HANDBOOK OF DIABETES MANAGEMENT

EDITED BY
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Springer

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This book is dedicated to the memory of Carter Marshall, MD, MPH who passed away this year. Dr. Marshall is remembered for his lifetime commitment and achievements in improving the quality of our healthcare system. We deeply thank Dr. Marshall for providing inspiration and professional guidance to many of the contributing authors.

About the Editors

Donna Zazworsky, MS, RN, CCM, FAAN, is an internationally known expert in case management and disease management with community populations. She is the manager of the Diabetes Care and Community Outreach Centers for Carondelet Health Network, a three hospital healthcare organization and a member of Ascension Health. The Centers have provided the longest ADA-recognized diabetes self-management programs to people living in Southern Arizona's Pima and Santa Cruz counties. Ms. Zazworsky also works with St. Elizabeth of Hungary Clinic as a volunteer consultant on diabetes disease management issues and is the managing partner for Case Manager Solutions, LLC. On a personal note, Donna's mother and two maternal aunts have experienced the devastating complications of type 2 diabetes. Nine years ago, her mother suffered a stroke that has left her with left-sided weakness. Both aunts died of diabetes complications related to above the knee bilateral amputations and end stage renal disease. Not only is diabetes prevention a personal motivation for Donna, but case management and disease management systems provide a primary focus for her work in understanding and reducing barriers for people with diabetes.

Jane Nelson Bolin, RN, JD, PhD, is a professor and researcher in rural health and disease management at Texas A&M. On a personal note, Jane has had gestational diabetes during both of her pregnancies. Knowing that the incidence of getting type 2 diabetes at a later age is very high, Jane practices a personal prevention program that includes diet and exercise.

Vicki B. Gaubeca, MPH, is director of Public Affairs for the University of Arizona Mel and Enid Zuckerman College of Public Health. On a personal note, Vicki has had type 1 diabetes since she was a teenager. She knows the day-to-day struggles of self management and hopes that this handbook will lend insight to public health workers who help people with diabetes.

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Foreword

Diabetes—you read about it everywhere today. It's a hot topic in the news magazines, on the talk shows, in professional journals, in the daily paper—even in the rags at the grocery counter. Should you be interested? Of course! If you do not have diabetes, you probably know someone who does. You probably know many people who are either diabetic or prediabetic. I am interested in the topic because I was diagnosed almost two years ago with type 2 diabetes.

Many years ago, I was in the Miss America Pageant as Miss Arizona. I was a letterwoman on the University of Arizona women's swim team. I modeled for Mr. Blackwell of Hollywood, then I married my high school sweetheart and am now the mother of four children and the grandmother of six (number seven is on the way.). I knew how important it was to stay in shape, but life and time added pounds to my frame. I worked long hours, and pushed my limits. Even though I had been a nurse for more than 30 years, I refused to see the initial symptoms of diabetes and I rationalized the excessive thirst and frequent urination. I ignored how sleepy I felt at times, especially after a big meal. I told myself that I just wasn't able to sleep through the night like I used to do. I had recurrent yeast infections. All of these symptoms coincided with the thrills of menopause. I would tell myself also that this was what aging was about.

Then came the diagnosis of diabetes and I actually felt relief. Facing this reality made me understand why my body had become a stranger to me. I looked for all the information that I could get my hands on. And I found quite a bit of information in book stores and on the Internet. But I really wanted a comprehensive resource, something that would give me both educational and practical information about the diabetes epidemic that was facing the nation. I wanted to not only help myself but prepare my children so they would not have the same diagnosis in their future. I also wanted a manual to add to my professional library that would be a resource to me in both my nursing and law careers.

This handbook by expert professionals covers every aspect of diabetic care. It is a sound, evidence-based, culturally informative, practical approach to diabetes prevention and disease management. It also provides case studies which reflect the various clinical settings in which diabetes care takes place. There is information on the financial considerations of the population with diabetes and methods for computing direct and indirect costs of treatment. Special care issues of the prediabetic and the gestational diabetic are

addressed. It includes sample diets, exercise programs, and tools for assessing depression. This handbook is both interesting and fun. As a comprehensive resource, it is a bonus to health care professionals who appreciate the dramatic impact that the diagnosis of diabetes is having and will continue to have on the nation.

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Preface

The focus of this book is on the problem of diabetes and principles of effective diabetes population management. No one disputes that America is in the midst of an epidemic of diabetes. Recent estimates from the Centers for Disease Control and Prevention (CDC) on the percentage of the population with diabetes is 6.3%, or 18.2 million people, with the percentage of Hispanics at 8.2% (2 million) and Non-Hispanic blacks at 11.4% (2.7 million) (CDC, 2004). Conservatively, diabetes affects over 17 million Americans with another 16 million diagnosed as prediabetic, or at risk. In a recent study to be published in *Obesity Research*, researchers estimated that in the U.S., obesity-attributable medical expenditures reached $75 billion in 2003 and that taxpayers financed about half of these costs through Medicare and Medicaid. Obesity leads to a myriad of chronic health conditions; most common among those conditions is diabetes with all of its associated morbidity. Clearly, we all have a vested interest in finding solutions to this public health crisis.

Users of this book will notice that the substance of each chapter is enhanced by the authors' own personal and professional experience of dealing personally with the challenges of diabetes. Collectively, each of our clinical and professional lives have been affected by diabetes compelling us to create prevention programs, investigate treatments, and create methods of managing this complex and deceitfully subtle disease that manages to steal productivity and health from such a large percentage of the American public.

The concerns that launched our efforts to document methods of disease management were formed through daily exchanges with patients and clinicians each attempting to better understand this disease known as diabetes. Concerns led to development of models of clinical and community management which in turn led to documentation that these methods had resulted in reduced morbidity and ultimately reduced mortality.

A recurring theme of every chapter, from every contributor, is the vast complexity and diversity of the population of persons with diabetes. While statistics are fairly straightforward, they tell us that diabetes is a significant, national problem that will require the efforts of all health professionals and their patients if it is to be addressed in a meaningful way.

Fittingly, our book is divided into the following four sections:

Part 1: The Diabetes Framework. This section addresses the picture of diabetes disease management and population management. The challenging issues of the diabetes quality initiatives and the chronic care model are thoughtfully explained to provide insight for those beginning to step into this next level of care. The cultural competency and

technology chapters offer a broader overview of development and application.

Part 2: Caring for People with Diabetes. This section covers evidence-based practice for the complex facets of diabetes care. The chapters on the Origins of Diabetes and Medication Management cover the most up-to-date research on these two topics. These chapters also offer the latest standards of practice in diabetes management. The Nutrition and Glycemic Index chapter provides the readers with a plethora of information related to the glycemic index, diet recommendations, and how other highly promoted diets measure up to the scientific rubric. Behavioral health and self-management issues and interventions are explained and practice applications are given. Finally, sick day planning, travel, surgery and foot care are covered, including specific tips to give patients when facing any of these issues.

Part 3. Special Care Issues. This section addresses the complexities of caring for a diverse population. First there is the area of Prediabetes. A relatively new term describing a stage of diabetes serves as a trigger for people and providers to look at lifestyle issues more aggressively—with the intent to prevent the onset of diabetes.

Gestational diabetes must be addressed. Although usually a temporary condition triggered by pregnancy, gestational diabetes has been a precursor to the onset of diabetes at a later age.

Chronic kidney disease (CKD) has become more pronounced with the newly-defined stages of CKD. Diabetes is one of the leading causes of renal disease leading to dialysis and transplantation. A more aggressive effort is being made to promote early detection of disease.

Other issues related to the uninsured, rural populations and border communities are also confronted in this section. Each of these issues present difficult challenges for providers and the healthcare team. Helpful tips are offered and are based on many years of hands-on experience.

Finally, two other areas that are covered in this section are Complimentary Medicine and the emerging technology of Self–Management Systems and telehealth care. This section offers a summary of other uses of technology to support the patient in their quest to be better self managers.

Part 4: Business Issues. Without question, diabetes disease management cannot be performed without addressing the business aspects related to legal and regulatory issues, health policy initiatives, economic rationale, funding sources and marketing components. This section provides the reader with valuable knowledge to start and manage a successful diabetes program.

Part 5: Case Studies. Finally, this section provides case studies that have demonstrated success with evidence-based practices shaped for a variety of populations. These case studies offer helpful tools and share their lessons learned—following the motto: Share willingly and steal mercilessly.

This handbook only begins to cover the incredible work that is going on around the country. It is time to share our experiences so that other providers will glean those pieces that fit for their practices. In the long run, it will be our communities that will benefit.

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I

The Diabetes Framework

1

Essentials of Quality Improvement with Special Reference to Diabetes

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ORIGINS OF QUALITY IMPROVEMENT IN DIABETES

Quality improvement (QI) in medicine can be traced to Sir Thomas Percival (1740–1804) who, in 1803, advocated hospital programs to improve the quality of care provided by physicians (www.whonamedit.com/doctor.cfm/2558.html, 2005). QI in the United States began with Ernest Codman (1869–1940), a Boston surgeon who lost his appointment to the Harvard Medical School faculty because of his persistent call for study of surgical outcomes. Codman's ideas were eventually incorporated into the newly established American College of Surgery and he was instrumental in the establishment of the Joint Commission on Accreditation of Health Care Organizations (JCAHO) (Murray, 2000). The principles and methodology of QI owe much to the process of continuous quality improvement (CQI) pioneered by business guru Edward Deming (Aguayo, 1990).

The application of quality concepts to diabetes was problematic as long as medicine was more or less powerless to restrain a virtually inevitable downhill course resulting in death a few years after diagnosis. The discovery of insulin by Banting and Best in 1921 revolutionized diabetes care and established insulin as the *sine qua non* of quality diabetes management. While it was immediately clear that insulin prolonged the lives of patients with diabetes, it was far less clear whether the strict control of diabetes led to fewer complications and still longer life. The answer to this question appeared with the publication of the famous Diabetes Control and Complications Trial (DCCT) in 1993. This study showed for the first time that strict control in patients with type 1 diabetes greatly reduced complications of the disease. The equally important United Kingdom Prospective Diabetes Study (UKPDS) provided similar evidence in favor of strict control in patients with type 2 diabetes (Straaton *et al*., 2000). Subsequent studies of patients with type 2 diabetes produced similar results. DCCT made QI a reality in diabetes management by enabling the development of management standards that were both measurable and known to improve patient well-being.

WHY DO QUALITY IMPROVEMENT

Obviously, QI is carried out to better the prognosis of individual patients with diabetes and other diseases, but there are other reasons as well. First, the quality of health care needs improvement (Institute of Medicine [IOM], 2001). As Robert Brook of the RAND Corporation once said of American health care, "When it's good, it's very, very good, but it's not very good very often." McGlynn *et al*. examined 439 performance measures for 30 acute and chronic illnesses. Of these 439 indicators, patients received 55% (McGlynn *et al*., 2003). This level of care extends to diabetes as well. Of 2,865 diabetes patients in 55 Midwestern community health centers, annual rates for diabetes performance measures included 26% for dilated eye examination, 51% for foot care, 66% for dietary instruction, and 27% for two or more HbA1c tests (Chin *et al*., 2000). Mean HbA1c in this group was 8.6%.

Second, the quality of care *can* be improved. In collaboration with Health Services Advisory Group (HSAG), Arizona's Medicare Quality Improvement Organization (QIO), six Medicare managed care organizations reduced mean HbA1c values from 8.9% to 7.9% and increased the proportion of patients with HbA1c values below 8.0% from 40% to 62%. The proportion of 14 performance measures provided to patients rose from 35% to 55% (Marshall *et al*., 2000).

Third, disparities in the level of care by race and income can be addressed through QI activities. Even when Medicare is paying the bill, minorities receive care that is inferior to whites (Skinner *et al*., 2003; Lavizzo-Mourey and Knickman, 2003).

Fourth, quality improvement can contribute to efforts to reduce the cost of medical care. Partly because of quality deficiencies, all illness and especially diabetes are very expensive both to the society as a whole and to the individual patient. Caring for a diabetes patient managed by diet and exercise alone who has no microvascular, cardiovascular, or neuropathic complications costs about $2,000 a year. The use of oral antidiabetic or antihypertensive agents increases this cost by 10–30% as does increased BMI and renal, cerebrovascular, or peripheral vascular disease. Patients with heart disease, angina, or insulin therapy boost the cost by 60–90%, and the cost is increased 11-fold in patients with end-stage renal disease (Brandle *et al*., 2003). QI is directed at improving provision of services and thereby reducing some of these costs. The managed care plans cited above reduced the number of physician office visits by 13% and doubled the number of services provided per visit.

Out-of-pocket costs for patients have risen as well. Drug costs have been rising at an annual rate of 13–14% (National Health Statistics Group, 2003) and as intermediaries such as managed care plans and employer-sponsored insurance shift costs to consumers, utilization of diabetes preventive services such as dilated eye exams and daily self-measurement of blood glucose decline as the out-of-pocket costs of these services rise (Karter *et al*., 2003). Once baseline data are available for a given condition, QI can document such changes and highlight the magnitude of unmet needs.

Finally, there is the question of value for money. Health care accounted for 15% of the nation's gross domestic in 2002. Although Americans spend twice as much on health care as the Europeans or Japanese, life expectancy in the United States is 2–3 years lower than it is in these areas (Mehring and Koretz, 2004). A significant part of this cost is the higher prevalence of obesity in this country and the concomitant diabetes, heart disease, and cancer to which it is related. In the absence of a way to prevent or cure obesity, diabetes, heart disease, and cancer, maximizing the quality of care is the most effective way to increase life expectancy, improve quality of life, and reduce costs.

THE CENTERS FOR MEDICARE AND MEDICAID SERVICES

The Centers for Medicare and Medicaid Services (CMS), an arm of the Social Security Administration, is the biggest purchaser of medical care in the country if not the world. Through Medicare directly and through Medicaid indirectly by way of several states, CMS is in a unique position to change the quality of medical care and is actively involved in doing so. It does this through centralized activities such as Pay-for-Performance (see below) and, at the state level, though a network of quality improvement organizations (QIOs) that work with hospitals, nursing homes, home health agencies, managed care plans, and, increasingly, individual physicians to improve quality through improvement projects targeting specific diseases like pneumonia, heart failure, and acute myocardial infarction (AMI) as well as adverse clinical events like surgical wound infections. The QIOs also accept and investigate complaints of beneficiaries regarding providers. CMS maintains two websites: www.cms.hhs.gov and www.medicare.gov. Although anyone can access either site, the former is oriented to professionals and the latter to consumers.

MEASURING QUALITY

Quality improvement in diabetes and other diseases is a set of activities undertaken to assure that patients receive the services known to minimize complications and maximize life expectancy. The essence of QI is the performance measure, used interchangeably with the term "indicator." Performance measures indicate how close to perfection (100%) a provider comes in making a service available to patients. Measures usually contain a time component that specifies the frequency of the service, e.g., HbA1c determination every quarter. The results of performance measures are binary and expressed as the proportion of patients receiving the service. The development of performance measures has become a business as QI gains acceptance. The National Quality Foundation, JCAHO, CMS, and a number of private companies all develop indicators. Indicators must be based on scientific evidence and reviewed frequently to assure that the evidence remains firm and that the measure itself has not been superseded by a new technology or medication.

Quality improvement projects (QIPs) compare what was to what is, i.e., baseline data to data collected after some interval of time, often monthly or quarterly. Projects always produce periodic reports that sum up the level of performance attained compared to baseline data. QIPs thus require baseline data, remeasurement data, and some sort of *intervention* designed to bring about a positive change during the interval between the two. QIPs typically take place within institutions either as an entirely internal activity or in collaboration with other providers and/or a QIO. QIP reports have three main uses: (1) informing the provider of care so they can improve further; (2) providing a comparison among providers; and (3) informing the consumer to facilitate an informed choice of provider.

Quality improvement projects must be distinguished from quality assessments. Quality assessment is a measure of the quality of care at a point in time—a cross-sectional snapshot. Assessments collect what is essentially baseline data to see if a QIP is needed. Assessments are thus searches for opportunities to improve care, and they often become the baseline against which the remeasurement is compared.

We also must distinguish between QI and the closely related area of patient safety, a term that incorporates medical errors. Patient safety burst upon the national consciousness with the Institute of Medicine's publication *To Err is Human: Building a Safer Health System* (IOM, 1999). QI and patient safety are different sides of the same coin. The difference is that QI focuses on elevating the quality of management of specific diseases like diabetes while patient safety looks across all

TABLE 1.1. The Structural Component of Quality Measurement

Component	What the component addresses
Facility	The physical environment. Is the building in which care occurs suitable for its use?
Organization/culture	How efficient and how effectively is the care provided? Does the "culture" of the organization support or hinder quality of care? What system changes might make care better? If the facility treats substantial numbers of minority patients, is it "culturally competent" to do so, e.g., in a facility treating Hispanics, is there an adequate cadre of Spanish-speaking staff? Is there sufficient knowledge of the culture and life situation of the patients to support quality care?
Finance	Is the facility fiscally sound?
Utilization	Who uses the facility, for what purpose, how often, and under what circumstances?
Manpower	Is the staffing adequate to the task, e.g., are there enough nursing staff to adequately provide for the number of patients served?
Societal	General problems that impact the quality of health care by influencing consumer behavior, but lie largely beyond the control of the provider, at least in the short run. Examples include steep annual increases in the price of pharmaceuticals; the high prevalence of Americans without health insurance; the decline in the number of people going into nursing at a time when that segment of the population most in need of nursing care, the elderly, is rapidly rising; and the unwitting or inappropriate use of alternative medicine that harms the user either directly or by delaying the seeking of proper medical care

diseases seeking to prevent *adverse events*. One of several national hospital improvement projects now underway addresses the prevention of surgical wound infection, an adverse event that is not tied to a specific disease, condition, or procedure. A second difference is that disease-oriented QI is primarily concerned with acts of omission, e.g., was the patient's hypertension treated? Patient safety usually addresses acts of commission, e.g., was the hypertensive patient given the wrong medicine or was he given the wrong dose. These differences should not obscure their underlying similarities. Both use the same process: find errors, be they of commission or omission, quantify them, intervene to bring about improvement, and remeasure to quantify improvement.

Quality improvement has three possible components: *structure*, *process*, and *outcome*. Two of these (process and outcome) are dynamic and one (structure) is relatively static. Structure has to do with the environment in which patient care takes place. Table 1.1 divides "structure" into its component parts.

Structural elements are often interdependent. For example, high fiscal performance in an organization is associated with cultural qualities that promote innovation (Fisher and Alford, 2000). Structure is often the basis of overall evaluation of providers such as the hierarchy of "best" hospitals published annually by *U.S. News and World Report*.

Process and outcome measures are disease specific, and, besides obvious structural problems like inadequate heating or very low nurse to patient ratios, it is seldom clear exactly what role the structural elements play as determinants of hands-on disease management (DM).

Outcome measures are intuitively appealing. They deal with endpoints such as changes in heart disease mortality among diabetes patients or lowered blood pressure among hypertensives. Unfortunately, using outcomes to measure quality, especially in comparing one provider to another, is fraught with difficulty. Different facilities have different patients. Even when providers serve the same population, the patients may and often do differ significantly from one provider to another. The provider with the sicker patients will usually have the worse outcome. Disparities in health, income, and education differ between entire population groups, and it is therefore difficult to compare outcomes

between providers who serve a largely poor, uneducated, ethnic minority to one whose patients are preponderantly white, educated, and relatively affluent. The use of outcomes requires risk adjustment—a way of taking into account differences in the patients served by a given provider. Risk adjustment methodologies are plentiful but there is no consensus as to which one is best, and it is inappropriate to compare outcomes when different risk adjustments have been applied. The other problem with outcomes is that the combination of patients changes over time even within the same provider. As a consequence, outcomes also will vary even though the quality of care provided remains unchanged. The ultimate outcome, death, is not usually attributable to the specific act of a given provider and may not, therefore, bear any relation whatever to the quality of care provided. Finally, in many diseases and especially in diabetes, the patient plays a major role in determining his own outcome. This role is rarely, if ever, included in quality measurement. For example, only about 75% of patients who receive prescriptions for β-blockers are taking this medication 6 months later (Butler *et al*., 2002). The outcome for the remaining 25% may be adversely affected by their lack of medication, but it would be most unusual for this factor to be taken into account in assessing the quality of care offered by the providers who manage these patients.

Process measures inherently incorporate the limitations of medicine. The process of care, when it includes every service known to be beneficial, is all the health care system has to offer. Every moviegoer is familiar with the 19th century doctor's classic line, usually spoken to a grieving widow, "We have done all that is humanly possible." An unfortunate outcome does not imply that more might have been done.

Process consists of both diagnostic and therapeutic actions. The latter are sometimes referred to as follow-up indicators or intermediate outcomes. Intermediate outcomes specify what should be done for the patient once his problem is known. Thus, as shown in Table 1.2, blood pressure determination is the diagnostic measure, the ACE inhibitor the patient receives if hypertensive is the intermediate measure, and the change in the incidence of the sequelae of hypertension, such as heart failure or stroke, is the outcome. Table 1.2 lists services that are commonly used as performance measures in diabetes.

It is usual for some subset of these measures, often as few as three or four, to be used as the basis of diabetes QI. HbA1c is always included, and retinal examination, feet examination, and blood pressure usually appear along with HbA1c. Sets of measures often differ as to frequency—annually, quarterly, monthly, every visit, etc.—and, unless the frequency is known, providers should not be compared even when they use the same indicators. The major problem with process indicators is that their application varies by physician provider so results are affected when, for example, a large number of patients are cared for by a poor physician performer. CMS has been doing national process based QIPs for about 10 years. Between 1998 and 2001, CMS projects that reported on improvements in pneumonia, immunizations, and diabetes among Medicare beneficiaries showed improvement, albeit modest, in all three areas (Jencks *et al*., 2003).

QUALITY IMPROVEMENT AND HEALTH SERVICES RESEARCH

The purpose of health services research is to uncover new knowledge about the delivery of health services. The purpose of QI is quite different. QI seeks to take information known from prior research and integrate it into the medical mainstream. It is the alchemy of incorporating the content of articles from the *New England Journal of Medicine* into usual practice by all providers. QI deals with that which is known to benefit patients. Research is trying to find out what benefits patients. On

TABLE 1.2. Commonly Used Performance Measures (Indicators) in Diabetes Management

Performance measures	Comment
Process measures	
Blood pressure quarterly	Often required at every visit
HbA1c quarterly	Sometimes required only once or twice annually
Foot examination twice a year	Often required at every visit; sometimes required at intervals greater than one year
Retinal examination yearly	Almost always specified that this examination must be done with eyes dilated and/or by an ophthalmologist
Lipid profile yearly	Usually includes total cholesterol, HDL and LDL cholesterol, triglycerides
Urine testing for protein yearly	Usually testing uses Micral; sometimes testing begins with dipstick and Micral is used if dipstick is negative
Serum creatinine	
Daily aspirin	
Immunization against influenza	
Immunization against community acquired pneumonia	
Blood pressure at the ankle to test for peripheral vascular disease	Not commonly used but will probably become more common
Diabetes education	
Nutrition instruction	Most type 2 patients need to be placed on diets to lose weight and all need to recognize the relationship between diet and diabetes
Exercise	Complements dieting and lowers blood sugar
Medication	Necessary to avoid episodes of hypoglycemia and to encourage proper use of medications, especially insulin
Use of home glucose meter	Meters are accurate to within ±20% of readout. Meters whose reading is based on whole blood give lower readouts than those based on plasma.[a] Patients who switch from one type to the other will find their disease suddenly getting much better or much worse or lead to the conclusion that the device does not work.
Follow-up (intermediate outcomes)	
ACE-I if hypertensive	ARBs are commonly substituted for ACE-Is
ACE-I if protein in urine	ARBs are commonly substituted for ACE-Is
Treatment if hyperlipemic	"Statin" drugs are increasingly used not only for hyperlipemia but also to prevent AMIs and CVAs.
Ophthalmologic referral if abnormal retinal exam	Not needed if examined by ophthalmologist

[a] All meter readings are based on whole blood. "Plasma" meters have a built in algorithm that converts whole blood reading to its plasma equivalent. The "plasma" reading should be 12–15% higher than the whole blood reading. Plasma readings are popular because they are closer to the value obtained when blood sugar is determined by a laboratory.

a practical level, the method of QI necessarily differs from that of research. Competent research always includes a control group. But control groups are problematic in QI because it is unethical to withhold that which is known to be beneficial from some patients while providing it to others. This is quite aside from the practical reality that no provider wants to be a control group. Finally, QI is often carried out among providers with no outside support. To conduct QI with the rigor of research would be prohibitively expensive without access to the kind of external support that is available to research. At the same time, QI and research are mutually supporting in that QI often becomes the basis for research just as research provides the knowledge applied by QI.

QUALITY IMPROVEMENT AND PATIENT SATISFACTION

A high level of patient satisfaction with the care they receive has long been considered a hallmark of quality. Providers frequently play up patient satisfaction in their advertising, and most health care institutions regularly sample patients to obtain feedback. While patient satisfaction and quality are seen as complementary, it is usually unclear just how much satisfaction is needed to denote quality. In a free market, a managed care plan with patient satisfaction approval of less than 85–90% or better is unusual for the simple reason that the dissatisfied simply disenroll. Enrollment of Medicare beneficiaries in managed care plans has been in free fall for about 5 years, a trend that began as plans addressed rising costs, first by dropping liberal prescription drug benefits and then by wholesale abandonment of patients and voluntarily withdrawal from the market. Generous provisions for managed care in the newly enacted Medicare Prescription Drug and Modernization Act of 2003 are intended to reverse both trends. Patient satisfaction played a key role in this downward spiral. As costs began to rise, stripping away the drug benefit greatly reduced patient satisfaction and reduced enrollment, leaving the plans with not only rising costs but declining income as well.

While this kind of patient satisfaction—voting with one's feet—has obvious ramifications where the patient has free choice, the role of patient satisfaction and its relationship to quality of care in hospitals is often less clear. A patient with diabetes who is hospitalized for an AMI is not likely to know if he was given an ACE inhibitor or β-blocker or even whether he should have been given one or both of these drugs. On the other hand, he would know when pressing the call button brought no assistance or how the food tasted or how well he was treated by the admitting staff. Patient satisfaction is a *de facto* outcome measure that reflects both characteristics of the hospital and the patients who experience the hospital. Like other outcome measures, patient satisfaction must be risk adjusted to enable comparison across providers. A risk adjustment scheme for patient satisfaction might include age, sex, race, education, self-reported health status, and why the patient is under treatment. Positive and negative experiences spread rapidly by word-of-mouth, and hospitals are very concerned about how its patients feel about them and recognize the importance of pleased clientele to market share. CMS and the Agency for Health Research and Quality (AHRQ) have jointly developed a standardized, risk adjusted patient satisfaction instrument called the Hospital Consumer Assessment of Health Plans Survey (HCAHPS). It is modeled after a previously developed instrument designed for managed care plans known as CAHPS, which is the same name without the "H." Instruments such as these can be used across providers and yield valid results.

Patient satisfaction and disease-specific quality assessment measure different aspects of quality. For this reason, it is not surprising that there is frequently no correlation between patient satisfaction and clinical quality as measured by performance indicators.

INTERVENTIONS

An intervention is any act that is taken to improve the quality of care provided to patients with a specified condition. An outpatient facility that provides continuing medical education for its physicians is intervening to improve diabetes care. Some interventions become so standardized and well studied that they themselves become quality measures such as diabetes education for patients. The success of interventions in bringing about positive change is far from certain. Interventions in one setting may seem to have no effect at all in, say, increasing the rate of lipid testing and yet work quite well in another setting. Interventions are influenced by the organizational and cultural environment in which they occur and the same intervention may be greeted

with enthusiasm by one provider and with disdain by another. Change in services provided after an intervention may thus reflect influence of the cultural climate rather than the intervention. Further, a QI may succeed primarily because the provider knows that he is being observed, thereby reflecting the well-known "Hawthorne effect." While the context of this discussion is interventions as part of QI projects, some interventions are quite different. The Medicare program may be seen as a huge intervention intended to improve care by removing financial barriers. The extensive QI activities of CMS throughout the United States, while not specifically geared to improvement directly attributable to the Medicare program, is intended to measure changes in the quality of care received by beneficiaries.

ORGANIZATIONAL CULTURE AND SYSTEM CHANGE

As experience grows with quality improvement, more and more emphasis is being placed on the environment in which the QIP is operating, i.e., the culture of the provider organization. It is not unusual for a QIP to produce a relative improvement of 30% or so and find thereafter that further improvement becomes extremely difficult. Further, when more than one provider is involved in the QIP, improved performance across providers is often similar and they often share performance characteristics. If provider A fails to examine a patient's feet, it is quite likely that provider B will not examine them either. When there is a very large gap between one provider and others, it often means that the organizational culture of the outstanding provider differs significantly from the norm. Organizational culture subsumes the shared perceptions, beliefs, and expectations of its personnel, and organizational culture mediates any effort to bring about change. Financial health, willingness to innovate, customer and employee satisfaction, and especially leadership, all seem to be key components of an organization's culture.[1] One can confidently expect to see major efforts to increase understanding of cultural influence so these can be harnessed in the cause of improved care.

TEN IMPORTANT CONSIDERATIONS IN QUALITY IMPROVEMENT

(1) *Weighted measures*. Most diabetes projects use several indicators similar to those in Table 1.2. It is not uncommon for those designing QIPs to make some indicators count more than others. This is the application of weights to the measures used. Thus, indicator A might count as 1.0 but indicator B count as 2.0, making B twice as important in scoring improvement than A. There are two problems with this. First, those being evaluated will concentrate on B at the expense of lower weighted indicators. Second, it is unusual for those considering the measures or being evaluated by them to agree on the relative weights to be used, thus undermining the credibility of the project.

(2) *Scoring improvement versus scoring performance*. If the goal of QI is to achieve a specified level of performance or to develop a hierarchy of providers from best to worst, the target of the QI effort is performance, i.e., the remeasurement value. Performance must be distinguished from improvement. As we have seen, QI requires two measurements, baseline and remeasurement following the application of an intervention. The difference between the two expresses the degree of improvement. If provider X examines the feet 20% of the time at baseline and 40% of the time at remeasurement, this is an improvement of 100% ((Remeasurement – Baseline/Baseline) X 100). Consider another provider, Y, who examined the feet of 70% of patients at baseline and 90% at remeasurement. Both providers increased performance by 20 percentage points, yet Y's improvement is only 28.6% $((90 - 70/7) \times 100 = 28.6\%)$. Y would appear to have improved far less than

X even though Y's baseline score was 3.5 times better and Y's remeasurement was 2.5 times better than X's. What is wrong with this picture? The problem has to do with the nature of percentages. The lower the baseline value, the greater the percentage increase at remeasurement. What is used to correct this difficulty is the *relative improvement*, sometimes referred to as the reduction in error rate, where the "error rate" is the difference between the baseline and 100%. Relative improvement thus ties the improvement score to the goal of all providers, which is providing the service in question to all patients, or 100%. It shows the extent to which the provider has narrowed the gap between what he provided at baseline and the goal of 100%. The formula is (100 − baseline) − (100 − remeasurement)/(100 − baseline) × 100. Using this formula, X improved 20% while Y improved 67%. Relative improvement also takes into consideration the well-known fact that it is easier to improve the lower your baseline score. It is harder to go from 90% to 95% than it is to go from 5% to 10%. Table 1.3 shows the relative improvement for any combination of baseline and remeasurement values. The shaded area shows the combination of baseline and remeasurement performance that result in a relative improvement of at least 50%.

(3) *Absolute versus relative standards*. What is the objective of a QI project comparing the management of diabetes among physician groups within a managed care plan? Is it absolute, i.e., everyone is expected to achieve a performance level of 90% and anything below that is unsatisfactory? Is it relative, i.e., success is defined by groups in the 90th percentile based on some sort of benchmarking hierarchy? For most purposes, relative standards are preferable in part because they are less likely to encounter significant resistance from providers and in part because relative standards are seen as more attainable than absolute. In addition, absolute standards may send the wrong message. If they are too high, no one will reach them, thereby undermining the face validity of the project and arousing provider hostility. If they are too low, everyone will reach them, in which case the project may be settling for performance that still has much room for improvement. Finding the right absolute standard can be difficult. One way of dealing with this problem is to deliberately start out with a relatively low standard that

TABLE 1.3. Relative Quality Improvement

	Baseline				Remeasurement					
	10	**20**	**30**	**40**	**50**	**60**	**70**	**80**	**90**	**100**
10	0.00	0.11	0.22	0.33	0.44	*0.56*	*0.67*	*0.78*	*0.89*	*1.00*
20	−0.25	0.00	0.13	0.25	0.38	*0.50*	*0.63*	*0.75*	*0.88*	*1.00*
30	−0.43	−0.14	0.00	0.14	0.29	0.43	*0.57*	*0.71*	*0.86*	*1.00*
40	−0.67	−0.33	−0.17	0.00	0.17	0.33	*0.50*	*0.67*	*0.83*	*1.00*
50	−1.01	−0.60	−0.40	−0.20	0.00	0.20	0.40	*0.60*	*0.80*	*1.00*
60	−1.53	−1.00	−0.75	−0.50	−0.25	0.00	0.25	*0.50*	*0.75*	*1.00*
70	−2.38	−1.67	−1.33	−1.00	−0.67	−0.33	0.00	0.33	*0.67*	*1.00*
80	−4.12	−3.00	−2.50	−2.00	−1.50	−1.00	−0.50	0.00	*0.50*	*1.00*
90	−8.00	−7.00	−6.00	−5.00	−4.00	−3.00	−2.00	−1.00	0.00	*1.00*

[1] For an excellent review of organizational culture, see Boan & Funderburk (Unpublished).

[2] One graphic device is the radar chart. Radar charts are not familiar to most consumers and many professionals. They can be constructed using Microsoft PowerPoint, which also contains a description of their use.

[3] This may seem to be a small amount but an official from one of the larger Phoenix hospitals told me that for his institution it was estimated to be worth about 1.5 million dollars.

