-by-step fashion. The complexity is then increased as the patient masters prior steps in a sequence of components ordered in terms of difficulty level. For example, exercise programs for chronically ill children could be limited to short periods and then gradually increased as the patient demonstrates mastery and increased stamina.

Tailoring regimens to patients' lifestyles and schedules can also reduce the demands of regimens. Clinicians can assess typical daily schedules of patients to determine how the prescribed regimen can be integrated into the patients' daily routines. It is usually easier to alter regimens than to alter established patient routines. To do this requires asking a patient and her family about a "typical day," the clinician obtaining information about what the child does from the time she wakes up until she goes to bed. The clinician then negotiates with the patient and family about how to integrate regimen requirements into the daily routine and to manage any anticipated problems (e.g., what to do when you are away from home and have to take medications). My colleagues and I worked with a girl with JRA who disliked doing specific exercises but enjoyed watching afternoon cartoons following school. We worked out a plan with the patient and her parents that allowed her to do exercises while watching cartoons (an innovation added by her mother was to briefly turn off the TV if she stopped exercising).

Patients sometimes stop regimens because they experience negative side effects. Providers need to help patients anticipate and minimize side-effects as much as possible. Some medications, such as antibiotics or NSAIDs, cause gastrointestinal irritation and pain, which can be reduced by taking medications with food or taking antacids. Exercise can also be painful, for anyone, but particularly for children with rheumatic diseases. Gradually increasing the intensity of exercise or exercising in a hot tub can minimize discomfort.

Summary of Organizational Strategies

Clinicians should avoid the tendency to assign "blame" to patients and their families for adherence problems. Clinicians might well look "inward" first, to determine what they do or fail to do that makes it more difficult for patients to follow prescribed medical regimens. Patients and families are burdened enough with the normal daily challenges of life plus additional problems created by disease and treatments. This burden can be lessened by reducing the complexity, costs, and aversive aspects of regimens.

BEHAVIORAL STRATEGIES FOR IMPROVING ADHERENCE

Parental Monitoring and Supervision

The lack of parental monitoring and supervision of medical treatments is a significant contributor to nonadherence, particularly for chronic disease regimens. This becomes critical as patients move into adolescence, where parental monitoring is episodic or nonexistent. Parents of a teenager can appreciate the conflict of trying to be sensitive to their teenager's need for autonomy while recognizing the necessity of providing continued monitoring and guidance. Clinicians need to emphasize to parents not to abruptly or completely discontinue monitoring and support of their children, even during adolescence.

In cooperation with their children, parents can monitor adherence to treatments using standard forms, such as that shown in Form 5.2. These forms can be placed on the refrigerator and parents and children can add check marks as particular regimen tasks have been completed. This type of monitoring may be used on a daily basis until adherence is consistently high, then faded out, and reinstated if adherence drops. Parents can also check medication supplies (e.g., pill containers or inhalers) and devices (e.g., blood glucose meters) for indirect evidence that their children are adherent or nonadherent.

Supervision of regimens needs to be done in a way that is sensitive to the developmental capabilities of children. With younger children, parents will likely

Form 5.2. A Form for Patients and Families to Monitor Adherence to Medical Regimens

Treatment regimen monitoring chart

Name_____ Dates_____

Regimen requirement	Sun	Mon	Tues	Wed	Thurs	Fri	Sat
Medications							
Exercises							
Diet							
Other							

have primary responsibility for administering treatments and monitoring disease symptoms. Supervision can then be reduced (but never completely discontinued) as children demonstrate that they can administer their treatments and monitor their disease symptoms consistently.

To avoid unnecessary conflict, parents should be cautioned to monitor and supervise regimens in a sympathetic and constructive way. They can sympathesize (e.g., "I understand that it's hard to remember to take your medicine") but also communicate to their children the importance of adherence and that they are available to help their children be consistent (e.g., "It's very important that you remember to take your medicine. Let's think of how we can help you to remember").

Prompting Adherence

During a conversation with an 11-year-old boy with JRA who had been referred to me for nonadherence to medications, I asked him what prevented him from being consistent in taking his medications. He said, "It doesn't remind me." Sometimes patients forget or their symptoms are apparently not salient enough to prompt adherence. In these situations, salient and reliable prompts are needed to promote adherence. This can be done in several ways. Monitoring adherence and pairing regimen tasks with regularly occurring events (e.g., taking medications with meals) may help to prompt adherence. Also, relatively inexpensive watches or pill containers are available that can be programmed to beep at multiple times during the day to prompt adherence.

Adherence Incentives

Ideally, patients are prescribed effective treatments that rapidly and pervasively resolve or control their health problems. Thus, the incentive to adhere is that patients get better, feel better, and do better. However, this ideal situation is not consistent with the experience of most patients, families, and providers. For example, NSAIDs in the treatment of JRA may not effectively control symptoms for at least 8 weeks from the initiation of therapy (Lovell et al., 1984). More immediate incentives or positive consequences need to be programmed to bridge the temporal gap between initial adherence and the more long-range benefits of adherence. If adherence is then sustained, maximal therapeutic effects may be obtained and provide "natural" consequences (in the form of improved health and function) to further maintain adherence.

My colleagues and I have taken this approach in utilizing token reinforcement and other programmed positive consequences to improve and sustain adherence to regimens for JRA (Pieper et al., 1989; Rapoff et al., 1984, 1988a,b) and asthma (da Costa, Rapoff, Lemanek, & Goldstein, 1997). The basic format has been similar. We worked with families to identify target adherence behaviors to

The Exchange Program for Improving Medication Adherence

The Exchange Program is a way for you to encourage your child to take his/her medications more consistently. It is based on the well-established principle that people tend to engage in behaviors that bring rewards and/or allow them to avoid unpleasant events. In order to earn basic privileges, your child will be required to take all his/her medications in front of you each day. Your child can also earn special privileges (usually engaged in on the weekend) by earning basics on a certain number of days per week. "Basic" and "special" privileges are described below with specific examples.

In addition to awarding privileges, it is very important to praise your child immediately after he/she takes his/her medications. In the long run, the positive attention you show to your child for taking his/her medications will be more important in encouraging further cooperation and responsibility for his/her treatment. If your child consistently takes his/her medications, he/she is more likely to feel better and be more active which should be rewarding for you and your child.

There are two types of privileges your child can earn: basic and special. Basic privileges include the use of the telephone, watching TV, and playing outdoors (but not off the property). Basic privileges are earned as a package, on a daily basis, and a day ahead of time. For example, if your child takes his/her medications on Monday, he/she earns basic privileges for Tuesday.

Your child can also earn special privileges depending on the number of days he/she has earned basics during the week (and you give permission). For the first week on the program, your child must earn basics on 4 of 7 days to earn a special privilege; for the second week, 5 of 7 days; for the third week, 6 of 7 days; and for the fourth week, 7 of 7 days. You and your child will come up with a list of special privileges which may include things like renting a movie, renting a video game, or going out for pizza.

To keep track of how often your child earns basics, use the attached form. This form will also help you determine if your child has earned basics on the number of days required per week to earn a special privilege. Posting this form on the refrigerator will help you and your child to remember to fill it out. Also, it will remind you to praise your child and to award privileges for taking his/her medications.

What if your child does not earn basics? This means that he/she cannot engage in basic privileges for the next day and is restricted to doing homework, school-related reading, and regular jobs and chores that you may assign. If your child does not earn basic privileges, you can be sympathetic and encourage your child to take his/her medications the next day in order to earn basics for the following day. However, it is vital that your child not be allowed to engage in basic privileges he/she has not earned. Children sometimes get upset about this but do not give in and let your child engage in privileges he/she has not earned. Also, avoid nagging or lecturing your child. This makes things worse.

Figure 5.3. A sample reinforcement program for improving adherence to medications. *Source*: Michael Rapoff, Ph.D., & Kathleen Lemanek, Ph.D., University of Kansas Medical Center, Department of Pediatrics, 3901 Rainbow Blvd., Kansas City, KS 66160-7330; 1998.

operationalize, measure, and alter. The reinforcement program involves giving tokens (points or chips) for adherence, taking away tokens for nonadherence, and requiring the patient to purchase basic and special privileges with the tokens. One such program, the Exchange Program, is reproduced in Fig. 5.3. These types of programs have been particularly effective in improving adherence to chronic disease regimens.

WEEKLY PRIVILEGE SUMMARY

Instructions: For each day, record the date, whether basic privileges have been earned for the next day, and your initials. At the end of the week, add up the total number of days basics were earned and whether your child met his/her weekly goal for earning a special privilege.

Day and date	Basics earned? (circle one): Y= Yes; N= No		Parent initials
Monday / /	Y	N	
Tuesday / /	Y	N	
Wednesday / /	Y	N	
Thursday / /	Y	N	
Friday / /	Y	N	
Saturday / /	Y	N	
Sunday / /			

Total Number of Days Basics Earned This Week =
My child met his/her weekly goal? (circle one): Yes No

Figure 5.3. (*Continued*)

Another frequently used strategy, particularly with adolescents, is contracting. Patients and their parents are taught basic communication and negotiation skills. They are then taught how to develop and implement written contracts specifying what the patient agrees to do, what the parents will provide in the way of consequences for adherence (or sometimes nonadherence), and how to monitor and evaluate patient and parent participation. A generic handout that describes this process is shown in Fig. 5.4.