[a] All meter readings are based on whole blood. "Plasma" meters have a built in algorithm that converts whole blood reading to its plasma equivalent. The "plasma" reading should be 12–15% higher than the whole blood reading. Plasma readings are popular because they are closer to the value obtained when blood sugar is determined by a laboratory.

most can reach. Such "victories" encourage further effort and the standard can be gradually raised over time.

(4) *Composites versus individual indicators*. The indicators comprising a QI project should be independent of all other indicators. That is, provision of one service should not flow automatically from provision of another. In addition, each indicator used is specific unto itself. It is incorrect to speak of high quality in diabetes care if this is based entirely on the proportion of patients receiving a dilated eye examination. It is also incorrect to express the quality of diabetes care as the simple average of the scores of the individual indicators. The average can be just as misleading as overemphasis on a single indicator. On the other hand, averages, also known as composites or aggregates, are the easiest way for a consumer to assess quality. It is the rare consumer who has sufficient knowledge to evaluate individual indicators. One way of dealing with this problem is to use average scores and include scores on individual indicators through the use of a graphic device so the patient can see exactly where two providers differ if he is so inclined.[2] Individual indicators on the other hand are most useful to professionals trying to pinpoint areas that need improvement. Composites are the preferred way of presenting data to consumers, albeit with the inclusion of indicator information as well.

(5) *Reliability of data*. Quality improvement projects get data from medical records and other sources of information about patients. Since, for example, the prescribing of an ACE inhibitor for a diabetes patient with hypertension is not actually observed, the patient's medical record is the only source of information. Or is it? It is often claimed, especially by those new to QI, that services are provided that do not find their way into the record. They feel that QIPs measure quality of documentation rather than quality of care. From a QI perspective, the two are one and the same because documentation is the only evidence that a service was provided. Further, payment is closely tied to documentation of services provided and there is thus a strong incentive for providers to record what they do. Be it reimbursement or QI, the rule is "if it isn't documented, it didn't happen."

(6) *Face validity*. The success of QI is wholly dependent on the cooperation of the providers whose data are being examined. This cooperation in turn depends on the face validity of the QI project. In other words, the project must make sense and be comprehensible to the provider-subjects. Project elements like scoring, weighting, documentation, rules governing patient inclusion, statistical analysis, etc., must be fully explained and fully understood before the project begins.

(7) *Evidence-based medicine*. Evidence-based medicine (EBM) is the rational basis for face validity. One of EBM's earliest advocates, David Sackett offered this definition: "Evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of the individual patient" (Sackett *et al*., 1997, p. 2). Best evidence is most commonly found in relevant, methodologically sound medical research and implies physician familiarity with such research. Such familiarity is often lacking even for the motivated physician due in part to the vastness of the medical literature and in part to the high proportion of published material whose methodology is flawed. Those conducting QI must use indicators that reflect a strong evidence base not only for credibility but also as an indirect means of educating physicians whose performance is being measured. EBM is the surest way of knowing that what is done for the patient is likely to benefit him.

(8) *The challenge of small case numbers*. Ideally, QI is a game everyone should play. However, providers with small numbers of patients are often, if not usually, exempted from QI because they have so few patients that the proportions are volatile and unreliable. One way to deal with this problem and include

all providers regardless of size is the adjusted percentage fraction (APF) (Weissman *et al*., 1999). The APF represents the best predictor of how a provider with small case numbers would perform if there were many patients. It is done by adding one to the numerator and two to the denominator, i.e., $APF = (N + 1)/(D + 2) \times 100$. The APF is part of a benchmarking methodology called achievable benchmarks of care (ABC). Because ABC uses relative rather than absolute standards, it is not universally accepted. However, this in no way depreciates the value of the APF. The APF and raw percentages tend to be very close at case numbers above 30, and beyond this number, raw percentages should be used. The APF is usually acceptable to providers once they understand its use and it solves a major difficulty. It is reasonable to expect that all providers who provide the same services should be equally accountable. The APF lets all the players into the game.

(9) *Flexibility in QI*. Locking in practices that may be scientifically obsolescent is a danger inherent in QI. Indicators should not be regarded as being beyond criticism or change. All indicators need to be reviewed at regular intervals to assure that they are not having a negative influence on provider practice. For example, if an indicator specifies the use of an ACE inhibitor for patients with acute myocardial infarction while many physicians favor the use of angiotensin receptor blockers (ARBs) instead because they have fewer side effects, the indicator should be reviewed. If review fails to demonstrate that ARBs are equal to ACE-Is for AMI patients, there is still an important problem. If the indicator is one widely used by CMS in a QIP involving Medicare patients in all U.S. hospitals, how will the research required to definitively demonstrate the value of ARBs relative to ACE-Is be carried out? In a case like this, a QIP may have the unintended and paradoxical consequence of freezing practices that should be reassessed. Similar flexibility is required to deal with indicators that may not be appropriate for all patients. The prudent physician would not advise his patient to take aspirin daily to prevent AMI if the same patient were taking warfarin for atrial fibrillation. One common way to deal with these issues is to count the indicator as having been completed if there is a note from the physician saying why the indicator service was withheld. Finally, sets of indicators should be open to additions and deletions as warranted. The list of process indicators in Table 1.2 shows what are commonly used; it is not meant to exclude all other potential indicators.

For a number of years, it has been the conventional wisdom that mortality from coronary artery bypass graft (CABG) is inversely proportional to hospital volume, and a volume standard for hospitals was usually set at no less than 200 cases per year (Hartz and Kuhn, 1994). The HSAG, Arizona's QIO, did an assessment of CABG surgery in the late 1990s and found that although mortality rates were comparable to national data, only two of the 20 hospitals offering CABG averaged 200 cases per year and that surgeon volume rather than hospital volume was the primary determinant of outcome (Marshall and Murcko, unpublished). These observations were recently supported by Birkmeyer *et al*. (2003). If, as it appears, CABG mortality does not depend on hospital volume, this standard needs to be revised and perhaps refocused on the individual surgeon. Volume requirements for CABG are written into law in New Jersey (New Jersey Administrative Code, n.d.) and Pennsylvania (Dethlefs *et al*., 1991) and how soon they are amended will be a major test of flexibility.

(10) *Limitations of indicator-specific QI*. The more indicators, the more one learns about the management of diabetes patients. However, as the list of indicators grows so does the expense of collecting data and, often, the intrusiveness of the entire project. To avoid overwhelming expense, indicators should be reviewed by performance. If an indicator service is provided to 95% of patients,

its value as an indicator is dubious because to a considerable extent it no longer represents an opportunity to improve care. The replacement of indicators as they become obsolete or reach full compliance also serves to maintain the attention of providers who are continually offered new challenges. In a somewhat different vein, QI is always incomplete because it rarely includes structural variables that affect the process of care such as the financial viability of the organization, the availability of sufficient personnel, or the satisfaction of patients with services provided. Even when this kind of information is available, it is difficult to relate it to indicator-specific quality as to cause and effect. QI reveals how diabetes is managed but does not divulge what changes in the organization, i.e., system changes, might serve to further improve care.

QI ON THE NATIONAL, STATE, AND REGIONAL LEVELS

Broadly applied QI activities such as these do not usually include any kind of formal remeasurement. Rather, they have been demonstrated in smaller venues to be effective and they are utilized based on this evidence. Their success is judged by changes in pertinent national, state, or regional data. An example would be a national education campaign to promote improved eating habits as a means of countering the related "epidemics" of obesity and diabetes. The success of such a program is not formally measured and it might be judged by a drop in the average weight of adults over time, fewer hospitalizations for diabetes or diabetes-related conditions, a fall in the sale of antidiabetic pharmaceuticals, etc. Results are rarely "clean" because our educational program is not the only source of information about nutrition and diabetes. Lots of smaller units such as state health departments, managed care plans, health centers, individual physicians, and a major segment of the food industry are all busy promoting the same thing. This is the problem of *confounding*. The effects of multiple factors on a response cannot be separated. The extent to which change in the desired direction is the result of the national effort or of a smaller unit effort or both remains unknown.

DISEASE MANAGEMENT

Targeted as a method to improve care and control rising health costs, DM is a movement backed primarily by insurers and managed care plans. DM focuses on high cost, high-risk patient populations, and aims to reduce costs by making visits to the physician secondary to measures taken by the patient himself. This is done under the guidance of a health care professional (nurse, educator, pharmacist, dietician, respiratory/physical/occupational therapist, etc.) who serves as case manager (also known as a disease manager or care manager). Standard protocols using evidenced-base guidelines are drawn up for each disease being managed, including such illnesses as depression, heart failure, and diabetes. The case manager communicates with the patient on a regular basis to assure that the patient is adhering to the protocol, thus improving the quality of care. Case managers are sometimes available 24 hours a day and further communication is provided through websites. The case manager is also in contact with the patient's physician and reminds him or her of services needed by specific patients. Disease management is a rapidly growing field that is increasingly offered through employers. A DM trial among Medicare beneficiaries is part of the Medicare Prescription Drug Benefit and Modernization Act of 2003. DM is not without flaws. Relationships between doctors and case managers are often frustrating to both parties, and the involvement of pharmaceutical houses in DM might be seen as a ploy to push prescription medications. Because it is of greatest interest to its backers, DM tends to be judged not by changes in quality but by changes in cost (Clark, Kim, 2004).

PUBLIC REPORTING AND PAY-FOR-PERFORMANCE

By far, the biggest player in contemporary QI is the Centers for Medicare and Medicaid Services. CMS now requires periodic public reporting of data on selected conditions and indicators from nursing homes, home health agencies, and managed care plans. Publicly reported data from managed care plans includes diabetes. In addition, hospitals face a small percentage loss of 0.4% of the increase in Medicare reimbursement for the following year if they do not agree to publicly report data.[3] There is little doubt that the data from individual physicians will become public in the near future. Public reporting is an intervention intended to stimulate quality improvement efforts and to enable consumers to make informed choices about providers. Forty percent of consumers say that a hospital's quality is important to them when choosing where to be admitted (*AHQA Matters*, 2004). How effective it will prove to be is not known, but it is uncertain that it will significantly affect patient's choice of hospital or nursing home since many patients have this choice made for them by their physician or managed care plan, and others make decisions based on such considerations as nearness to home, experience of friends and relatives, and general reputation.

Pay-for-performance is perhaps the ultimate intervention. Carried to its logical end point, it means that the patient is not paying for service or time; he is paying instead for a level of care identified and required by the payer. Pay-for-performance is not a new idea to health care. Indeed, in a free market, the consumer chooses to pay the provider he uses in the belief that the provider provides care that is worth the fee. Pay-for-performance tied to specific performance measures is new, however, and it would seem to be the most powerful of all interventions. A pay-for-performance demonstration is now underway involving a nationwide system of nonprofit hospitals. About 300 hospitals have agreed to tie their Medicare reimbursement in part to performance on 34 quality indicators covering AMI, heart failure, pneumonia, CABG surgery, and hip and knee replacement. The indicators bear the imprimatur of prominent organizations involved in QI such as JCAHO, National Quality Forum, Quality Improvement Organizations, and CMS itself. Using annual composite quality scores, hospitals that finish in the top decile (>90%) will receive a 2% bonus on Medicare reimbursement. Those in the second decile (>80%) will receive a 1% bonus. At the other end of the hierarchy, those in the ninth decile (>20%) will lose 1% whereas those in the bottom decile (<10%) will lose 2% after 2 years of such subpar performance (Medicare Fact Sheet, 2004).

ELECTRONIC MEDICAL RECORDS

Electronic medical records (EMR), sometimes called electronic health records (EHR), is QI's hitherto impossible dream. EMR compiles all the data on an individual patient in one electronically accessible database. A thorough EMR would include laboratory tests, radiology reports, inpatient notes for each hospitalization, outpatient notes for each visit and each physician visited, surgical notes, and medications. The patient's entire experience with the health care system would be immediately available to the current provider. Patient data could be sorted so that the specific problem of interest to a provider could be addressed and those interested in QI could be certain that the patient receives care up to the existing standard. It is the next logical step after disease management. To date, EMR is in use at large systems of care such as the Department of Defense and the Veterans' Administration. EMR is increasingly frequent in hospitals and managed care plans as well, often in a hybrid form that retains some features of the paper record. In these cases, EMRs reaching across hospitals or managed care plans are exceedingly rare. The biggest hurdle

to expanded use of the EMR is the individual physician or physician group. Cost, steep learning curves, avoidance of disruption of an ongoing method of record keeping, and doubts about the ability of EMR to live up to its advance billing are formidable barriers. Some of the doctor's concerns are real enough. Like any other electronic data storage device, security and confidentiality are major issues. There is no existing legislation that establishes ground rules for how medical information can be used, who should be able to access it, and which parts of the record should be accessible. Records accessed through the worldwide web are almost certainly vulnerable to access by the unauthorized and the curious. The number of parties with an interest in a patient record includes government agencies, insurance companies, health care administrators, managed care plans, physician groups, etc. Each of these is a potential source of unauthorized access by unauthorized personnel.

SUMMARY

Quality improvement in the management of a disease entity like diabetes is dependent on the knowledge that how the patient is managed has a positive impact on his well-being to a greater or lesser degree. Thus, one may trace the origins of QI in diabetes to the discovery of insulin in 1922 and the DCCT study of 1993. In many diseases, the result is death no matter what the physician does or does not do. Once the physician does what he can, he can do no more. For this reason, QI based on the process of care is more appropriate than QI based on patient outcomes.

Quality improvement uses specific activities that patients require, called "indicators" or "performance measures," to determine the quality of care. A typical indicator in diabetes care is whether a patient with diabetes received a timely eye examination. QI compares the difference between the completeness of the process of care at a baseline time to that at a later time. This difference in completeness in the rate of improvement is best expressed at the Reduction in Error Rate, i.e., the difference between the level of care achieved and the highest possible level, which is, of course, 100%. In contrast, quality assessment is "snapshot" of care as it existed at a point in time and does not measure improvement. Quality assessment often leads to QI, however, in which case the assessment becomes the baseline measurement. QI does not pertain only to diseases. It is equally applicable to issues of patient safety and patient satisfaction.

Among providers, hospitals and managed care plans probably have the most well-developed internal methods of quality improvement. QI is relatively new among nursing homes, home health agencies, and the offices of individual or groups of physicians. States are involved in QI through Medicaid and the activities of health departments, and there are a host of private or university-based programs that address quality issues. The biggest influence on improving quality, however, is the federal CMS. Medicare is the largest purchaser of health care in the United States, and Medicare beneficiaries account for a disproportionate number of hospital admissions, consumption of prescription drugs, and visits to physicians. Since Medicare reimburses providers for this care, its influence is enormous. QI activities of CMS are the responsibility of QIOs, one of which serves each state.

Recent developments in the field of QI include public reporting of selected patient care data by hospitals, nursing homes, managed care plans, home health agencies, and, increasingly, individual physicians. Public reporting is the precursor to pay-for-performance care under which high quality providers are rewarded by higher reimbursements and poor performers face reduced reimbursement. Much attention is now focused on the spread of electronic records to facilitate the access of patient information to those providing for his care. Attention also is increasingly directed to the corporate "culture" under which care is provided and whether the

characteristics that define this culture promote or impede high-quality care.

Quality improvement is a work in progress with vast potential benefits for patients. As fiscal rewards become more important, such incentives will not only stimulate improvement efforts by providers but also provide a concrete payoff for their efforts.

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2

The Chronic Care Model

Blueprint for Improving Total Diabetes Care

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Problems cannot be solved at the same level of awareness that created them.

—Albert Einstein

INTRODUCTION

Chronic disease is a national epidemic. Over 100 million Americans, including nearly 80% of seniors, suffer illness, disability, and death related to chronic illnesses. One in five seniors has five or more chronic conditions, visits on average 14 different physicians, and uses an average of 50 different prescription medications per year. Two-thirds of Medicare funds are used to care for the 20% of seniors with five or more chronic illnesses, while the proportion of Americans with one or more chronic conditions is growing steadily. Diabetes, through its myriad complications, accounts for upwards of 20% of America's chronic illness burden. Diabetes-associated heart disease, stroke, high blood pressure, blindness, kidney disease, amputations, nervous system disease, obesity, and dental disease can be prevented or lessened by proactive chronic-illness care, yet less than half of those diagnosed with diabetes receive care that is consistent with guidelines (Bodenheimer *et al*., 2002; Casalino *et al*., 2003; Hoffman *et al*., 1996; Murcko, 2004, March/April; National Center for Health Statistics, 2003).

The Chronic Care Model (CCM; Wagner, 1998) is an elegant, intuitive, evidence-based model that is both practical and useful, and addresses the root causes of the well-articulated gap between the "health care we have and the care we could have" [Institute of Medicine (IOM), 2001, p. 1] for patients with diabetes and other chronic

illnesses. This chapter describes the principles and practical application of the CCM.

CLOSING THE QUALITY CHASM FOR THE CHRONICALLY ILL

The acute care focus of our health care system is probably the most formidable barrier to optimal chronic care delivery (Wagner, 1998). In the workaday office world, chronic disease management regularly takes a backseat to the sore throat, sprain, or most recent test results. Limited by inadequate time, and relying on already overwhelmed provider memories, our health care falls short of the IOM's *Crossing the Quality Chasm* "STEEEP" (IOM, 2001) aims for health care: Safe, Timely, Effective, Efficient, Equitable, and Patient-centered. The *Chasm* authors challenge us to redesign our care so that it meets needs of our patients with chronic illness by:

- a continuous healing relationship,
- regular clinical assessments,
- effective clinical management,
- information and ongoing support for self-management,
- a shared care plan, and
- active, sustained follow-up.

Redesigning our care systems while still meeting day-to-day patient needs requires a blueprint that is consistent with the best evidence; provides a common taxonomy, terminology, and framework that is useful for local and national quality improvement; and is relevant across all chronic conditions. Based on our experience as Arizona's Medicare-designated Quality Improvement Organization [QIO; American Health Quality Association (AHQA), n.d.], we believe that the CCM, coupled with the Institute for Healthcare Improvement (IHI, n.d.-a; IHI, n.d.-b) Collaborative framework (described below) meets these needs for a broad spectrum of health care organizations.

THE *CHRONIC CARE MODEL*: A MULTIDIMENSIONAL SOLUTION

> *The* Chronic Care Model *is not a quick fix or magic bullet. It is a multidimensional solution to a complex problem.*
>
> **—Edward Wagner**
> Chronic Care Model *architect*

Background

According to Dr. Edward Wagner, successful chronic-illness care improvement initiatives have three key features:

1. a clear definition of optimal care,
2. a roadmap for changing the system, and
3. an effective improvement strategy.

Derived from the early 1990s work by the Group Health Cooperative of Puget Sound MacColl Institute for Healthcare Innovation (Seattle, WA) the CCM (Figure 2.1) is a six-element distillation of successful chronic care delivery interventions. The model is based on the recognition that chronic care takes place within these three overlapping spheres [Improving Chronic Illness Care (ICIC), n.d.; Murcko, 2004; Wagner, 1998]:

- community, including its resources and myriad public and private policies,
- health care system, including its payment mechanisms and policies, and
- provider organizations, ranging from the single physician practice to large, multi-office corporations.

As we discuss the details of the CCM in the next section, you are invited to take the "CCM plunge": identify the sphere(s) into which you as professional, health system leader, patient, and/or citizen can exert the greatest contributions toward ICIC, and create your action plan.

Fundamental Care Unit

The heart of the CCM is predicated upon the creation of the fundamental care unit: a *prepared, proactive practice team* delivering care to an *informed, activated patient*. This prepared, proactive practice team uses

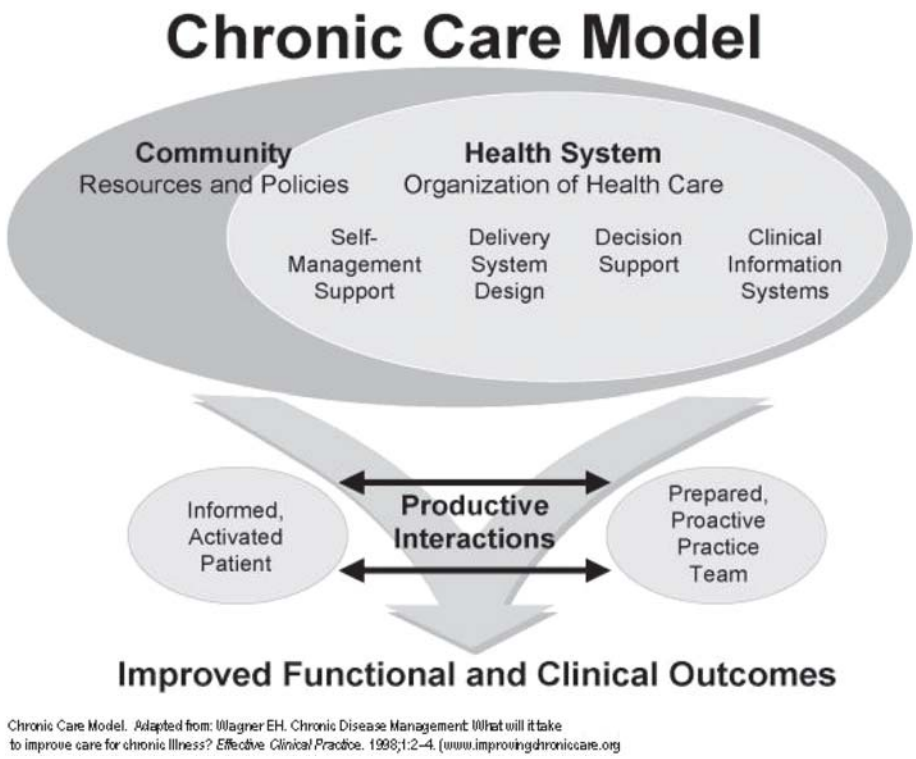

FIGURE 2.1. Chronic Care Model. Used with permission of *Effective Clinical Practice*.

evidence-based clinical information, is prepared with patient-specific data before each visit, and each team member is empowered by having designated roles to contribute to the patient experience and optimized outcome. The informed, activated patient (includes family and/or caregiver) understands his condition, the role he plays in the management of his own health, is confident of his self-management skills, and knows what to expect from the health care system. This unit, repeated many times over, delivers simultaneously improved functional and clinical outcomes, i.e., the right care for the right patient in the right place at the right time (Murcko, 2004 May/June).

Chronic Care Model Defined

The well-studied and validated interventions (Wagner, 1998; Wagner 1996; Von Korff, 1997; Bodenheimer et al., 2002; Casalino et al., 2003) that comprise the CCM are: community resources and policies, health system organization, self-management support, delivery system design, decision support, and clinical information systems.

Community Resources acknowledges the growing importance of linking patients with community programs and services to mobilize these resources to meet patient needs. As professionals, we are challenged to:

- Encourage patients to participate in effective community programs, particularly exercise and educational programs.
- Form partnerships with community organizations to identify, support, and develop interventions that fill gaps in needed services, including the creation and dissemination of resource guides, development of outreach programs using lay workers/health coaches, and the sponsorship of community events.
- Advocate for policies to improve patient care, including the crafting of messages for the public.

Examples include case managers to coordinate referral to community resources, peer group support groups, televised self-management courses, working with dentists, offering patient incentives for self-management activities, and diabetes walks.

Organization of Health Care addresses the culture and policies of the system in which care takes place. The mission, business plan, and goals of your organization must clearly promote safe, high-quality care. Organization leaders are role models who:

- Visibly support improvement at all organizational levels, starting with the leadership team.
- Endorse effective improvement strategies aimed at comprehensive system change.
- Encourage open and systematic handling of errors and quality problems to improve care.
- Provide incentives based on quality of care.
- Develop agreements that facilitate care coordination within and across organizations.

Examples include pay-for-performance incentives (Murcko, 2004, May/June), formation of a chronic-care department, recruitment of senior leaders, and use of the CCM in initiative designs.

Self-management support includes activities that empower and prepare patients to understand their health behaviors and to develop strategies to live life as fully as possible. Simultaneously, as the most rewarding yet most challenging CCM component, we strive to:

- Emphasize the patient's central role in managing his health.
- Use effective, culturally competent self-management support strategies that include assessment approaches, goal setting, action planning, problem solving, and follow-up.
- Organize internal and community resources to provide ongoing self-management support to patients.

Examples include lay-health coach development and use, goal sheets, low literacy materials, and patient guidelines (Wagner, 2001a; Wagner, 2001b).

Delivery system design refers to the organization and scheduling of planned proactive care to assure effective, efficient clinical care, and self-management support. The key features of delivery-system design include the need to:

- Define roles clearly and distribute tasks among empowered team members.
- Use planned interactions, including group medical appointments for self-management training, to support evidence-based care.
- Provide clinical case-management services (when available) for complex patients.
- Ensure regular follow-up by the care team.
- Give care that patients understand and that fits with their cultural background.

Examples include revised team roles with scripted activities, group visits/planned visits, posted notices to remove shoes and socks, telemedicine use, and health care coach assignments.

Clinical information systems allow practices to integrate patient and population data to facilitate efficient, effective, and proactive care. Electronic patient tracking tools, such as electronic disease and population health registry modules, are essential to:

- Improve patient health outcomes and promotion of early intervention strategies.
- Provide timely reminders and feedback to patients, health care managers, and providers.
- Identify relevant subpopulations based on specific or multiple clinical parameters (conditions, comorbidities, evidence-based measures, etc.) for proactive care. Facilitate individual and patient population care planning.
- Share information with patients and providers to coordinate care and support self-care and self-education about relevant evidence-based guidelines.
- Monitor performance of practice teams and the care system.
- Reduce clinical practice variation by embedding evidence-based measures that describe care pathways into daily clinical practice.

- Improve patient safety by reducing medication errors of omission or commission.
- Establish connectivity to other clinical stakeholders so information between providers and patients can be shared [primary care provider (PCP)-referred specialist, health plan disease management nurses, patient self-report health risk assessment survey results for PCPs, etc.].
- Reduce malpractice liability costs by documenting conformity with defensible medical standards.
- Automate reporting and assessing of outcomes for individuals and patient populations.
- Save time with easy access to clinically useful information on individuals as well as groups of patients.

Examples include registry/electronic health record use, performance feedback, preaddressed reminders, linking labs, and pharmacy data to registry.

Decision support promotes clinical care that is consistent with scientific evidence and patient preferences through several mechanisms:

- Embed evidence-based guidelines into daily clinical practice by implementing protocols, reminders, and the use of standing orders that make it easy to do the right thing for each patient.
- Share evidence-based guidelines and information with patients to encourage their participation.
- Use proven provider education methods, such as academic detailing and motivational interviewing that inspire behavior change.
- Integrate specialist expertise with primary care through regular access and discussion.

Examples include flow sheets, progress note templates, referral guidelines design and use, pocket cards, and registry data use to discuss adherence to guidelines.

Focusing on these six essential CCM components (Figure 2.2) can foster productive interactions between patients who take an active part in their care and providers who are supported by resources and expertise.

IMPROVEMENT COLLABORATIVES ACCELERATE CCM ADOPTION

Redesigning health care systems to improve chronic-illness care is not easy. One way to accelerate change is by working collaboratively with other organizations that share similar goals. The implementation of the CCM through participation in an IHI Breakthrough Series (BTS) Collaborative (ICIC, n.d.) is a systematic approach that has been demonstrated to improve health care delivery (IHI, n.d.-b). A collaborative is a systematic approach to health care quality improvement in which organizations test and measure practice innovations. Practices accelerate learning and spread the implementation of best practices by sharing via a series of structured venues. A collaborative comprises three main phases: development, planning, and execution (American Health Quality Association, n.d.).

Development Phase

During the development phase, activities are conducted to create supporting materials for an IHI BTS-style collaborative. These activities include the prerequisites of topic selection and convening the expert panel that assists the supporting material creators in the development of a document that is broadly defined as a collaborative framework. The collaborative framework has three components: a charter, a change package, and a measurement strategy.

The *charter* includes the problem statement, mission and goals, and methods and expectations. The charter presents the gap between science and current practice. Ideally, a business case is included as well. The charter also describes the common aim of all participants—to work together to achieve breakthrough results that one organization working alone would not achieve.

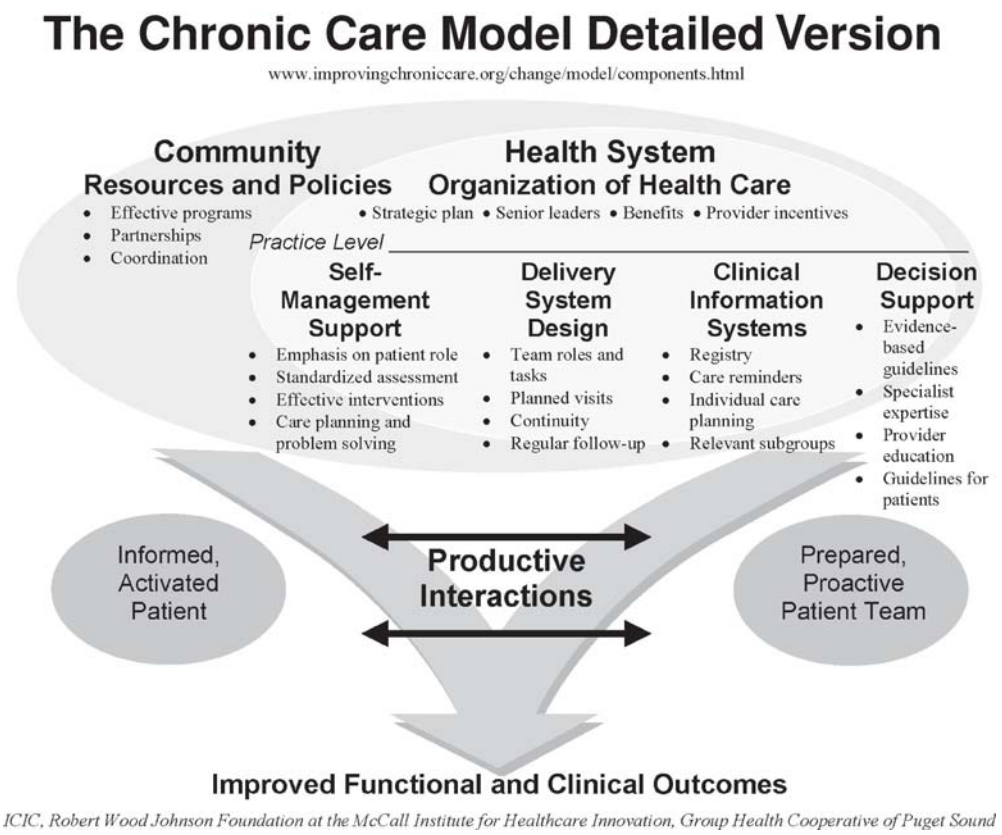

FIGURE 2.2. Chronic Care Model, detailed version. Used with permission of *Effective Clinical Practice*.

A *change package* is the second major component of the collaborative framework. The change package organizes the key elements of a high-performing system, representing the ideal system of care for the collaborative topic. The purpose of the change package is to provide guidance to the collaborative participants on changes they can make that will result in improvements.

The *measurement strategy* is a compilation of outcomes, processes, and balancing measures. These measures, required and/or optional, are tracked over the course of the collaborative and demonstrate that a team's changes resulted in improvements and, therefore, spreading this work throughout the organization is imperative. Key measures are required to assess progress on each team's aim.

Planning Phase

During the planning phase, collaborative sponsors prepare for the kickoff of the collaborative. This involves recruiting participants, developing marketing materials, and preparing the sponsor team for the capture of data and information necessary for assessing impact.

Execution Phase

This phase occurs over 12–16 months, begins with prework, and culminates in a final meeting "outcomes congress" that showcases participant results and promotes expansion or "spread" of successful chronic-care strategies. Over the course of the collaborative, teams from each organization attend

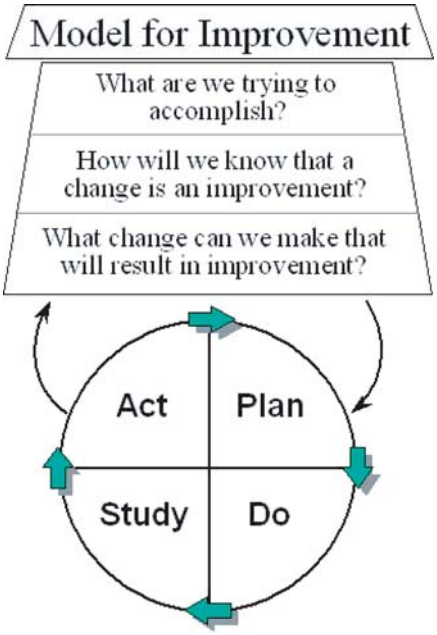

FIGURE 2.3. Model for Improvement (Langley et al., 1996, p. 10).

periodic learning sessions, which include the incorporation of the CCM within their organizations, and the examination and sharing of "best strategies" for improving care. Refining and evaluating internal systems changes using the *model for improvement* (Figure 2.3) are built upon the Plan–Do–Study–Act (PSDA) cycle (Figure 2.4). Between learning sessions, teams refine their plans with input from the core faculty of recognized experts in chronic-condition care and measurement, and submit monthly reports to their organizational and collaborative leaders.

The IHI-style collaboratives improve on traditional quality-improvement programs by encouraging participants to "share openly and steal shamelessly," so that, by using actual tests and examples, they learn from one an other's mistakes as well as successes. Collaboratives are also action-oriented: teams make changes to their organizations within a week of attending a learning session. Participants get instant access to the strategies best proven for chronic-illness care. Since the first IHI BTS collaborative in 1995, more than 700 teams from over 450 North American health care organizations have successfully participated in a collaborative, including those sponsored by the ICIC program (see Figure 2.5).