Discipline Strategies

In lecturing to medical students rotating through pediatrics on the topic of medical adherence, I ask them if they have seen "bratty" behaviors on the inpatient ward among chronically ill children. Invariably they describe incidents where children with cancer or other chronic diseases are exhibiting negative behaviors and their parents respond ineffectively. I tell the medical students that we need to appreciate how difficult it is for parents of chronically (and maybe terminally) ill children to discipline their children who have enough negatives in their lives. Studies show that these parents, relative to parents of healthy children, are more likely to excuse

their children's misbehavior and fail to set and enforce consistent limits (Ivers, Drotar, Dahms, Doershuk, & Stern, 1994; Walker, Garber, & Van Slyke, 1995). My colleagues and I try to explain to parents of ill children that setting and enforcing reasonable limits is vital to fostering self-discipline in their children. We emphasize to the parents that their children will need more self-discipline than healthy children because their children have to cope not only with the regular demands of life but also with the consequences (such as adhering to complex regimens) of living with a chronic health problem. Clinicians need to provide parents with concrete recommendations for effective discipline.

Negotiating and Contracting for Behavior Change Guidelines for Families

This handout is for parents and children/adolescents who want to learn how to negotiate and contract for changes in behaviors that have a negative impact on the family. To negotiate means to "meet and discuss with another in order to reach an agreement." A contract is a written agreement of what has been worked out in negotiations. By adhering to the following guidelines, most families find that they can work out disagreements in a constructive way. Some families may need the assistance of a professional counselor, at least initially, to implement these guidelines.

How to Negotiate (the Family Meeting)

Choose a *convenient time* to meet as a family. After dinner is usually a good time since most families are together at this time and it does not compete with other activities. Take the phone off the hook to avoid interruptions and set a specific time limit for discussions. Most families meet at least once a week for about 30–60 minutes.

Avoid family meetings after there has been a big "blowup." Wait until anger has subsided and then set a time for discussion.

Choose someone to *lead the family meeting.* (This is most often a parent.) The leader is responsible for making sure the family meeting is orderly and positive with everyone having a chance to be heard.

Several *rules for effective negotiation* should be followed during family meetings:

Leader Encourages Everyone to Speak. The leader should ask if anyone has anything to discuss. Start with one person and then go to the next. This will help to avoid confusion and give everyone a chance to be heard. Discuss one or two issues per family meeting. Don't try to solve all problems in one meeting. The leader should make sure everyone stays on task and does not shift to other issues or problems not under discussion for a particular meeting.

Use "I" Messages. Family members should specify problems/complaints in a constructive and nonattacking way. For example, a parent is upset because one of the children has not been completing homework assignments. Instead of saying, "You have been irresponsible and lazy about doing your homework," the parent might say, "I am concerned that because your homework

Figure 5.4. Sample handout on negotiating and contracting. *Source*: Michael Rapoff, Ph.D., 1988, University of Kansas Medical Center, Department of Pediatrics, 3901 Rainbow Blvd., Kansas City, KS 66160-7330.

assignments have not been getting done, your grades will suffer. I would like to see you be consistent in completing daily homework assignments." These "I" messages (the second example) are much more likely to lead to effective problem solving as compared to "you" messages, which often lead to name-calling and defensiveness on the other person's part.

Communicate Constructively. Children (and parents sometimes) may need to be reminded about how to state problems/complaints in a constructive way. If a family member begins to state a complaint in an attacking or nonconstructive way, the leader should politely interrupt the person and remind him or her to state the problem in a constructive way. Occasionally (particularly when families first begin having meetings), a child or teenager may interrupt others and continue to speak in a negative way during discussions. This person can be asked to leave the meeting (for a short time) until he or she cools off. Most children and teenagers will correct this negative pattern if they receive constructive feedback and realize that decisions that affect them will be made without their input if they choose to be disruptive during family meetings.

Offer Solutions. Once the specific problem has been identified in a constructive way, the person who identified the problem should suggest a possible solution. Others are then encouraged to offer their opinions.

Plan for Monitoring and Evaluating Solutions. A plan to solve the problem should then be voted on. The plan should include a specific way to monitor how it is working and a time limit for determining if the plan has been effective.

Develop Written Contracts. To formalize solutions to problems, families may find it helpful to draw up a written contract that specifies the conditions of agreements reached during family meetings. The next section provides details of how to develop contracts.

Parents may find it necessary to overrule a decision made in a family meeting.

This should only be done under unusual circumstances and after the reasons have been thoroughly discussed with the children.

Contracting for Behavior Change. To be effective, contracts should be positive, mutually negotiated, and fair to all parties. Contracts should focus on specific behaviors (responsibilities) to be performed instead of vague references and descriptions. (For example, "Pick up dirty clothes in bedroom and put them in a hamper each night" is a better description than "Be more responsible about cleaning the bedroom.")

Contracts should specify rewards/privileges that will be given after behaviors are performed. Specific ways to monitor the terms of the contract should be spelled out clearly. The time period that the contract is in effect should be specified. At the end of the contract period, there should be a review of the contract with modifications made as necessary. Contracts can also include a bonus for performance that exceeds some specified level and a penalty for failure to perform to some minimum level. (This is optional.)

Figure 5.4. (*Continued*)

Sample Contract

Effective Date: April 11, 1998
Family Contract For: John Jones and Mr. and Mrs. Jones

Responsibilities	*Privileges*
John will complete the following regimen components each day: take pancreatic enzymes with each meal and snack; administer inhaled antibiotic and bronchodilator medications in the morning, in the afternoon, and in the evening; do chest physiotherapy 3 times; and take DNASE inhaled medication once.	If John completes his all of his regimen requirements each day, he can have phone and TV privileges in the evening. If John completes all of his daily regimen requirements on 6 of 7 consecutive days, he can go out with his friends on Friday or Saturday night. If John completes all of his daily regimen requirements on 7 of 7 consecutive days, he can go out with his friends on Friday or Saturday night.

Monitoring: Mr. or Mrs. Jones will directly observe whether John completes his daily regimen requirements at least during the first two weeks this contract is in effect. For each two consecutive weeks during which John completes all daily regimen requirements, Mr. or Mrs. Jones will observe on one less day until John is observed on 3 of 7 days. They will then observe periodically and at unannounced times.

Bonus: If John completes all regimen requirements each day without reminders by parents, he can use the family car on one of his weekend nights with his friends.

Penalty: None.

John
Mr. Jones
Mrs. Jones

Figure 5.4. (*Continued*)

So what is "effective discipline"? There is general agreement that skilled or effective discipline involves the following: (1) a positive environment that promotes appropriate behavior, (2) regular monitoring of children's behavior, (3) ignoring trivial or minor problems, (4) structuring the environment and redirecting children to more appropriate choices, (5) consistent consequences for negative behaviors (such as time-out or other sanctions), and (6) following up. In contrast, undesirable discipline involves inconsistency, noncontingent consequences, harsh punishment, and negative parental demeanor (Socolar et al., 1997). Clinicians need to emphasize to parents that effective discipline is not just punishment for negative behaviors. However, in spite of parents' best efforts to provide positive consequences for appropriate behavior, all children (even those with chronic diseases) have to be subject to negative consequences for misbehavior at times (which may include refusing to adhere to their medical regimens).

My colleagues and I often recommend using time-out for younger children (less than 10 years of age) for outright refusals to complete regimen tasks (and oppositional and aggressive behavior in general). The basic time-out format is familiar to most readers, our protocol for time-out, specifically for medical nonadherence, can be found in Fig. 5.5. For older children, we recommend response cost procedures, such as token fines and brief "grounding" periods that can be reduced by completing extra chores. However, these negative consequences should only considered when other strategies previously described (e.g., reducing negative side effects and positive incentives) have been attempted and found to be inadequate to improve adherence.

Using Time-Out for Medical Nonadherence: Guidelines for Parents

Time-out is a discipline strategy to reduce negative behaviors. It involves placing your child in a dull place for a short time immediately following an unacceptable behavior. Time-out is generally used with children aged 18 months to 10 years. It is effective in reducing problem behaviors such as tantrums, hitting, not minding, and many others. Time-out works best when combined with positive attention and other consequences for appropriate behaviors.

This handout describes the use of time-out when children refuse to take medications, do special exercises, or follow other treatments that have been prescribed by a physician or therapist (so-called "medical nonadherence"). If children do not follow their medical treatments consistently, they may not get the full benefits of therapy. They may even become more seriously ill or disabled by their illness.

Please note that time-out for medical nonadherence should only be used when other techniques have been tried, such as making the regimens easier to follow, reducing negative side effects of regimens, and educating children about their illness and treatment.

A. *Preparing to Use Time-out*
   1. Purchase a small portable kitchen timer.
   2. Select a place for time-out—such as a chair in the kitchen. It needs to be a dull place, *not* scary or dangerous. Make sure it is a place where your child can't see the TV or play with toys.
   3. There needs to be agreement between all caregivers in the home about how to use time-out and when to use it.

B. *Practicing Time-out*
   1. Before using time-out, discuss it with your child during a time he or she is not in trouble.
   2. Tell your child there are two rules when in time-out:
      Rule 1: The time will start only when your child is quiet. If your child yells, cries, talks, or says bad words, the timer is reset as soon as he or she is quiet.
      Rule 2: If your child leaves time-out early, you will lead him or her back to time-out without saying anything and restart the time when he or she is quiet.
   3. After explaining the rules and having your child repeat them, do a practice time-out to make sure he or she understands the rules.

Figure 5.5. Sample handout on time-out for medical nonadherence. *Source:* Michael Rapoff, Ph.D., University of Kansas Medical Center, Department of Pediatrics, 3901 Rainbow Blvd., Kansas City, KS 66160-7330.

C. *Steps for Doing Time-out*

Step 1: If your child refuses to take his or her medicine (for example), say to your child, "You are not taking your medicine like I asked you to, you have to go to time-out." Say this calmly and only once. Don't threaten or warn your child. If your child does not go to time-out right away, physically guide him or her to time-out. This may mean walking with your child, taking your child by the hand and leading him or her, or (for little ones) carrying him or her to time-out.