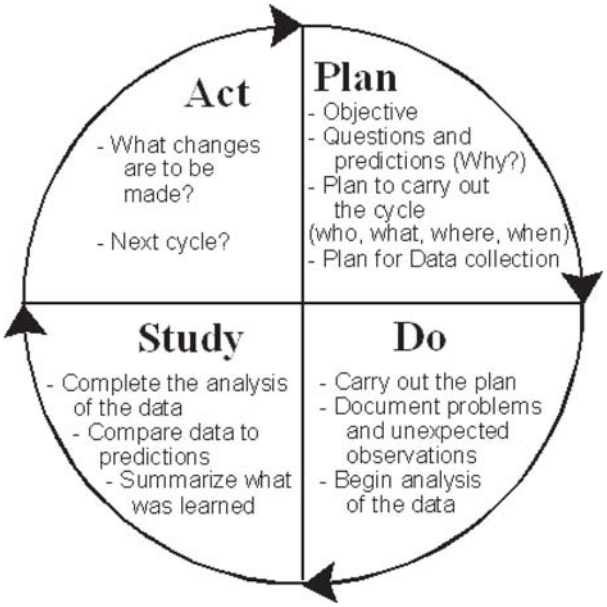

FIGURE 2.4. PDSA Improvement Cycle (Langley et al., 1996, p. 7).

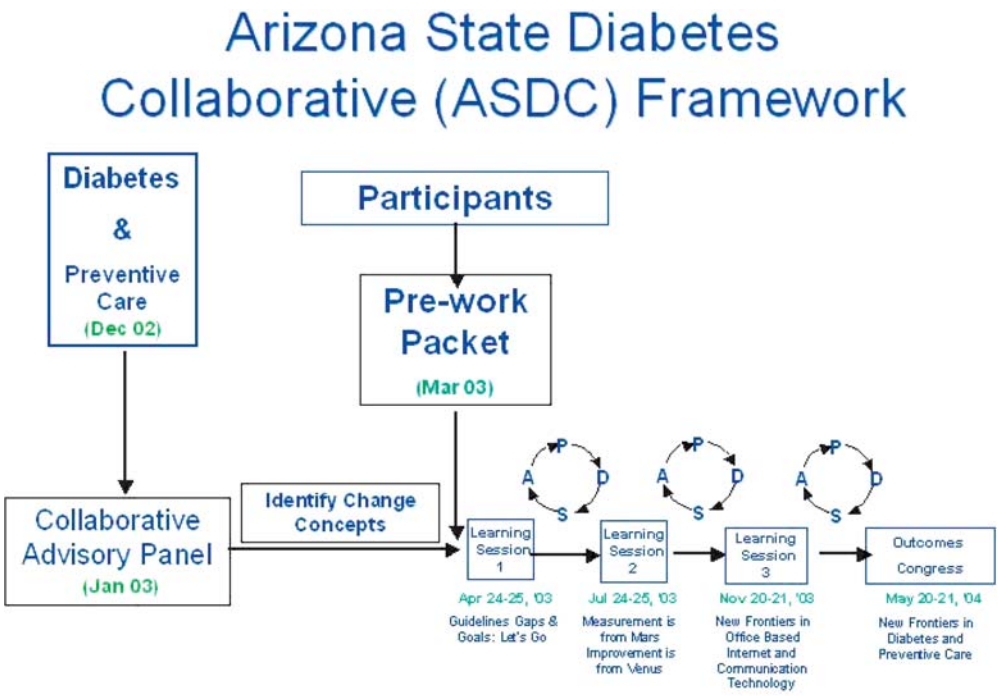

FIGURE 2.5. ASDC Framework. Based on IHI BTS (IHI, n.d.-a; IHI, n.d.-b).

STATE AND REGIONAL COLLABORATIVES IMPROVE CHRONIC-ILLNESS CARE

Breakthrough series collaboratives range from small, local practice groups to large, national initiatives, such as those sponsored by the Bureau of Primary Health Care for community health centers (IHI, n.d.-a; IHI, n.d.-b). Diabetes is (and has been) the focus for numerous collaboratives, as outlined in Table 2.1, creating a community rich in experience for all to draw upon. Detailed resources are available from the sponsoring organizations which can be used "shamelessly" by those with a similar mission.

BUSINESS CASE FOR QUALITY IMPROVEMENT?

Multipronged efforts, such as those using the CCM, have met with clinical as well as financial success (IHI, n.d.-a; IHI, n.d.-b; Murcko 2004, May/June; ICIC, n.d.; Wagner *et al*., 2003). Interventions that are too narrow in scope or weak with regard to system change have minimal impact health outcomes and cost, and have, for some, created skepticism about engaging in improving chronic care. In addition, many disease-management programs have fallen short of the overly optimistic expectations they create (Wagner *et al*., 1999).

The typical reported cost of CCM interventions ranges from $200 to $500 per patient per year, with savings varying in condition and population (ICIC, n.d.). Cost savings may be greatest for congestive heart failure (and for asthma, among populations with high rates of hospitalization), with less short-term returns on investment for diabetes.

Revenues generally rise in the fee-for-service environment, since checkups and screenings not routine to acute care can increase billable utilization. Patients who receive better care also are less likely to

TABLE 2.1. Regional and Statewide IHI BTS-style Diabetes Collaboratives

State	Sponsors	Total Diabetes Collaboratives	Years
Alaska	Qualis Health[a]	1	2000–2002
Arizona	Health Services Advisory Group,[a] State Diabetes Control Program	2	2002–2004
Arkansas	University of Arkansas, State Diabetes Control Program, Arkansas Foundation for Medical Care[a]	1	2002
California	Lumetra[a]	1	2003–2004
Hawaii	Mountain-Pacific Quality Health Foundation[a]	1	2003–2004
Idaho	Qualis Health[a]	1	2003
Illinois	Midwest Business Group On Health, Institute of Medicine of Chicago, Illinois Foundation for Quality Healthcare[a]	2	2002
Iowa	Iowa Foundation for Medical Care[a]	1	2003–2004
Indiana	State Department of Health Services, Health Care Excel[a]	2	2003–2004
Kentucky	Health Care Excel[a]	1	2004
Maine	MaineHealth	2	2003–2004
Missouri	MissouriPRO[a]	2	2002–2003
Nevada	HealthInsight[a]	2	2002–2004
New Mexico	New Mexico Medical Review Association[a]	2	2001–2004
New York	IPRO[a]	1	2003
North Carolina	State Diabetes Control Program, Medical Review of North Carolina[a]	2	2003–2004
North Dakota	North Dakota Health Care Review, Inc.[a]	1	2003
Oregon	Oregon Medical Professional Review Organization[a]	2	2001–2004
Rhode Island	State Department of Health Services, Quality Partners of Rhode Island[a]	2	2003–2004
Utah	HealthInsight[a]	2	2002–2004
Vermont	Vermont Program for Quality In Health Care	3	2001–2004
Washington	State Diabetes Control Program, Department of Health, Qualis Health[a]	4	2000–2004
Wisconsin	MetaStar[a]	2	2002–2004

[a] State Medicare Quality Improvement Organizations (QIOs). Additional information regarding each QIO can be obtained at http://www.cms.hhs.gov or www.ahqa.org. Organizations sponsoring collaboratives are encouraged to centralize contact information on the ICIC Web site, http://www.improvingchroniccare.org.

leave for another practice, which reduces the fixed costs of establishing new patients. Capitated systems benefit from reductions in hospitalizations and specialty care. Systems also can use low-cost patient contacts (e.g., telephone calls), and low-cost personnel for some services. Both systems benefit from patient loyalty and enhanced provider productivity.

Satisfaction with visits, especially early visits, is a powerful predictor of continued use. The better the interaction between the patient and the team of providers, the more likely a patient is to be satisfied—and a satisfied patient is more likely to stay. Current data are unclear about impacts on new enrollment. A system that provides better care for people with illnesses may attract chronically ill patients, although there are no clear data to suggest this outcome (ICIC, n.d.).

MEDICARE QUALITY IMPROVEMENT ORGANIZATIONS: QUALITY PARTNERS

The IHI and ICIC have recently partnered with the Centers for Medicare & Medicaid Services (CMS, n.d.) through its QIO program. For the past 20 years, under

Congressional mandate, CMS has maintained contracts in each state with a community-based organization. These entities, formally known as peer review organizations (PROs), are now designated as QIOs to more accurately reflect their CMS-directed change in focus from case review to *case-based* and *systems-based quality improvement*. The QIO goals are to improve the quality of health care services provided to people with Medicare and to safeguard the integrity of the Medicare trust fund.

The QIO mission is to collaborate with providers and patients to achieve significant and continuing improvement in the quality, safety, and effectiveness of health care at the community level. With a diverse staff comprising of physicians, nurses, statisticians, communications experts, and other professionals focused in the four priority settings (physicians' offices, hospitals, nursing homes, and home health agencies) of Medicare's Health Care Quality Improvement Program (HCQIP), QIOs, such as our organization, Health Services Advisory Group, Inc. (HSAG), employ the following general strategy:

- Identify opportunities to improve care.
- Analyze national and state-level quality performance data.
- Communicate with professional and provider communities about performance measures and their use in quality improvement projects.
- Design and collaborate on quality improvement projects that emphasize improving systems of care.
- Implement effective quality improvement strategies and evaluate the success of quality improvement activities.
- Use pretested educational materials for providers and patients, including supporting CMS public reporting of performance measures.
- Foster collaboration among providers, payers, and others to improve care and increase the value of health care expenditures.

Together with many national organizations, CMS has selected "priority topics" (i.e., conditions that represent important causes of morbidity and mortality among the U.S. population as a whole and specifically, seniors) to focus the work of providers and QIOs. CMS and national partners have developed "quality measures" for the priority topics, and have agreed upon certain evidence-based intervention strategies upon which to base local interventions. MedQIC, http://www.medqic.org, is a searchable, online clearinghouse of public-domain, evidence-based materials launched in late 2003 to support the quality improvement activities of providers and QIOs. In addition to its capacity as a comprehensive depository of information, MedQIC is designed to serve as a dynamic internet-based community for medical professionals and QIOs to exchange ideas, quickly contribute and distribute new resources, and connect users nationwide.

As might be expected, diabetes and cardiovascular diseases are prominent among the CMS clinical priorities, and interventions using the CCM top lists of national and state-based quality improvement activities (See Table 2.1). QIOs collaborate with public and private provider and payer organizations locally and nationally through CMS and its sister U.S. Department of Health and Human Services (HHS) divisions: Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), National Institutes of Health (NIH), Health Resources

TABLE 2.2. ASDC Core Measure Set

Measure	Measure definition[a]	Target (%)
HbA1c	Most recent HbA1c < 7%	75
LDL	Most recent LDL < 100 mg/dl	85
Blood pressure	Most recent BP < 130/80 mmHg	75
Eye exam	Dilated eye exam	70
Self-Management goal	Self-management goal(s)	70

[a] A detailed description of measurement strategy can be found in the ASDC Pre-Work Handbook, http://www.azdin.com.

and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), Indian Health Service (IHS; CMS, 2004), and through other national health quality organizations—such as the AHQA and the national QIO association.

Additional assistance for providers, plans, and QIOs to promote quality and safety related to chronic care is being made available through the legislation making the most sweeping changes in Medicare since its inception more than 20 years ago. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) includes several specific studies (Sections 649 and 721) to identify new ways to deliver and reimburse for care provided to those with chronic disease. Under Section 721, CMS is required to sign three-year contracts with "chronic care improvement organizations" to develop, test, and evaluate programs to improve the quality of chronic-illness care. Section 649 established a three-year demonstration project to pay physicians at four United States sites to adapt and use health information technology and outcomes measures to promote continuity of care or minimize chronic conditions. The terminology, taxonomy, and concepts of the MMA have the CCM as their foundation. The influence of the federal government upon acceleration of health information technology is detailed in "Chapter 6".

CASE STUDY

The Health Services Advisory Group (HSAG), Arizona's Medicare QIO supported by a Robert Wood Johnson grant, organized a statewide diabetes collaborative [Arizona State Diabetes Collaborative (ASDC)]. ASDC was developed and supported by a statewide community coalition of over 80 organizations, the Arizona Diabetes Initiative (AzDIn). By titling and tasking AzDIn workgroups according to the CCM elements (Figure 2.2), public and private sector health care leadership learned the CCM terminology and concepts and became acquainted with the framework and implementation of IHI BTS-style Collaboratives. This is graphically portrayed by overlays on an Arizona map (Figure 2.6).

Predating by nearly 2 years the actual execution of ASDC, AzDIn provided a culture change nexus that manifested itself through ASDC and in the adoption and use of the CCM and collaborative framework in managed care, state health departments, academics, consumer organizations, and vendors' activities.

The goals of ASDC (Murcko, 2004) were to:

- Promote awareness and adoption of the CCM with particular emphasis on dissemination of information, communications technology, and a change package of quality improvement activities.
- Create and support multistakeholder improvement activities through alignment of state and national diabetes quality improvement work coordinated by HSAG.
- Identify and assist a diverse provider base of early adopters, both demographically and geographically.
- Develop participants' individual and collective improvement skills for ongoing CCM-based patient safety and quality improvement activities.

ASDC comprised 65 participating practices throughout Arizona, representing the diverse settings of small-group community primary-care practice, academic and teaching practice, and the state network of federally qualified community health centers. The practices participated in one of three tracks, including an intensive track with expectations to implement a full range of collaborative interventions, a "collaborative-lite" track with expectations to implement a partial package of interventions, and a more peripheral track with expectations to implement at least one diabetes improvement activity.

Effectiveness of ASDC was measured by two categories of outcomes. First, a standard (core) diabetes set of quality indicators selected by the advisory panel were

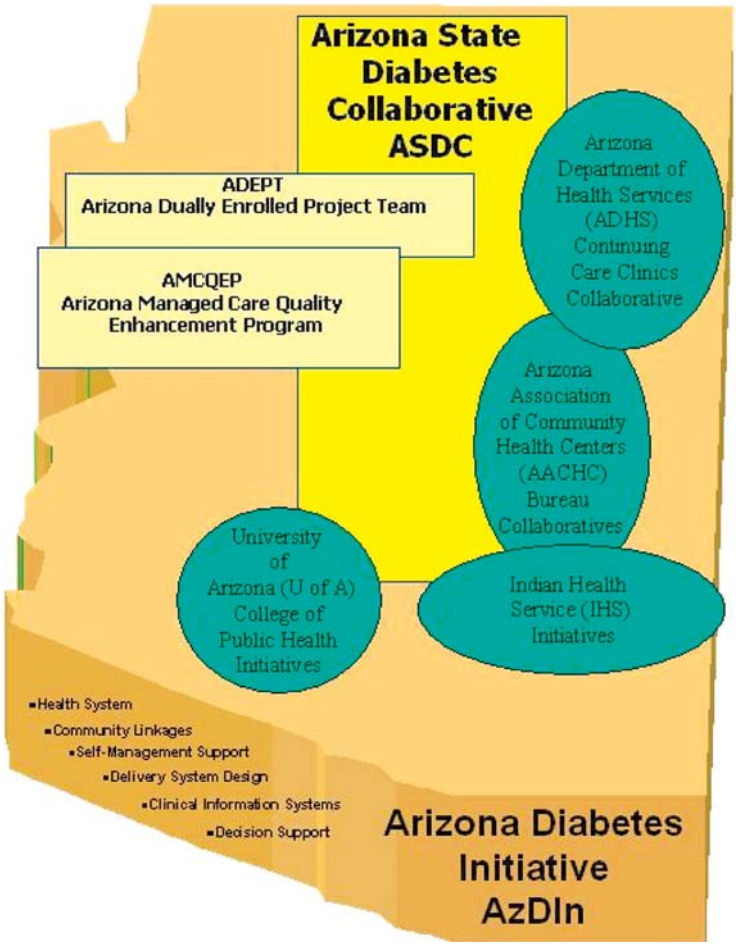

FIGURE 2.6. Synchronous collaboratives: Arizona state diabetes collaborative (Murcko, 2004) sponsoring organizations and partnerships.

tracked to measure clinical effectiveness. Second, communications and culture change indicators were measured to assess adoption of a quality culture in practice. Practices also had the ability to collect a set of optional diabetes* and preventive care indicators, as well as assistance in designing related measures to meet their own needs (e.g., two practices tracked referrals for eye care to validate their assumption that they were making the referral, but either the patient was not adherent to the advice and/or the specialist was not providing the feedback to the PCP; Table 2.2).

Each practice was asked to identify a cohort of diabetes patients, aged 18–75, with at least one diabetes visit during the preceding 12 months. Table 3 presents the results for the 12 participating practices in the intensive collaborative track.

Three practices implemented the innovative Delivery System Design intervention, group visits (IHI, n.d.-a; IHI, n.d.-b; McCulloch *et al*., 1998). These practices noted a clinically important increase in the quality of care indicators, including control of HbA1c values, blood pressure, and lipids, as well as the provision of eye care. In view of the

TABLE 2.3. Performance of ASDC Collaborative Teams (12 Teams)

Measure	June 2003 N = 2,536 patients (%)	April 2004 N = 3,327 patients (%)
HbA1c < 7.0%	33.7	37.9
LDL < 100	41.2	46.2
Blood pressure	32.1	32.8
Eye exam	43.3	27.1
Self-management goal	14.8	31.7

Note: Overall, HbA1c decreased from 7.85% at baseline to 7.47% at remeasurement.

remarkable success of these three group-visit programs, group visits have been targeted for spread efforts, starting with the formation of a task force to facilitate future activities.

The centerpiece of ASDC was implementation of the Clinical Information System component: electronic disease tracking software evaluation, installation, and use. Care interventions and other patient information that teams need to track and deliver the desired care must be balanced with the level of effort to collect information, number of measures used to focus patient encounters, and the time required to enter data. Collaborative participants learned to evaluate patient tracking/population monitoring software, including the ability of the product to concurrently:

1. focus on multiple disease states and conditions,
2. coordinate patient care,
3. proactively track conditions and the health status of individual patients and populations of patients,
4. support outreach, and
5. report outcomes.

After piloting a public domain—but resource-intensive—"stand-alone" registry, HSAG's PDSA included the purchase of a limited number of software licenses for DocSite Patient Planner (DocSite, n.d.), a web-based registry meeting established requirements for an optimal registry product. The licenses were provided at no cost to practices who committed to the intensive collaborative track—but did not possess the software and/or expertise necessary to record and electronically transit ASDC measures. Data entered at the practice level were aggregated monthly by HSAG and displayed on the secure HSAG extranet portal. Participants could view and print individual results as well as collaborative aggregate data. Practices using other registries (non-DocSite users) submitted summary data through the HSAG Web site, and results were incorporated into the monthly reports.

A sample of the challenges encountered by ASDC participants and sponsors included staff turnover, competing priorities with limited resources, inconsistent senior leader support, and too slowly evolving expertise in information technology and population management by participants and sponsors. ASDC confronted these challenges by accessing and presenting top-notch faculty and programming, multipronged, frequent, and multilevel communication, incentive award programs, and an easily accessible (web-based), frequently refreshed series of training modules. The advice and information obtained from ICIC, IHI, and other sponsoring organizations (see Table 2.1) (AHQA, n.d.; IHI, n.d.-a; IHI, n.d.-b; Murcko, 2004, May/June; MedQIC, n.d.) also was invaluable.

ASDC's reach will be expanded by ASDC-2 to common diabetes comorbidities, e.g., congestive heart failure, hypertension, and depression, with the focus on implementation of an array of information technology resources. This community-wide effort includes development of the infrastructure to support financial and nonfinancial incentives for providers and patients, i.e., a "pay-for-performance" component (Murcko, 2004, May/June, p.14).

SUMMARY

Employing the CCM in collaboration with actual and virtual peers can help you

transform the care you deliver to those with diabetes and other chronic illnesses by establishing:

- Well-developed processes and incentives for making changes in the care-delivery system.
- Behaviorally sophisticated self-management support systems that give priority to improving and sustaining patients' ability to manage their own care.
- Functional care teams and practice systems, such as appointments and follow-ups, to meet the unique needs of patients with chronic illness.
- Evidence-based guidelines and guideline supports through provider education, reminders, and increased and effective interactions between primary care physicians' and referral physicians' information systems—including disease registries, tracking systems, and reminder systems.

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3

Promoting Cultural Competence through Community Partnerships

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"Pray to God not for the life you want, but for the strength to live the life you have been given.
—Gurumayi Chidvilasananda, 2003

INTRODUCTION

There has never been a greater need for the understanding of cultural proficiency in the global society we find ourselves today. A global society assumes an understanding and acceptance of each other's cultural assets and liabilities and does not imply the idea of the "melting pot" concept of the 1970s and 1980s or the "salad" concept of the 1990s. It is rather a more sophisticated understanding and acceptance of what each human being brings to the table of negotiation.

The political climate that existed in the United States when it started the war in Iraq and the lack of and/or inclusion of NATO members are perfect examples of an opportunity to promote cultural proficiency. The exact role of each country is carefully defined, not so much because of the will but rather because of the assets and liabilities that each country possesses. The political dispute whether a country joined the coalition to restore civil life in Iraq has important significance on its cultural competence at the international level.

This chapter will discuss what cultural competence is and the different levels of cultural competencies. Tools that assist in measuring the cultural competence will also be reviewed. Cultural sensitivity is an important component for cultural competence and will be part of the discussion on competence in this chapter. Also note that cultural terms used within this chapter are not rigidly defined (e.g., Hispanic, Mexican American, and Latino may be used interchangeably) and can be interpreted by the context in which they are discussed.

The challenge in a global society is how do we as professionals work with individuals from diverse cultures and with perspectives different from our own? Every field needs to ask this question. Microsoft, for example, has

been able to diversify its components to meet the global needs of our society, but this also applies to the basic principles in virtually every language and culture in the world. Health care professionals who wish to care universally with a personal touch must understand the process of culture and culture change in individuals.

Considering culture helps us understand the values, attitudes, and behaviors of others, it also aids in avoiding stereotypes and biases that can undermine our efforts. In terms of care delivery, culture plays a critical role in the development of services that truly respond to the needs of the recipient. As a common definition, culture is the shared values, traditions, norms, customs, arts, history, folklore, and institutions of a group of people (Leininger, 1997). Traditions are not the only factors that influence culture. Culture is influenced virtually by everything we are (see Table 3.1). Not considering culture in the health care setting may lead to misunderstandings and most importantly create inaccessibility to care. In turn, this may be a root cause of health disparities that result in an increased financial burden on society and increased barriers for marginalized population to contribute to society.

Demographic information from the U.S. Census (1993) begins to paint a picture of diversity and cultural disparities. Minority groups are no longer a minority. From 1970 to 2050, it is expected that the proportion of minority groups in the U.S. population will rise from 16% to 50%. The issue of health disparity in the United States is so grave that healthy people 2010 has made its main goal to decrease these disparities. As an example, the death rate for all cancers is 30% higher for African Americans than for Whites. Hispanics living in the United States are almost twice as likely to die from diabetes than are non-Hispanic Whites.

TABLE 3.1. Factors that Influence Culture

Age
Gender
Geography
Socio-economic status
Educational attainment
Individual experiences
Place of birth
Length of residency in U.S.A.

These disparities can be explained by several key factors. For example, they can be addressed by the educational level and poverty. In the 65+ population, which is the largest growing age group in the United States, the percentage of non-Hispanic Whites with a high school diploma or higher is 71.6% compared to 29.4% for Hispanics. In the same age group, the percentage of non-Hispanic Whites with a bachelor's degree or higher is 16% compared to 7.0% for non-Hispanic Blacks. When comparing poverty and inequities, non-Hispanic Blacks are almost three times poorer than non-Hispanic White people. By recognizing the disparities in the level of education and poverty, we begin to see a relationship between cultural factors and health inequities.

Cultural competence not only plays a key role for the professional who is delivering care, but also for the recipient of this care. Cultural competence is a set of cultural behaviors and attitudes integrated into the practice methods of a system, agency, or its professionals, enabling them to work effectively in cross-cultural situations. Given that almost any situation can be classified as cross cultural, knowledge of cultural competence becomes the key to providing effective healthcare.

Before we can achieve competency, an understanding of how culture change occurs can provide us with a framework to interpret people's behavior. There are generally four models discussed in the literature of culture change or acculturation that explain the process. Three of these models are a result of the work carried out by the Social Science Research Council in the mid-1930s, which identified acculturation as an area of scientific inquiry that required the attention of sociologists and anthropologists (Broom *et al*., 1954).

		New Culture	
		High	**Low**
Host Culture	**High**	**Assimilated**	**Bicultural**
	Low	**Marginalized**	**Acculturated**

FIGURE 3.1. The two-culture matrix model.

From there, Keefe and Padilla presented three models of acculturation that included, for the first time in the literature, the idea of biculturalism (Keefe & Padilla, 1987). These models grew mostly from the civil unrest in the United States in the 1960s and 1970s, and have evolved as our understanding of human behavior has grown. These models include: the single continuum model, the multidimensional model, the bicultural model, and the two-culture matrix model.

These models range from culture change in one direction, to equal culture change in both directions, to culture trait gain and loss, and to the matrix model. For example, the first model, the single-continuum model assumes the gradual replacement of traditional cultural traits with Anglo American traits. There was a trend in the early 1950s, when it was "unpatriotic" to speak anything but English and, as a result, many children of non-White cultures never learned their parents' language of origin. Oral stories from many of these people relate that their parents were afraid that their children would be discriminated against or treated differently for speaking the parents' original language. This generation is now between 50 and 60 years old. This is an illustration of a replacement of a cultural trait with an Anglo American trait.

The two-culture matrix model can be most helpful in understanding culture change and in clearly articulating the dynamic movement of cultural behavior. The matrix model proposes that at any given time for any given trait, people can be at different stages of culture change, depending on their level of knowledge and the change in the new and original culture. Figure 1 shows a simple matrix that can be used to interpret where individuals are at any trait in terms of their culture change process. For example, you may encounter many people in the health or community setting who identify themselves not as Mexican, nor American, but as being in the middle of both cultures. These individuals in the matrix model are at the margin of two cultures and in terms of their behavior, they are denied meaningful roles in either culture. Marginality, according to many anthropologists and psychologists, can result in a type of cultural schizophrenia. These individuals would fall in quadrant 3. The two-culture matrix model is interpreted by taking into consideration where individuals are in terms of cultural traits in the host and new culture.

> For example, someone who is not acculturated in language would be an individual who knows a little English, is low in the new culture, and is high in Spanish or the host culture. They would fall in quadrant 1. At the same time, they can be high in the trait of cultural exposure of both the new and the original or host culture falling in quadrant 2. This knowledge can quickly translate to application of care. An individual such as this one is most likely to be open to other ways of accepting or receiving care, but unless it is done in the host language, the recipient will most likely not accept it.
>
> Someone who is acculturated in the trait of language would be high in the new culture and low in the host culture falling in quadrant 4.

This matrix begins to illustrate the complexity of culture change, but it can also be useful in providing care. We know, for

example, from research results on the relationship between cultural factors and health care that language, religion, and eating preferences are key to determining the health care outcomes of an intervention (Domino & Acosta, 1987).

In terms of providing health care, how culture change occurs can begin to give the health provider a framework to evaluate health behaviors. If research shows that language, religion, and eating patterns are the highest determinants of cultural change, then a health professional can begin to make an assessment of those traits and adjust teaching or information accordingly. Much research has been done on many areas of care and acculturation. More attention is being paid by researchers to identify the different levels of generations in a cultural group, since we know that older generations are usually closer to their traditional traits than younger generations.

How then do you begin to understand how culturally competent you are as a caregiver, as a nurse, as a researcher, as a business owner, or as a consumer? It can begin with a simple introductory class on cultural competence, but it does not end there. What our society has failed to acknowledge is that immigrants as well as nonimmigrants are in a constant evolution of development when it comes to culture. The mass media reflects this change in many areas. Take for example, Taco Bell's latest slogan "Think outside the bun." Tortillas as the alternative to buns are being widely accepted by many groups besides Hispanics. The models presented earlier have different paradigms that establish the rules and boundaries for the ways we see things. These paradigms can assist in interpreting the behavior of someone who is non-White and where they are in their process of culture change.

Communication is one of the most basic means of getting your idea across, but when it comes down to communicating with someone outside your comfort zone, things can become a little unnerving. Say for example, you have a Korean patient, and no one in your health care organization speaks or understands Korean. Some might choose to avoid the patient; some may choose to make use of the translator service available in almost every health care institution. Communication is one of the many factors that lead to cultural sensitivity, which, in turn, increases cultural competence. Like acculturation, cultural competence is a path, a continuum that we constantly are managing and growing in.

Denial
Defense
Minimization
Acceptance
Adaptation
Integration

FIGURE 3.2. Continuum of Intercultural Sensitivity (Bennett, 1993).

You might be asking, what about me? How will I know how culturally competent I am? Dissonance between a health care provider's beliefs and respect for cultural differences and behaviors will leave you with inefficient health care. A provider becomes more culturally proficient as these factors match and become more refined with experience. As a type of report card, you can check your actions against the items in Figure 2 and decide where you are in the continuum. The list of items in Figure 2 can also be useful in evaluating a department or agency for competency. Just as every human being has certain developmental processes to achieve during their lifetime, cultural competence practice is a long developmental process.

During the 1960s and 1970s, it was perfectly acceptable to say, "I treat everyone the same." This was considered a fair and liberal way to treat others. However, this stance assumes that sameness equals fairness, an assumption that only holds true if the values and norms of people involved in an interaction are similar. In order to move beyond the assumption of similarity, Milton Bennett authored the Developmental Model of Intercultural Sensitivity (Bennett, 1993). According to this model, such a statement places an individual at an early stage of intercultural sensitivity.

The first stage, *denial*, does not recognize cultural differences. It would represent someone seeing no color. The second stage, *defense*, recognizes some differences, but sees them as negative. Part of cultural sensitivity requires that we step outside ourselves to observe without judgment. This takes some practice. *Minimization* involves a lack of awareness of the projection of our own cultural values and seeing our own values as superior. For example, the political model of the United States is often painted as the ideal model for many other countries. *Acceptance* shifts the perspective to understanding that the same behavior can mean different things in different cultures. For example, the common Mexican saying "Mi casa es su casa," is equivalent to extending your home here in America. However, in the Mexican culture, the degree of integration into the family expected of a guest is much more intense and interactive. *Adaptation* is when a person can evaluate other's behavior from their frame of reference and can adapt their own behavior to fit the norms of a different culture. *Integration* is the final stage and it includes shifting the frame of references and integrating the identity issues that may result from that behavior. For example, as a Mexican individual, your own Mexican peers may interpret integrating Anglo music into your everyday life as having "Anglosized" yourself. Managing cultural differences between cultures and among peers of the same culture requires a savvy culture broker who can turn the outcome into a communal rather than a separating experience.

SUMMARY

To know that a person comes from a certain ethnic background does not tell us where they are in terms of their values and behaviors. However, it can alert us to possible arenas of miscommunication, and can lead us to closer observations about where they are in the development of culture change. In addition, the stages of intercultural sensitivity can be used for our own evaluation as we make interpretations of the behaviors of others.

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FURTHER READING

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3A

Hispanic American Culture and Diabetes

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In 2000, 2 million Hispanic people (8.2%) had diabetes. Hispanic Americans made up 12.5% of the U.S. population. The U.S. Census divides Hispanics into Mexican, Puerto Rican, Cuban, and other Hispanic subgroups (http://quickfacts.census.gov/qfd/states/00000.html). Mexican Americans are 1.5 times more likely to have diabetes than non-Hispanic Whites of similar age. Puerto Ricans are 1.8 times more likely to have diabetes diagnosed than non-Hispanics Whites (Centers for Disease Control and Prevention, 2004). The prevalence of diagnosed diabetes for Hispanic males (4.46%) in 2002 was higher than for females (4.39%) (http://www.cdc.gov/diabetes/statistics/prev/national/tprevhmemage.htm). These demographics can be improved by having more of a cultural awareness of how diabetes plays a role in the life of Hispanics and suggesting healthy ways to control diabetes that work with their cultural practices.

Diabetes is more common among middle-aged and elder Hispanic Americans. For Hispanic Americans, 50 or older, about 25–30% have been diagnosed or undiagnosed with diabetes (http://diabetes.niddk.nih.gov/dm/pubs/hispanicamerican/index.htm). Diabetes is not a topic that is shameful for these age groups. Among adults and elders with diabetes, diabetes is a common topic of conversation. A reason for this is that Hispanics like to know who has had diabetes and how they treated it. Using examples of how people deal with diabetes is a good way to teach the Hispanic population about self-management.

Compliance in taking medications for adults and elderly is usually good at the beginning, but over time this stops because they feel better and decide to discontinue their medication. When they feel unhealthy again, they typically resume a healthier diet and their medications. Being compliant in dieting is not as successful sometimes for older Hispanics because they do not want to stop eating foods that they have been eating their whole lives. Adults are more compliant than the older generations depending on whether or not they are more acculturated and have more health awareness. Educating Hispanic patients about diabetes complications and how to avoid these via better self-management is essential and, typically, motivates adult and elderly Hispanics to be more compliant because they fear getting the complications.

Obesity, being overweight, low fiber intake, high dietary fat, and lack of exercise are modifiable risk factors for diabetes. These risk factors are higher in Mexican American adolescents than non-Hispanic White adolescents (De La Torre and Estrada, 2001). The younger generations of Hispanics do not feel like talking about diabetes as much as older generations because it is perceived as something that older and overweight people have and, therefore, they feel they should not have it because they are young. Having to adapt to the changes in diet and medication is embarrassing for them and they do not feel that they are having normal lives. Compliance in taking medications and diet are higher for the younger generation than for the older because they are more acculturated and demonstrate lifestyles more oriented to health promotion and preventing diseases (Lipson *et al*., 1996). Younger generations also are more likely to have the support of their family to motivate their compliance. Talking about diabetes complications can cause a great deal of worry for young Hispanics, so enforcing a healthier lifestyle instead is a better way to increase compliance in self-management.