Step 2: When your child is sitting in time-out quietly, set the time for a specific number of minutes. A good rule of thumb is a maximum of 1 minute of *quiet* for each year of life. A 2-year-old would have 2 minutes; a 3-year-old, 3 minutes; and a 5-year-old, 5 minutes.

For children over 5 years, the maximum quiet time is still 5 minutes. If your child makes noises, talks, screams, or cries, reset the time without saying a single word to your child. Do this each time he or she makes any sounds. If your child leaves time-out before the quiet time is up, lead him or her back to time-out and restart the time.

Step 3: After your child has finished time-out, go to him or her and say, "You have been quiet, would you like to get out now?" Your child has to say yes or nod his or her head. If he or she refuses, then restart the time. Don't say this from across the room.

Step 4: After time-out is over, ask your child if he or she is ready to take the medicine (or do other things the doctor or therapist prescribed). If he or she still refuses, place him or her back in time-out and repeat steps 1, 2, and 3. If your child takes his or her medicine, praise him or her and give other rewards you may have agreed to provide.

D. *Special Problems*

What if your child takes medicine but then spits it out or throws it up? Check with your doctor about giving another dose (especially if your child swallows some of the medicine). In most cases, you can just give a replacement dose after time-out.

What if a brother or sister teases or gives attention to the child in time-out? Make them take the child's place in time-out. That usually stops them from teasing or giving attention to the child in time-out.

What if your child gets so upset in time-out that it makes his or her illness worse? Check with your child's doctor. In most cases, children should be required to finish time-out as outlined above. In rare cases, medical treatment (such as inhaler medications for children with asthma) may be necessary before resuming the time-out.

Figure 5.5. (*Continued*)

Self-Management Strategies

A variety of strategies can be described under the rubric of self-management, including goal setting, monitoring, and self-administered consequences. Two general strategies will be highlighted here: problem solving and cognitive restructuring. Children with chronic diseases are faced with many challenges that require effective problem-solving skills, which generally involve the following steps: (1) recognizing and defining the problem, (2) generating possible solutions, (3) developing and implementing a plan, (4) evaluating the outcome of the plan, and (5) revising or selecting another plan if unsuccessful. These skills are especially important as children move into adolescence and are faced with peer influ-

ences and social situations that may lead them to compromise their health. Problem solving can be rehearsed with patients using standard or patient-generated vignettes. For example, the following vignette relates to glucose testing for patients with diabetes (from Thomas, Peterson, & Goldstein, 1997, p. 559):

"Now, imagine that your friends ask you to a video game arcade, and it's almost time for you to test your glucose. You don't have your test materials with you, and your friends are impatient to leave. If you stop and test, they will leave without you."

Patients can also be asked to keep a diary to identify situations where they are tempted to make compromises related to their regimens that can have deleterious effects on their health. They can then cycle through the problem-solving steps to come up with a plan for managing these challenges.

Cognitive (Kendall, 1993) and contemporary behavior (Hayes, 1989) theories emphasize the influence of thoughts or self-generated rules on behavior. Cognitive processes can contribute to adherence problems in two general ways: (1) patients and/or families can fail to generate rules or thoughts about diseases and regimens when it would be helpful to do so (e.g., "I need to take my medications consistently to give them a chance to work") or (2) patients and/or families may generate counterproductive rules or thoughts (e.g., " I'll take my medicine depending on how I feel"). When patients fail to generate helpful thoughts, clinicians can assist them by suggesting helpful thoughts or rules that support better adherence to medical regimens. When they generate unhelpful thoughts, clinicians can help patients challenge or test the validity of these thoughts and substitute more helpful ways to think about their diseases and medical treatments. When teaching patients and their families such cognitive restructuring techniques, clinicians need to recognize the importance of context in evaluating whether thoughts are helpful or not. Table 5.2 provides examples of adherence-relevant thoughts and the contexts under which these thoughts can lead to positive or negative outcomes for patients.

Psychotherapeutic Interventions

In some cases, medical nonadherence can be embedded in, or exist concurrently with, more serious patient or family problems (Rapoff & Barnard, 1991). For some patients, this may be part of a broader pattern of externalizing (e.g., oppositional behavior) or internalizing (e.g., depression) problems. There may also be significant parental or family problems (e.g., parental depression, marital conflict, or abuse). Children with chronic health problems and their parents are at risk for psychological morbidity and most do not receive necessary mental health services (Bauman, Drotar, Leventhal, Perrin, & Pless, 1997). Psychosocial problems may need to be addressed before or concurrent with efforts to manage medical nonadherence by mental health professionals who have extensive experience with children and families in medical settings. However, underlying patient or family

Table 5.2. Adherence-Related Thoughts about Treatments and Diseases that Can Have Positive or Negative Consequences

Thought	Possible positive consequences	Possible negative consequences
"I take my medicine depending on how I feel; sometimes more, sometimes less."	Useful guide for PRN (as needed) medications, if the person can appropriately match with symptoms	Failure to achieve therapeutic drug level for continuous regimens
"This medicine is causing harm or making me feel worse."	Could avoid potentially serious side effects	Premature discontinuation of effective treatment (especially when side-effects are not serious, temporary, and can be minimized)
"This medicine (treatment) is not helping."	Discuss with provider and treatment is modified or other treatments are added	Premature discontinuation of effective treatment (especially if insufficient time has elapsed to judge efficacy)
"I don't really have this disease."	If true, then avoids unnecessary treatments with possible negative side effects	If false, heightens the potential for decreased quantity and quality of life
"My disease is not that bad."	If true, then unnecessary treatments are avoided	If false, heightens the potential for decreased quantity and quality of life

dysfunction is rarely the primary contributor to medical nonadherence and providers would do well to look elsewhere unless their evaluation reveals the presence of significant patient or family dysfunction.

Summary of Behavioral Strategies

There are a number of cognitive–behavior change strategies available to assist patients and their families to improve and sustain adherence to medical regimens. They have been found to be the most effective adherence-improvement strategies, particularly for chronic disease regimens (Rapoff & Barnard, 1991). However, clinicians must be careful to individualize interventions to address the unique environmental and cognitive contexts of specific patients and their families.

INDIVIDUALIZING INTERVENTIONS: BARRIERS TO ADHERENCE AND FUNCTIONAL ANALYSIS

Whether a particular strategy or set of strategies is effective in a given clinical context depends on how well variables relevant for an individual patient and family

have been identified and can be modified to improve adherence. Indeed, "one size does not fit all." Clinicians need to individualize interventions to address the unique environmental and person-related factors that impact adherence. Two such strategies will be discussed here: (1) addressing unique "barriers" or obstacles to adherence and (2) functional analysis or identifying functional relationships that are applicable to particular behaviors for particular patients and their families.

Barriers to Adherence

The purpose of this approach is to obtain patient and family perspectives on potential events or situations that may interfere with adequate adherence. This can be done by structured interviews, questionnaires, or having patients keep written diaries. An example of a standard questionnaire that assesses barriers to adherence for adolescents and adults with insulin-dependent diabetes is shown in Form 5.3. This questionnaire assesses potential obstacles to dietary, insulin injection, exercise, and glucose testing adherence. Patients indicate how frequently a particular situation is a problem for them on a seven-point scale (with 1 being "very rarely" and 7 being "daily"). Scores on this questionnaire have been found to correlate significantly with self-reported adherence (Glasgow et al., 1986). Similar questionnaires need to be developed and tested for other chronic diseases and for younger children.

Another approach to obtaining information about barriers is to conduct structured interviews with patients and their families. For example, my colleagues and I routinely interview patients and their parents separately and ask: "What gets in the way of you taking your medicines [or doing exercises, following your diet, and so forth]?" One young man with JRA I interviewed mentioned several barriers related to taking his anti-inflammatory medication: (1) It was harder to remember to take his medications when he was not hurting, (2) when he was under time pressures in the morning to get ready for school and catch the school bus, he sometimes forget, (3) when he got back home late in the evening from after-school activities, he was tired, ate supper, and after he went to bed, he did not want to get out of bed even if he remembered he had not taken his evening dose, and (4) he admitted that when he was angry with his parents, he would not take his medicine to "get back at my parents."

Once information has been obtained about barriers to adherence unique to a particular patient and family, interventions can be designed to overcome these specific barriers. For example, clinicians can engage patients in problem solving to identify potential ways to reduce barriers. With the abovementioned patient with JRA, we strategized about several options to overcome barriers, such as prompting himself to take medications by setting his watch alarm and ways to manage his anger toward his parents without compromising his health (e.g., conflict resolution and cognitive restructuring of anger-inducing thoughts).

Form 5.3. Barriers to Adherence Questionnaire for Patients with IDDM

Read the following situations and, using the scale below, indicate how often each problem situation occurs for you. It is important that you rate every situation.
How frequently is this situation a problem for you? (Choose one number)

(1)	(2)	(3)	(4)	(5)	(6)	(7)
Very rarely	Once per month	Twice per month	Once per week	Twice per week	More than twice per week	Daily

_____ 1. It is embarrassing to eat when the people around me are not eating (D).
_____ 2. It is inconvenient to inject my insulin when I am not at home (I).
_____ 3. Bad weather interferes with my regular exercise routine (E).
_____ 4. When my blood glucose tests are high my mother (or other family member) wants to know why (G).
_____ 5. I am in the middle of an activity with friends when I realize it is time to have my afternoon snack (D).
_____ 6. On a weekend, it is difficult to get up at the regular time to take my shot (I).
_____ 7. It is too much trouble to write down the results of my blood tests (G).
_____ 8. I don't have my blood testing materials when it is time to do the testing (G).
_____ 9. I just don't like to exercise (E).
_____ 10. It is easy to make a mistake on the number of food exchanges in a meal (D).
_____ 11. Sometimes I don't draw the proper amount of insulin into the syringe (I).
_____ 12. I feel out of place testing my blood at school or work during the day (G).
_____ 13. After eating what I am allowed at a meal, I still feel hungry (D).
_____ 14. It is hard for me to regulate my exercise, because I work or go to school all week long; then I exercise a lot on the weekend (E).
_____ 15. A watch or a clock with a second hand is not available to time my blood test (G).

Note: Letters in parentheses indicate subscales: D, diet; I, insulin; E, exercise; G, glucose testing. Items on glucose testing were changed from the original by deleting references to urine testing, as blood glucose testing is the current standard of practice.
From "Barriers to regimen adherence among persons with insulin-dependent diabetes," by R. E. Glasgow, K. D. McCaul, and L. C. Schafer, 1986, *Journal of Behavioral Medicine, 9,* p. 68. Copyright 1986 by Plenum Press. Adapted with permission.

Functional Analysis

This strategy involves identifying relevant, modifiable, and (potentially) causal variables that are applicable to a specified set of target behaviors for particular patients and their families (cf. Haynes & O'Brien, 1990). Although this approach has been historically aligned with applied behavior analysis (see special issue of the *Journal of Applied Behavior Analysis*, 1994, Vol. 27, No. 2), its applicability has been extended to clinical psychology in general (Sturmey, 1996). The following steps for conducting a functional analysis can be gleaned from the literature:

- Target behaviors are operationally defined.
- Antecedent events that predict the occurrence or nonoccurrence of target behaviors are identified. Hypotheses are developed concerning the consequences that maintain behaviors (or could maintain behaviors, in the case of low-rate appropriate behaviors), which are of two major types: to obtain something desirable or to avoid/escape something undesirable.
- Direct observational data are collected when possible to provide at least correlational confirmation of hypotheses about antecedent and consequent events (Horner, 1994; O'Neill, Horner, Albin, Storey, & Sprague, 1990).

Contrary to misconceptions about applied behavior analysis, private events (such as thoughts, feelings, and physiological events) can be entered into a functional analysis as target behaviors (e.g., pain intensity), antecedent events (e.g., dysfunctional thoughts), or consequent events (e.g., pain reduction as consequence of taking medications). However, private events are not afforded any special status compared with other variables.

Information obtained for a functional analysis can be obtained by structured interviews, questionnaires, or (preferably) by direct observation over extended periods of time (see O'Neill et al., 1990, for examples of each). Results of the functional analysis are then clinically or experimentally tested by modifying antecedent and consequent conditions and assessing the effects on target behaviors. For example, my colleagues and I worked with a 7-year-old girl with severe JRA who was nonadherent to medications, wearing wrist or knee splints at night, and doing a prone lying exercise to prevent hip contractures (Rapoff et al., 1984). Extensive interviews with this patient and her parents and direct observations in the home were conducted to identify relevant variables that contributed to her nonadherence. Antecedent conditions identified included proximal or more specific events (e.g., mother having to excessively prompt and "nag" the child to adhere) and more molar events (e.g., large family with limited financial resources and a mother who felt "overwhelmed" with general child-rearing tasks and stressors of having to care for a child with a severely limiting disease). Consequent conditions identified included the lack of positive consequences for adherence (e.g., child was ignored when she was adherent because she was doing "what was expected" of her) and the almost exclusive reliance on verbal reprimands as a consequence for nonadherence. A token reinforcement and time-out program was implemented to address these antecedent and consequent conditions and we assisted the family in finding financial support for medical and psychosocial services. Also, we worked with the mother on establishing effective child-rearing skills with all of her children. This intervention was effective in improving adherence to each regimen component and there was some evidence of improved joint function.

CONCLUSIONS

Interventions for improving adherence to medical regimens are often suggested in the literature but there is clearly a need to individualize these interventions based on an assessment of the unique personal, family, and environmental factors that are present for particular patients and families. Such a thorough assessment will better equip clinicians to identify educational approaches, changes in health care delivery, and behavior change strategies that may be helpful in improving adherence. There is much to be done in this area as few intervention studies have been reported in the literature. The adherence intervention literature will be reviewed next and recommendations for future research and clinical directions offered.

6

Review of Adherence Intervention Studies and Recommendations for Research and Clinical Practice

In spite of over three decades of research on the prevalence, correlates, and consequences of medical nonadherence, relatively few studies have sought to validate interventions for improving adherence. There have been negligible efforts to test interventions and demonstrate that improved adherence actually produces clinical and QOL benefits for patients and their families. This volume will conclude with a review of the limited literature on improving adherence to regimens for acute and chronic pediatric diseases and suggestions about how to improve future research and clinical practice.

LEARNER OBJECTIVES

- Summarize and critique the literature on improving adherence to regimens for acute pediatric diseases.
- Summarize and critique the literature on improving adherence to regimens for chronic pediatric diseases.
- Describe strategies for improving research on pediatric medical adherence.
- Describe ways to improve clinical strategies for assessing and improving pediatric medical adherence.

INTERVENTION STUDIES ON IMPROVING ADHERENCE TO REGIMENS FOR ACUTE PEDIATRIC DISEASES

Surprisingly, few studies have experimentally investigated strategies for improving adherence to regimens for acute diseases, such as antibiotics in the treatment of otitis media. A total of seven were located for this review (see Table 6.1). The ma-

Table 6.1. Adherence Intervention Studies Targeting Acute Disease Regimens in Pediatrics

Reference	Sample and disease	Regimen and measure	Procedures	Outcome
Colcher & Bass (1972)	*N*=300 Pharyngitis	Penicillin Urine assay	Random assignment to three groups: Gr. 1=penicillin injection; Gr. 2= oral penicillin and routine instructions; Gr. 3= oral penicillin and extended counseling regarding medication use and written instructions	Adherence by group: Gr. 1=87%; Gr. 2= 58%; and Gr. 3=80%. No significant difference in treatment failures. Significantly higher relapse rate in Gr. 2 vs. Grs. 1 and 3
Fink et al. (1969)	*N*=274 Various acute illnesses	Medications Interviews and medical records	Random assignment to experimental group (special counseling by family health management specialist) or control group (usual care)	Adherence 69% in experimental group vs. 18% in control group
Finney et al. (1985)	*N*=73 (1–12 yr) Otitis media	Antibiotics Pill count and urine assay	Random assignment to experimental group (educational handout, monitoring, and mid-regimen phone reminder) or control group (standard care).	Adherence was significantly higher in experimental group (82%) vs. the control group (49%). No significant difference in resolution of otitis media.
Kulik & Carlino (1987)	*N*=89 (1–14 yr) Otitis media	Antibiotics Parental report (urine assay for 10 patients)	Random assignment to commitment (physician asked parents for verbal commitment to give all medications) and choice of manipulations (parents could choose between two different antibiotics)	High-commitment patients had significantly higher adherence (97%) vs. low-commitment patients (91%). Choice condition not significant. No significant differences in resolution of otitis media

Maiman et al. (1988)	*N*=771 (*M*=46 mo) Otitis media	Antibiotics Pill counts and parental report	Pediatricians randomly assigned to control or one of two continuing medical education programs: tutorial with printed materials (TPM) or mailed printed materials only (MPM). Content of education included communication of information, simplifying regimens, and modifying health beliefs	Patients of pediatricians in TPM group significantly less likely to miss doses as assessed by pill counts; but MPM group missed significantly fewer doses as assessed by parental report
Mattar et al. (1975)	*N*=233 (1–12 yr) Otitis media	Antibiotics Pill counts	Education group (*N*=33) compared to controls (*n*=200); no random assignment. Education group parents given written instructions and monitoring form by pharmacy personnel	Significantly higher adherence for education group (51%) vs. controls (8.5%).
Williams et al. (1986)	*N*=90 (2–24 mo; *M*=7.6 mo) Otitis media	Antibiotics Parental report, bottle measurement, and urine assay	Patients randomly assigned to one of three groups: control, slide-tape (parents shown in clinic, emphasizing importance of adherence), or follow-up phone call (parents phoned on 4th day of therapy to encourage continued adherence)	No significant differences on any adherence measure between groups

jority of the studies focused on antibiotic regimens for otitis media. In the aggregate, these studies support the efficacy of extended counseling about medications from a physician or pharmacy personnel and phone reminders as strategies for significantly enhancing adherence to medications. One study also found that having parents verbally commit to dispense prescribed medications was effective in raising adherence to antibiotics for otitis media (Kulik & Carlino, 1987). Another study was instructive in showing that continuing education programs for pediatricians that focus on strategies for improving adherence (such as simplifying regimens) can be effective in improving adherence to antibiotics for otitis media (Maiman, Becker, Liptak, Nazarian, & Rounds, 1988). On a negative note, few studies assessed whether improved adherence resulted in improvements in treatment outcomes. Two of the three studies that did assess treatment outcomes found no differences in resolution of otitis media (Finney, Friman, Rapoff, & Christophersen, 1985; Kulik & Carlino, 1987).

INTERVENTION STUDIES ON IMPROVING ADHERENCE TO REGIMENS FOR CHRONIC PEDIATRIC DISEASES

Compared with regimens for acute diseases, there are many more experimental studies that have examined the efficacy of strategies for improving adherence to chronic disease regimens. A total of 27 studies were located for this review (see Table 6.2). The majority of these studies focused on adherence to regimens for diabetes or asthma. Also, nearly half of the studies focused on adherence to medications, which is understandable given the primacy of medications in the treatment of chronic diseases.