Hispanics have a great amount of trust in medications and they feel that changing their diet will not help them as much with their diabetes. It is suggested to emphasize diet as if it were being prescribed to them instead of it being something that is suggested (Lipson *et al*., 1996). According to a U.S. Department of Health and Humans Services publication, *Quality Health Services for Hispanics: The Cultural Competency Component*, the Hispanic populations tend to eat their traditional diets. Acculturation among immigrant Hispanics weakens the positive health factors by eating unhealthy American foods. The Hispanic diet is high in fiber, green leafy vegetables, relies on vegetable rather than animal proteins, and includes few dairy products. Countries that produce cattle tend to include a greater amount of animal protein (National Alliance for Hispanic Health, 2000). Eating is a social aspect for Hispanic families and it is a challenge to detour from the foods that the rest of the family eats when a person has diabetes. Having separate food served for the person with diabetes makes them feel left out of the family's activities. If the family tends to eat traditional Hispanic foods, it may be that the person with diabetes needs to cut the amount of servings that they eat, so they do not have to eat separately from their families. Encouraging the family to eat more traditional Hispanic home-cooked foods will help the patient consume healthy foods.

A large number of Hispanic people have jobs that require physical labor, but it is not the kind of exercise that contributes to aerobic activities. A study in San Antonio, Texas, found that Mexican Americans engaged in aerobic exercise less often than any other group. A study conducted by the Centers for Disease Control and Prevention found that high school adolescent males are about twice as likely as adolescent females to report engaging in vigorous physical activities (National Alliance for Hispanic Health, 2000). No matter what age or sex, Hispanics need to be constantly told about the benefits of making aerobic activities part of their lives. Providing suggestions on how to start easily integrating exercise into the day is a good way to motivate people.

The Hispanic population is diverse in cultural behaviors based on individuals origin. The information given here provides only broad information and suggestions that should be applicable to all Hispanics. Efforts toward making this population understand the severity of diabetes and the importance of improved self-management is critical because of the immense prevalence of diabetes for this group.

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3B

Cultural Competency

Native Americans

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There are more than 500 Native American tribal organizations who maintain cultural identification through tribal affiliations or community recognition. There exist a diversity of language, culture, location, lifestyle, and genetic heritage among American Indians and Alaska Natives (AI/AN) (National Diabetes Information Clearinghouse [NDIC], 2002). In 2002, the U.S. Bureau of the Census estimated the American Indian and Alaska Native population to be 2,475,956 or 0.9% of the total U.S. population.

The prevalence of diabetes among American Indians and Alaska Native has reached epidemic proportions. According to a fact sheet provided by the Centers for Disease Control and Prevention, 14.9% of AI/AN 20 years or older and receiving care from the Institute of Health Services (IHS) have diabetes. Regionally, diabetes is least common among Alaska Natives (8.2%) and most common among American Indians in the Southeastern United States (27.8%). On average, AI/AN are 2.3 times as likely to have diabetes as non-Hispanic Whites of similar age (Centers for Disease Control and Prevention [CDC], 2003).

The Association of American Indian Physicians reported one tribe, the Pima Indians of Arizona, as having the highest rate of diabetes in the world. About 50% of Pimas between the age of 30 and 64 have diabetes (Association of American Indian Physicians [AAIP], 2001). The prevalence of diagnosed diabetes among AI/AN females (15.9%) in 2002 was higher than males (14.5%) (CDC Morbidity and Mortality Weekly Report, 2003). These demographics indicate that the prevalence of diabetes will continue to increase as risk factors increase and the population continues to age.

Interventions that promote exercise, improve nutrition by reducing fat and calorie intake, and reduce body weight have been shown to prevent and delay the onset of diabetes among persons developing type 2 diabetes (CDC Morbidity and Mortality Weekly, 2003). With the help of these interventions and the awareness of diabetes and the incorporation of cultural practices and beliefs, the

prevalence of diabetes will decrease in the AI/AN population.

Cultural beliefs and values toward having diabetes among Native Americans is to "Identify and reinforce values on total well-being" (The Pathways, 1999). With the help of traditional medicine and western medicine, one is able to treat and heal the physical and emotional well-being of the individual. In many cases, a patient may consult a traditional healer to diagnose or remove the cause of a disease before consulting a western physician to cure the symptoms (http://erc.msh.org/quality&culture), (Providers Guide to Quality and Culture, 1999, accessed July 24, 2004). According to the Provider's Guide to Quality and Culture, ". . . Indians use "white man's medicine" to treat "white man's diseases" (e.g., diabetes, cancer, gallbladder disease) and use Indian medicine to treat Indian problems (e.g., pain, disturbed family relationships resulting in physical symptoms, sicknesses of the spirit)." American Indians tend to believe that a disease such as diabetes is only a side effect and that the real problem is soul loss, intrusive objects, spirit intrusion or possession, breach of taboo, and witchcraft or sorcery. Because of this belief, they do not seek the help that they need for diabetes. This delays the necessary and proper education and intervention that is needed to control and prevent diabetes.

This also affects the compliance of diabetes management by not taking the medication they need for diabetes, because they do not want to believe the doctor's diagnosis of diabetes and that it is due to traditional illnesses. This is more common among adults and the elderly.

In the end, the combined use of traditional and modern medicine is used to help and manage diabetes. This incorporation of traditional practices of healing with western medicine is an efficient way to begin and follow through in management of diabetes.

Diet and physical activity have changed tremendously over the past several decades for American Indians and Alaska Natives. The changed diets are higher in fat and calories than traditional diets. Increased fat consumption, decreased physical activity, and obesity are some of the major contributors to diabetes. These changes are highly associated with the increased prevalence of type 2 diabetes. Researchers suggest that "if minority populations returned to their native diet and lifestyle, the risk of diabetes could be reduced and people who already have the disease might be healthier" (Marchand, L, available at: http://diabetes.niddk.nih.gov/dm/pubs/pima/focus/focus.htm, 2002).

American Indian communities have developed school-based programs, such as Pathways and Quest, to increase physical activity, improve diet, and reduce obesity among children. Other programs emphasize traditional physical activities such as running, horseback riding, and walking. Adults and the elderly are encouraged to do these types of activities. As mentioned, "Traditional diets were low in fat with season variability, but high fat predominate today. Indian fried bread, mutton stews, and other rich soups and stews are common foods among American Indians" (Lipson *et al*., 2003, p. 14–15). One obstacle that is faced with someone who has diabetes is to have separate foods served that meet the diet requirement. Doing this makes them feel as if they were different. Yet some do not want others to know why they have a different food diet.

Open discussions about having diabetes to relatives and friends do not usually happen because they want to maintain their privacy, especially among adults and the elderly. One way to deal with this is to have traditional foods, but in smaller portions.

Compliance to diabetes management among young adults is "faced with unique challenges such as lack of symptoms, absence of family support and denial of the disease" (The Pathways, 1998). Many times they think that they are young and that diabetes is something young adults should not have to worry about or be concerned with.

To successfully manage the disease, the motivation to adopt healthy eating habits and adequate coping skills are needed to adapt to living with diabetes. Among adults and the elderly, storytelling (a traditional education tool) to communicate information and skills about diabetes is a more successful means of managing the disease (Griffin *et al*., 1999). This is exemplified in a program as a story "Through the Eyes of the Eagle" among the Pueblo Indians, which "helps participants recognize the problem of diabetes through culturally relevant medium of storytelling" (Griffin *et al*., 1999). Sensitivity toward AI/AN cultural traditions and their integration into programs and curriculums help and assist in their understanding of diabetes management, which, in turn, provides behavioral changes toward living with diabetes in a healthy way.

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4

Preparing for the Technology Revolution in Health Care

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Quality is something we expect in every service encounter we experience. From the grocery store where we shop to the restaurants in which we eat, we are very attentive to those aspects of service that do not measure up to our expectations of quality and we expect someone to correct it so that it does meet our expectations. When we think of health care, which also is a service industry, we have thoughts about the quality of the encounters we have personally experienced or that of friends or loved ones. The quality of many of those encounters could be considered good, but we also are aware of the poor quality side of health care. But how do we come to the conclusion about whether the overall quality of any service experience is good or bad? If what we experience firsthand or read or hear about a particular service experience consists of a mixture of mostly good and a little bad, and without anything else to suggest that it should be otherwise or that it is different anywhere else, we will naturally make such service levels our expectation and accept them as the norm.

The problem with doing this is the apparent assumption people often have that those who are involved in the service delivery are doing the best they can and that if there were room for any significant improvement in the quality of the service, they would provide it. In a competitive market environment, this assumption would be absolutely correct because those who do not adjust their service quality to meet or exceed that of their competitor will find themselves out of business.

In order to effectively compete in a market, there are two fundamental questions that need to be answered:

- What is my competitor doing?
- Where am I relative to my competitor?

However, to answer those two fundamental questions requires knowledge based on information about both parties. This is where the distinction between health care and other service industries arises. With perhaps the exception of multi-hospital communities where the population is not sufficient to ensure all hospital facilities are at optimal operating

census capacity at all times and thereby driving competition, health care is not viewed as a competitive market, especially by those delivering the care. With a lack of a sense of competition, the first key question (what is my competitor doing?) is never asked, which makes the second key question (where am I relative to my competitor?) of little or no value. Further, without the perception of competition and when financial circumstances are favorable, there is little if any incentive to collect any information about measures pertaining to quality performance or outcomes. Hence, any information pertaining to the quality of health care services provided at the practice level is largely anecdotal. This is the situation today in health care—no competition means little or no improvement. A recent article in the Harvard Business Review (Porter and Tiesbeg, 2004, pp. 65–66), summarizes the situation more succinctly:

> The U.S. health care system has registered unsatisfactory performance in both costs and quality over many years. While this might be expected in a state-controlled sector, it is nearly unimaginable in a competitive market—and in the United States, health care is largely private and subject to more competition than virtually anyplace else in the world.
>
> In healthy competition, relentless improvements in processes and methods drive down costs. Product and service quality rise steadily. Innovation leads to new and better approaches, which diffuse widely and rapidly. Uncompetitive providers are restructured or go out of business. Value-adjusted prices fall, and the market expands. This is the trajectory common to all well-functioning industries—computers, mobile communications, banking, and many others.
>
> Health care could not be more different. Costs are high and rising, despite efforts to reduce them, and these rising costs cannot be explained by improvements in quality. Quite the opposite: medical services are restricted or rationed, many patients receive care that lags currently accepted procedures or standards and high rates of preventable medical error persist. There are wide and inexplicable differences in costs and quality among providers and across geographic areas. Moreover, the differences in quality of care last for long periods because the diffusion of best practices is extraordinarily slow. It takes, on average, 17 years for the results of clinical trials to become standard clinical practice. Important constituencies in health care view innovation as a problem rather than a crucial driver of success. Taken together, these outcomes are inconceivable in a well-functioning market. They are intolerable in health care, with life and quality at stake. We believe that competition is the root of the problem with U.S. health care performance.

Stemming from the Institute of Medicine (IOM, 2000) report, which identified that thousands die each year unnecessarily in our health care system due to medical errors, the spotlight has been on health care in all settings to eliminate errors and improve the quality of the services provided. This report raised the awareness of the problems in health care across the country and claimed that health care should and could be much better. As a result, expectations changed from accepting historical health care quality as the norm (*the way we have always done it*) and began demanding the health care industry make those quality improvement changes that would significantly improve patient safety. In the 4 years since the release of that IOM report, there is no longer a question of whether the system needs to be improved, but the challenge is how do we go about improving it.

If quality improvement is the product of incentive and measures, how do we change a noncompetitive industry (which lacks both incentive and measures) into one that exhibits the characteristics of one that is competitive (having both incentive and measures)? One method could be by creating a community, state, and national information infrastructure and system that creates incentives for change and identifies and collects the measures that will determine whether improvements are being made.

This method was the major focus of the *Secretarial Summit on Health Information Technology* sponsored by the U.S. Secretary of Health and Human Services in Washington D.C. July 21–23, 2004. The newly appointed National Health Information Technology Coordinator, Dr. David Brailer opened the summit with the presentation of

his framework for strategic action (Thompson and Brailer, 2004) for implementing a national health care information infrastructure designed to realize a vision of electronic health records for Americans within a decade. The summit was attended by broad representation from across the industry by leaders who not only recognize the need for change, but who all agreed to actively participate or continue participating to achieve the objectives.

These individuals and groups represented and communicated a groundswell of support and determination to bring health care into the 21st century through the infusion of information technology. Senator Bill Frist, Senate Majority Leader, emphasized the importance of ensuring that the technologies brought to health care need to be, ". . . patient centered, consumer driven, and provider friendly, and that they need to be powered by information, choice, and control." Quality improvement in any industry begins with measurement of that which is to be improved. But unless there is a method of systematic remeasuring after the initial baseline measure, there is no way to know whether the actions to improve have had the intended results. As one summit presenter remarked, "You don't pay attention to what you don't measure."

While the summit emphasized the importance of information technology, it also was clearly communicated that technology alone will not solve the problems. Technology is an improvement enabler, the successful implementation and use of which is dependent on the user and how well they know how to use it and how well they have adapted their workflows and processes to accommodate it. Fortunately, we have a great history of quality improvement in other industries that can help bring success to our efforts to bring quality improvement to the health care industry.

During the 1970s and 1980s, there were huge gains in product quality improvements in the manufacturing industry. This was achieved by two key factors: a strong competitive market (incentive and measures), and the adoption and application of quality improvement techniques. The same quality evolution that occurred in the manufacturing industry, and transformed it, will need to occur in the health care industry to transform it as well. This is not to say that there have not been any improvements in health care. Just as in the manufacturing industry in which there were companies that initiated quality improvement techniques before competition made it essential for others to follow, there have been initiatives and studies, many that are currently ongoing, that have found the best ways, or *best practices*, needed to bring quality improvement changes to health care in some areas. Adopting and applying these best practices is what remains to be done on a national basis to realize quality improvement gains in health care that have been realized in the manufacturing industry.

The costs for significant change in health care quality improvement are going to be significant, both in dollars and the impacts it will have on the workflow and processes. Reflecting back to the manufacturing industry, the costs of achieving significant quality improvement often meant changing their legacy systems, infrastructure, workflow, and processes in the business setting. This is expected to be the same for the health care industry.

As we anticipate the changes that are certain to come in the health care industry, we need to look within our daily activities for what we can do to make improvements today and what we can do to make that effort continuous and embrace the changes as they come.

Some areas of health care may be more challenging than others in realizing quality improvement changes. Chronic disease management may be one such area due to the closer relationship and interdependence needed between providers and their patient population. The provider can provide the best care possible, but if the patient does not participate in self-care management, then the quality improvement outcomes for diabetes, for instance, will not be achieved. It is very important to be aware of the available resources that can help provide the guidance for these special

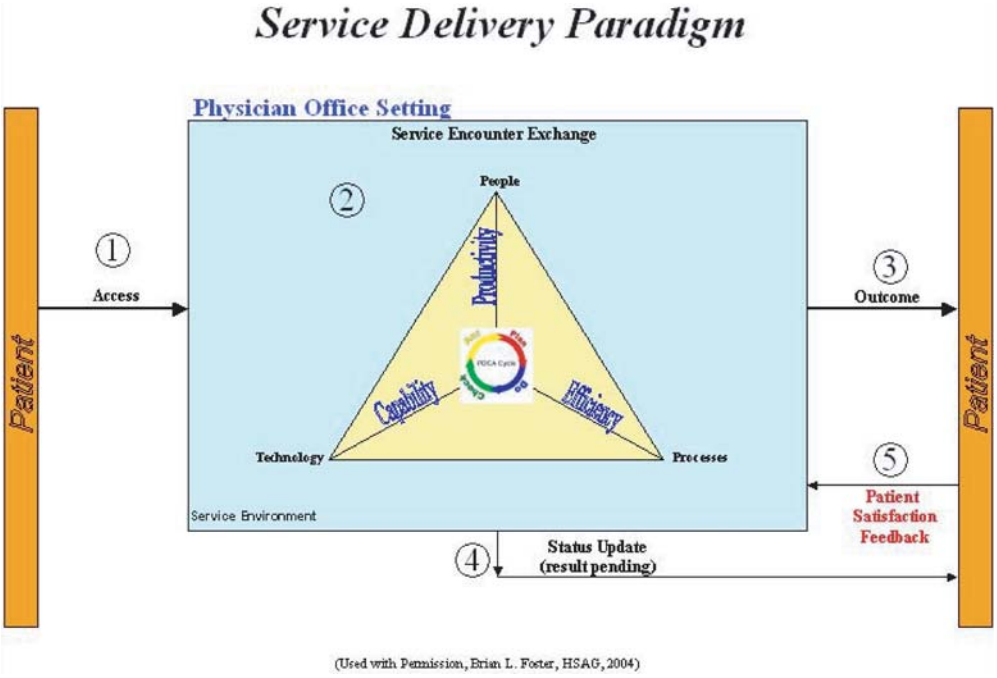

FIGURE 4.1.

health care settings. The implementation of the Chronic Care Model (Improving Chronic Illness Care, n.d.) is just such a resource. (See an excellent overview of the Chronic Care Model by Dr. Anita Murcko in "Chapter 3" of this handbook.)

In addition to the awareness of resources within the health care industry, we also will need to look at how we do business on a daily basis. As mentioned, the changes needed in health care amount to a paradigm shift from *the way we have always done it* to new ways that achieve the desired improvements. Achieving this paradigm shift in health care will require significant change in and continuous synthesis of the components that comprise the triad of service delivery which are common to any competitive service industry: *People, Processes, and Technology.*

Figure 4.1 encapsulates the service delivery paradigm that contains the various components that comprise the entire service delivery experience. The center triangle shows the triad previously identified: people, processes, and technology, which will be the center of focus for the remainder of this chapter after stepping through a brief overview of the five service delivery segments of the paradigm.

Service begins with a customer who accesses a service provider (1). Once accessed, the customer goes through the service encounter exchange (2), followed by an outcome or result (3) of the exchange. Any expected information the customer is waiting for or that could be of value to the customer from the service provider is provided once available (4). Finally, the customer has a means of providing their customer satisfaction feedback to the service provider (5).

This service paradigm general diagram can be applied to virtually any service provider including restaurants, retail stores, auto parts stores, fast food chains, travel agencies, etc., anywhere that a customer interacts with a service provider of any kind, including, of course, health care services from hospitals

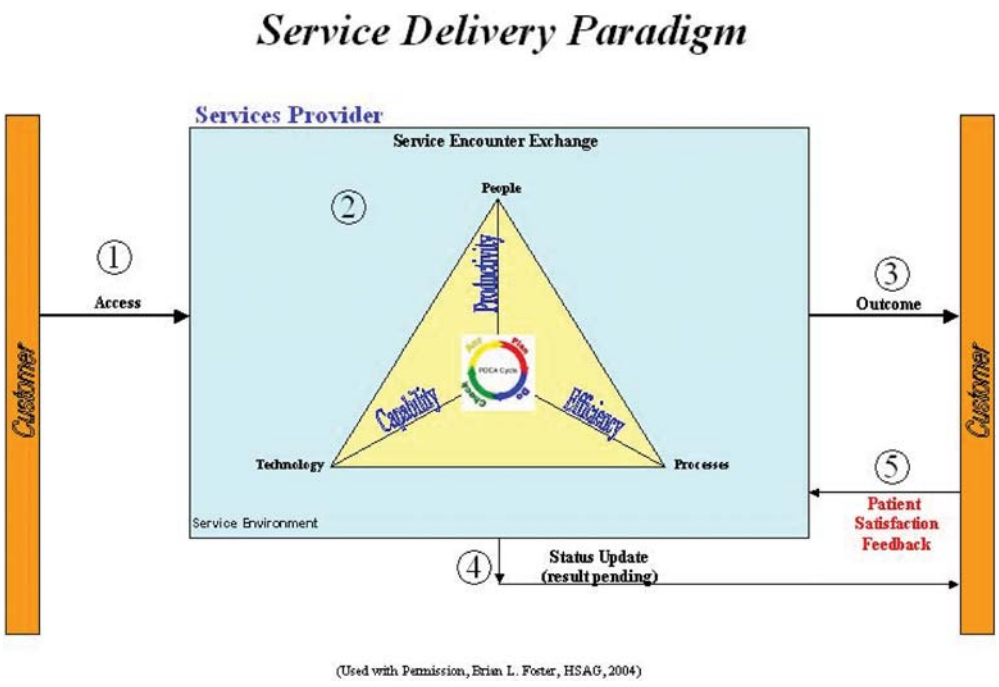

FIGURE 4.2.

and individual physician practices. Figure 4.2 reflects a modification of the general diagram for application in a physician office setting with the service delivery segments adjusted as follows:

Service entry or access: This element defines how the patient gains access to the service setting. Depending on the design of the practice, access generally happens by having a scheduled appointment.

Service encounter exchange: It is here, in the service environment, that the patient enters the series of processes, or workflow, designed by the practice. This segment consists of an exchange of information between the provider, staff, and the patient.

Service encounter results: This is the initial area of assessment of the results of the encounter exchange at the point of patient departure. Was the experience what it should have or could have been? Did all the important information get exchanged?

Status update: Any pending information for the patient is provided here, such as lab results and appointment reminders, and so on.

Feedback: This final but equally important component is essential for keeping the patient and the provider informed. From the patient perspective, feedback is provided by the physician as to the status of any pending tests performed during the visit. From the physician perspective, feedback is provided from the patient as to their satisfaction with the quality of the services provided during their visit(s).

As we consider the changes that are coming as a result of the national interests and demands for health care quality improvement, we need to have a more holistic view of the health care setting in which we function in order to maximize our quality improvement effectiveness and efficiency. By clearly understanding the interdependence between the triad components: people, process, and technology utilized each day in our service delivery settings, we will be able to more effectively apply quality improvement techniques in a more focused and deliberate manner, thereby enhancing the likelihood for success.

The triangular area in Figure 4.2 shows the interconnectedness and interdependence of the service delivery triad. In an ideal, balanced setting, we would have the right people with the right skills and experience, providing optimal *productivity*, by utilizing and fully exploiting the *capability* of the right technology for the job through the effective development and use of the right processes for maximum *efficiency*. Balance is achieved and maintained by adjusting each component of the triad as needed, continuously. The mechanism that is used to continuously keep the triad components in balance is the diligent and perpetual application of quality improvement techniques, such as the Plan, Do, Check, Act (PDCA) improvement cycle (Dartmouth Medical School, 2004), as reflected in the center of the triangle in Figure 4.2.

Quality improvement techniques must be applied to every aspect of service delivery: (1) access; (2) service encounter experience; (3) service outcome; (4) status update; and (5) customer satisfaction feedback. The application of quality improvement necessitates measures and measurement to know whether improvement efforts are actually succeeding. This is the very basis of evidenced-based best practices and why it is important to adopt them—the hard work of determining the best approaches have already been determined through continuous process improvement with evidence to support them. Each of the service delivery areas must have a process identified and documented for it. From the process there needs to be a set of key indicators (or measures) that will determine, through continuous measurement, whether the service delivery quality objectives are being achieved in that area. The following identifies some possible measure points for each area:

(1) *Access:*
Reasonable times available on provider schedules to meet patient needs Wait/hold time before call is answered Professionalism/demeanor of scheduler Schedule reminders

(2) *Encounter exchange:*
Professionalism/demeanor of office staff Environment considerations—temperature Responsiveness to patient needs/questions Timeliness of provider to seeing patient Communication/education of patient Patient information collected/recorded Clinical information collected/recorded

(3) *Outcome:*
Patient informed appropriately and understands Prescriptions provided Follow-up identified and communicated

(4) *Status update:*
Patient contacted in timely manner

(5) *Customer satisfaction feedback:*
Many of the above items could be used as the basis of a patient satisfaction survey to determine their assessment of the service delivered.

The feedback provided by a patient satisfaction survey should not be a surprise since we should be measuring many if not all of the survey components internally. While it is an important measure, patient feedback should not be the only method for measuring the quality of our internal processes. The central principles for process improvement, as applied in the manufacturing industry, suggests that we know the quality of our product before it leaves our door rather than relying only on customers (patients) to tell us some time after the fact that there is a problem. To achieve this, there must be internal measures taken as the patient moves through our internal processes and workflow.

Each service delivery area has certain people, processes, and technology associated with it. The holistic approach to quality improvement in our service delivery environment requires us to look at all areas of the service delivery function individually as well as collectively to determine whether office workflow is designed (or needs to be redesigned) to function optimally with the service triad components for each service delivery area.

Everything detailed above, the national interest and focus on health care quality improvement, the service delivery paradigm, and the importance and value of applying quality

improvement techniques, brings us to the individual and collective components of the service delivery triad (people, processes, and technology) and the huge importance each will play in the effort to achieve significant quality improvement in the health care industry. As we look to what we can do today to begin this improvement process, we must evaluate each component to ensure they are equipped and ready to perform the crucial functions they must perform to ensure success, starting with the most important of the three—our People.

People: Without doubt people are health care's most valuable resource. It is the *people* who utilize the *technology* within defined *processes* that collectively provide the *service encounters* that our patients experience. If our people lack the skills, experience, or customer service attitude necessary for the service areas in which they are placed, we should expect that service quality will be diminished and the entire service encounter as a whole will be less than optimal.

As the shift in health care quality begins to occur, there will be an increase in the demand on the skills that our people will need to ensure our service encounter environments are adequately postured to embrace the changes that are coming. To ensure readiness, there should be a minimum skill set for every employee in a health care service encounter business environment, which should include intermediate skills in quality improvement techniques, intermediate computer skills, and intermediate skills utilizing standard office management software, such as word processing and spreadsheets. A broader and more valuable skill set would include the previous items as well as skills in creating a simple database and mastering a report writing application, such as Crystal Reports.

While it may be that the database and report writing skills will not be used on a frequency that would require an intermediate level expertise, some minimal skills in those areas will help provide a rudimentary understanding of the information systems applications that are used in the various aspects of the physician office, such as scheduling, billing, computerized physician order entry, electronic health records, and so on, which all have databases at their core and from which reports will be needed. Someone with at least the basic office applications skills would have a shorter learning curve for new, yet similar, clinical applications than one who does not. The skills the people possess, especially the quality improvement techniques, will be essential in effectively creating and managing the dynamic processes that comprise the workflow in the physician office.

Process is defined as a series of actions, changes, or functions bringing about a result (www.dictionary.com). We use processes to get things done, so it is important that they are efficient and remain appropriate for the purpose for which they were designed. As we think about our daily lives, from the moment our alarm clock awakens us in the morning until we fall asleep at night, our days are filled with processes, possibly hundreds of them, all of finite duration with a predetermined beginning and end.

Our work environment is made up of processes too; scheduling, billing, charting, reminding, mailing, analyzing, decision making, etc., and many of these processes include the use of technology (software applications) to achieve the process objective. If processes are inefficient, following inefficient processes will replicate inefficiency and waste, which increases costs. A properly designed and managed process, on the other hand, provides consistent results and assures continued efficiency by having only the minimum steps needed to accomplish the objective.

Following a process can be expected to produce the same result each time, thereby minimizing the variations (waste) that may otherwise occur when not following a process. A process that is documented well provides the ability to identify key measure points to determine the effectiveness and efficiency of

the process. There are several factors that can necessitate the change of a process:

Environmental conditions: Office air conditioning/heating not functioning properly.

Technology: Installing a new electronic health record (EHR) application.

People: Turnover or skill changes.

To improve a process, there must be a method of measuring the results of the process as well as key steps that make up the process. This is where process improvement techniques come in. With a poorly designed process some things might get done, but without process improvement things done poorly will never get better. Given the changes that are perpetually affecting our environment, it is reasonable to expect that a process will need to be changed at some time to accommodate those environmental and technological changes. This being the case, the techniques we utilize must take this changing nature into account and provide for continuous process improvement.

The interdependent relationship between the service delivery triad components (people, processes, and technology) should be evident. Any significant change in any one of the triad components, or of the environment in which they operate, will likely have an impact and necessitate a change in one or more of the other components. Consequently, it is essential that when significant changes occur in any of the components, whether planned or unplanned, a review of the other components be conducted to determine whether changes are needed in them as well. One of the significant changes to processes is brought about by changes in our technology.

Technology: This is the component of the service delivery triad that gives organizations the greatest challenges. This is due to the complex nature of many of the technologies employed in the health care work environment. Implementing a new scheduling, billing, or practice management system, for example, can cause significant upheaval in the workplace as configuration and testing is going on. There also is training that needs to be conducted and a learning curve is required for staff to reach a level of proficiency that has minimal mistakes. None of these things can be avoided; they are all integral components of growth and improvement.

Before a decision is made for any new technology system, careful considerations need to be made to ensure the product selected is the best one. Some of those considerations are not about the new application itself, but about the infrastructure into which it is to be placed. Consider, for example, the following modes of application deployment and their pros and cons:

ASP (Application Service Provider—where the application access is provided via secure internet connection using a web browser such as Microsoft's Internet Explorer)

Pros: Desktop computer and broadband internet access is all that is required to access and use the application. Least complicated approach. Server hardware in the physician office is not needed, which means that data backups and application upgrades and hardware maintenance are handled at the ASP facilities thereby minimizing the added housekeeping responsibilities and disruptions in the physician office.

Cons: Application access subject to dependability of internet access. Clinical data is not readily available for analysis or *ad hoc* reporting. Access to clinical data limited to whatever is available through the application (unless other arrangements are made with vendor).

Office based (application requires a server at the physician office)

Pros: Clinical information is retained locally and may be readily accessible for analysis and reporting needs.

Cons: Server hardware in physician office—upgrades, backups, maintenance, and other housekeeping activities may impact office staff. Most complicated approach. Support disruptions from two possible sources: application vendor and hardware maintenance.

Neither of these options can be said to be the *right* solution as much of it depends on the risk tolerance or aversion of the

decision makers and which model is a best fit for them. Such decisions are often made after considerable consultation with multiple vendors and with association representatives, such as the American College of Physicians (ACP), American Academy of Family Physicians (AAFP), and so on who have evaluated various systems on behalf of their members.

Other considerations include:

Application Integration: the need for new applications to integrate or interface with existing applications. Interfaces may need to be developed for one system to be able to *talk* to the other. Interface development and testing add significant costs to an implementation.

Security: in addition to privacy standards that are already in place, the Health Insurance Portability and Accountability Act (HIPAA) guidelines require strict security measures to be in place by April of 2005. Vendors who are proposing new systems need to be able to certify that their systems are HIPAA compliant.

In addition to needs assessment/evaluation tools provided by health care professional associations, there are a number of websites that offer helpful information as well on various subjects that may be of interest to physician offices:

Electronic Medical Record (EMR/EHR):
http://www.expert-system.com/howtobuy.htm
http://www.emrconsultant.com/

Computerized Physician Order Entry (CPOE):
http://www.insidehealth.com/info.cpoestudy.go.html

Registries:
http://www.docsite.com/whyReg.htm

Workflow assessment:
http://www.globalvisioninc.com/en/services/workflow.asp
http://www.icsbhs.org/presentations/pawlson.pdf

Quality Improvement Tools:
http://www.dartmouth.edu/~ogehome/CQI/index.html

CONCLUSION

Significant technology changes are coming to health care that will revolutionize the way health care is delivered. The 10-year strategic plan, mentioned at the beginning of this chapter, proposes sweeping changes across the health care industry, including the creation of an electronic health record for all Americans. Along with these changes will be significant health care quality improvements across the entire industry. But, the revolution will not be easy and it will not be rapid. This chapter identified several ways to prepare for and accommodate those significant changes:

- Having a holistic view of the health care system so changes can be more readily applied and adopted in a broader context.
- Understanding the components of the service delivery paradigm in how they can be applied in the physician office environment to initiate and sustain continuous quality improvement.
- Adopting evidenced-based best practices, since the hard work of finding the best process has already been done.
- Ensuring health care employees have intermediate skills in quality improvement techniques (PDSA), computer literacy, and standard office applications.
- Understanding the interdependencies of the service delivery triad (people, processes, and technology) to determine where significant changes may drive other changes in our work environment and where opportunities may arise for process improvement changes.
- Giving consideration to the various methods for technology implementations and the effects each can have in the physician office environment.
- Using professional associations and other references for consideration when assessing the need for various clinical applications quality improvement tools.

Health care is already an exciting and challenging industry to be in so it will be very interesting to see what the next few years will bring. There is a heightened sense of expectation as we stand at the cusp of the same kinds of changes that revolutionized the manufacturing industry.

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II

Caring for People with Diabetes

5

Concepts on the Origin of Diabetes

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ORIGIN OF TYPE 1 DIABETES MELLITUS

Type 1 diabetes mellitus results from progressive destruction of the insulin producing beta cells in the islets of Langerhans. This disease most frequently occurs in persons of European descent and is less common in other racial groups. The incidence ranges from a low of 1–2 per 100,000 per year in Japan to as high as 40 per 100,000 per year in Finland (Green *et al*., 1992). In the United States, the prevalence of type 1 diabetes mellitus by the age of 20 is about 1.7 cases per 1,000 people and the overall annual incidence is approximately 18 new cases per 100,000 people younger than 20. The risk of developing type 1 diabetes before age 20 is approximately 0.5% (American Diabetes Association [ADA], 1996). The incidence appears to be age-dependent with increase occurring from birth to a first peak around puberty. A second peak in the onset of the disease is noted in those in their 20s to 30s. This later presentation of type 1 diabetes appears to have the same pathogenic origin as in the earlier presentation. Pathogenesis in type 1 diabetes mellitus differs from type 2 diabetes mellitus in that there is actual deficiency of insulin whereas in type 2 diabetes mellitus it is insulin resistance that plays the fundamental role (ADA, 2004; Becker, 2000).

What Causes Islet Cell Destruction?

Genetic Factors

Susceptibility to develop diabetes is conferred by genes in the HLA region. The lifelong risk of type 1 diabetes increased in close relatives of a patient with type 1 diabetes and the risk appear to be about 6% in offspring, 5% in siblings, and about 30% in identical twins (Atkinson and Maclaren, 1994). The main gene associated with a predisposition to type 1 diabetes mellitus is the major histocompatibility complex (MHC) on chromosome 6 in the HLA region. A single, unique amino acid transition in this HLA protein is present in about 95% of patients with type 1 diabetes, but is also present in about 20% of the U.S. population. Thus, it is not sufficient to have the genetic predisposition, otherwise 20% of the adult population would have the disease.