Several conclusions seem warranted from a review of these studies. Educational strategies are rarely attempted in isolation but usually combined with behavioral strategies, such as monitoring and positive reinforcement. Educational strategies alone may just have limited impact on improving adherence. Or possibly, patients selected for adherence interventions may have been exposed to educational efforts that obviously failed to promote acceptable adherence. The primary organizational strategy employed to improve adherence has been simplifying regimens. Reducing the number of daily medications did enhance adherence to medications for asthma (Tinkelman, Vanderpool, Carroll, Page, & Spangler, 1980) and JRA (Rapoff et al., 1988a). By far the most frequently tested and effective strategies have been behaviorally based, including increased monitoring (e.g., Eney & Goldstein, 1976), explicit training and feedback (e.g., Epstein et al., 1981), contracting (e.g, Gross, 1983), and token systems (e.g., Rapoff et al., 1984).

One of the more intriguing studies reviewed in Table 6.2 employed a parent simulation component (Satin, La Greca, Zigo, & Skyler, 1989). Parents of children with insulin-dependent diabetes simulated their children's regimen by (1) injecting

Table 6.2. Adherence Intervention Studies Targeting Chronic Disease Regimens in Pediatrics

Reference	Sample & disease	Regimen & measure	Procedures	Outcome
Eney & Goldstein (1976)	*N*=90 (3–16 yr) Asthma	Theophylline Serum/salivary assays	Random selection but not assignment to two groups: Gr. 1 had no specific intervention. Gr. 2 patients informed that drug ingestion was being monitored and physicians were more "directive" in discussing adherence	11% of patients in Gr. 1 had therapeutic drug levels vs. 42% in Gr. 2
da Costa et al. (1997)	*N*=2 (8 & 10 yr) Asthma	Inhaled corticosteroids Electronic monitor	Withdrawal design Following baseline, patients given education and token system intervention, followed by withdrawal of intervention	Education and token system improved adherence, and withdrawal and reinstatement of token system for one patient demonstrated effectiveness of that system Some improvements in pulmonary function for one patient
Smith et al. (1986)	*N*=196 (5–16 yr) Asthma	Medications Parent and physician ratings	Pretest, posttest control group design. Intervention group received educational and behavioral strategies (written information, tailoring of regimen, and increased monitoring)	Significantly higher adherence for intervention group (78%) vs. control group (55%)
Smith et al. (1994)	*N*=53 (5–15 yr) Asthma	Medications Investigator ratings	One group, pre/posttest design. Baseline followed by educational and behavioral strategies (written information, tailoring of regimen, and increased monitoring)	Significant increase in adherence from 73% (pre-) to 83% (post-assessment). Significant improvement in asthma severity and pulmonary function
Tinkelman et al. (1980)	*N*=20 (11–18 yr) Asthma	Theophylline Serum assay and pill counts	Random assignment to short-acting (q 6 hr) or sustained-release (q 12hrs) theophylline. Dosing instructions given for both preparations.	Significantly higher adherence with sustained-release vs. short-acting theophylline by pill counts No significant difference in serum levels

(*continued*)

Table 6.2. (*Continued*)

Reference	Sample & disease	Regimen & measure	Procedures	Outcome
Gordis & Markowitz (1971)	*N*=17 Cardiac (rheumatic fever or heart disease)	Prophylactic penicillin Urine assay	Random assignment to two groups: continuous care (same physician, increased accessibility, and comprehensive care) and specialty care (different physicians seen and treated only for rheumatic fever)	No significant differences between groups on adherence
Carney et al. (1983)	*N*=3 (10–14 yr) Diabetes	Blood glucose testing Patient records and used testing strips Ghb levels	Multiple baseline across subjects with baseline followed by point system exchanged for money and special activities	All 3 patients showed improvement in % of tests performed, with 2 patients improving from <5% in baseline to 87 and 93% after treatment. Gains were maintained at 4-mo follow-up Ghb levels improved from baseline (10.1, 15.2, and 9.1%) to follow-up (9.4, 11.7, and 6.0%)
Epstein et al. (1981)	*N*=17 (6–16 yr) Diabetes	Urine glucose testing Direct observation	Random assignment to practice condition (patients tested 20 prepared samples but not informed of results) or feedback condition (patients tested samples and given feedback about accuracy)	Mean number of correct urine glucose estimations was significantly higher for feedback (7.2) vs. practice (3.8) conditions posttraining
Gilbert et al. (1982)	*N*=28 (6–9 yr) Diabetes	Insulin injections Direct observations (observers rating pass/fail on 27 items related to insulin injection)	Random assignment to treatment or control group; treatment group shown peer-modeling film depicting successful self-injection; control group shown nutrition film	Older girls viewing peer-modeling film showed greater self-injection skill than older girls viewing the control film

Gross (1983)	*N*=4 (10–12 yr) Diabetes	Urine testing Patient report (with parent counts of used test tablets as a reliability check; overall agreement averaged 80%)	Multiple baseline across subjects; following baseline, patients received self-management training and developed a behavioral contract with parents	Frequency of urine testing improved for all patients; mean % of days urine testing was done 4 times per day increased from 9% during baseline to 74% during self-management condition; at 2- and 4-wk follow-up, frequency of testing dropped for 2 of 4 patients
Gross et al. (1985)	*N*=14 (9–13 yr) Diabetes	Diet, glucose testing, and insulin injections Parental report	Random assignment to control or experimental group (included multiple-baseline design) Self-management training (negotiating, contracting, etc.)	Improvements noted in specific adherence behaviors for experimental group patients. No difference in metabolic control between groups
Lowe & Lutzker (1979)	*N*=1 (9 yr) Diabetes	Urine testing, diet, and foot care Direct observation by parent and sibling	Multiple baseline across behaviors Education and token system	Education effective in improving dietary adherence; token system increased adherence to urine testing (from baseline mean of 16% to 97%) and foot care (from baseline mean of 72% to 100%)
Satin et al. (1989)	*N*=32 (*M*=14.6 yr) Diabetes	Insulin use Urine glucose testing Diet Exercise Parental ratings of self-care (1=very careful to 5=careless) Ghb levels Attitudes toward teenager with diabetes scales Family Environment Scale	Random assignment to one of three groups: Gr. 1—patients and parents met for 6 weekly sessions to discuss diabetes and management; Gr. 2—as for Gr. 1 plus parent simulation of diabetes regimen; Gr. 3—control group	No significant differences between groups in self-care ratings. Significant decrease in Ghb levels at 6 wk postintervention for Gr. 2 vs. Gr. 3. Significant difference in attitudes towards teenager with diabetes (more positive) for Grs. 1 and 2

(*continued*)

Table 6.2. (*Continued*)

Reference	Sample & disease	Regimen & measure	Procedures	Outcome
Schafer et al. (1982)	*N*=3 (16–18 yr) Diabetes	Urine glucose testing, Insulin Use Exercise wearing diabetic information bracelet, and Blood glucose testing assessed by patient self-monitoring records	Multiple baseline across behaviors design with baseline followed by goal setting and (if needed) contingency contracting conditions.	Goal setting alone effective in improving adherence to wearing bracelet, exercise, and urine testing for subject 1 and for urine testing and exercise for subject 2; goal setting plus contracting improved adherence to insulin use for subject 2; nothing effective for subject 3 who was experiencing severe family problems
Snyder (1987)	*N*=1 (14 yr) Diabetes	Insulin use Urine glucose testing Diet Patient self-monitoring records with independent checks by mother and school nurse	Quasiexperimental single-subject design Following self-monitoring baseline, patient exposed to self-monitoring plus monetary incentives and then to an additional condition involving hospitalization contingent on hypo- or hyperglycemic episodes for 36 hr in a private room with no TV, visitors, books, and minimal staff interaction Behavioral contracting and communication/conflict resolution training was also implemented for antisocial behavior and mother–child conflict	Mean number of diabetes self-care activities performed was 5.6 during self-monitoring baseline, 6.3 during self-monitoring + reinforcement, and 8.5 during self-monitoring + reinforcement + punishment; 1-mo follow-up showed maintenance of gains Also, decreases in antisocial behavior and conflicts and increases in school attendance noted However, anecdotal reports at 6- mo posttreatment indicated deterioration of gains with patient hospitalized for drug abuse

Wysocki et al. (1989)	*N*=42 (*M*=14 yr) Diabetes	Blood glucose testing Insulin use Diet Exercise Automated recording of blood glucose (reflectance meters) 24-hr recall patient and parent interviews Ghb levels Attitudes towards diabetes and diabetes adjustment scales	30 patients randomly assigned to meter-alone (MA) or meter-plus-contract (MC) groups. Remaining 12 patients in conventional-therapy (CT) control group MA gr patients earned money for bringing meters to clinic. MC gr patients earned money contingent on glucose testing frequency	By 8th week, MC group had significantly higher frequency of glucose testing No differences in overall adherence, Ghb levels, or patient/parent attitudes and adjustment to diabetes
Gilbert & Varni (1988)	*N*=1 (10 yr) Hemophilia	Factor replacement therapy Observation of patient completing factor replacement using a behavior checklist	Case study with baseline, treatment and 4½ mo follow-up measures obtained; following baseline, nurse modeled correct performance of factor replacement skills, had patient rehearse skills, gave corrective feedback as needed, and praised for correct performance	Mean adherence to proper technique ranged from 0 to 89% across factor replacement behavioral categories during baseline; this range improved to 83 to 98% during treatment and 100% during follow-up
Greenan-Fowler et al. (1987)	*N*=10 (8–15 yr) Hemophilia	Home physical therapy program Patient report (written records) and attendance at exercise class	One group, repeated measures quasiexperimental design; following baseline, patients and parents were exposed to behavior management training (shaping, token system, etc.) for 12 wk; follow-up assessments were done at 3, 6, and 9 mo posttreatment	Adherence to exercises significantly higher during treatment (*M*=96%), 3-month (*M*=91%) and 6-mo (*M*=85%) follow-up compared with baseline (*M*=55%) but not at 9-mo follow-up (*M*=63%); session attendance did not vary significantly between measurement periods