We will discuss the coincident environmental factors that contribute to trigger diabetes. There are other non-MHC genes that induce type 1 diabetes mellitus and these are chromosome 11, chromosome 15, and chromosome 2. In addition, at least 16 other regions have shown linkage with type 1 diabetes mellitus.

Autoimmunity

Antibodies to islet cells develop over a period of time but can be seen much earlier in life. Only after sufficient numbers of islet cells are destroyed do clinical manifestations appear. In real life situations, manifestations of type 1 diabetes mellitus, which include hyperglycemia and ketosis, occur late in the course of the disease: that is, after most of the islet cells are destroyed (this may not be true based on the animal studies).

There is a large body of evidence that indicates that the autoimmune mechanism leads to the destruction of beta cells. By far, this appears to be the most common mechanism for beta-cell destruction.

Insulin antibody titers are inversely correlated with age suggesting that the presence of these autoantibodies in the younger population indicate that islet cells are destroyed early in the course of the disease as compared to the adults. Islet cell antibodies appear to contribute to the immunologic environment that permits the full-blown immune destruction of islets to occur. Studies in autoimmune animal models of type 1 diabetes demonstrate that depletion of B-lymphocytes (the cells making the autoantibodies) with monoclonal antibodies will significantly retard the development of diabetes in these animals.

There are several antigens in the pancreatic beta cells that may be responsible for the triggering and progression of islet cell injury. By far, the common antigen that has been identified to which antibodies are detected is the enzyme glutamic acid decarboxylase (GAD). This is present in islets and is also seen in central nervous system and testes (Baekkeskov *et al.*, 1990). Antibodies to GAD (anti-GAD antibodies) are present in at least 70% of the patients with type 1 diabetes. Insulin also is another potent autoantigen and there is evidence that antibodies to insulin may even appear before the anti-GAD antibodies. Other autoimmune diseases may coexist since the same autoimmune response may trigger antibodies to other organ systems. Example of such diseases includes adrenal insufficiency and poly glandular autoimmune disease.

Autoantibodies appear as early as 9–12 months of age in individuals susceptible to type 1 diabetes and they are seen in 3–8% of first-degree relatives of type 1 diabetes. Half of these individuals will develop the disease eventually (Besser, 2002). Although this can be used to predict the susceptibility to type 1 diabetes, currently it is only used in research settings. To have a complete autoimmune response, the body requires the activity of T-lymphocytes or the cellular limb of the immune system. These white blood cells, unlike the B-lymphocytes, do not produce antibodies, but instead are involved in the interaction with antigen presenting cells called dendritic cells that are always present in the islet. The T-lymphocytes also produce cytokines, which are proteins that interact with other cells, that recruit more white cells to the site of the inflammatory event in the islet. Cytokines also trigger an enormous number of chemical events that lead to the production of other factors that ultimately lead to the destruction of the islets.

Environmental Factors

The fact that type 1 diabetes is not 100% concordant indicates that environmental factors must be playing a role in the development of the disease. A wide range of environmental factors may play a role including common viruses, foods, and vaccines (Upto-Date, 2004).

Viruses can cause diabetes either by directly infecting and destroying beta cells or by triggering an autoimmune response. Although

the former is a rare phenomenon, the latter could be a possibility and this is supported by long-term follow-up of patients with congenital rubella syndrome. The timing of the infection appears to influence the induction of type 1 diabetes mellitus since the disease is observed only in cases of *in utero* exposure. Postnatal exposure to the illness does not appear to be associated with the risk. This reflects the fact that the timing of infection at the time of organ differentiation is important, which includes islet cell differentiation. Several other viruses have been implicated in the pathogenesis including coxsackie and mumps viruses, but no definite association has been found. One popular theory for the past decade has been that because of the similarity between the surface proteins produced by some viruses, like coxsackie B27, a common sore throat virus, the immune system misidentifies the beta cells in the islet as being similar enough to the virus that they too are destroyed. In support of this suggestion is the observation that titers of antibodies in the blood to these viruses rise and fall just before the autoantibodies rise and fall. This up and down change in antibody concentrations generally goes on for years for the patient who presents with diabetes.

Dietary factors may influence the development of type 1 diabetes mellitus. A common factor considered includes cow's milk. It is thought that exposure to cow-milk protein early in life may lead to the development of type 1 diabetes. But the available data are controversial and the definite association has not been made (Norris *et al*., 1996). Other dietary factors implicated are the content of nitrates in drinking water and introduction of cereals early in life. Once again data are controversial here.

Although it was once thought that about 90% of the beta cells are required to be destroyed before hyperglycemia occurs, it has been shown in animal studies that hyperglycemia can be seen with even 30–50% of beta-cell mass destruction. This could be in part due to the inhibitory effect of cytokines released from inflammatory cells in the islets. This suggests that hyperglycemia does not imply irreversible destruction of beta cells and interruption of the autoimmune process. Even at this stage it may allow substantial recovery of the beta-cell mass.

Tying all of this together, a series of trials have been conducted trying to prevent the progression of type 1 diabetes after it is initiated. Potent immunologic medications commonly used as antirejection drugs in kidney transplant patients have been used to forstall the full expression of the disease. Unfortunately, the medications have significant toxicity associated with them, and they only worked to attenuate the immune destruction of the islets for as long as they were used.

One recent trial used either oral or subcutaneous insulin injections in the "prediabetes" phase in a group of highly genetically predisposed individuals. The results, unfortunately, demonstrated no benefit in this type of attempt at desensitization to this potential disease initiating protein. In special strains of mice, 80% of the females in the litters develop type 1 diabetes. Injection of a small amount of GAD during the first week of life prevented 100% of the development of the disease (DPP, 2002). Such human trials are underway now.

ORIGIN OF TYPE 2 DIABETES

Within recent history, many health care practitioners believed that type 2 diabetes was the result of overeating. While clearly excess calorie consumption contributes to triggering the overt disease, there is clearly a genetic predisposition that is emerging. The primary distinction between type 1 and type 2 diabetes is that during the prodromal phase of the type 2 diabetes, the patient is grossly hyperinsulinemic. Only after a long duration of the disease does type 2 progress to relative insulin deficiency, and, even then, this is not an absolute. Instead, type 2 diabetes is a state of insulin resistance that is present even in young adults; that is, more insulin is required to control blood sugar concentrations.

Recent data collected by Petersen *et al*. (2004) at Yale summarize clearly that an inherited defect in muscle metabolism plays a pivotal role in the development of type 2 diabetes. In these elegant studies, subjects between an average of 26–28 years of age were screened for insulin sensitivity with an intravenous (IV) glucose tolerance test. In this experiment, the rate of return to a normal, baseline glucose concentration after a bolus of 50% dextrose is an index of insulin sensitivity. Those with normal insulin sensitivity return to baseline glucose values quickly, while those who are resistant returned more slowly. A bell-shaped distribution of insulin sensitivity was developed in these sedentary, otherwise normal individuals. Subjects from both ends of the spectrum were investigated further with a conventional oral glucose tolerance test. The peak glucose concentrations were elevated only modestly during the test (peak values of about 155 mg/dl compared to those from the other end of the bell-shaped curve who were approximately 140 mg/dl at maximum). However, those persons who had the slowest rate of return (least insulin sensitivity) by the IV test generated substantially higher insulin concentrations to maintain a normal glucose concentration. This hyperinsulinemia is the hallmark of type 2 diabetes. These normal appearing, normal body weight, insulin resistant subjects also had to have at least one parent or grandparent with diabetes and one other first-degree relative with diabetes to be further characterized. Fasting rates of liver glucose production were equivalent between these two groups, while the rate of glucose uptake by muscle was greatly diminished in the resistant subjects. Finally, the investigators demonstrated that these normal weight subjects with the high insulin levels had more fat and less ATP (the stored form of energy) in their muscle.

Taken together, this fundamentally means that type 2 diabetes is an inherited defect in muscle energy production. Low rates of fat oxidation permit the accumulation of triglyceride and free fatty acids in muscle, which in turn, leads to a change in the biochemical pathways responsible for normal muscle glucose uptake. Muscle is responsible for roughly 80% of glucose disposal.

Fasting plasma glucose concentration in the morning after awakening is not determined by the final meal the evening before, but instead, it is the result of the difference between how fast glucose is being produced and how fast it is being cleared. The liver is the primary site of glucose production (with a contribution from the kidneys) while skeletal muscle accounts for a large fraction of the glucose disposal (the brain actually accounts for about 60% of systemic glucose production fasting—but this is a constant amount whether we are fasting or eating). Thus, a high glucose concentration is either the result of excessive glucose production from the liver or inadequate glucose clearance by muscle.

The primary regulator of glucose production from the liver is the insulin concentration in the blood coming from the pancreas to the liver. If the primary defect is in muscle glucose uptake, then the body's compensation could be to reduce rates of liver glucose production to match the defect in clearance. Indeed, beta cells sense minor increments in glucose concentrations from inadequate glucose clearance. In turn, insulin secretion is raised to signal the liver to diminish glucose production since the systemic glucose concentration is satisfactory to supply the brain and other critical organs with their preferred energy substrate, glucose.

What the inherited defects in glucose uptake in muscle might be has been the subject of investigations that have spanned decades. Although the exact explanation has not been elucidated, we can summarize some of the key findings. The disposal of glucose into muscle is triggered by insulin binding to the insulin receptor on muscle cell surfaces. Defects in the insulin receptor itself have been found leading to insulin resistance, but this is extraordinarily rare. After insulin binds to its receptor, a chain of enzymatically driven phosporylation steps ultimately

lead to the mobilization of glucose transport protein pools, which wait to be activated as cell's cytosol and mobilized to the cell surface causing glucose to traverse the plasma membrane. Dozens of steps are involved in this "signal transduction" of insulin binding and ultimately result in increased muscle glucose uptake. An inherited defect in any one of the genes responsible for producing these proteins could theoretically lead to exactly the same thing—type 2 diabetes with insulin resistance. Dissection of this complicated chain of chemical events has allowed us to discover some of these defects, but a complete discussion of the investigations in this part of the story is well beyond the scope of this chapter. Suffice it to say that type 2 diabetes is not one disease, but is a family of diseases with a unifying inherited feature of poor glucose uptake by muscle (usually).

Undoubtedly, inherited defects in two other critical organs also will account for part of the origin of type 2 diabetes in humans. First, there are primary beta-cell defects in insulin secretion from what would otherwise look like histologically normal islets. Mutations in the key initial enzyme in catabolizing glucose, hexokinase, in beta cells have been demonstrated in patients with early onset type 2 diabetes, Maturity Diabetes of Youth (MODY). Patients with this disease have high glucose concentrations around age 8–10, are not overweight, generally do not have ketoacidsosis (as is seen in type 1 diabetes in children) and they have a strong family history of early onset diabetes that appears to be autosomal dominant in origin. Since hexokinase traps glucose when it converts it into glucose-6-phosphate, a beta cell deficient in this enzyme cannot "sense" the systemic glucose concentration and therefore does not know when to appropriately release insulin. Other beta-cell defects are being discovered in some kindred of patients with diabetes. Following the above description, it should be clear that primary hepatic defects in excessive glucose production would also be potential causes of diabetes by causing excessive liver glucose production. Defects in hnf-4-alpha, a nuclear transcription activating factor necessary for normal insulin sensitivity have been described as the etiology of type 2 diabetes in people of Finnish descent.

Beyond insulin signaling, beta-cell function and liver glucose production are more metabolic etiologies of this disease that, while rare, also demonstrate how elegantly regulated human glucose concentrations really are. PPAR-gamma is a nuclear transcription activating protein expressed in fat, muscle, liver, and blood vessels. Initially thought to be only involved in regulating genes involved in fat cell differentiation and lipid oxidation, rare subjects with mutations in this protein have now been described and they have diabetes. Interestingly, these subjects have rather mundane clinical presentations (gestational diabetes, typical midlife presentation of diabetes, and one earlier onset diabetes in a woman with polycystic ovarian disease). While PPAR-gamma mutations are unlikely to explain more than a couple percent of the entire problem, activators of this protein, known as thiazolidinediones, have been developed and have demonstrated remarkable antidiabetic effects. Although the complete discussion of all of the physiologic results of activating this protein is also beyond the scope of this chapter, one gene regulated by this pathway merits its description. Adiponectin is a protein produced from fat cells that has a multitude of metabolic functions after it is released into the circulation (Phillips, 2003). One of these functions is to increase fatty acid oxidation in muscle. Recalling that one of the fundamental underlying defects that antedates the development of frank hyperglycemia is the accumulation of triglyceride in muscle, one could imagine that adiponectin deficiency or subnormal activity would result in muscle fat accumulation and consequently impaired glucose transport (as described above). Mutations in the adiponectin gene have been documented to be associated with insulin resistance, but again, this is observed in perhaps

only 4% of the patients with type 2 diabetes. A probable major action of PPAR-gamma activation in fat cells is to activate the adiponectin gene, increasing adiponectin protein production, and elevated adiponectin concentrations turn on fatty acid oxidation, which should lead to a normalization of muscle glucose uptake.

This mechanism would explain the action of the thiazolidinediones. Clinicians have long sought to explain why increased body fat mass would lead to insulin resistance. As fat mass increases, adiponectin levels fall, which could contribute to reduced glucose uptake by muscle. Interestingly, as fat mass falls, adiponectin levels rise, which would explain part of the improvement in diabetes control associated with weight loss.

No discussion on the origin of type 2 diabetes would be complete without a discussion of why a sedentary lifestyle, independent of weight gain, might contribute to the development of type 2 diabetes. The Diabetes Prevention Program (DPP) included a limb of intensified lifestyle modification that not only included improved nutrition (reduced calories) but also increased energy expenditure (DPP, 2002). Muscle uses glucose as its fuel, and when muscle contracts, glucose uptake increases. This is not only a local effect, but also a systemic one. Exercise in one arm increases glucose uptake in the contralateral arm.

In association with weight loss, exercise in the DPP produced a nearly 60% prevention of diabetes compared to nonexercised control subjects with impaired glucose tolerance over a 4-year time span. Due to this very potent effect on the prevention of type 2 diabetes, strategies of how to incorporate exercise as a routine part of every day in every person at risk is essential. The use of the diabetes medication Metformin at 850 mg twice daily was only sufficient to prevent about 26% of the conversion rate.

Preliminary reports on the use of Troglitazone, the first thiazolidinedione, used in the DPP in 585 patients before it was withdrawn from the market appeared to prevent 75% of the conversion to type 2 diabetes out of the high-risk population at one year after discontinuing the drug. This effect was unfortunately entirely lost by the end of the 4-year study. Along this same line of thinking, women with histories of gestational diabetes have been treated with Troglitazone and demonstrated to have a 56% reduction in the subsequent conversion to type 2 diabetes in the postpartum period compared to placebo treated women (Buchanan *et al*., 2002). Since 75% of women with a history of gestational diabetes later develop type 2 diabetes in their adult lives, this is an amazing finding.

In summary, the origin of type 2 diabetes is multidimensional. Certainly inherited defects in muscle glucose production are responsible for a large number of the cases. However, this defect is not sufficient to cause the disease. A secondary defect in beta-cell function in the islet must occur to reduce the compensatory hyperinsulinemia that masks insulin resistance for years. In this sense, diabetes is a two-step disease: one in muscle, one in the islet. Primary beta-cell defects can lead to type 2 diabetes in youth, while primary hepatic mutations that lead to reduced liver insulin sensitivity can cause diabetes in some populations. Undoubtedly, there will be many other defects discovered that enhance the likelihood that one will develop insulin resistance and be predisposed to diabetes.

STANDARDS OF CARE FOR BOTH FORMS OF DIABETES

The ADA has developed a comprehensive list of standards of care for the patient with diabetes. The recommendations encompass risk-reducing strategies that work for either form of the disease—so there is no need to remember that a risk factor is unique to only type 1 versus type 2. Since hyperglycemia is the defining value for diabetes, targets for metabolic control are the focus for both disease processes.

All of this care should be conducted during routine quarterly visits to the primary care provider. Given the number of organ systems involved in the average patient, less frequent visits are likely to lead to suboptimal management.

Quarterly HbA1c. HbA1c is worthwhile being measured at quarterly intervals given the entire red cell mass turns over in that period of time. The ADA recommends an HbA1c value of less than 7.0% (the American Association of Clinical Endocrinologists recommends less than 6.5%). In order to achieve this target, fasting glucose concentrations should be near 110 mg/dl, 2-hour postprandial values should be less than 160 mg/dl, and bedtime glucose concentrations less than 120 mg/dl. Naturally, every patient is unique and these targets must be tailored to that person's individual needs and limitations. Patients with gastroparesis for instance have greater difficulty making the 2-hour postprandial glucose less than 160, and those patients with hypoglycemia unawareness perhaps need a slightly higher glucose prior to going to sleep in order to minimize nocturnal hypoglycemia.

Quarterly blood pressure. Since most of the complications of diabetes are vascular in origin, other parameters are also relevant. Blood pressure is a major contributor to both micro- and macrovascular complications. The target value is less than 120/80. The preferred first line agent in type 1 diabetes is an angiotensin converting enzyme inhibitor, and either an ACE or an angiotensin-II receptor blocking agent (particularly in the setting of microalbumenuria).

Lipids. Cholesterol values are also aggressively managed since diabetes is a cornonary disease risk equivalent. Thus, LDL values should be treated to less than 100 mg/dl and many would say to near 70 mg/dl. Desirable HDL values are greater than 45 in men and 50 mg/dl in women. Triglycerides, commonly elevated as part of the metabolic syndrome in type 2 diabetes, should be treated to less than 150 mg/dl.

Annual physical exam. Because physical exam findings of early complications trigger additional preventive management.

Annual retinopathy. Each patient should have an annual eye exam. Patients with type 2 diabetes may be followed at slightly longer intervals given that retinopathy does not seem to be as common.

Annual microalbumin. Every patient should have urine for microalbumin tested annually since finding it leads to institution of ACE inhibitor therapy even if the patient is not hypertensive due to the renal protective effects of the compounds (see Chapter 16 for more information).

Because all medications have side effects, monitoring pathways for drug clearance are important, especially for Metformin, which is partially cleared through the kidneys. Thus, creatinine of greater than 1.4 mg/dl (or a glomerular filtration rate less than 60 ml/min) should preclude use of Metformin since 20% of its clearance is through the kidneys and its accumulation leads to lactic acidosis.

Annual foot exam. Each patient should have their feet examined annually, and a microfilament test done on the sole of each foot to assess intactness of sensation (see Chapter 12 for more information).

Only about 4,000 board certified endocrinologists practice in the United States and there are estimated to be over 19 million people with either type 1 or type 2 diabetes. Certainly, the average type 1 diabetes patient will benefit from interaction with an endocrinologist and a team of certified diabetes educators. Complicated type 2 diabetes cases are also appropriate for endocrine consult, but the basics of care must be under the direction of well-educated primary providers just based on the shear volume of cases. Certified diabetes educators are another resource that can provide extraordinary help in patient management.

For online reference to current standards of care, please refer to the ADA Web site: http://care.diabetesjournals.org/cgi/content/full/27/suppl_1/s15.

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6

Medication Management

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OVERVIEW OF DIABETES MEDICATION MANAGEMENT

This chapter will review the current options and trends in the pharmacologic management of type 1 and type 2 diabetes mellitus (DM). The overall treatment goals for both type 1 and type 2 DM is to maintain tight glycemic control while minimizing the risk of hypoglycemia. This chapter will examine different types of insulin, insulin regimens, and insulin delivery systems utilized in the management of type 1 DM patients. In the discussion of type 2 DM, the characteristics of the oral medications available for treatment will be reviewed, as well as treatment strategies and rationale for combination therapies.

MEDICATION MANAGEMENT FOR TYPE 1 DIABETES MELLITUS

Since the discovery of insulin by Banting and Best in 1921, huge strides have been made in the areas of insulin therapy and insulin delivery (Banting *et al.*, 1922). Patients with type 1 DM require the administration of exogenous insulin to support their body's metabolic needs. In type 1 DM studies, such as the Diabetes Control and Complications Trial (DCCT), it has been established that improving glycemic control can prevent or delay microvascular complications. The results in this study were obtained by intensive insulin therapy, multiple daily injections, or an insulin pump with frequent blood glucose monitoring. The greatest side effect experienced by these patients is an increased risk of hypoglycemia (Diabetes Control and Complications Trial Research Group, 1993). Today, new innovations in insulin analogs and insulin delivery systems are being designed to help attain "tight" glycemic control while minimizing the risk of hypoglycemia.

To better understand insulin treatment strategies, it is helpful to understand the body's normal insulin release patterns. The body has two basic types of insulin secretion: first, basal insulin is released from the pancreas during the fasting state, which comprises about 50% of our insulin requirements, the second type of insulin secretion is prandial insulin release. This occurs in normally functioning pancreases in response to the ingestion of food. There are two prandial

TABLE 6.1. Insulin Types

	Characteristics of insulin		
	Onset (h)	**Peak (h)**	**Duration (h)**
Rapid acting			
Insulin aspart (Novolog®)	0.25[a]	1–2	3–5
Insulin lispro (Humalog®)	0.25[a]	0.5–1.5	3–5
Insulin glulisine (Apidra®)	0.25[a]	0.5–1.5	3–5
Short acting			
Regular (Humulin®, Novolin®)	0.5–1.0	2–4	5–8
Intermediate acting			
NPH (Humulin N®, Novolin N®)	1–2	4–12	16–20
Lente (Humulin L®, Novolin L®)	1–2	7–15	18–24
Long acting			
Insulin glargine (Lantus®)	1–2	No peak effect	20–24
Ultralente®	4–6	8–12	36

[a] Onset of action is affected by injection site, exercise, and mixing of insulin.

insulin releases, phase 1 and phase 2. Phase 1 insulin release occurs immediately after the ingestion of food (<10 minutes), whereas phase 2 insulin release is stimulated by phase 1 and occurs about 20–30 minutes after the ingestion of food (Cefalu, 2004). Remembering the body's natural insulin release patterns will help understand the types of insulin and the dosing regimens utilized when managing type 1 DM patients. The premise of insulin administration in type 1 DM patients is an attempt to mimic the body's natural insulin release patterns.

TYPES OF INSULIN

When assessing a patient's insulin regimen, it is helpful to understand the differences among the various types of insulin with regard to onset of action, peak effect, and duration of action. The types of insulin are classified into four categories: rapid-acting, short-acting, intermediate-acting, and long-acting insulin (see Table 6.1).

Rapid-acting insulin (lispro, aspart, and glulisine) and short-acting insulin (regular insulin) are designed to mimic the body's natural insulin release in the response to a meal (prandial). With the introduction of the rapid-acting insulin analogs, short-acting insulin has fallen out of favor due to its longer onset and duration of action in comparison to rapid-acting insulin. Intermediate-acting and long-acting insulins are used to meet the body's basal insulin requirements. Intermediate-acting insulin such as neutral protamine Hagedorn (NPH: Humulin N®, Novolin N®) and insulin lente (Humulin L®, Novolin L®) are usually dosed twice a day to provide 24-hour insulin coverage. However, because these insulins have a peak effect, they do not truly represent a constant "flat" basal insulin release. Long-acting insulins have a 24-hour duration of action and are dosed once daily. Insulin ultralente (Ultralente®) has been the mainstay of long-acting insulins until recently. The introduction of insulin glargine (Lantus®) has provided a new alternative in the group of long-acting insulins, in that it provides a constant blood concentration without a pronounced peak (Reinhart and Panning, 2002).

INSULIN REGIMENS

The ideal insulin regimen would mimic endogenous insulin secretion, both basal and prandial insulin release patterns. Mealtime insulin would be provided as a bolus insulin

dose before the meal and have a duration of action to cover both phase 1 and 2 prandial insulin release patterns. Thus, the ideal premeal insulin would have a fast onset and short duration of action. The ideal basal insulin would be a continuous, predictable 24-hour insulin release.

The most common insulin regimens are twice daily injections, multiple-daily injections, and flexible insulin regimens. Twice daily injections are simple regimens that usually consist of a combination of a rapid-acting or short-acting insulin and intermediate-acting insulin dose in the morning (prebreakfast) and evening (predinner). This type of regimen has been associated with midday hypoglycemia (if lunch is delayed or skipped) and/or nocturnal hypoglycemia. If nocturnal hypoglycemia becomes a reoccurring problem, the intermediate-acting insulin dose can be shifted to bedtime; however, this will increase the number of daily injections to three (Hirsch, 1998). To facilitate twice daily injections, there are several premixed insulin products available (see Table 6.2).

More intensive insulin therapies such as multidaily injections or flexible insulin regimens (also known as basal–bolus insulin therapy) allow more flexibility in lifestyle, but also require more frequent blood glucose monitoring. Multidaily injection regimens comprise a rapid-acting insulin or short-acting insulin dose before meals and an intermediate-acting or long-acting insulin dose at bedtime. Patients learn how to adjust their doses based on previous trends in blood glucose results. This is also known as pattern management. Basal–bolus regimens are more complex and require commitment from the patient and access to a diabetes self-management education program. With this type of regimen the patient determines their premeal rapid-acting or short-acting insulin dose based on their premeal blood glucose levels, the carbohydrate content of their meal (by carbohydrate counting), and other factors that may affect blood glucose levels (exercise, stress, illness, menstrual cycle, etc.). The long-acting basal insulin dose is given usually at bedtime; however, some patients may administer their basal dose in the morning.

TABLE 6.2. Premixed Insulin Products

Product	Mixture components
Humalog® 75/25	75% insulin lispro protamine suspension 25% insulin lispro
Humulin® 70/30	70% human insulin isophane suspension 30% regular human insulin
Humulin® 50/50	50% human insulin isophane suspension 50% regular human insulin
Novolog® 70/30	70% human insulin isophane suspension 30% regular human insulin
Novolin® 70/30	75% insulin aspart protamine suspension 25% insulin aspart

INSULIN DELIVERY

Traditionally, insulin doses have been delivered by subcutaneous injections. There are several devices available such as insulin pens, jet injectors, and insulin pumps that have improved insulin delivery. Advantages of insulin pens include: greater convenience, easily carried, smaller gauge needle for injection, are disposable, and provide accurate dosing via a dial on the pen (Bohannon, 1999).

An alternative to administering insulin with a needle is jet injectors. These devices deliver insulin with a high-pressure stream of insulin into the skin. These devices are more costly; however, they may offer an alternative to patients with severe needle phobias (American Diabetes Association, 2004a).

Continuous subcutaneous insulin infusion (CSII) is a method utilized to implement intensive blood glucose management and can provide improved lifestyle flexibility. CSII or more commonly referred to as "insulin pump" therapy, requires motivation, and a strong commitment from the patient and/or the patient's family. Patients considering insulin pump therapy need to be motivated and

taught how to use the insulin pump, make insulin adjustments, count carbohydrates, and trouble shoot potential problems with the insulin pump. Frequent blood glucose monitoring is required with insulin pump therapy (American Diabetes Association, 2004b).

There are two different types of insulin pumps: external infusion pumps and implantable insulin pumps. External insulin pumps consist of an external infusion pump with an insulin reservoir that delivers a predetermined amount of insulin through flexible tubing with a catheter indwelling that is inserted subcutaneously (Lenhard and Reeves, 2001). The external pump is about the size of a pager, and has a refillable insulin reservoir. Implantable insulin pumps are surgically placed into the subcutaneous tissue of the abdomen. A catheter delivers the insulin to the intraperitoneal cavity. Over time, the body will form a fibrous tissue layer around the pump so it stays in place and does not cause discomfort. The insulin pump contains a reservoir that is refilled by the patient's physician every 1–3 months (Selam, 1999).

INSULIN INNOVATIONS

There has been a considerable amount of research into noninvasive insulin delivery systems. Two of these include intranasal delivery and inhaled insulin delivery. The feasibility of intranasal insulin delivery has been demonstrated; however, poor absorption through the nasal membranes has been a limitation. Several approaches have been tried to improve the absorption through the nasal passages, but an increase in nasal irritations was experienced. This approach to insulin delivery is still in development. The delivery of insulin by inhalation has had greater success and is in the later phases of development. Several studies are underway examining the safety and effectiveness of inhaled insulin (AERx® iDMS) and inhaled insulin Exubera® (Cefalu, 2004; Adis International Limited, 2004). Of all the research into noninvasive insulin delivery, it appears that the pulmonary delivery of insulin will likely be the first new innovation to become available within the next few years.

MEDICATION MANAGEMENT FOR TYPE 2 DIABETES MELLITUS

Type 2 DM is a progressive chronic disease that despite adherence to lifestyle modifications, patients will eventually require pharmacologic intervention to maintain blood glucose goals (United Kingdom Prospective Diabetes Study 24, 1998a). In the past decade, landmark trials have shown that intensive therapy in addition to lifestyle changes will reduce the incidence of microvascular complications (United Kingdom Prospective Study Group, 1998b). To obtain the desired blood glucose levels achieved in these studies, multiple medications with different mechanisms of action were often utilized (Turner *et al.*, 1999). The availability of multiple drug classes with varying modes of action has increased the complexity of type 2 DM medication regimens.

In this section, the medications available for the treatment of type 2 DM will be reviewed. The physiologic actions of the medication groups include: stimulating the release of insulin from the pancreas, decreasing gastrointestinal (GI) absorption of glucose, increasing insulin sensitivity, and decreasing glucose production from the liver. In some cases, patients may require exogenous insulin administration when oral medications no longer maintain adequate blood glucose control. The medication classes that are currently available and their mechanisms of action are described in Table 6.3.

INSULIN SECRETAGOGUES

The group of medications known as the insulin secretagogues includes sulfonylureas (SFU) and meglitinides (Table 6.4). The first class of oral medications approved for the

TABLE 6.3. Characteristics of Type 2 Diabetes Oral Medications

Medication	Generic name	Brand name	Primary mechanism of action
First-generation sulfonylureas	Tolbutamide	Orinase®	Stimulates the release of insulin from pancreatic beta cells
	Tolazamide	Tolinase®	
	Chlorpropamide	Diabinese®	
Second-generation sulfonylureas	Glyburide	DiaBeta®	
		Micronase®	
		Glynase®	
	Glipizide	Glucotrol®	
		Glucotrol XL®	
	Glimepiride	Amaryl®	
Meglitinides	Repaglinide	Prandin®	Stimulates a rapid release of insulin from the pancreas
	Nateglinide	Starlix®	
Biguanide	Metformin	Glucophage®	Decreases blood glucose production from the liver
		Glucophage XR®	
Alpha-glucosidase inhibitors	Acarbose	Precose®	Inhibits the digestion of starches; which results in delayed glucose absorption and lessens postprandial hyperglycemia
	Miglitol	Glyset®	
Thiazolidinediones	Pioglitazone	Actos®	Increases insulin sensitivity in the liver, adipose, and skeletal muscle tissue; results in increased glucose uptake
	Rosiglitazone	Avandia®	

treatment of type 2 DM were introduced in the 1950s, these are known as the first-generation SFUs. The second-generation of SFUs were introduced in the 1980s. These agents are more potent on a milligram per milligram basis and have a longer duration of action, with the exception of chlorpropamide (Table 6.4). The SFUs exert their blood glucose lowering effect by directly stimulating pancreatic beta cells to release insulin. This stimulation of insulin release mobilizes metabolic pathways that affect glucose, protein, and lipid metabolism. This effect can translate into a modest weight gain for patients taking SFUs. Due to the direct effect SFUs have on the pancreas, the most common side effect is hypoglycemia. Additional side effects that patients may experience include dermatologic reactions and GI disturbances such as abdominal pain and flatulence (Rendell, 2004).

The meglitinides, nateglinide (Starlix®), and repaglinide (Prandin®) are also insulin secretagogues. They differ from SFUs in producing a more rapid and shorter insulin response. Because of this, these medications are taken right before a meal, and have a greater effect on postprandial hyperglycemia and lesser effect on overnight fasting hyperglycemia (Owens, 1998). These medications have a lower risk of hypoglycemia, however, it still is a potential side effect especially if the patient skips a meal (Damsbo *et al.*, 1999).

BIGUANIDES

Metformin (Glucophage®, Glucophage XR®) is a biguanide that has been used in many countries since the 1950s, but was not approved for use in the United States until 1995 (DeFronzo, 1999). The primary mechanism of action for metformin is that it decreases hepatic glucose production. To a lesser extent, metformin exerts its blood glucose lowering effect by decreasing glucose absorption from the intestinal tract, and

TABLE 6.4. Dosing Information for the Insulin Secretagogues

Medication	Trade name	Starting dose (mg)	Total daily dose (mg)	Dosage frequency
Tolbutamide	Orinase®	500	3,000	Three times daily
Chlorpropamide	Diabinese®	100	500	Once daily
Tolazamide	Tolinase®	100	1,000	Twice daily
Glyburide	Diabeta®	2.5–5	10–20	Once–twice daily
	Micronase®			
	Glynase®	1.5–3	6–12	Once–twice daily
Glipizide	Glucotrol®	5–10	20–40	Twice daily
	Glucotrol XL®	5	20	Once daily
Glimepiride	Amaryl®	1–2	8	Once daily
Repaglinide	Prandin®	0.5–2	16	Two–three times daily, before meals
Nateglinide	Starlix®	60	120	Two–three times daily, before meals

increasing insulin sensitivity in peripheral tissues (Hundal *et al.*, 2000).

Two advantages of receiving metformin monotherapy are that patients usually do not experience weight gain (some patients may even experience a modest weight loss) and the absence of hypoglycemia as a side effect. This may make metformin an attractive choice when selecting an oral medication for a type 2 DM patient. Another benefit of metformin monotherapy is that it has not been associated with adverse effects on lipid profiles (United Kingdom Prospective Study Group, 1998c). However, metformin is not indicated for all patients. Metformin is primarily eliminated from the body via the kidneys; therefore, it is contraindicated in patients with compromised renal function. This may lead to an accumulation of metformin and place the patient at risk for developing lactic acidosis. Therefore, metformin should not be used in patients with a serum creatinine $\geq$1.4 mg/dl in females and $\geq$1.5 mg/dl in males. Metformin also should be avoided in patients with congestive heart failure requiring drug therapy, liver disease, excessive alcohol use, and recent myocardial infarction. Patients receiving metformin who undergo radiologic studies involving iodinated contrast media should temporarily stop taking metformin and have it withheld for 48 hours. It may be restarted once adequate renal function has been confirmed (DeFronzo, 1999).

When starting metformin, the patient may experience gastrointestinal side effects such as nausea, vomiting, diarrhea, and flatulence. These effects may be minimized by starting with a lower initial dose (see Table 6.5). Other common side effects associated with metformin therapy include headache and abdominal discomfort (Rendell and Kirchain, 2000).

When metformin monotherapy is no longer able to provide adequate blood glucose control, other oral diabetes medications or insulin may be added and used in combination with metformin (Turner and Holman, 1995). Combination therapy with metformin is common, therefore, several combined tablet formulations have been marketed. These products are available in different dosage strengths; the combination products include metformin and glyburide (Glucovance®) and metformin and rosiglitazone (Avandamet®).

ALPHA-GLUCOSIDASE INHIBITORS

There are two medications available in this class, acarbose (Precose®) and miglitol (Glyset®). These agents have a direct effect

TABLE 6.5. Dosing Information for Oral Type 2 Diabetes Medications

Medication	Trade name	Starting dose (mg)	Total daily dose (mg)	Dosage frequency
Metformin	Glucophage®	500	2,000–2,550	Twice daily
	Glucophage XR®	500	2,000	Once daily, with evening meal
Acarbose	Precose®	12.5–25	50–100	Three times daily, before meals
Miglitol	Glyset®	12.5–25	50–100	Three times daily, before meals
Pioglitazone	Actos®	15	30–45	Once daily
Rosiglitazone	Avandia®	4	8	Once or twice daily

on postprandial blood glucose levels by delaying the digestion and absorption of carbohydrates from the intestinal tract (Rendell and Kirchain, 2000). When used as monotherapy, these agents will not cause hypoglycemia. However, when used with insulin or an insulin secretagogue patients may experience a hypoglycemic reaction. This is an important fact to remember when counseling patients on treating low blood glucose reactions. The patient should be instructed to ingest pure glucose (such as glucose tablets) since these agents delay the absorption of carbohydrates (McCormick and Quinn, 2002).

A limitation to the use of these medications is the high frequency of gastrointestinal side effects. Studies have shown that as many as 30–40% of patients taking these medications will experience GI side effects such as flatulence, bloating, cramping, and diarrhea. The GI side effects can be minimized by starting with a low dose and slowly increasing it over time (see Table 6.5). These medications must be present in the small intestine with food; therefore, each dose should be taken at the start of the meal (DeFronzo, 1999; Rendell and Kirchain, 2000). The maximal effectiveness of acarbose and miglitol therapy is seen in patients adhering to a diet consisting of >50% carbohydrates (Feinglos and Bethel, 1999). These medications should not be used in patients with inflammatory bowel disease, elevated serum creatinine (>2.0 mg/dl), or cirrohsis of the liver (DeFronzo, 1999).

THIAZOLIDINEDIONES

The thiazolidinediones (TZDs) include pioglitazone (Actos®) and rosiglitazone (Avandia®), they are often referred to as the "glitazones." These medications are insulin sensitizers, that is, they enhance glucose uptake in skeletal muscle, adipose tissue, and the liver. They also decrease glucose production from the liver. The uniqueness of these medications is their ability to decrease insulin resistance, an important target in the metabolic anomalies of type 2 diabetes (Grossman, 2002).

The unique action of TZDs is also the basis for other metabolic effects they have on the body. A common side effect of TZDs is weight gain due to the increased volume of fat cells (DeFronzo, 1999). The average weight gain reported in studies varies from 1 to 9 lbs; it has been demonstrated that the greatest weight gain occurs when a TZD is used in combination with insulin or an SFU (Grossman, 2002). The effects TZDs have on lipids are variable, data suggest that pioglitazone (Actos®) may have a more desirable effect than rosiglitazone (Avandia®) (Buse *et al.*, 2004). TZDs may have a favorable effect on blood pressure (Rendell, 2004).

When therapy with a TZD is initiated, several things need to be considered. First, the blood glucose lowering effect of a TZD is usually not seen until 2–4 weeks after therapy is initiated, with the maximum effect

at 8–12 weeks. Therefore, it is important to allow enough time to assess the effectiveness the TZD has on the patient's glycemic control. Fluid retention and edema should be monitored when TZD therapy is started, and are not recommended for patients with New York Heart Association (NYHA) class 3 and 4 heart failure (McCormick and Quinn, 2002). Patients with liver dysfunction should not receive TZD therapy, and liver function monitoring is recommended for all patients prior to the initiation of treatment and periodically thereafter. Premenopausal anovulatory women with insulin resistance that start TZD therapy should be informed of the possible resumption of ovulation due to their improved insulin sensitivity. Appropriate methods of contraception should be discussed if needed (Avandia® Product Information, 2004; Actos® Product Information, 2003).

COMBINATION THERAPY

Over time, the ability to maintain adequate blood glucose control with monotherapy diminishes. When this occurs, an additional oral agent or insulin may be added to the patient's regimen (Turner *et al.*, 1999). When deciding what medication to add, the selection is influenced by the patient's current therapy. The second medication or "add-on" therapy is usually an agent with a different physiologic effect. For example, SFU therapy plus an alpha-glucosidase inhibitor is effective; however, the addition of metformin or insulin to SFU therapy provides a greater reduction in blood glucose levels (Calle-Pascual *et al.*, 1995). In addition, when a TZD is added to SFU therapy a significant reduction in blood glucose levels is achieved; however, the patient may experience a significant weight gain. This is also true when insulin therapy is added to SFU therapy (Kipnes *et al.*, 2001). Metformin and insulin therapy effectively reduces blood glucose levels and has a lower incidence of weight gain than insulin and SFU therapy or insulin therapy alone (Furlong *et al.*, 2002). Metformin and TZD therapy augment insulin's action differently and have been found to have a synergistic benefit in lowering blood glucose levels (Fonseca *et al.*, 2000). Finally, an emerging trend is triple oral therapy. Although this has been seen in practice for awhile, more data are becoming available to support the efficacy and safety of triple oral therapy (Bell and Ovalle, 2002).

The use of insulin injections in combination with oral medications is another approach to achieve glycemic control. The addition of an intermediate-acting insulin (NPH insulin or insulin lente) or long-acting insulin (insulin ultralente or insulin glargine) to SFU therapy is an effective option to obtain glycemic control. A common practice is the addition of bedtime insulin to daytime SFU therapy, this is referred to as "BIDS" therapy. The advantage of this combination is lower blood glucose levels in the morning; however, there is a potential increase in nocturnal hypoglycemic reactions with BIDS therapy (Riddle *et al.*, 1989). The introduction of insulin glargine (Lantus®) offers bedtime insulin therapy with less nocturnal hypoglycemia (Yki-Jarvinen *et al*., 2000). Over time, patients with type 2 diabetes may require multiple doses of different types of insulin, both rapid-acting and long-acting, a regimen that more resembles a patient with type 1 DM.

ACCESSING MEDICATIONS

Although there have been great advances in therapeutic options for type 1 and type 2 diabetes, not all patients have had the opportunity to benefit. Two barriers in accessing or obtaining medications are: (1) the large percentage of the population that lacks health insurance, and (2) the skyrocketing costs of prescription medications. There are several foundations and organizations that have resources available to assist patients in obtaining prescription medications. These resources

TABLE 6.6. Patient Assistance Program Resources

www.phrma.org
www.rxassist.org
www.helpingpatients.org
www.needymeds.com

are listed in Table 6.6. To access these programs, paperwork and supporting financial documents may be required. A limited supply (usually 3 months) of medications is usually provided per application.

CONCLUSION

The approach to managing type 1 and type 2 DM varies greatly; however, the overall goal is to attain glucose homeostasis. Patients with type 1 diabetes require exogenous insulin administration whereas, for those with type 2 diabetes oral medications and insulin are utilized. There have been large accomplishments in the area of diabetes treatments, as well as exciting research is underway that will provide knowledge and treatments to improve the quality of care for patients with DM.

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7

Nutrition for Individuals with Diabetes

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Significant advances in the understanding of the pathophysiologies of type 1 and type 2 diabetes mellitus (DM) have been made in the past century, and particularly in the past 30 years. About 10% of people with diabetes have type 1 DM, and about 90% have type 2 DM. These numbers include a small percentage of individuals with latent autoimmune diabetes of adulthood, which has some features of both type 1 and type 2 DM.

In type 1 DM, there is a deficiency of insulin, and the focus of treatment involves use of insulin to control an individual's blood glucose. In type 2 DM, which can be caused by a number of different disorders, patients exhibit insulin resistance, altered insulin secretion, and elevated blood glucose. Prior to developing type 2 DM, an individual has impaired glucose tolerance (also called "prediabetes"), with mildly elevated blood glucose levels and elevated insulin levels. It has been estimated that about 16 million Americans have prediabetes, and somewhere between 1% and 10% of them will go on to develop diabetes every year.

People with diabetes have an increased risk of lipid abnormalities, atherosclerosis, heart attacks, strokes, kidney disease, peripheral neuropathy, and blindness. There is enough evidence that improved glucose control, cholesterol profile, and blood pressure decreases the morbidity and mortality associated with diabetes. In addition, the Diabetes Prevention Program showed that individuals with impaired glucose tolerance who exercised 30 minutes five times per week, who decreased their dietary fat intake to less than 25% of their total caloric intake, and who lost 7% of their initial body weight decreased their risk of developing type 2 DM by 58% compared to study participants who were in the placebo group. This result was better than study participants who were treated with metformin, who had a 31% decreased risk of developing type 2 DM.

In the last 30 years, the prevalence of type 2 DM has tripled. This is due in large part to a dramatic increase in obesity. Obese individuals (those with a Body Mass Index or "BMI" greater than 30) are at a fivefold greater risk to develop type 2 DM than those with a BMI less than 25. Since approximately 80% of people with type 2 DM are overweight, weight loss is a crucial component of treatment. Inherent challenges exist in setting up a diet plan that allows an individual to be

TABLE 7.1. Determining Body Mass Index How to use this chart:
1 Find height (in feet and inches) in the left column
2 Look across the row to find weight (in pounds)
3 Find the number at the top of the column to determine the BMI

BMI	19	20	21	22	23	24	25	26	27	28	29	30	35	40
Height (ft/inches)	Weight (lbs)													
4′ 10″	91	96	100	105	110	115	119	124	129	134	138	143	167	191
4′ 11″	94	99	104	109	114	119	124	128	133	138	143	148	173	198
5′	97	102	107	112	118	123	128	133	138	143	148	153	179	204
5′ 1″	100	106	111	116	122	127	132	137	143	148	153	158	185	211
5′ 2″	104	109	115	120	126	131	136	142	147	153	158	164	191	218
5′ 3″	107	113	118	124	130	135	141	146	152	158	163	169	197	225
5′ 4″	110	116	122	128	134	140	145	151	157	163	169	174	204	232
5′ 5″	114	120	126	132	138	144	150	156	162	168	174	180	210	240
5′ 6″	118	124	130	136	142	148	155	161	167	173	179	186	216	247
5′ 7″	121	127	134	140	146	153	159	166	172	178	185	191	223	255
5′ 8″	125	131	138	144	151	158	164	171	177	184	190	197	230	262
5′ 9″	128	135	142	149	155	162	169	176	182	189	196	203	236	270
5′ 10″	132	139	146	153	160	167	174	181	188	195	202	207	243	278
5′ 11″	136	143	150	157	165	172	179	186	193	200	208	215	250	286
6′	140	147	154	162	169	177	184	191	199	206	213	221	258	294
6′ 1″	144	151	159	166	174	182	189	197	204	212	219	227	265	302
6′ 2″	148	155	163	171	179	186	194	202	210	218	225	233	272	311
6′ 3″	152	160	168	176	184	192	200	208	216	224	232	240	279	319
6′ 4″	156	164	172	180	189	197	205	213	221	230	238	246	287	328

BMI = weight/height^2.
Source: From American Association of Diabetes Educators (2003). Core Curriculum for Diabetes Education, Diabetes Management Therapies, Chicago, IL.

content with food choices, physically comfortable (e.g., not hungry all the time), and which can be maintained over time.

The objective of this chapter is to discuss principles of good nutrition and the importance of exercise in the prevention or control of diabetes.

Using Medical Nutrition Therapy (sometimes referred to as MNT), maintaining an optimal weight, and exercising daily are crucial in the treatment of both type 1 and type 2 DM, and in individuals with impaired glucose tolerance.

Medical Nutrition Therapy is the use of specific nutrition interventions to treat an illness or condition. It involves the provision of individualized nutrition care including assessment, education, goal-setting for lifestyle change, and follow-up evaluation (American Association of Diabetes Educators, 2003).

Optimal weight is easily defined by using the BMI. This is calculated by the formula:

$$\text{BMI} = [\text{weight (lbs)}/\text{height (inches)}^2] \times 703.$$

If you are using the metric system, the formula is:

$$\text{BMI} = \text{weight (kg)}/\text{height (m)}^2.$$

BMI tables are available to simplify identifying an individual's BMI

A BMI less than 25 is currently defined as normal, 25–30 is defined as overweight, and greater than 30 is defined as obese. As greater numbers of Americans, both children and adults, become obese, we are seeing increasing numbers of people with type 2 diabetes—even in children.

Different people have different philosophies about food. "Shall I eat to live? Or

shall I live to eat?" Whether or not diabetes is present, the individual subconsciously chooses to follow one of these paths. Food and eating are essential for existence but must be balanced against energy expenditure if one is to maintain a healthy weight. In Western civilizations, many people have chosen, to their detriment, the second option—"I live to eat." To further complicate matters, modern lifestyles do not require exercise on a regular basis. As a result, there is a growing epidemic of obesity and diabetes, and an associated increased morbidity and mortality for individuals and an increased economic burden on the health care system.

People from different cultures and ethnic backgrounds frequently abandon their traditional diets in favor of the Western diet. For example, the Pima Indians of Arizona incorporated the Western diet and lifestyle with disastrous consequences (Whitney and Rolfes, 1996). Until about 1930, their diet included fish, venison, fruit, legumes, cactus, and seeds. A scarcity of native foods led to their replacement with white flour products, sugar, animal fats (lard and butter), and convenience foods. Traditional exercises (hunting and working in the fields) were replaced with more sedentary activities. The Pima Indians now have the highest per capita rate of diabetes in the world.

The challenge for health care professionals is to reverse the trend toward obesity among our diverse population. Tools for reversing this trend involve Medical Nutrition Therapy (MNT), weight loss (if indicated) to achieve ideal body weight, and regular daily exercise.

Medical Nutrition Therapy for diabetes has undergone dramatic change over the past century (see Table 7.2). Prior to the introduction of insulin therapy in 1921, people with diabetes were subjected to starvation diets.

Before 1994, many patients received generic American Diabetes Association (ADA) meal plans based upon certain kcalorie levels ranging from 1,500 to 2,400 kcalories/day. Treatment strategies have changed and ideally each patient should receive an individual meal plan based on height/weight, BMI, laboratory readings, current nutritional intake, food preferences, lifestyle, and pertinent medications.

TABLE 7.2. Historical Perspective of Nutrition Recommendations

	Distribution of Kcalories (%)		
Year	**Carbohydrate**	**Protein**	**Fat**
Before 1921		Starvation diets	
1921	20	10	70
1950	40	20	40
1971	45	20	35
1986	Up to 60	12–20	<30
1994	[a]	10–20	[a,b]

[a] Amount is based on nutritional assessment and treatment goals.
[b] Less than 10% of kcalories from saturated fats.
Source: American Diabetes Association (1997).

In order to improve diabetes care, the ADA has developed evidence-based nutrition recommendations that are implemented in MNT (American Diabetes Association, 2002a&b). The goals of MNT may be summarized as follows:

1. To achieve and maintain:
   - Normoglycemia,
   - Lipid profiles within normal limits, and
   - Blood pressure levels within normal limits.
2. To prevent and treat complications of diabetes.
3. To improve health with appropriate food choices and physical activity.
4. To address the needs of individuals with sensitivity to cultural/ethnic preferences.

Medical Nutrition Therapy has been shown to improve glycemic control, as demonstrated by improved hemoglobin A_1c. Table 7.3 shows the positive effect on hemoglobin A_1c (HbA_1c) levels of patients who received MNT.

Studies demonstrate that a registered dietitian (RD) is best qualified to provide MNT. Although an RD is the ideal provider for

TABLE 7.3. Effect of MNT on HbA_1c (Franz *et al*., 1995; Kulkarni *et al*., 1998; UKPDS Group, 1990)

Type 1 newly diagnosed	Type 2 newly diagnosed	Type 2 of 4 years duration
1% decrease HbA_1c	2% decrease HbA_1c	1% decrease HbA_1c

nutrition counseling, it is essential that all health care professionals understand and support the vital role of MNT in the treatment of the patient with diabetes.

CURRENT ADA RECOMMENDATIONS FOR MACRONUTRIENTS (Whitney and Rolfes, 1996)

Macronutrients may be defined as those elements required in the greatest amounts for normal physiologic body processes. These include carbohydrate, fat, protein, and water. In contrast, micronutrients are those elements required in small amounts for normal body processes and include vitamins, minerals, and trace elements.

Carbohydrates

The term carbohydrates is derived from carbo (carbon) and hydrate (with water). Carbohydrates provide the energy (fuel) required to perform our daily activities. The brain needs glucose to function optimally, and muscles need glycogen. Under starvation conditions, the brain can utilize ketone bodies that are breakdown products of fatty acids, but ketone bodies are a less efficient energy source. Under these circumstances, individuals often complain of feeling groggy and having headaches.

Therefore, carbohydrates are an essential component of a well-balanced diet in all individuals, whether or not diabetes is present. Recommended carbohydrate sources include: whole grain products, fruits, vegetables, and low-fat milk products.

Fiber

Fiber intake by people with diabetes is encouraged in the same amounts as recommended for the general population. The Institute of Medicine (IOM) Dietary Recommended Intakes (DRI) for daily fiber intake is 25 g for females less than 50 years old, 21 g for older females, 38 g for males less than 50 years, and 30 g for older males. Fiber requirements also decrease with reduced food consumption.

Information regarding the fiber content of various foods may be found in reference materials (Bowes *et al*., 1998) and on food labels. Individuals who consume adequate quantities of fruit, vegetables, and whole grains on a daily basis can easily incorporate sufficient fiber into their daily menus.

Nutritive Sweeteners

Nutritive sweeteners (sucrose, fructose, sugar alcohols, and nonnutritive sweeteners) have been the subject of debate in the past few years. The current recommendations follow.

Sucrose (Table Sugar)

In the past, it was thought that sugar (e.g., jelly, candy) was digested and absorbed more rapidly than starch (e.g., bread, potatoes). Scientific evidence has disproved the widespread belief that sucrose causes rapid and dramatic blood glucose elevations. Therefore, sugar-containing foods may be incorporated into the meal plan, but may not be taken in addition to the total carbohydrate allowance! Preference should be given to carbohydrates that provide essential nutrients such as whole grain bread and a variety of vegetables. In general, since jelly and candy provide empty kcalories only, they should not be eaten on a regular basis.

Fructose

Fructose, the sugar found in fruits, is metabolized by a different pathway than starch or sucrose and is absorbed more slowly. Therefore, it does not cause a rapid increase in blood glucose levels. It is a potentially useful sweetener for individuals with diabetes. However, if consumed in large amounts, fructose can be associated with dyslipidemia.

Studies have demonstrated that in the U.S. population, approximately 33% of dietary fructose is obtained from natural sources including fruits and vegetables. The remaining 67% comes from food and beverages in which fructose is frequently listed on the food label as "high fructose corn syrup." The latter contributes empty kcalories that exacerbate the obesity epidemic and dyslipidemia.

Empty kcalories do not provide essential nutrients; they only provide energy. Individual daily kcaloric requirements are not as large as we would like to assume. One, therefore, must concentrate his/her essential nutrient intake in the daily allotted kcalories. In order to consume adequate essential nutrients, an individual needs to use his/her kcaloric allotment judiciously. Intake of foods containing empty kcalories should therefore be minimized. Foods containing empty kcalories have the predominant function of making people overweight.

The practical approach is to encourage moderate consumption of fruit, while discouraging foods and beverages with added fructose.

Sugar Alcohols (Polyols)

These compounds are closely related to carbohydrates. Hydrogenated starch hydrolysate, sorbitol, mannitol are included in this category. They are listed on the food labels of sugar-free products and frequently have the "-ol" suffix (e.g., maltitol). Used as sweeteners, they produce a lower glycemic response than sucrose or glucose. Since they are only partially absorbed from the small intestine, they are lower in kcalories than sucrose, fructose, or glucose. They have 2 kcal/g instead of 4 kcal/g found in carbohydrates. Therefore, a product labeled *sugar free* does not necessarily mean *kcalorie free*. Also, certain sugar alcohols can cause diarrhea if taken in quantities greater than 10 g/day.

Nonnutritive Sweeteners

Certain low-kcalorie sweeteners have been approved as safe for consumption by the FDA. Included in this category are:

- Saccharin (e.g., Sweet and Low),
- Aspartame (e.g., Equal or Nutrasweet),
- Acesulfame K (e.g., Sweet One),
- Sucralose (e.g., Splenda).

These sweeteners provide an acceptable alternative to sugar if consumed in moderation. The FDA has defined an Acceptable Daily Intake, which is the amount that may be taken on a daily basis without risk to overall health (Powers, 1999). Although these sweeteners may be used in moderation, individuals should be encouraged to take food and beverages in their natural form without added sugar or sweeteners.

What is a "Net Carb?"

"Net carbs" is a term seen on food labels. Since the FDA prohibits the use of undefined nutrient claims, manufacturers should not use terms such as "low carb" and have instead started using "Net carb." This term is derived by a manufacturer subtracting sugar alcohols, fiber, and any other carbohydrates that minimally impact blood glucose levels from the food's carbohydrate content. The definition of "Net carb" is imprecise, however, because there is no standard definition for "minimal impact" on blood glucose levels. In addition, the actual impact on blood glucose level may well not have been proven (Bonnie Liebman, MS. Director of Nutrition, *Nutrition Action Health Letter*, March 2004, pp. 8–9).

The Glycemic Index

This concept was first developed in 1981 by Dr. David Jenkins at the University of Toronto in Canada. In their belief that all carbohydrates are *not* equal, Dr. Jenkins and his team tested the effect of many carbohydrate foods on blood glucose levels (Brand-Miller *et al*., 2003).

Studies in the United States, Europe, Canada, and Australia have demonstrated that the glycemic index (GI) may be a valuable tool in the nutrition therapy of the individual with diabetes. Since low-GI foods cause a less pronounced rise in blood sugar, they may be less insulinogenic than high-GI foods. This effect may decrease some of the stress placed on the pancreas to produce insulin, and thereby decrease the rate at which individuals with insulin resistance progress to type 2 DM. Since insulin plays a role in storing fat, lower postprandial insulin levels may help decrease the tendency toward weight gain and subsequent development of further insulin resistance. In addition, lower GI foods seem to result in greater satiety than higher GI foods. Consumption of lower GI foods may, therefore, decrease the urge to overeat. As of January 2005, the use of the glycemic index is recommended by the ADA as well as The Harvard School of Public Health and Boston Children's Hospital.

The glycemic index is the classification of foods based on their effect upon blood glucose levels. Glucose, having a strong impact on these levels, is used as a standard and has the value set at 100 on this scale. Other foods are then classified on a scale of 0–100 or more, depending on their effect on blood glucose levels.

Using standardized procedures, hundreds of foods have been tested and classified. Carbohydrates that are broken down rapidly and have an immediate impact upon blood glucose are termed high-GI foods, whereas those foods that are gradually broken down and do not immediately impact blood glucose levels are termed low-GI foods. The categories (and values) used to define the different glycemic indices are high (70 or more), intermediate (56 to 69) and low (55 or less).

It is reasonable for individuals with diabetes to substitute some low-GI foods for high-GI foods in their daily menus. The most practical way to use the glycemic index is to encourage use of low-GI foods within the prescribed meal plan. For instance, one could substitute whole grain, pumpernickel, or sourdough bread for white bread made from enriched wheat flour. Another example would be substituting All Bran cereal or Oatmeal for a higher glycemic cereal such as Corn Flakes. For more information about glycemic indices of foods that have been tested in this way, please refer to *The Glucose Revolution Life Plan* by Brand-Miller *et al*. (2001).

Perhaps even more helpful than the glycemic index is the concept of glycemic load, which incorporates both the quantity of carbohydrate in a meal as well as its glycemic index. The glycemic load may be calculated by multiplying the glycemic index percentage by grams of carbohydrate. Care must be taken when considering these concepts. A high glycemic index does not necessarily equate to a high glycemic load. If we consider a low-GI food, such as chick peas, one notes that a serving size of chick peas (150 g or 1 cup) contains 30 g of carbohydrate and has a glycemic index of 28. The glycemic load for 1 cup of chick peas is, therefore, $30 \times 0.28 = 8.4$. Similarly, a high-GI food such as potatoes has a standard serving size of 150 g (1 cup) and contains 30 g of carbohydrates. It has a glycemic index of 85, and the glycemic load for a serving of potatoes is 30×0.85 or 25.5, which is quite high. The complication in these concepts occurs with foods such as popcorn, which has a high glycemic index, but does not contain many grams of carbohydrates. Popcorn has a glycemic index of 72, and an individual might therefore think popcorn should be avoided. That is not the case, however, since a standard serving size of two cups contains only 11 g of

carbohydrate. Therefore, the glycemic load of a standard serving of popcorn is 7.92, which is quite low. One can readily see, then, that even though popcorn has a high glycemic index, a standard serving has a low glycemic load. When considering use of the glycemic index, one should also make a point of calculating the glycemic load.

Another consideration is that milk and milk products (yogurt, ice cream) have a low glycemic index when consumed without additional sugar. They are, however, fairly insulinogenic; the significance of this property in an individual with prediabetes is currently unclear.

Protein

People frequently associate protein with meat and muscle strength, and overestimate the quantity required in an individual's diet. Not only is protein essential for muscle, it is required for structural integrity and function of all cells. In addition to meat, there are many sources of protein (see Table 7.4).

Most adults eat considerably more than the Recommended Daily Allowance (RDA) for protein. While the usual daily protein intake is about 1.0 g protein per kg of body weight, the RDA for protein is about 0.8 g/kg of body weight. This means that a typical 70 kg individual would consume approximately 70 g of protein per day, contrasted with an RDA of 56 g. In individuals with poorly controlled diabetes, the protein requirement may be slightly higher than those with optimal diabetic control. In patients with impaired renal function, the protein requirement is generally reduced to try to prevent further loss of renal function.

A well-balanced meal plan with appropriate numbers of servings from each food group will ensure optimum protein intake. Portion size is the key to attaining and maintaining an optimum daily protein intake.

Type of Protein

Certain types of poultry and meats are recommended over others because of their content of total fat and saturated fat. Table 7.4 illustrates preferred and not preferred protein sources.

Fat

Controversy and confusion surround the issue of dietary fat intake. It is well documented that in individuals with diabetes, there is a two to four times greater risk of

TABLE 7.4. Preferred and Not Preferred Protein Sources

	Preferred	Not Preferred
Poultry	Skinless chicken or turkey breast	Duck, goose
Fish	All types; the best choices have more omega-3 fatty acids: Salmon, tuna, mackerel and sardines	–
Meat	Beef: eye of round, very lean ground beef. Pork: tenderloin, very lean ground pork	Prime rib, spare ribs, sausages, bologna
Cheese	Low fat cottage cheese Part skim mozzarella	All regular cheese, including cheddar. Soft cheese, e.g., Brie
Eggs	Egg white, egg substitute	Egg yolks
Peanut butter	In 100% natural form	Those processed with partially hydrogenated oil; those containing high fructose corn syrup
Soy products, tofu	All types are good protein sources. Check the food labels for carbohydrate content.	–

TABLE 7.5. Effects of Various Types of Fat on Lipid Profile

	Total cholesterol	High-density lipoprotein	Low-density lipoprotein	Triglyceride
Monounsaturated fats	↓	↑	↓	↓
N-6 (omega-6) polyunsaturated fats	?	?	?	–
N-3 (omega-3) polyunsaturated fats	?	–	↑	↓
Saturated fats	↑	–	↑	–
Transunsaturated fats	↑	↓	↑	–

developing Coronary Artery Disease (CAD) than that seen in the general population. These individuals have a risk profile comparable to that seen in individuals who have already sustained a myocardial infarction. Because dyslipidemia is a risk for CAD, in people with diabetes the recommendations for optimal lipid profiles are more stringent than in the general population.

The lipid profile comprises total cholesterol, high-density lipoprotein (HDL or "good cholesterol"), low-density lipoprotein (LDL or "bad cholesterol"), and triglycerides (TG). High-density lipoproteins carry fatty acids from the arteries to the liver, and appear to protect the arteries and promote plaque removal. Low-density lipoproteins promote the accumulation of plaque in arteries.

There are different kinds of fats: monounsaturated, polyunsaturated, saturated fats, and transunsaturated fats. See Table 7.6 for examples of fats in these different categories.

Ingestion of monounsaturated and polyunsaturated fats (especially omega-3 polyunsaturated fats) tend to improve the lipid profile. Since saturated fat has a major unfavorable impact on LDL levels, the primary goals of MNT are to reduce saturated fat and modify cholesterol intake (cholesterol is only found in animal products, including meat, cheese, and egg yolks).

Transunsaturated fats (or "trans fats") also unfavorably impact the lipid profile, raising the LDL and lowering the HDL levels. Trans fats occur naturally in meats and dairy products. They are also formed during the hydrogenation of vegetable oils, and therefore occur in fried foods, margarine, and spreads. Intake of trans fats should be minimized.

Table 7.5 (American Diabetes Association, 2002a&b) summarizes the effect of different fat sources upon lipid profiles.

As you can see, not all fats are equal! The types of fats that predominate in different foods are listed in Table 7.6 (Bowes *et al*., 1998; Brand-Miller *et al*., 2001).

An individual's total fat intake should not exceed 30% of total kcalories. Strategies to decrease fat intake include:

- choosing lean cuts of meat,
- using low-fat dairy products,
- using low-fat soft margarines and spreads, and
- using less fat in food preparation.

Water

Water is an essential nutrient critical for life, involved in all body processes (Whitney and Rolfes, 1996). Water comprises between 50% and 75% of the body weight. Without water, an individual can survive only for a few days. Water needs vary depending upon age, climate, and activity. Additional water will be required in hot, dry weather conditions, or during intense physical exertion. Intake recommendations are also based upon energy expenditure, e.g., an individual who expends 2,000 kcal per day needs about 2–3 liters (seven to eleven 8-oz cups) of water each day. When an individual has a water deficit, the first symptom usually noted is thirst. A recent report from the Institute of Medicine noted that the vast majority of healthy people adequately meet their daily hydration requirements

TABLE 7.6. Types of Fats that Predominate in Different Foods

Source	Monounsaturated ☺	Polyunsaturated N-6 😐	Polyunsaturated N-3/Omega 3 ☺	Saturated ☹	Trans unsaturated ☹
Fats/oils	Olive oil, canola oil, peanut oil	Corn oil, safflower oil, sunflower oil, soybean oil	Flaxseed oil, canola oil	Lard or shortening, butter, cream, sour cream, cream cheese	Hard/stick margarines, partially hydrogenated vegetable oils
Other foods	Peanuts, almonds, cashews, peanut butter, avocado, olives	Walnuts, margarine, mayonnaise	Flaxseed, salmon, mackerel, tuna, rainbow trout, sardines	Fatty meat, coconut, bacon, chitterlings, sausages	Processed baked goods, deep fried foods, crackers/snacks containing partially hydrogenated oil

by letting thirst be their guide (Institute of Medicine, 2004). A good rule of thumb is to drink enough water to keep one's urine clear. This is particularly true in dry environments.

The best source of water is water itself, but foods such as fruits and vegetables contribute a significant amount of fluid to the daily intake. Because caffeine and alcohol cause fluid loss, beverages not recommended as fluid sources include tea, coffee, soda, and alcoholic beverages.

All individuals, including people with diabetes should be encouraged to drink adequate amounts of water every day to prevent dehydration. Elderly people, who have reduced thirst sensation, are at increased risk of dehydration and should especially be encouraged to drink fluids in adequate quantities.

In keeping with achieving the goal of weight loss, overweight individuals may find that the habit of drinking one or two glasses of water prior to a meal promotes a feeling of satiety and may help to decrease the consumption of excess kcalories.

Micronutrients

Consumption of adequate vitamins, minerals, and trace elements is crucial for the health and well-being of all individuals. Micronutrient recommendations are similar for individuals with or without diabetes (American Diabetes Association, 2002a&b). However, deficiencies may occur in those with uncontrolled diabetes due to altered metabolic processes.

The Institute of Medicine Food and Nutrition Board has established four estimates of Dietary Reference Intake (DRI) to determine the amount of micronutrients required by an individual on a daily basis (Institute of Medicine, 2002):

- Estimated average requirement (EAR).
- Recommended dietary allowance (RDA).
- Adequate intake (AI).
- Tolerable upper limit (UL).

For our purposes, the RDA is most helpful, and is defined as the amount of a micronutrient required to meet the needs of 97–98% of healthy individuals. There is currently no evidence to support the view that consumption of vitamin and mineral supplements is beneficial, unless there is an underlying micronutrient deficiency, with the following exceptions:

- Folate supplements must be taken before and during pregnancy to prevent birth defects in the infant.
- Calcium and Vitamin D supplements are recommended for older adults in order to prevent bone disease.

Having said that, we acknowledge that in this fast-paced age, many people do not consume a well-balanced diet. This is particularly true for the elderly, for pregnant or lactating women, for strict vegetarians, and for those following very low-kcalorie regimens. This also is true for individuals following very low carb diets. In these cases, it is prudent to suggest a daily multivitamin supplement, which provides no more and no less than 100% of the RDA. Generic pharmacy brands are quite acceptable.