(*continued*)

Table 6.2. (*Continued*)

Reference	Sample & disease	Regimen & measure	Procedures	Outcome
Sergis-Davenport & Varni (1983)	*N*=12 parents of 10 children with hemophilia	Factor replacement therapy Direct observation using a behavior checklist	Nonrandom assignment to treatment or control group; parents in treatment group were given systematic training in factor replacement therapy in 2-hr weekly visits over a 4- to 8-wk period; control group parents did not receive special training	Mean % of correct performance in factor replacement skills increased significantly from 15% at baseline to 92% during intervention for treatment group parents; percentages significantly higher for treatment vs. control group at follow-up
Rapoff et al. (1984)	*N*=1 (7 yr) JRA	Medications, splints, and prone lying exercise Parent observations with interobserver reliability checks in home (mean agreement=94% for medications and 100% for splints and prone lying)	Multiple baseline across behaviors with 10-wk follow-up; token system introduced following baseline	Baseline mean adherence was 59% for medications, 0% for splints and prone lying exercise; improved to 95, 77, and 71%, respectively during treatment and 90, 91, and 80%, at 10-wk follow-up
Rapoff et al. (1988a)	*N*=1 (14 yr) JRA	Medications Pill counts Disease activity measures	Single-subject withdrawal design. Following baseline, regimen simplified (q.i.d. to t.i.d.); token system in the home for 10 wk, then withdrawn for 7 wk, reinstated for 7 wk, and then maintenance phase for 8 wk (where token system reintroduced if adherence was <80% for 2 consecutive wk) Token system then completely withdrawn	Mean adherence levels by condition were: baseline=44%; simplified regimen=59%; token system=100%; withdrawal of token system=77%; token system reinstated=99%; maintenance phase=92%; 9-mo follow-up=97% Less disease activity evident during simplified regimen and token system phases

Rapoff et al. (1988b)	*N*=3 (3, 10, & 13 yr) JRA	Medication Pill counts and adherence ratings on a 5-point scale (1=very nonadherent to 5= very adherent) from parents by phone on a weekly basis	Multiple baseline across subjects; following baseline, home visit made to provide verbal and written information on medications, importance of adherence, monitoring, and positive reinforcement; parents asked to mail in completed monitoring forms on a weekly basis; 4-mo follow-up	Mean adherence by pill counts at baseline= 44, 38, and 54%; during intervention=49, 97, and 92%; at follow-up=24, 56, and 89%; for patients 1, 2, and 3 respectively; mean parental adherence ratings at baseline=2.4, 3.4, and 3.3; during intervention=2.2, 5, and 4.1; at follow-up=3, 3.5, and 4.8
Pieper et al. (1989)	*N*=3 (11–18 yr) Rheumatic diseases	Medications Pill counts	Multiple baseline across subjects. Following baseline, patients and parents given instructions in clinic about medications, adherence, and monitoring/reinforcement strategies	Because over- as well as underdosing occurred, patients classified as adherent if pill counts indicated 80–120% of doses were taken The mean % of pill counts in acceptable range were: baseline=38, 7, and 33%; intervention=89, 67, and 88%; 6-mo follow-up=100% for all patients; 12-mo follow-up=67% for 2 patients.
Beck et al. (1980)	*N*=21 (3–20 yr; *M*=14.6 yr) Renal failure	Immunosuppressive drugs, posttransplant. Pill counts	One-group, pre/post test design Baseline assessment followed by 6 mo of physician counseling and regimen simplification when feasible	Initially 9 of 21 were nonadherent (43%); 4 of these 9 remained nonadherent, while 5 were adherent after 6 mo of physician counseling
Carton & Schweitzer (1996)	*N*=1 (10 yr) Renal disease	Hemodialysis Direct observation	ABAB single-subject design. Baseline followed by token system, which was withdrawn, reinstated, and faded	Nonadherence to hemodialysis reduced with token system and worsened when token system was withdrawn; nonadherence remained low at 3- and 6-mo follow-up

(*continued*)

Table 6.2. (*Continued*)

Reference	Sample & disease	Regimen & measure	Procedures	Outcome
Magrab & Papadopoulou (1977)	*N*=4 Renal failure	Dietary regimen Weight, blood & urine tests (nitrogen and potassium levels)	Reversal design Baseline and token system conditions	Weight gain acceptable during treatment vs. baseline. Some improvements in nitrogen and potassium levels for 2 children
Dawson & Jamieson (1971)	*N*=30 (6 mo-12 yr) Seizure Disorder	Medications Blood assays over a 6-mo period	One group pre and posttest quasiexperimental design; after initial blood levels were obtained, patients were monitored monthly by assays with parental and patient knowledge	At beginning of study, only 25% of sample had therapeutic blood levels, & this increased to 80% by end of study

themselves twice daily with normal saline, (2) testing and recording urinary glucose and ketones, (3) following a meal plan, including avoiding concentrated sweets, (4) following an exercise plan, (5) recording "hypoglycemic" episodes (missing or delaying meals and snacks or failing to consume extra snacks with extra activity), and (6) submitting to a blood test for glycosylated hemoglobin. After the simulation period, the parents were asked about difficulties they encountered in following the simulated regimen and how this affected the way they viewed their teenager with diabetes. Simulation coupled with weekly support and educational sessions resulted in improvements in metabolic control relative to a control group. Interestingly, simulations have also been employed with medical students (Kastrissios et al., 1996) and physicians and nurses (Morse, Simon, & Balson, 1993) to increase their awareness of barriers to adherence and address these barriers with their patients.

About one-third of the studies reviewed in Table 6.2 attempted to assess changes in treatment outcomes. Of these eight studies, two reported no significant improvements (Gross, Magalnick, & Richardson, 1985; Wysocki, Green, & Huxtable, 1989), three reported some improvements (da Costa et al., 1997; Magrab & Papadopoulou, 1977; Rapoff et al., 1988a), and three demonstrated clear improvements in treatment outcomes (Carney, Schechter, & Davis, 1983; Satin et al., 1989; Smith, Seale, Ley, Mellis, & Shaw, 1994).

SUMMARY OF ADHERENCE INTERVENTION STUDIES

This review and others support the general conclusion that educational and organizational strategies are effective in improving adherence to regimens for acute diseases (Haynes, Taylor, & Sackett, 1979; Meichenbaum & Turk, 1987; Rapoff & Barnard, 1991; Rapoff & Christophersen, 1982; Varni & Wallander, 1984). However, behavioral techniques are necessary additions to educational and organizational strategies for improving adherence to regimens for chronic diseases. Token systems in particular have been the most validated of the behavioral procedures for improving adherence to chronic disease regimens. In spite of these positive results, few studies assessed clinical outcomes for patients and even fewer showed unequivocal improvements in outcomes attributable to improved adherence. Based on this review and the material presented throughout this book, several research and clinical recommendations can be offered.

RECOMMENDATIONS FOR RESEARCH ON PEDIATRIC MEDICAL ADHERENCE

The Absence but Value of Theories

Virtually all of the theories that offer predictions about why patients adhere or fail to adhere to medical regimens have been based on studies with adults. The validity

and utility of downward extensions of these models to children and adolescents need to be verified. Theories are important in that they influence how studies are designed and how researchers react to and make sense of data obtained from their studies. Clinicians and researchers should be careful in adopting existing theories that fail to adequately address the developmental needs, challenges, and capacities of children of various ages and stages of development. For example, assessing self-efficacy perceptions would be relevant for children after they acquire the necessary language and cognitive facility to make these types of judgments about their capabilities to perform a given action. Before they acquire the prerequisite skills, the self-efficacy judgments of parents or caretakers would seem to be more relevant.

Correlation and Causation: What Did We Learn in Elementary Statistics?

In elementary statistics classes, clinicians are taught the maxim that "correlation does not equal causation." This message may have been delivered but many do not react as though the message was heard. As previously reviewed, much of the literature is concerned with identifying correlates and predictors of adherence. When reading these studies, the conclusions are often framed as though causal variables have been identified. However, the most stringent test of proposed causal variables is to systematically alter them and observe the effects of these variables on adherence. There is a vast amount of data on adherence correlates but there are woefully few studies that have experimentally tested the utility of these correlates in altering adherence.

One reason for the paucity experimental studies may be that many of these correlates or predictors have limited utility because they are *marker* or *higher level* variables (Haynes, 1992). A marker variable (such as age, gender, and SES) is one that is statistically associated with a parameter but does not have causal properties. In essence, they "mark" other variables that may function as causal agents. For example, adolescents are more likely to be nonadherent to medical regimens but why might adolescents be more nonadherent? The answer to this question would help elucidate potential underlying causal mechanisms. For example, adolescents seek to be more independent and their parents do not monitor and supervise them as closely, which can contribute to medical nonadherence.

Other adherence correlates are higher-level variables, which are molar or more inferential variables (e.g., "family cohesion"). Higher-level variables are of limited utility because they subsume multiple causal pathways and are subject to greater measurement problems (Haynes, 1992). To be experimentally tested, higher-level variables need to be disentangled and translated into lower, more utilitarian levels. For example, what are the elements of "cohesive" families? What do cohesive families look like in terms of how they interact, solve problems, and con-

duct their lives? The answers to these questions are more likely to lead to specific and testable hypotheses regarding causal mechanisms.

Samples and Regimens

There is a need to expand the focus of adherence intervention studies to include patients with acute diseases other than otitis media and chronic diseases other than diabetes. There is also a need to focus on nonmedication regimens, such as exercising, diet, and other lifestyle changes that are central to preventing or minimizing the impact of diseases. Because there are relatively small numbers of homogeneous patients with specific chronic diseases in most settings, a noncategorical approach may be useful (Stein & Jessop, 1989). This approach assumes that chronic illnesses generically present similar challenges and demands (such as adhering to daily medication regimens) which can be studied by including patients with a variety of chronic diseases. It also assumes that there may be generic causal variables (such as the negative side effects of regimens) that could be manipulated to alter adherence to a variety of treatment regimens. Whether this type of noncategorical approach proves to be useful has yet to be demonstrated but seems worthy of consideration.

Another issue is which patients should be the focus of adherence intervention studies. Some investigators have recommended recruiting "inception cohorts" or all newly diagnosed patients initially prescribed a particular regimen to treat a particular disease (Sackett & Snow, 1979). The adherence of this inception cohort could be monitored longitudinally and interventions could be introduced when adherence declines for a proportion of the cohort. This might be considered a "primary prevention strategy" in that the goal is to prevent or intervene early in the process before adherence problems can have deleterious effects. My colleagues and I have recently completed a study that took this approach. We recruited newly diagnosed patients with JRA and randomly assigned them to an adherence intervention or attention-placebo control group. Patients in the adherence intervention group received a clinic-based intervention by a nurse utilizing educational and behavioral strategies for maintaining adherence. The control group received an educational intervention from the nurse focussing on JRA and its treatment, but not specific adherence enhancement strategies. Results after the first 3 months post-interventions showed that patients in the adherence intervention group were significantly more adherent to medications (as measured by an electronic monitor) compared with the control group and these differences continued over the remaining 9 months of the study. However, we failed to find any significant differences in treatment outcomes or health care costs between the two groups. We have plans to do more long-term follow-up with these patients to assess their adherence and to determine if treatment outcome and health care cost differences emerged over a longer period of time. It remains to be seen whether this primary prevention approach is useful in altering health outcomes and medical costs for patients.

An alternative might be to employ a "secondary or tertiary prevention approach." This would involve monitoring adherence in a representative sample of patients and intervening only with those who demonstrate low adherence that appears to be negatively impacting their health. That is the approach my colleagues and I took in our earlier adherence intervention studies involving patients with rheumatic diseases who the referring rheumatologists believed had less than optimal responses to medications because of low adherence. The advantage of this approach is that one intervenes only with those who could most benefit from adherence improvement, i.e., those whose adherence levels compromise the potential benefits of treatment.

Perhaps primary and secondary prevention strategies could be combined. The adherence of representative samples of children with chronic diseases could be monitored from the time they are diagnosed. Interventions could then be offered to those patients who meet two criteria: (1) their adherence drops below some acceptable level (e.g., <80%) and (2) they are beginning to experience compromised health and well-being as a result of this drop in adherence. This seems like a "win–win" strategy for employing interventions with those patients who could benefit the most.

Adherence and Treatment Outcome Assessments

There are assets and liabilities associated with all measures of adherence. Therefore, the use of multiple measures seems to be a prudent strategy for yielding a more complete assessment of adherence. The "gold" standard for assessing adherence to medications might be the combination of assays and automated measures. Automated measures would provide continuous and precise data on the frequency and timing of presumed medication use while periodic assays could help to confirm actual ingestion of medications. The gold standard for nonmedication regimens might be the combination of structured interviews by telephone to obtain periodic and precise information on the frequency and timing of regimen tasks (e.g., the frequency and timing of meals for children with diabetes) combined with direct observations by parents or caretakers periodically to confirm these reports. Also, research is needed to establish what level of adherence is necessary for particular regimens to produce acceptable therapeutic outcomes. In general, this has not been done for most pediatric disease regimens. Some assay data are available to determine "therapeutic" levels of medications but these data only indirectly assess patient behavior. Whether a drug level is therapeutic or not does not depend solely on how, when, or how often patients take their medications. Other factors must be considered, such as the way the drug is metabolized.

The value of adherence intervention studies is the potential for improving the disease and health status of children. This requires adequate measures of clinical outcomes, including traditional disease activity and QOL measures. Most stud-

ies have not assessed the impact of adherence interventions on clinical outcomes or have inappropriately used clinical outcome measures as proxy measures of adherence. Adherence measures focus on quantitative and qualitative aspects of behavior while treatment outcomes focus on the possible consequences of adherence on the health and well-being of patients. Both are vital but separate phenomena that need to be assessed.

Assessing and Protecting the Integrity of Adherence Interventions

While attention has been focused on assessing and protecting the integrity of outcome measures variables (e.g., the reliability, validity, and accuracy of adherence measures), most adherence studies do not address the integrity of adherence interventions. This is also true for psychotherapeutic interventions in general (Waltz, Addis, Koerner, & Jacobson, 1993). For most studies, there is no confirmation that those conducting interventions adhered to a specific intervention protocol in a consistent and competent manner. Without such information, it is difficult to draw firm conclusions about the effects of interventions. The resulting consequences could be that ineffective interventions appear to be effective or effective interventions might appear to be ineffective (Peterson, Homer, & Wonderlich, 1982). Even if effective results are achieved, it may be difficult to replicate the results without an adequate assessment of treatment integrity.

To assess treatment integrity, intervention protocols need to be developed that specify the precise elements of treatment interventions, preferably in the form of treatment manuals. Protocol checklists can then be developed to monitor the performance of those conducting interventions to determine if they are implementing the protocols in the desired fashion. Monitoring can be done by video- or audiotaping a representative proportion of intervention sessions to determine if the interveners are adequately following the protocols. My colleagues and I have employed research assistants to directly observe intervention sessions and to monitor adherence to specific protocols. The advantage of direct monitoring is that the person doing the intervention can be prompted to implement elements of the protocol that were inadvertently missed.

A related issue is whether patients and families implement interventions in a consistent way. In essence, this involves assessing adherence to the adherence intervention. This is almost never done for adherence intervention studies, possibly because of the logistics of monitoring patient adherence to interventions. My colleagues and I did attempt to do this in one study (da Costa et al., 1997). The primary adherence intervention was a token (point) system program whereby patients with asthma earned daily privileges for adhering to their inhaled corticosteroid medication regimen. To assess whether the token system was being implemented as planned, we had parents record daily point totals and compared these records with the automated chronolog measure of daily adherence. Parents of both patients in this

study correctly awarded points on 75% or more of the days the token system was in effect. On all but one occasion, errors consisted of awarding maximum points on days when adherence was below 100%. Future studies should include measures of treatment integrity that assess how consistently and accurately protocols are administered by those who intervene and by those who receive interventions.

Experimental Design and Conduct of Adherence Studies

There is a need to move beyond correlational studies to experimental manipulations of variables to improve adherence. The choice of experimental designs is critical. Single-subject designs may be particularly well-suited for adherence intervention studies for chronic disease regimens as they accommodate small sample sizes (Barlow & Hersen, 1984). They also require repeated assessments of adherence and clinical outcomes over time, thus providing a more representative data base on individual patient trends for these measures. Single-subject designs are also flexible, thus allowing for changes in standard treatment protocols consistent with a functional analysis of variables that uniquely affect the adherence of individual patients.

Conventional between-group designs could be employed when sufficient numbers of patients are available. True experimental between-group designs require random assignment of patients to groups and are enhanced when an attention-placebo group is included to rule out the effects of simply paying more attention to those assigned to intervention groups. Randomized, prospective between-group designs require adequate sample sizes to achieve sufficient statistical power. This argues for multicenter collaborative research studies. Researchers investigating new medical treatments have long recognized the value of multisite investigations, particularly for chronic illnesses that affect a relatively small number of people. These types of studies require careful attention to ensuring consistency in measures, experimental procedures, and treatment integrity across sites. Regardless of whether single-subject or between-group designs are employed, the basic requirement is still the same. Studies must be designed, executed, and analyzed well enough to convince informed colleagues that successful results can be attributed to interventions that were tested.

CLINICAL RECOMMENDATIONS FOR ASSESSING AND IMPROVING ADHERENCE

Establishing a Cooperative, Family-Centered Clinical Alliance

Medical adherence issues need to be addressed within the context of a collaborative and supportive relationship between patients, their families, and providers. A

critical part of such a cooperative clinical alliance is to set explicit and mutually agreed-upon treatment goals. Patients and their families will be more inclined to follow medical treatment plans that incorporate functional goals, such as maintaining social relationships with family and peers, academic success, and participation in activities of daily life. Greater involvement of patients in this clinical alliance should occur as they enter adolescence, which recognizes their need for autonomy and their increased cognitive sophistication (Crockett & Petersen, 1993). Patients and their families expect (and rightly so) to have a more active role in their health care. After all, they are the ones who have to balance medical treatment requirements and their normal day-to-day activities and obligations. Clinicians should strive to be empathetic, nonjudgmental, and sensitive to the unique concerns, barriers, and resources of patients and their families.

In pediatrics, clinicians often say "we don't treat patients, we treat families." Adherence to medical regimens (or the lack thereof) occurs in a family context. For children under 7 years of age, parents or caregivers are primarily or exclusively responsible for implementing prescribed medical treatments. I recently consulted with the family of a child who had systemic-onset JRA and was in the hospital for a severe exacerbation of her disease. She was cared for at home primarily by her mother. Her two teenage sisters helped with the patients' care when the mother had to be away from home because of other obligations. The patient's sisters expressed concerns that they may not know what to do if she became seriously ill while their mother was away. I recommended that the sisters, along with the mother and the patient, be involved in the discharge meeting with the medical staff to address these concerns. The medical treatment of chronically ill children is a family affair and relevant family members need to be involved in this process.