The use of megadoses of vitamins and minerals must be strongly discouraged. Individuals should be warned about the potential toxic effects of megadosing.

Herbal Preparations

Studies on certain herbal preparations, such as ginseng, have shown positive effects on glycemia in the short term. However, there is no evidence of long-term benefit with use of herbal supplements. More importantly in 1994, The Dietary Supplement Health and Education Act (DSHEA) mandated that dietary supplements would be regulated like foods instead of drugs and are not required to be tested unless proved to be unsafe. The FDA can remove them if there is proof that they are unsafe but does not otherwise monitor or regulate them prior to marketing, as it does with the prescription drugs. Consequently, the concentration of active ingredients can vary greatly from brand to brand. Because processing methods are not standardized, unwanted and potentially dangerous contaminants can sometimes be found in these products. Misidentification of the plants can occur, some herbal products can have unexpected side effects. For instance, ginseng usage may be associated with bruising. Lastly, interactions between herbal and other medications can be potentially dangerous. Therefore, health care providers need to carefully ask their patients appropriate questions about all their medications and supplements.

Sodium

Studies have shown that limiting sodium intake (total 2,400 mg/day) and decreased body weight (in obese individuals) both improve blood pressure levels, though few studies have been performed specifically upon persons with diabetes. To reduce sodium intake, one should:

- avoid processed, canned, or preserved foods,
- use minimal salt in food preparation,
- use herbs, spices, lemon juice, lime juice, or vinegar (instead of salt) to add flavor, and
- use minimal salad dressings, salted chips, nuts, bacon bits.

The recommended sodium intake is 2,400 mg/day. For reference purposes, one teaspoon of table salt is equal to 2,300 mg.

ALCOHOL (ETHYL ALCOHOL OR ETHANOL)

Alcohol has been consumed by mankind for over 5,000 years (Whitney and Rolfes, 1996). Moderation is the key!

For individuals with diabetes, there are certain points to remember:

- Alcohol blocks glucose production by the liver and may induce hypoglycemia ☹
- Alcohol may adversely affect the action of medications ☹
- Excess alcohol use may cause malabsorption, altered nutrient metabolism, and malnutrition ☹
- Excess alcohol use may cause hypertension ☹
- Alcohol may be used *in moderation* with doctor's permission ☺
- Alcohol use *in moderation* may induce improved insulin sensitivity ☺
- Alcohol use *in moderation* may reduce the risk of CAD ☺

Moderate alcohol consumption is defined as one drink per day for an adult woman

and two drinks per day for an adult man. One drink per day is not the same as seven drinks on the weekend. The definition of one drink is: 12 oz beer *or* 5 oz glass wine *or* $1\frac{1}{2}$ oz spirits.

The response of a person with diabetes to alcohol is unpredictable; alcohol consumption can result in hypoglycemia, normoglycemia, or hyperglycemia. Because of the hypoglycemia risk, if alcohol is to be ingested, it should accompany a meal and the individual should consider checking blood glucose after the meal.

One should remember that, like fat, alcohol has a high kcaloric content. One gram of alcohol provides 7 kcal compared to 1 g of fat, which provides 9 kcal. Kcalories from alcohol do not provide nutrients, and therefore provide empty kcalories.

Importance of Weight Loss

We face an amazing paradox in the United States in that there is a high value placed on appearing slender and fit, yet at the same time, increasing numbers of our population are overweight or obese. People turn to diets popularized in the media for guidance—and what an array of different opinions they receive! "Cut out all carbs!" "You may be addicted to sugar . . . even if you don't know it!" "Cut out all fat (a view that is now somewhat passé)." "Get into the Zone." "Follow the New Revolution." Some of these diets have some basis in fact; others appear to include a fair bit of wishful thinking. Only the Mediterranean diet and the diet and lifestyle approach documented in *The Okinawa Program* (Wilcox *et al*., 2001) have any long-term results to back up their promises.

Use of low carbohydrate diets, less than 60 g/day (Bravata *et al.*, 2003) has become popular in the nutrition management of individuals with diabetes. Strict adherence to these diets induces an initial rapid weight loss followed by sustained weight loss at a faster rate than that seen with simple kcalorie restriction. The initial weight loss is largely attributed to fluid losses associated with glycogen storage depletion. Another hypothesis is that weight loss is related to lower insulin levels secondary to decreased carbohydrate intake.

After glycogen stores in the liver and muscles are depleted, an individual develops ketosis and consequent loss of appetite. Protein intake may also help with the increased satiety that is reported on this diet.

Because low-carbohydrate, high-protein diets can increase work for the kidneys, decreased renal function, which is a common condition in people with diabetes, is a contraindication to this type of diet.

In a year-long study (Foster et al., 2003) involving weight loss, which compared the use of a high protein/low-carbohydrate diet with simply decreasing total daily kcalories, individuals in the high protein/low carbohydrate diet group lost more weight initially. However, after one year there was little difference between the amount of weight lost by members of the two groups.

Since the introduction of low-carbohydrate diets, there has been concern that the ketotic state generated could predispose people with diabetes to diabetic ketoacidosis. Until these questions are answered, such regimens must not be used by those individuals with type 1 or Gestational Diabetes. Other concerns are that these regimens are unbalanced and can lead to nutritional deficiencies and constipation. Lastly, high-protein diets appear to be associated with increased calcium excretion and the concern about risk of developing osteopenia exists.

While searching for sound dietary advice, patients often question their physicians, who are commonly so busy with their practices that they unfortunately have little time to read and evaluate the latest trends in diet books, and therefore are unable to provide answers. To address this dilemma, we have reviewed a number of the diet books currently available, and present our analysis in

Table 7.7. Although an individual's diet is best tailored to that individual, we found that some of the books may be quite helpful in providing general concepts and some facts consistent with what is currently understood to be nutritionally and physiologically correct. We also found that with any book that makes unrealistic claims, that unnecessarily redefines nutritional terms (e.g., uses phrases like, "what I like to call _____," etc), and/or is written in a bombastic tone, one is well advised to proceed with caution. This also holds true for books containing many testimonials and little scientific documentation.

Understanding *why* an individual overeats can be very helpful in assisting the necessary lifestyle changes. Does she eat because she is hungry? Or is she bored? Anxious? Lonely? Is it a compulsion? Does he drink 3 or 4 beers daily because he is thirsty and just likes the flavor? Or is he self-medicating? Or is he an alcoholic? Does he eat way too fast and stuff himself before his body has a chance to tell him that he is full? Or does he just *really like* all those flavors and simply cannot stop eating? Does she limit her kcalories all day, and by midevening find herself so famished that she snarfs down everything in sight? The reasons an individual overeats are as multifactorial and varied as the individual. Understanding an individual's relationship with food is crucial in helping him or her to successfully make long-term changes in his or her approach to food. Psychologic counseling would best address these self-destructive behaviors. A number of diet/self-help books also address these issues, for instance, *Dr. Kushner's Personality Type Diet* (Kushner and Kushner, 2003) and *Dr. Phil's Ultimate Weight Loss Solution* (McGraw, 2003).

Exercise

No weight loss/weight maintenance program is complete without an exercise program, which needs to be incorporated into an individual's long-term lifestyle. Lack of exercise is a risk factor comparable to having an unfavorable cholesterol profile or smoking cigarettes. It is crucial that everyone incorporates exercise into his or her daily routine. It does not have to be difficult, and can be accomplished simply by taking a brisk 30-minute walk daily. But it must become a part of an individual's lifestyle.

One of the cruel facts of life is that muscle has a higher metabolic rate than fat. Therefore, when an individual's ratio of muscle to fat decreases, so does the metabolic rate. If a person loses weight and loses more muscle than fat, his/her metabolic rate will decrease. Resumption of eating his/her prior diet will therefore boomerang his/her weight to a higher level than it was prior to attempting weight loss.

ESSENTIALS OF DIET PLANNING: ESTIMATING KCALORIC NEEDS

Factors to take into account for diet planning include age, gender, BMI, family history, medications, physical activity, laboratory profile, current nutritional intake, and readiness to change.

Kcaloric needs for *weight maintenance* can be roughly estimated using Table 7.8.

Since 1 lb of body fat is equal to 3,500 kcal (Whitney and Rolfes, 1996), overweight or obese individuals who require kcalorie reduction typically need to decrease total kcalories by 250–500 per day. For example, an obese individual who is 62 inches (5′ 2″) tall and weighs 190 lb has a BMI of 35. To maintain this weight, the individual is very likely eating 1,900 kcal/day (190 lbs × 10 kcal/lb = 1,900 kcal). To lose one half to one pound per week, this person needs to reduce the kcaloric intake by 250–500 kcal/day, and will be recommended a kcaloric range of 1,400–1,650 kcalories/day.

TABLE 7.7. Comparison of Popular Diets

Diet	Basic premise	Strengths	Weaknesses	Suitable for long-term use?	Overall assessment for people with diabetes
The Carbohydrate Addicts Diet	Postulates that eating most of one's starchy carbohydrates at one meal lasting less than 1 hour keeps insulin levels low and promotes weight loss. With this diet, one eats a variant of the formula: 1 or 2 "complementary meals" and 1 "reward meal" per day. No snacks are allowed. A "complementary meal" has 3–4 oz of meat, fish or fowl or 2 oz of cheese, and 2 cups of vegetables or salad. A "reward meal" is "whatever you desire, in whatever quantity you wish," but one must complete that meal in 1 hour.	None are apparent.	Not a balanced diet. Does not distinguish between the different kinds of carbohydrates or fats in one's diet.	No.	Not a balanced diet. Not appropriate for people with diabetes.
Dr. Atkins' New Diet Revolution	Postulates that a diet very low in carbohydrates and high in protein and fats causes weight loss (mostly fat). Four phases involved: (1) Induction (most severe carbohydrate restriction) (2) Ongoing weight loss (less restricted carb intake) (3) Premaintenance (more liberalized carb intake) (4) Maintenance (maximally liberalized carb intake, as long as you do not gain weight)	Rapid initial weight loss may keep people motivated.	Induction phase can be boring. People on this diet often do not feel good, as the brain prefers glucose rather than ketones for fuel. On this diet, normal individuals will have a mild metabolic acidosis, which will affect calcium excretion. One cannot eat enough calcium to meet the RDA (without supplementation) in the induction phase. People with diabetes who have renal disease are at risk for diabetic ketoacidosis (DKA). The diet is contraindicated in anyone with renal disease. One cannot	No. Unless one supplements fiber intake, this diet will cause constipation. Because of the metabolic acidosis, potential for osteoporosis exists. Unless one exercises, there will be muscle loss along with fat loss and if one resumes eating as before, one will have	Not appropriate for people with diabetes. Absolutely contraindicated in individuals with diabetes where renal disease is present.

(*continued*)

TABLE 7.7. (*Continued*)

Diet	Basic premise	Strengths	Weaknesses	Suitable for long-term use?	Overall assessment for people with diabetes
			ingest adequate micronutrients on the induction phase without supplementation. The diet does not differentiate between the different kinds of fats. Homocysteine is a byproduct of protein metabolism and is implicated in CAD. Because of the high protein intake, homocysteine levels may be elevated with this diet.	subsequent weight gain to a higher level than original baseline. Long-term effects unknown.	
Eating Well for Optimum Health	Eat only foods that are shown to be healthy. Exercise to maintain lean body mass. Recommendations include low-GI carbohydrates, appropriate protein intake, primarily monounsaturated, omega-3 and some omega-6 PUFAs, and lots of fruits and vegetables. Avoid high glycemic index carbs, and saturated and trans fats.	Recommendations appear to be balanced and based on fact.		Yes. It appears to be a reasonable, balanced approach, although no long-term studies are yet available.	He recommends a balanced approach, and supplies factual information. The book appears to be an excellent resource and is easy to read. The recommendations appear well-grounded.
Enter the Zone	Eicosanoids regulate everything important in your body. Eating a strict ratio of carbs to proteins can promote formation of the "good" eicosanoids, which promotes health. Losing weight is not achieved by cutting kcalories, it is achieved by being "In The Zone," eating a strict ratio of 40% carbs, 30% protein, and 30% fat.	He recommends aerobic exercise, 6 hours/week. He recommends low-GI carbohydrates and monounsaturated fats, and avoiding trans and saturated fats.	While he presents a lot of good information, there appears to be some problematic statements such as when he calls arachidonic acid a "villain fat" that you should not eat because it is a "chemical building block for *all* bad eicosanoids." In fact, arachidonic acid is a "building block" for all the eicosanoids that he mentions. This makes one question some of his other conclusions.	Questionable. The ratios of carb, protein, and fat do not follow current recommended ADA dietary guidelines.	Long-term effects are unknown. The diet would be difficult for most people to follow. Without more long-term data, we cannot recommend this diet.

The New Glucose Revolution	This book discusses research that has been done on carbohydrates that shows that some are digested quickly (high glycemic index or "GI") and some are digested slowly (low GI), and states that it is beneficial for humans to incorporate more low-GI carbohydrates into their diets.	Gives a good discussion about the differences in carbohydrates.	This book only provides information about carbohydrates—it does not discuss protein intake or the different types of fat. Also, the concept of glycemic LOAD is more important than glycemic index, and if glycemic load is misunderstood, confusion will arise about the carbohydrate research in this book.	Yes—in as much as one uses it to address his/her carbohydrate intake	Carbohydrates are an important part of an individual's diet. This book is helpful to better understand the carbohydrate portion of one's diet.
Jenny Craig	We were unable to obtain much information about this diet program.				
Dr. Kushner's Personality Type Diet	There are forces in our modern lifestyle that promote weight gain. The book identifies maladaptive patterns regarding eating, exercising, and coping that make it difficult for an individual to lose weight.	The book outlines healthy diet information as well maladaptive eating patterns, and has tools to help the reader identify which of those patterns are most active in his/her life. Suggestions for change and improving those patterns are provided. The importance of exercise is included.	Requires prior knowledge of basic nutrition concepts.	Yes.	This is a well thought-out, reasonable book, which provides appropriate diet information and uses cognitive behavioral therapy to help an individual improve on current behavior patterns, with the goal of weight loss and improved fitness.
The Mediterranean Heart Diet	One should eat plenty of fresh fruits and colorful vegetables, healthy whole grains and legumes, olive oil, yogurt, cheese, a little fish, and at least six 8-oz glasses of water/day and a touch of wine. Small amounts of meat (less than l oz/person) are recommended. Lots of physical activities are recommended, as are portion control,	It involves a whole lifestyle plan. Recommendations appear well thought-out and reasonable.	This book does not differentiate between low-GI and high-GI foods.	Yes.	Population studies of people on the Mediterranean diet have shown improved longevity. The current assessment of the Mediterranean diet is that the whole diet and lifestyle is important, not just using olive oil. Additional input from a registered dietitian would be helpful for individuals with diabetes.

(*continued*)

TABLE 7.7. (*Continued*)

Diet	Basic premise	Strengths	Weaknesses	Suitable for long-term use?	Overall assessment for people with diabetes
	smoking cessation, getting enough sleep and relaxation, and getting regular check-ups.				
Suzanne Somer's Eat Cheat and Melt the Fat Away	"Food combining"—keeping protein and fat intake separate from carbohydrate intake—causes weight loss.	Recommends avoiding processed foods. She seems to recommend some low-GI foods and avoidance of trans fats. However, not infrequently her recommendations are not consistent with accepted scientific research and nutrition science. Also, confusion results from her lack of use of standard nutrition terminology.	Her diet recommendations are not based on currently accepted nutrition science. When she includes discussion of physiology (e.g., what happens in "the burn," it is not based on scientific fact.) Inventing her own diet terminology and "food groupings" makes her dietary explanations and recommendations confusing and dubious.	No.	Some of her recommendations appear sound; others do not appear to have a scientific basis. The lack of use of standard food definitions can cause confusion to the reader: for instance, recommending "real" fats as good, and not distinguishing between monounsaturated, polyunsaturated, saturated, and trans fats. Cannot recommend this diet for people with diabetes.
The New Sugar Busters	Postulates that eating a diet of natural unrefined sugars, whole unprocessed grains, vegetables, fruit, lean meats, and fiber will have a positive effect on insulin and glucagon levels. Recommends 40% carbs, 30% protein, 30% fat.	Recommends exercise. Recommends controlling portion size. Recommends low-GI carbs, monounsaturated fats and omega-3 polyunsaturated fats, and avoidance of trans and saturated fats.	Appears fairly restrictive—some people may have difficulty with the rigidity of the diet over time.	Questionable. The ratios of carb, protein, and fat do not follow current recommended ADA dietary guidelines.	Many of the recommendations appear reasonable. However, additional input for individuals with diabetes from a registered dietitian would be helpful.
The Okinawa Program	By following the traditional diet, exercise and lifestyle of the Okinawan elders, one can lose weight and improve his/her health and longevity. Recommends 7+ servings of vegetables and fruits/day, 7+ servings of whole grains/day, 3 servings of	Recommendations appear to be well-grounded in fact and are well thought-out.	None noted.	Yes. This is one of the few diet books that has long-term evidence that this diet actually promotes health and longevity.	This appears to be a well-written, well-researched book. The data are clearly presented. The diet and lifestyle recommendations appear sound. Appears appropriate for individuals with diabetes.

	flavonoid-rich foods, 1–3 soy products/day, 1–3 omega-3 rich servings/day, minimal dairy products and meat, 3 calcium-rich foods/day. Discusses portion size and eating only until 80% satiety. Recommends avoiding saturated fat and trans fats, and omega-6 to omega-3 ratio of 3:1 or 4:1. Recommends green tea (especially Jasmine tea). Allows up to 7 servings of high-protein meats/poultry/eggs per week. Alcohol in moderation or not at all. Consider a multivitamin. Lifestyle considerations include spiritual life, stress reduction, learning to manage hostility and anger, developing a sense of humor, and practicing conscious awareness.			
The Omega Diet	This is the traditional diet of Crete, whose population has been shown to have a significantly decreased CAD and cancer mortality rate. Suggests there is an optimal level of omega-3 PUFAs that people should consume. One should enrich the diet with omega-3 fats; use monounsaturated oils as primary oils; eat 7+ fruits and veggies daily; eat more vegetable proteins: peas, beans, nuts; avoid saturated fat; avoid oils high in omega-6 fatty acids, reduce the intake of trans fatty acids.	Excellent discussion of fats. This is one of the few diet books for which there is long-term evidence that it actually promotes health and longevity.	This appears to be a healthy diet.	Appears appropriate for individuals with diabetes. Additional input from a registered dietitian would be helpful.

(*continued*)

TABLE 7.7. (*Continued*)

Diet	Basic premise	Strengths	Weaknesses	Suitable for long-term use?	Overall assessment for people with diabetes
The Ultimate Weight Solution (Dr. Phil MacGraw)	To be successful in losing weight and maintaining a healthy weight, one needs to have a realistic goal weight, and successfully employ positive psychological and behavioral strategies which Dr. Phil calls the "7 keys" to permanent weight loss: 1. "right thinking" 2. "healing feelings" 3. Set up a no-fail environment 4. "habit control" 5. "food control" 6. "intentional exercise" 7. support system	He presents a useful paradigm, tools, and helpful ideas and instructions for behavioral change. He strongly encourages exercise.	We disagree with his assertion that "BMI is not an accurate method for assessing your weight." Some of his diet recommendations could be argued, such as his recommendation to eat nuts and seeds "very sparingly," but most of the recommendations appear to be sound.	Yes.	The behavioral part of his recommendations is excellent and appropriate. The actual diet recommendations appear reasonable for diabetes. Additional input from a registered dietitian would be helpful for individuals with diabetes.
The South Beach Diet	Phase 1 low carb, rapid weight loss. Phase 2 introduce "good" carbs, slower weight loss Phase 3 weight maintenance.	May heighten motivation due to potential for rapid weight loss in Phase 1.	Claims are made that following this diet's recommendations will change one's chemistries and insulin resistance. It is not clear that data exist to back up this claim. The reference to "good" and "bad" carbs is simplistic. Appropriate portion sizes are not defined. This can be a problem for individuals who lack a feeling of satiety to tell them when to quit eating. No guidelines are given for Phase 3, except to say that if you are gaining weight you need to go back to Phase 1. Lastly, this book does not place sufficient emphasis on exercise.	Possibly.	Possibly. However, caution is advised if one has diabetic renal disease, because Phase 1 could promote metabolic acidosis. Additional input from a registered dietitian would be helpful for individuals with diabetes.

Weight Watcher's Complete Cookbook and Program Basics	Decrease overall food intake. Increase caloric output by exercising. Reshape behavior to learn positive attitudes and strategies for dealing with weight loss challenges. Provides a support group. Recommends eating a variety of foods; 50–60% carbohydrates; less than 30% fats, and eating appropriately to maintain a healthy weight.	This program has helped many people lose excess weight, and maintain their appropriate weight.	Does not discriminate between the low-GI and high-GI carbohydrates or the different kinds of fats.	Yes.	This appears to be a reasonable approach. The only suggestion we could make would be to consider more attention to avoiding saturated and trans fats.

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Disclaimer: This is our analysis of these books. We neither confirm nor refute the conclusions expressed in these publications.

TABLE 7.8. Kcaloric needs for Weight Maintenance

Obese or very inactive persons, chronic dieters	10–12 kcal/lb (20 kcal/kg)
Individuals >55 years old, active women, sedentary men	13 kcal/lb (25 kcal/kg)
Active men, very active women	15 kcal/lb (30 kcal/kg)
Thin or very active men	20 kcal/lb (40 kcal/kg)

Source: Estimating approximate energy requirements in adults. A core curriculum for Diabetes Management Therapies (2003), p. 29.

In order to calculate macronutrient quantities for a meal plan, one must recall that 1 g of fat equals 9 kcalories, 1 g carbohydrate equals 4 kcalories, and 1 g protein equals 4 kcalories. Therefore, fat contains twice the number of kcalories of either protein or carbohydrate.

Macronutrient components of one serving of various food groups are listed in Table 7.9.

Portion size is crucial. Examples of servings from each macronutrient group are given in Table 7.10.

Of the three macronutrient groups, carbohydrates have the greatest impact upon blood glucose levels. The effect of fat on blood sugar is one-tenth of the effect of carbohydrates. (Freeman and Krapeck, 2003). Protein has minimal effect on blood sugar provided the serving size is not excessive.

The first and most important step in nutrition education is for patients with diabetes to recognize which foods contain carbohydrates, and to differentiate them from foods containing fats and proteins. The use of food models is helpful in this process.

After completing an estimation of kcaloric needs, one needs to consider the number of servings per day required from each food group that depends on the kcalorie level appropriate for each individual as previously determined (Table 7.11).

Various teaching methods may be used in meal planning. Some examples include:

- Carbohydrate counting,
- Exchange method,
- Plate method, and
- Simple rules of healthy eating.

Education material on these methods may be found at the end of this chapter.

TABLE 7.9. Exchange Lists for Meal Planning (American Diabetes Association, 2003)

Groups/lists	Carbohydrate (g/serving)	Protein (g/serving)	Fat (g/serving)	Kcalories
Carbohydrates				
Starch	15	3	0–1	80
Fruit	15	–	–	60
Milk				
Low-fat (skim)	12	8	0–3	90
Reduced fat (2%)	12	8	5	120
Whole	12	8	8	150
Other carbohydrates	15	varies	varies	varies
Nonstarchy vegetables[a]	5	2	–	25
Meat and meat substitutes				
Very lean	–	7	0–1	35
Lean	–	7	3	55
Medium fat	–	7	5	75
High fat	–	7	8	100
Fat	–	–	5	45

Some sources feel the following vegetables may be eaten freely: cabbage, celery, cucumber, green onion, hot pepper, mushrooms, radish, endive, escarole, lettuce, spinach.

TABLE 7.10. Examples of Servings from Each Macronutrient Group

Food group	Portion size
One starch	One slice bread or $^1/_4$ bagel
One fruit	One small orange
One milk	One 8-oz glass of low-fat milk
One vegetable	One cup raw or $^1/_2$ cup cooked
One meat (protein)	One oz (cooked) poultry, fish or meat
One fat	One tsp oil or margarine

People with type 1 diabetes should be introduced to carbohydrate counting so patients can learn how to balance insulin dose with carbohydrate intake. Patients on multiple daily injections or the insulin pump should understand carbohydrate-to-insulin ratios. There are resources to teach these techniques. One example is *Complete Guide to Carb Counting* (Warshaw and Kulkami, 2001). Patients should also learn the principles of healthy eating.

People with type 2 diabetes can be taught a combination of carbohydrate counting and/or the exchange method. In some patients, the plate method with simple rules of healthy eating may be appropriate.

The technique used will depend upon many factors including patient understanding, type of medication, and readiness to change. *Each patient differs and the teaching method must be tailored to meet their individual needs.*

TABLE 7.11. Exchange Method—Portions Needed for a Balanced Diet at a Given Caloric Intake (The Type 2 Diabetes Meal Planner)

Kcalories	1,200	1,500	1,800	2,000	2,500
Food group					
Starch	5	7	8	9	11
Fruit	3	3	4	4	6
Milk	2	2	3	3	3
Vegetables	2	2	3	4	5
Meat (ozs)	4	4	6	6	8
Fat	3	4	4	5	6

Source: The Type 2 Diabetes Meal Planner, Bristol-Myers Squibb (1999).

Introduction to Carbohydrate Counting

One carbohydrate serving = 15 g = one starch (one slice bread) = one fruit (one small orange) = a glass of milk (one 8-oz glass). Therefore, in this sample meal there are three carbohydrate servings or 45 g.

2 slices of bread = 2 carbohydrate servings
1 egg = 0 carbohydrate servings
1 tsp margarine = 0 carbohydrate servings
1 glass milk = 1 carbohydrate serving
Total = 3 carbohydrate servings

As one considers carbohydrates, it is important to remember that:

- *Not all starches are equal.* Whole grains are digested and absorbed more slowly than white flour products including white bread and refined cereals. Increased fiber content lowers the rate of absorption.
- *Not all fruits are equal.* Whole fruits containing fiber (e.g., strawberries) do not rapidly impact blood glucose and are recommended over low fiber fruits (e.g., melons), which tend to cause rapid blood glucose elevations. Acidic fruits also do not rapidly impact blood glucose levels.
- *Not all milks are equal.* Skim milk has fewer fat grams and fewer kcalories than whole milk.

Key concepts for nutrition management for all patients with diabetes include:

- Balance, variety, moderation!
- Take appropriate number of servings at meals and snacks throughout the day.
- Consume meals and snacks at regular times throughout the day.
- Drink adequate amount of water every day.

Food Label Reading (See Education Materials in the Appendix)

One should follow a step-by-step approach to reading food labels. First, look at *serving size* on which all the information printed on the food label is based. Then, look

at *total carbohydrate* in bold print. Sugar, starches, and dietary fiber are included in the total carbohydrate. The magic number for total carbohydrate = 15 g = 1 serving. When choosing foods, look for those containing less kcalories, less total fat, less saturated fat, less trans fat, less cholesterol and sodium, and more dietary fiber.

CASE STUDY

Now let us put the above recommendations to use within a case that we invented for you.

John Smith is a 55-year-old male with newly diagnosed type 2 diabetes mellitus. He also has had hyperlipidemia and hypertension for 4 years. His family history is positive for type 2 DM in his mother who died from myocardial infarction at age 48. At the time of her death, she had end-stage renal failure and was on dialysis.

Mr. Smith is married and self-employed. His wife works full time. He has a sedentary lifestyle. He smokes 1 pack/day of cigarettes. He has three alcoholic drinks per night on average, and six per night on weekends.

His height is 5′ 8″, and weight is 230 lb, giving him a BMI of 35.

His current lab profile includes an HbA_1c of 9.0, total cholesterol of 225, HDL of 29, LDL of 141, and TG of 310.

His medications include metformin (Glucophage) 500 mg twice a day, atorvastatin (Lipitor) 20 mg at bed time, and quinapril (Accupril) 20 mg every day.

Mr. Smith states, "I need to control my diabetes. I don't want to die like my Mom did."

Mr. Smith's food recall for one day is given in Table 7.12.

He states, "sometimes I eat more; sometimes I eat less. This was a particularly 'hungry' day."

Intake Analysis

Recall that 1 g of carbohydrate is equal to 4 kcal. His total carbohydrates = 395 g. Therefore, 395 g × 4 kcal/g = 1,580 kcal. Thus,

TABLE 7.12. Mr. Smith's Food Recall

Meal/time (24:00 clock) food	Carbohydrate (g)	Carbohydrate servings	Kcalories
Breakfast 7:30 AM			
Orange juice 8 oz	27	2	112
Coffee 12 oz			8
Sugar 4 tsp	16	1	60
Doughnuts (2)	46	3	384
Lunch 12:00 noon			
Nachos and cheese	36	2.5	346
Soda 12 oz	38	2.5	152
Snack 3:00 PM			
Chocolate cakes 1 individual pack	42	3	243
Soda 12 oz	38	2.5	152
Dinner 6:00 PM			
Big Mac	42	3	560
Salad 5.5 oz	5	–	60
Ranch dressing 2 Tbsp	2	–	150
Large fries	46	3	400
Soda 12 oz	38	2.5	152
Evening 9:00 PM			
Beer bud light (three 12-oz cans)	19	1	330
Grand total	395	26	3,109

~50% of his total kcalories come from carbohydrate, which on first glance appears to fall within the recommended guidelines. Unfortunately, one half of his carbohydrate intake consists of empty kcalories from sodas, sugar-containing foods, and beer. The remaining kcalories are derived from fat, protein, and alcohol. His protein intake is adequate, but contains significant saturated fat. He is also getting saturated and trans fat from the cupcakes, the French fries, and nachos and cheese. He is eating excessive saturated and trans fats, and not ingesting appropriate quantities of monounsaturated or omega-3 polyunsaturated fats. Therefore, his current intake is not balanced.

Using the formula given in Table 7.8, one can estimate his daily kcaloric needs for weight maintenance as follows: 230 (his weight in pounds) $\times$ 10 = 2,300. In order for him to lose half to one lb per week, he needs to decrease his daily intake by 250–500 kcal (2,300 $-$ 250 = 2,050; 2,300 $-$ 500 = 1,800). Therefore, his estimated daily kcaloric range for his desired weight is 1,800–2,050.

Assuming his daily needs to be 2,000 kcal, the appropriate number of servings from each food group is listed in Table 7.11. For 2,000 kcal, the total number of carbohydrate servings would be 16, consisting of 9 starch, 4 fruit, and 3 milk servings. Nonstarchy vegetables would be unrestricted. His recommended food intake is approximately two-thirds of his current daily intake of 26 servings (see Table 7.11).

In order to evenly distribute his daily allowance, one could suggest that he divide his total intake from all food groups between three meals and two snacks. A thorough review of his food preferences would assist him to make appropriate food choices. He should decrease his alcohol intake to two drinks or less per day. He needs to quit smoking, and he needs to incorporate regular exercise into his routine. This means a lot of changes in his diet and lifestyle, and he might be more successful if it is done in a stepwise fashion. Since this gentleman has stated that he does not wish to "die like his mom," one may hope that he will be adequately motivated to be successful over the long term. However, he will need regular follow-up to help him stay on track.

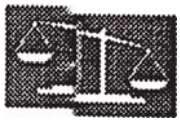
SUMMARY

Individual meal plans must be tailored to the needs of each individual with diabetes. One size does not fit all. The percentages of carbohydrates, fats, and proteins recommended by the ADA should be used when creating a meal plan. Regarding carbohydrates, the glycemic index (glycemic load) may be important. Since the individual glycemic response to carbohydrate foods varies considerably, self-monitoring of blood glucose is an essential part of the overall care plan. With regard to fats, emphasis should be placed on decreasing saturated and trans unsaturated fats and increasing monounsaturated and omega-3 polyunsaturated fats. Variety in one's meal plan is crucial, as is the portion size. One should beware fad diets, especially those that ignore accepted scientific studies about physiologic and metabolic processes. Remember that change in an individual's lifestyle occurs slowly—backsliding will probably occur. Also, for some people, their current meal plan is almost as important to them as their religion. You might walk into a minefield when discussing it. Proceed with caution!

APPENDIX: TEACHING MATERIALS

Nutrition and Diabetes

- **Good nutrition is the key**
- You don't have to buy special foods
- The food that is good for you is good for the whole family
- Try not to think of it as a diet. Instead think "healthy meal plan"

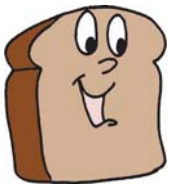


- **Variety**
- Eat a variety of foods each day
- Well balanced meal plan

- **Regular meals**
- Eat at least three times each day
- Try not to skip meals
- Eat about the same amount of food each day

- **Limit sugar**
- Foods that contain a lot of sugar will raise your blood sugar level

- **Eat carbohydrate foods in moderation**
- These foods affect your blood sugar level
- Try not to eat too much at one time
- Potatoes tortillas bread rice fruit milk



- **Eat less fat and salt**
- Some foods contain a lot of fat
- Limit the amount of these foods
- Butter margarine cooking oils
- Hot dogs bacon fast food
- Try not to add fat and salt during cooking or at the table

- **Increase fiber**
- Choose high fiber foods
- Fiber helps to lower your blood sugar level
- Try to eat whole fruits instead of fruit juice
- Whole grains whole fruits and vegetables

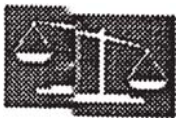
- **Increase fluid**
- Your body needs approximately 6–8 cups fluid daily
- The best fluid is water!

- **Healthy body weight**
- Try to maintain a healthy weight
- If you need to lose weight, eat smaller portions
- Weight loss – if needed – will help to improve your blood sugar levels

Nutrición y Diabetes

- **Buena nutrición es la clave**
- La comida que es buena para usted es buena para toda su familia
- No tiene que comprar comidas especiales o de "dieta"
- No trate de pensarlo como una "dieta" Es un plan de comida saludable.