Assessing Adherence

The more sophisticated and costly measures of adherence, such as electronic monitors, are simply not feasible at this time for routine clinical practice. Soliciting patient and caretaker reports about adherence remains the most direct and practical way to assess adherence in clinical practice. The way questions are posed can affect how willingly and accurately patients and caregivers report about adherence. Framing questions in a nonjudgmental and time-limited fashion will likely yield more honest and useful reports about adherence. Structured telephone interviews appear to be clinically feasible and would limit recall bias. Also, structured interviews allow clinicians to address ongoing concerns and barriers related to adherence that are revealed by patients and caretakers during periodic telephone interviews.

Strategies for Improving and Maintaining Adherence

Education, although not sufficient for improving adherence to chronic disease regimens, is necessary. Comprehensive instruction and training is a foundation for

furthering adherence to prescribed treatments. This begins when patients are diagnosed with an illness and is an ongoing and fluid process in the care of chronically ill patients. Proper education may even be sufficient for ensuring adherence to regimens for acute diseases.

More than education is needed when treating chronically ill children. Physicians need to consider ways to simplify and reduce the aversiveness of regimens they prescribe. Behavior change strategies (particularly monitoring, contracting, and token systems) are also necessary and represent the most effective strategies for improving and maintaining adherence to chronic disease regimens. Promising interventions for older children and adolescents involve training in self-management strategies such as self-monitoring, problem solving, and cognitive restructuring. Form 6.1 is a checklist of options for enhancing adherence that clinicians can consider.

There are many skilled practitioners who have developed and refined strategies for improving adherence. They need to work with researchers in developing and testing adherence enhancement protocols. Once these protocols have been empirically validated, they need to be packaged as treatment manuals that can be disseminated to providers in other clinical settings.

Care must be taken when attempting to "manualize" and disseminate adherence interventions. Standardized adherence interventions need to incorporate ways to address unique barriers or functional variables that affect adherence to

Form 6.1. Checklist of Provider Options for Enhancing Adherence to Medical Regimens

Medical Adherence-Enhancement Options Checklist for Providers

1. Made sure patient and family know what to do, why, and how to do it ____
2. Informed patient and family about disease, causes, course, and prognosis ____
3. Reviewed benefits of consistent adherence ____
4. Anticipated and reviewed possible (or actual) barriers to adherence and strategies for addressing barriers ____
5. Provided a consumer-friendly clinical setting ____
6. Made the regimen as simple as possible and minimized negative side effects ____
7. Encouraged increased parental supervision and provided monitoring form ____
8. Encouraged patient and family to provide cues or prompts for adherence ____
9. Discussed possible positive consequences for adherence ____
10. Reviewed discipline strategies when child is persistently nonadherent ____
11. Reviewed self-management strategies with older patients, such as problem solving and cognitive restructuring ____
12. Referred patient and family for psychotherapy to address more serious problems that exist concurrently with nonadherence or directly contribute to nonadherence ____

Source: Michael Rapoff, Ph.D., University of Kansas Medical Center, Department of Pediatrics, 3901 Rainbow Blvd., Kansas City, KS 66160-7330.

medical regimens for individual patients and families. This will require extensive clinical interviewing and observations to uncover unique determinants and barriers to adherence for particular patients, families, and regimens.

The Inflated Importance of Adherence

What a paradoxical way to end a book that has emphasized the importance of adherence in improving the health and well-being of children. There are, however, broader psychosocial and medical contexts to consider. Patient nonadherence may be part of a mosaic of patient and family struggles. Medical adherence problems may be symptomatic or exist concurrently with patient and/or family dysfunction. For example, a depressed adolescent who has a chronic disease may not have the energy and coping resources to adequately adhere to a complicated medical regimen. These psychological problems need to be addressed by competent mental health personnel who have extensive experience working with patients and families in pediatric settings.

Additionally, the outcome of medical treatment does not solely depend on adherence. There are other factors to consider. Subtherapeutic drug assay levels may reflect low adherence but can also be the result of inadequate dosing, pharmacokinetic variations in drug metabolism, and interactions with other drugs. But, the overall message of this book is still relevant. When confronted with less than adequate outcomes in the treatment of acute and chronic diseases, a reasonable beginning is to investigate the contribution of patient adherence.

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Appendix

Publications, Organizations, and Website Resources on Specific Pediatric Diseases

ASTHMA

Publications

American Lung Association Asthma Advisory Group, & Edelman, N. (1997). *American Lung Association family guide to asthma and allergies*. New York: Little, Brown.

National Asthma Education and Prevention Program. (1997). *Expert Panel Report 2: Guidelines for the diagnosis and management of asthma*. Bethesda: National Institutes of Health (Publication No. 97-4051).

Plaut, T.F. (1988). *Children with asthma: A manual for parents*. Amherst, MA: Pedipress.

Organizations

American Academy of Allergy, Asthma, and Immunology, 611 E. Wells St., Milwaukee, WI 53202; phone: 414-272-6071

American Lung Association, 1740 Broadway, New York, NY 10019; phone: 1-800-586-4872

National Asthma Education and Prevention Program (NAEPP), 4733 Bethesda Ave., Suite 530, Bethesda, MD 20814-4820; phone: 301-251-1222

Websites[1]

http://www.aaaai.org (American Academy of Allergy, Asthma, and Immunology)

http://www.lungusa.org (American Lung Association)

[1] Website addresses change frequently. Although websites listed are sanctioned by reputable organizations, patients and families should be cautioned about accessing information from the web and should be encouraged to consult with their physician.

CANCER

Publications

National Institutes of Health (1988). *Young people with cancer: A handbook for parents* (NIH Publication No. 93-2378). Washington, DC: U.S. Government Printing Office.

Organizations

American Cancer Society, 1599 Clifton Rd., NE, Atlanta, GA 30329; phone: 800-227-2345
Candlelighters Childhood Cancer Foundation, 7910 Woodmont Ave., Suite 460, Bethesda, MD 20814-3015; phone: 800-366-2223

Websites

http://www.candlelighters.org (Candlelighters Childhood Cancer Foundation)

CYSTIC FIBROSIS

Publications

Cystic Fibrosis Foundation (1997). *Clinical practice guidelines for cystic fibrosis*. Bethesda: Author.
Ryan, L.L. (1996). *Cystic fibrosis: A handbook for teachers*. Bethesda: Cystic Fibrosis Foundation.

Organizations

The Cystic Fibrosis Foundation, 6931 Arlington Rd., Bethesda, MD 20814; phone: 800-344-4823

Websites

http://www.cff.org (Cystic Fibrosis Foundation)

DIABETES MELLITUS (INSULIN DEPENDENT)

Publications

Daneman, D. (1991). When should your child take charge? *Diabetes Forecast*, 61–66.
Moore, W.V., Olson, J., Barnard, M., & Knapp, K. (undated). *Care and control of type i diabetes* (available from Martha Barnard, Ph.D., Department of Pediatrics, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160-7330).

Organizations

American Diabetes Association, 1660 Duke St., Alexandria, VA 22314; phone: 800-232-3472
Juvenile Diabetes Foundation, 120 Wall St., New York, NY 10005-4001; phone: 800-533-2873

National Diabetes Information Clearinghouse, Box NDIC, Bethesda, MD 20892; phone: 301-654-3327

Websites

http://www.diabetes.org/custom.asp (American Diabetes Association)
http://www.jdfcure.com/about.htm (Juvenile Diabetes Association)

HEMOPHILIA

Publications

For pamphlets and booklets related to hemophilia, contact the National Hemophilia Foundation and ask for their publications catalog.

Organizations

National Hemophilia Foundation, 116 W. 32nd St., 11th Floor, New York, NY 10001; phone: 800-424-2634

Websites

http://www.hemophilia.org (National Hemophilia Foundation)
http://www.web-depot.com/hemophilia (Hemophilia Homepage)

JUVENILE RHEUMATOID ARTHRITIS

Publications

Brewer, E., & Angel, K. (1995). *Parenting a child with arthritis: A practical, empathic guide to help you and your child live with arthritis.* Los Angeles: Lowell House.
Cassidy, J., & Petty, R. (1995). *Textbook of pediatric rheumatology* (3rd ed.). Philadelphia: Saunders.

Organizations

American Juvenile Arthritis Organization, 1314 Spring St., NW, Atlanta, GA 30309; phone: 404-872-7100

Websites

http://www.arthritis.org/ajao/ (American Juvenile Arthritis Organization)

OTITIS MEDIA

Publications

Stool, S.E., Berg, A.O., Berman, S., et al. (1994, July). *Otitis media with effusion in children* (Guideline Technical Report No. 12, AHCPR Publication No. 95-0621). Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services.

Organizations

National Institute on Deafness and Other Communication Disorders, Information Clearinghouse, 1 Communication Ave., Bethesda, MD 29892-3456; Phone: 800-241-1044

Websites

http://www.nih.gov/nidcd (National Institute on Deafness and Other Communication Disorders)

SEIZURE DISORDERS

Publications

Freeman, J.M., Vining, E.P.G., & Pillas, D.J. (1990). *Seizures and epilepsy in childhood: A guide for parents*. Baltimore: Johns Hopkins University Press.

Organizations

The Epilepsy Foundation of America , 4351 Garden City Dr., Landover, MD 20785-2267; phone: 800-332-1000

Websites

http://www.efa.org (Epilepsy Foundation of America)

Index