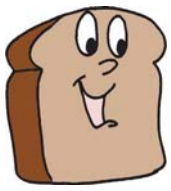
- **Variedad**
- Coma una variedad de alimentos diarios
- Un plan de comida balanceada



- **Coma con regularidad**
- Coma por lo menos tres veces al dia
- No deje sus tres comidas

- **Limite azúcar**
- Los alimentos que contienen mucha azúcar hacen subir el nivel de azúcar en la sangre

- **Coma los carbohidratos en moderación**
- Estos alimentos afectan al nivel de azúcar en la sangre.
- No coma demasiado a un tiempo
- **papas tortillas pan arroz frutas leche**

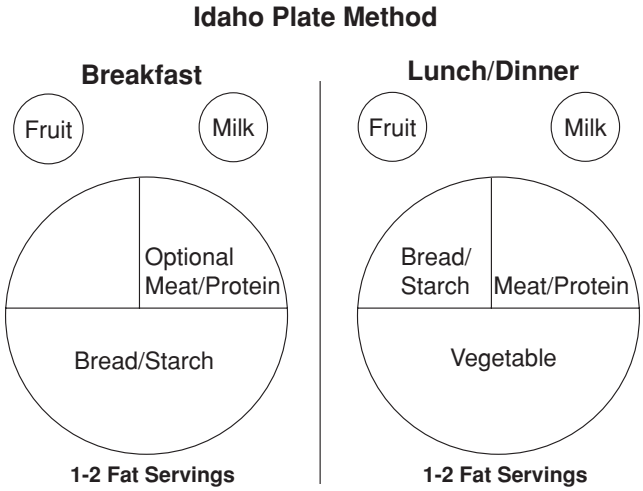


- **Coma menos grasa y sal**
- Unos alimentos contienen mucha grasa
- Limite la cantidad de estos alimentos
- **mantequilla margarina aceite**
- **salchichas tocino comida "rapida"**
- **No añada grasa y sal al cocinar**

- **Mas Fibra**
- Escoja los alimentos ricos en fibra
- La fibra le ayuda bajar el nivel de azúcar en la sangre
- Coma **fruta entera** en vez de **jugo de fruta**
- **Granos integrales tortillas de maiz frutas enteras verduras**

- **Liquidos**
- Su cuerpo necesita 6–8 vasos de líquido diario
- Lo mejor es agua

- **Peso saludable**
- Si usted quiere perder peso, coma porciones más pequeñas
- Si puede perder unas libras, el nivel de azúcar en la sangre va a mejorar



THE TYPE 2 DIABETES MEAL PLANNER

Good Meal Plannig Can Help You Better Control Your Blood Sugar

Eating healthy foods and adding variety to your menus is easier than you think. Your doctor or healthcare provider can help you develop a meal plan that helps control your blood sugar. This sheet can help you make that plan more interesting by providing substitution options, so you don't have to eat the same foods all the time. It also helps if you eat a balanced diet, eat meals at the same time every day, avoid skipping meals, and eat food portions that are indicated by your individual meal plan. The American Diabetes Association recommends good eating habits along with being physically active as an important part of any good type 2 diabetes self-management plan.

Here's how you can easily choose foods that fit your type 2 diabetes meal plan:

- Find your total daily kcalorie level on the chart to the right.
- Using the chart, plan your menus for the day with serving amounts from each food group.

- Look at the sample meal plan below to see how you can do this.
- Give your meals variety by choosing other items from the same food groups. See the choices listed on the other side.

Kcalorie Meal Plans (Daily)	1,200	1,500	1,800	2,000	2,500
Starch	5	7	8	9	11
Fruit	3	3	4	4	6
Milk	2	2	3	3	3
Vegetables	2	2	3	4	5
Meat & Meat Substitutes	4	4	6	6	8
Fat	3	4	4	5	6

Sample Meal Plans

To develop a meal plan at a higher kcalorie level, you can add food-group servings to the 1,200 kcalorie meal plan, as indicated below.

1,200 Kcalories	1,200 Sample Menu	1,500 Kcalories	1,800 kcalories	2,000 Kcalories	2,500 Kcalories
Breakfast 1 Starch 1 Fruit 1 Milk	English muffin 1/2 Banana (medium) 1/2 Hot cocoa mix (artificially sweetened) 1 envelope	**Add** 1 Starch	**Add** 1 Starch	**Add** 1 Starch 1 Fat	**Add** 2 Starch 1 Fat 1Fruit
Lunch 1 Starch 2 Meat 1 Vegetable 1 Fruit 1 Fat	Tortilla (6″ across) 1 oz Chicken 1 oz Cheese 1 oz Beans Apple (raw—2″ across) Salad dressing (reduced-kcalorie) 2 Tbsp	1 Starch	1 Starch 1 Meat 1 Milk	1 Starch 1 Milk 1 Fat 1 Vegetable	1 Starch 1 Meat 1 Vegetable 1 Fat 1 Milk
Afternoon Snack Nothing				1 Starch	1 Starch 1 Meat 1 Fruit
Dinner 2 Starch 2 Meat 1 Vegetable 1 Fruit 2 Fat	Rice 1/3 cup Corn chips 1 oz Chicken 2 oz Onions Butter1 tsp Oil 1 tsp Canned fruit in juice 1/2 cup	1 Fat	1 Starch 1 Meat 1 Vegetable 1 Fat	1 Starch 2 Meat 1 Vegetable	2 Starch 2 Meat 2 Vegetable 1 Fat
Evening Snack 1 Starch 1 Milk	Low-fat or nonfat milk 8 oz Popcorn 3 cups		1 Fruit	1 Fruit	1 Fruit

ADD VARIETY TO YOUR TYPE 2 DIABETES MEAL PLAN

Choose Foods You Like that Still Add Up to the Right Kcalorie Count

Starch

1 serving = 80 kcalories
(each item listed is 1 serving)

Cereal/Beans/Grains/Pasta
Cereal (cooked) 1/2 cup
Beans (cooked or canned) 1/3 cup
Rice (cooked) 1/3 cup
Pasta (cooked) 1/2 cup

Starchy Vegetables
Corn (cooked) 1/2 cup
Corn on the cob (6″ piece) 1
Peas (cooked) 1/2 cup
Plantain (green, cooked) 1/3 cup
Potato (small—3 oz) 1 cup
Squash (winter, cooked) 1 cup
Yam or sweet potato 1/2 cup

Breads
Bagel or English muffin 1/2 or 1 oz
Bread (slice or roll) 1 oz
Crackers, snack 4–5
Graham crackers 3 squares
Hamburger or hot dog bun 1/2 oz or 1 oz
Popcorn (plain, unbuttered) 3 cups
Tortilla (6″ across) 1

Fruit

1 serving = 60 kcalories
(each item listed is 1 serving)

Apple (raw—2″ across) 1
Banana (medium) 1/2
Cherries 12
Dried fruit 1/4 cup
Canned fruit in juice or water 1/2 cup
Grapes 12–15
Raisins 2 Tbsp
Apple, orange, or grapefruit juice 1/2 cup
Cranberry, grape, or prune juice 1/3 cup

Milk

1 serving = 90–100 kcalories
(each item listed is 1 serving)

Low-fat or nonfat milk 8 oz
Low-fat or nonfat buttermilk 8 oz
Yogurt (nonfat, plain, or artificially sweetened) 8 oz
Hot cocoa mix (artificially sweetened) 1 envelope

Vegetables

1 serving = 25 kcalories
(A serving is 1/2 cup of cooked vegetables or 1 cup of raw vegetables)

Beets
Broccoli
Cabbage
Carrots
Greens
Mushrooms
Okra
Onions
Pea pods
Peppers
Spinach
Tomatoes
Water chestnuts

Meat and Meat Substitutes

Lean Meats
1 serving = 35–55 kcalories
(each item listed is 1 serving)

Cheese (1–3 grams of fat) 1 oz
Chicken (white, no skin) 1 oz
Cottage cheese 1/4 cup
Fish (cod, flounder, tuna) 1 oz
Lean beef (flank, round, sirloin) 1 oz
Shellfish (clams, crab, lobster, shrimp) 1 oz
Turkey (white, no skin) 1 oz

Medium/High-Fat Meats
1 serving contains 75–100 kcalories
(each item listed is 1 serving)

Beef 1 oz
Chitterlings 1 oz

Chicken (dark meat, no skin) 1 oz
Eggs 1
Pork (spareribs, barbecue, chops, cutlets) 1 oz
Sausage 1 oz
Wieners 1 oz

Fats

1 serving = 5 grams fat, 45 kcalories
(each item listed is 1 serving)

Avocado (4″ across) $^1/_8$
Bacon 1 slice
Butter 1 tsp
Cream (light, table, coffee, sour) 2 Tbsp
Cream cheese 1 Tbsp
Margarine 1 tsp
Mayonnaise 1 tsp
Mayonnaise (reduced-fat) 1 Tbsp
Nondairy creamer (liquid) 2 Tbsp
Nondairy creamer (dry) 4 tsp
Oil 1 tsp
Nuts or seeds 1 Tbsp
Pesto sauce 2 tsp
Salad dressing (reduced-kcalorie) 2 Tbsp

Free Foods

Free foods are foods or beverages with less than 20 kcalories. They have little or no effect on blood sugar levels.

UNLIMITED SERVINGS

Beverages
Bouillon
Broth
Club soda
Coffee
Drink mixes (sugar-free)
Mineral water
Tea

Seasonings
Flavoring extracts
Garlic or garlic powder
Herbs (fresh or dried)
Mustard (prepared)
Soy sauce
Vinegar

Sweet Substitutes
Gelatin desserts (sugar-free)
Gum (sugar-free)
Popsicles (sugar-free)
Sugar substitutes

LIMIT TO 2–3 SERVINGS A DAY

Fruits
Cranberries (no sugar added) $^1/_2$ cup
Rhubarb (no sugar added) $^1/_2$ cup

Sweet Substitutes
Jam or jelly (sugar-free) 2 tsp
Whipped topping 2 Tbsp
Spreadable fruit (no sugar added) 1 tsp

Condiments
Catsup 1 Tbsp
Salad dressing (reduced-kcalorie) 2 Tbsp
Taco sauce 2 Tbsp

EL PLANIFICADOR DE COMIDAS PARA LA DIABETES TIPO 2

La planificación adecuada de sus comidas puede ayudarle a mejorar el control de su azúcar en la sangre

El comer alimentos sanos dentro de un menú variado, es más fácil de lo que usted piensa. Su médico o profesional de la atención médica, puede ayudarle a desarrollar un plan de comidas que le ayude a controlar su nivel de azúcar en la sangre. Esta hoja también puede ayudarle a preparar un plan más conveniente, ofreciéndole opciones de distintos alimentos para que usted no tenga que comer siempre lo mismo.

Asimismo, le ayudará a tener una dieta más balanceada, comer a la misma hora todos los días, evitar el salto de comidas y comer las porciones de alimentos indicadas en su plan de comidas individual. La Asociación Americana de la Diabetes recomienda observar buenos hábitos alimenticios junto con la actividad física, como parte de cualquier plan adecuado para el control personal de la diabetes tipo 2.

Aquí tiene un método fácil para seleccionar los alimentos más apropiados para su plan de comidas de la diabetes tipo 2.

- Busque su nivel total de calorías diarias en la tabla de la derecha.
- Use la tabla para planificar su menú del día con porciones de cada grupo de alimentos.
- Revise el plan de comidas presentado abajo para determinar cómo usted puede seguirlo.
- Añada variedad a sus comidas seleccionando otros alimentos dentro del mismo grupo. Vea las opciones presentadas en el otro lado.

Planes de Comidas por Calorías (Diarias)	**1,200**	**1,500**	**1,800**	**2,000**	**2,500**
Almidones	5	7	8	9	11
Frutas	3	3	4	4	6
Leche	2	2	3	3	3
Verduras	2	2	3	4	5
Carnes y Sustitutos de la Carne	4	4	6	6	8
Grasas	3	4	4	5	6

Ejemplos de planes de comidas

Para desarrollar un plan a un nivel más alto de calorías, usted puede añadir porciones de los grupos de alimentos al plan de comidas de 1,200 calorías, según se indica abajo.

1,200 Calorías	Ejemplo de Menú de 1,200 Calorías	1,500 Calorías	1,800 Calorías	2,000 Calorías	2,500 Calorías
Desayuno 1 Almidones 1 Frutas 1 Leche	English muffin $^1/_2$ Banana (mediana) $^1/_2$ Mezcla de chocolate caliente (endulzada artificialmente) 1 sobre	**Añada** 1 Almidones	**Añada** 1 Almidones	**Añada** 1 Almidones 1 Grasas	**Añada** 2 Almidones 1 Grasas 1Frutas
Almuerzo 1 Almidones 2 Carnes 1 Verduras 1 Frutas 1 Grasas	Tortilla (6″ de diámetro) 1 oz Pollo 1 oz Queso 1 oz Frijoles Manzana (cruda—2″ de diámetro) Aderezo de ensalada (calorías reducidas) 2 cdas	1 Almidones	1 Almidones 1 Carnes 1 Leche	1 Almidones 1 Leche 1 Grasas 1 Verduras	1 Almidones 1 Carnes 1 Verduras 1 Grasas 1 Leche
Merienda por la tarde Nada				1 Almidones	1 Almidones 1 Carnes 1 Frutas
Cena 2 Almidones 2 Carnes 1 Verduras 1 Frutas 2 Grasas	Arroz $^1/_3$ taza Chips de maíz 1 oz Pollo 2 oz Cebollas Mantequilla 1 cdta Aceite 1 cdta Fruta enlatada en jugo $^1/_2$ taza	1 Grasas	1 Almidones 1 Carnes 1 Verduras 1 Grasas	1 Almidones 2 Carnes 1 Verduras	2 Almidones 2 Carnes 2 Verduras 1 Grasas
Merienda por la noche 1 Almidones 1 Leche	Leche (sin grasa o grasa reducida) 8 oz Rositas de maíz 3 tazas		1 Frutas	1 Frutas	1 Frutas

AÑADA VARIEDAD A SU PLAN DE COMIDAS DE LA DIABETES TIPO 2

Seleccione los alimentos que le gusten hasta el conteo correcto de calorías

Almidones

1 porción = 80 calorías
(cada renglón indicado es 1 porción)

Cereales, Frijoles, Granos, Pastas
Cereal (cocido) $^1/_2$ taza
Frijoles (cocidos o enlatados) $^1/_3$ taza
Arroz (cocido) $^1/_3$ tata
Pasta (cocida) $^1/_2$ taza

Verduras de Féculas
Maíz (cocido) $^1/_2$ taza
Maíz en mazorca (pedazo de 6″) 1
Guisantes (cocidos) $^1/_2$ taza
Plátano (verde, cocido) $^1/_3$ taza
Papa (pequeña—3 oz) 1 taza
Calabaza (cocida) 1 taza
Batata o boniato $^1/_2$ taza

Panes
Bagel o English muffin $^1/_2$ o 1 oz
Pan (rebanada o panecillo) 1 oz
Galletas de merienda 4–5
Galletas Graham 3
Pan de hamburguesa o perro caliente $^1/_2$ oz or 1 oz
Rositas de maíz (sin mantequilla) 3 tazas
Tortilla (6″ de diámetro) 1

Frutas

1 porción = 60 calorías
(cada renglón indicado es 1 porción)

Manzana (cruda—2″ de diámetro) 1
Banana (mediana) $^1/_2$
Cerezas 12
Fruta seca $^1/_4$ taza
Fruta enlatada en jugo o agua $^1/_2$ taza
Uvas 12–15
Pasas 2 cdas
Jugo de manzana, naranja o toronja $^1/_2$ taza
Jugo de arándanos, uvas o ciruela $^1/_3$ taza

Leche

1 porción = 90–100 calorías
(cada renglón indicado es 1 porción)

Leche (sin grasa o grasa reducida) 8 oz
Crema (sin grasa o grasa reducida) 8 oz
Yogurt (sin grasa, sólo o endulzado artificialmente) 8 oz
Mezcla de chocolate caliente (endulzada artificialmente) 1 sobre

Verduras

1 porción = 25 calorías
(Una porción es $^1/_2$ taza de verduras cocidas o 1 taza de verduras crudas)

Remolacha
Brecol
Col
Zanahorias
Hojas verdes
Champiñones
Quingombó
Cebollas
Vainas de guisantes
Pimientos
Espinaca
Tomates
Castaña de agua

Carnes y Sustitutos de la Carne

Carnes Magras
1 porción = 35–55 calorías
(cada renglón indicado es 1 porción)

Queso (1–3 gramos de grasa) 1 oz
Pollo (pechuga sin piel) 1 oz
Requesón $^1/_4$ cup
Pescado (bacalao, lenguado, atún) 1 oz
Carne de res magra (falda, bola, solomillo) 1 oz
Mariscos (almejas, cangrejo, langosta, camarones) 1 oz
Pavo (pechuga sin piel) 1 oz

Carnes Medianas/Altas en Grasa
1 porción 75–100 calorías
(cada renglón indicado es 1 porción)

Res 1 oz
Tripas de puerco 1 oz
Pollo (no de pechuga sin piel) 1 oz
Huevos 1
Puerco (costillas, barbacoa, chuletas) 1 oz
Salchicha 1 oz
Perros calientes 1 oz

Grasas

1 porción = 5 gramos de grasa, 45 calorías
(cada renglón indicado es 1 porción)

Aguacate (4″ de diámetro) $^1/_8$
Tocino 1 lasca
Mantequilla 1 cdta
Crema (ligera de mesa, café, agria) 2 cdas
Queso crema 1 cda
Margarina 1 cdta
Mayonesa 1 cdta
Mayonesa (grasa reducida) 1 cda
Crema no láctea para café (líquido) 2 cdas
Crema no láctea para café (polvo) 4 cdtas
Aceite 1 cdta
Nueces o semillas 1 cda
Salsa de pesto 2 cdtas
Aderezo de ensalada (calorías reducidas) 2 cdas

Alimentos Libres

Los alimentos libres son las comidas o bebidas que tienen menos de 20 calorías.
Tienen poco o ningún efecto en los niveles de azúcar en la sangre.

PORCIONES ILIMITADAS

Bebidas
Cubitos de caldo
Caldo
Agua carbonatada
Café
Mezcla de refresco (sin azúcar)
Agua mineral
Té

Sazones
Extractos
Ajo o ajo en polvo
Especies (frescas o secas)
Mostaza (preparada)
Salsa de soya
Vinagre

Sustitutos de Dulces
Postres de gelatina (sin azúcar)
Chicle (sin azúcar)
Paleta helada (sin azúcar)
Sustitutos del azúcar

LÍMITE DE 2 A 3 PORCIONES AL DÍA

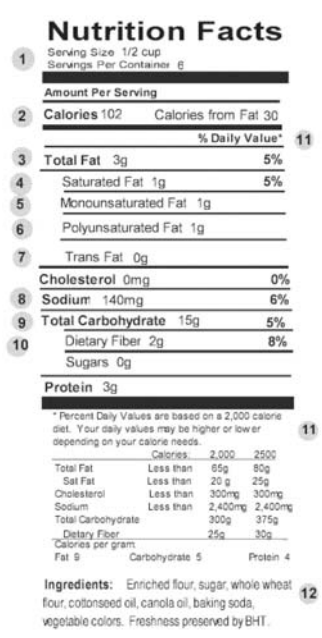
Frutas
Arándanos (sin azúcar añadida) $^1/_2$ taza
Ruibarbo (sin azúcar añadida) $^1/_2$ taza

Sustitutos de Dulces
Mermelada o jalea (sin azúcar) 2 cdtas
Crema batida artificial 2 cdas
Compota de frutas (sin azúcar añadida) 1 cdta

Condimentos
Ketchup 1 cda
Aderezo de ensalada (calorías reducidas) 2 cdas
Salsa de taco 2 cdas

What To Look For When You Read A Label

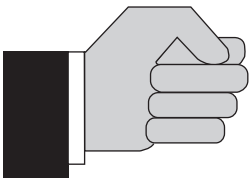
1. **SERVING SIZE**—This is the quantity to which all the following nutrients refer. E.g. if you eat double the serving size, you must double the nutrient value (calories, fat grams, etc).
2. **CALORIES**—The amount of energy in one serving size.
3. **TOTAL FAT**—You want to keep the daily fat intake to less than or equal to 30% of the day's calories.
4. **SATURATED FAT**—You want this to be minimal.
5. **MONOUNSATURATED FAT**—This should be the primary kind of fat in your diet.
6. **POLYUNSATURATED FAT**—This category is of limited value. You want to maximize consumption of the omega-3 fats. Therefore, you need to look at the ingredients list to see the types of fats included in this food. Please refer to Table 8 for more information on which foods contain omega-3 polyunsaturated fats.
7. **TRANS FAT**—You want this to be as close to ZERO as possible



8. **SODIUM**—Try to consume as little as possible. (READ THE LABELS!) A low sodium diet contains less than 2,400 mg/day.
9. **CARBOHYDRATES**— **The total carbohydrates** is most important value to consider. Dietary fiber, sugars, and other starches are included in **total carbohydrates.**
10. **FIBER**—In general, the higher the fiber content, the lower the blood glucose spike that results from eating this food.
11. **PERCENT DAILY VALUE**—Don't waste your time on this. These percentages provide some information, but it's really not very helpful.
12. **INGREDIENTS—**The higher the item is on the list, the greater the amount of it is in this food. Look here for specifics on fats, and food components that you want to avoid, such as high fructose corn syrup.

LIFESKILLS™ TEACHING GUIDE

How to Get a



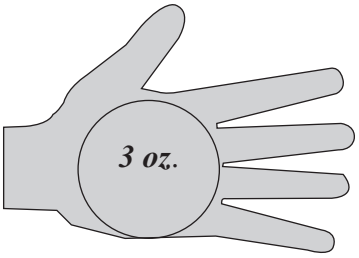
"Hand" Le on Serving Sizes

You're trying harder than ever to manage your diabetes. You take your medicine on time, exercise regularly and even eat right. Still your blood sugars are all over the place! The problem might be the serving size of your food. One key to more consistent blood sugars is consistent food intake especially carbohydrates (sugars and starches).

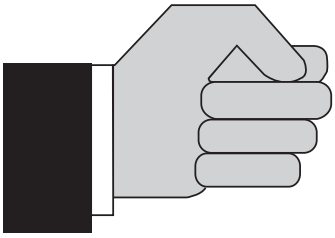
For example, if one day you eat one cup of cereal and the next day you eat $1\frac{1}{2}$ cups because you ate from a larger bowl, you will get more carbohydrate and a higher a blood sugar. Keeping the serving size the same helps keep the grams of carbohydrate the same and blood sugars more consistent.

Weighing and measuring your food and determining the sizes of your dishes at home will help. The difference in your dishes and glasses will surprise you.

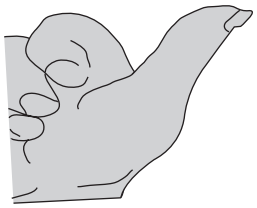
How can you measure food when you are eating out? Try the ***Hand Method***.



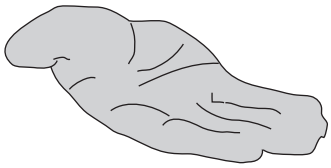
- **your palm is about three ounces of cooked meat (four ounces for a man's palm)**



- **your fist is eight ounces of liquid**
- **your fist is also about the size of a piece of fruit, 3 knuckles are one small potato**



- **your thumb nail is one teaspoon**



- **your cupped hand is $^1/_2$ cup**

Use your hand to determine the serving sizes of foods served in restaurants. Try pasta with marinara sauce, French bread and salad with dressing.

Does the pasta look like one handful, two or more? Most likely 2–3 handfuls. Two handfuls (1 cup) is 3 servings of carbohydrate. The bread is one serving per slice (hand size). One fist of marinara sauce is also one carbohydrate. The salad is free but not the salad dressing.

By our calculations we have determined that your dinner has five (5) carbohydrate choices. You may have more if you eat more than one slice of bread or 1 cup pasta.

How does this compare to your meal plan? If your plan only allows three carbohydrate choices, you have gone over and can expect a high blood sugar. If you take insulin you can adjust your dose to cover the extra carbohydrate. But, if you are taking diabetes pills it would be best to stick to your plan.

Either eat less of the pasta or skip the bread. You might also ask for an appetizer size if you have a hard time leaving food on your plate or share the entree with a friend.

Your Special Nutrition Needs for Diabetes

Food provides energy or "fuel" for your body. This is measured in kcalories. These kcalories come from carbohydrates, protein, fat and alcohol. Each plays a specific role in the body.

Carbohydrates come from breads, grains, cereals, some vegetables, fruit & juice, sugar and milk. Carbohydrates are an important source of energy and B vitamins. They also have the greatest effect on your blood sugar.

You may have been asked to count carbohydrate grams or choices. Keeping the carbohydrate content of your meals the same from day to day helps in blood sugar control.

If you are using the *Food Guide Pyramid* for meal planning, the carbohydrate food groups are: bread, grains & starchy vegetables, fruit, milk and sugars. Most meal plans consider one serving from each of these groups to be a carbohydrate (carb) choice. Each choice is 15 grams of carbohydrate.

Your Meal Plan may allow 3–4 carbs per meal depending on your kcalories. Four carb choices would be 2 slices of bread, 1 cup of milk and 1 small piece of fruit. It could also be 1 medium potato and 2 cookies.

Try to keep your carbohydrate foods consistent in total choices or grams from day to day. Most older adults should have 10–14 carbohydrate choices per day depending on their kcalories. Lower kcalories use 10 choices, higher kcalories use 14 choices. Spread the choices throughout the day and the food groups. Carbohydrates should be 40 to 50% of your total kcalories.

Protein is our building block that preserves and repairs body tissue. It also helps antibodies fight infection. The best choices are lean meats like skinless chicken, trimmed round or flank steak, lean pork chops and fish. Cheese, cottage cheese, eggs and beans are also good protein foods. Limit eggs to 3 per week and use low fat cheese. Protein should be about 15–20% of your total kcalories.

Fat comes from animal and vegetable sources. Animal sources are mostly saturated fat which should be limited. This is the type of fat that clogs arteries. Unsaturated fats (poly and mono) are the fats of choice. These come from vegetable sources. Monounsaturated fats when substituted for saturated fat can help lower blood cholesterol. Rich sources are olive, canola and peanut oil. Total fat should about 30% of your daily kcalories. Some physicians and dietitians allow more fat if it is from monounsaturated foods.

Cholesterol is a waxy, fat-like substance. It is part of the plaque that clogs arteries. Limit cholesterol to 300 mg/day. A 3 ounce serving of lean meat or chicken has about 75 mg of cholesterol. One egg has about 280 mg.

Alcohol should only be used in moderation ($\leq$2 drinks/day men, $\leq$1 drink/day women) and

with physician permission. If you take insulin, always eat when drinking alcohol. Alcohol contains 7 kcalories per gram.

Other Issues

Sodium should be limited to 2400 to 3000 mg/day. If you have high blood pressure, limit sodium to <2400 mg/day. Do not use salt in cooking. Use herbs and spices. Also, limit processed foods, canned vegetables, soups and fast foods. These are high in sodium.

Fiber (found in many fruits and vegetables) helps the digestive tract run smoothly and prevents constipation. Some fibers also may help lower blood cholesterol. Goal is 25–35 gm per day.

Water is important to keeping you hydrated. Water helps keep your kidneys healthy. Be sure to drink 6–8 glasses of water daily.

Vitamins & Minerals

Each vitamin and mineral plays an important role in maintaining lifelong healthy bodies. Some of the more important are included here. The Recommended Daily Allowance (RDA) or Recommended Dietary Intake (DRI) is given. Try to include sources of these vitamins and minerals daily. If you cannot include all sources you may need a supplement.

Vitamin A: important for healthy eyes, skin and to help fight disease. Good sources include bright orange and dark green leafy vegetables*, bok choy*, cantaloupe, pumpkin, dairy products and fortified margarine. RDA is 5000 IU/day.

B vitamins: the B-complex group aids in carbohydrate metabolism, promotes appetite and nerve function. Good sources include whole grains, legumes, dairy products, nuts, pork and other lean meats. RDA and RDI vary for the B vitamins.

Vitamin C: helps fight disease and reduce risk of heart disease. Good sources include citrus fruits, broccoli*, cantaloupe, papaya, strawberries, and spinach. RDA is 90 mg/day for males and females, and 35 mg/day extra for smokers.

Vitamin D: helps bones and teeth harden and increases calcium and phosphorus absorption. Good sources include vitamin D enriched dairy foods, fish oils and sunlight. RDA is 400 IU/day.

Vitamin E: antioxidant vitamin which helps in fighting disease. Good sources include vegetable oils, margarine, eggs, whole grains, wheat germ and leafy greens. RDA is 15 mg/day or 22 IU natural Vit E. Estimated safe daily intake is 800–1000 mg/day.

Minerals

Calcium: critical to strong bones and teeth. Good sources include all dairy products, dried peas and beans, and most dark leafy greens. RDI for adults ranges from 1000–1300 mg/day. The body can't absorb calcium without vitamin D.

Chromium: may have an effect on lowering blood sugar in chromium deficient people. Patients getting total parenteral nutrition may experience improvement in peripheral neuropathy after chromium replacement. Sources are brewer's yeast, liver, kidney, wheat germ, corn oil, whole grains, meats and cheese. RDI is 25–30 mcg/day. Estimated safe daily intake 50–200 mcg/day.

Iron: helps carry oxygen in the blood. Good sources are red meat, liver, molasses, dried beans and enriched whole grains. Animal sources are better than plant sources. RDA range for adults is 8–15 mg/day.

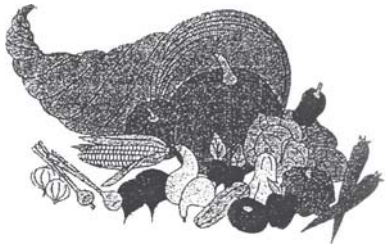
Magnesium: used by bones and teeth. It is vital to carbohydrate metabolism by activating different enzymes. Good sources include green vegetables, avocados, bananas, whole grains,

peanut butter and nuts. RDA range for adults is 320–420 mg/day. Estimated safe daily intake is 350 mg/dl.

Potassium: works in concert with sodium to maintain the body's fluid balance. It is also involved in carbohydrate and protein metabolism. Good sources include most fruits, vegetables and low fat yogurt. RDA is not established. Safe levels are between 1875–5625 mg/day.

Zinc: strengthens your immune system. Also important in metabolism of carbohydrates, fats and proteins. Good sources include meat, dark poultry, shellfish, legumes and whole grains. RDA is 15 mg/day. Safe levels are 40 mg/day.

If you feel you can't get all your needed nutrients, consider a multivitamin. Chose a supplement that contains a broad spectrum of vitamins and minerals.



* *cruciferous (cabbage vegetables) which may help reduce the risk of some cancers*

(Diabetes Education Society, 535 Detroit St, Denver, CO 80206 Telephone: (303) 670 7310 or (800) 659 5808 Web page: www.diabetesedu.org E mail: diabetes@diabetesedu.org)

INTRODUCTION TO CARBOHYDRATE COUNTING

Why count carbohydrates or "carbs"?

Carbs raise your blood sugar so you need to know:

- Which foods contain carbs.
- How many carbs are in these foods.
- How many carbs you usually consume each day.
- How many carbs **you need** each day.
- How to check your blood sugar so you can balance your meals with medication and exercise and **achieve good control of your diabetes!**

This packet provides information about foods that **do** and foods that **do not** contain carbs. You will find a sample meal plan and a guide to reading food labels. To help figure out how many carbs **you** need each day, it's a good idea to talk to a Registered Dietitian. You should also learn how to check your blood sugar.

- **Knowledge and understanding are keys to your success.**

Let's start by looking at the foods you can eat **freely.** ☺

Low or no carb vegetables !

Low or no carb vegetables are:	**Examples include**
Low kcalorie and great sources of vitamins, minerals, and fiber. Try to eat veggies at least 2 or 3 times a day.	Asparagus, Broccoli, Carrots, Peppers, Cabbage, Cauliflower, Green beans, Celery, Cucumber, Mushrooms, Onions, Romaine Scallions, Summer squash, Zucchini

On the following page you will find out which vegetables you need to include in your carb counting meal plan.

Which foods contain carbs? They are found in three main groups of foods:

- **Starches** including breads, grains, cereals, crackers, starchy vegetables
- **Fruits** all varieties
- **Milks** including milk, yogurt

You can either count carbs in grams or servings. Whichever way you choose, it's a good idea to remember **the number fifteen because**

- **One carb serving equals 15 grams** ☺

Each of the following **carb servings** contains approximately **15 grams**

Breads	**Cereals and Grains**	**Milk and Yogurt**
Bagel, **1/4 of 1 whole**	Bran cereal, **1/2 cup**	Milk Skim, 1%, 2% **1 cup**
Bread, **1 slice or 1 oz**	Bran flakes, **3/4 cup**	Dry milk powder, **1/3 cup**
English muffin, **1/2 of 1 whole**	Oatmeal, cooked **1/2 cup**	Evaporated milk, **1/2 cup**
Pancake or waffle, **1–4 inch**	Flour, **3 Tbsp**	Yogurt plain, **1 cup***
Tortilla corn / flour, **1–6 inch**	Rice cooked **1/3 cup**	Yogurt, sweetened, **1/2 cup**
	Pasta cooked **1/3 cup**	Soy milk, **1 cup**
Crackers and Snacks	**Starchy Vegetables**	**Fruits**
Graham Crackers, **3 squares**	Beans, pinto **1/2 cup cooked**	Apple or orange, **1 small**
Popcorn, **3 cups**	Peas, **1/2 cup**	Banana, **1/2 medium**
Rice cakes, **2–4 inch**	Lentils, **1/2 cup cooked**	Canned fruit, **1/2 cup****
Saltine—type crackers, **6**	Corn or Hominy, **1/2 cup**	Grapes, **17 small**
	Potato, **1 small or 3 oz**	Juice orange, apple, **1/2 cup**
	Sweet potato, **1/2 cup**	Strawberries **1 1/4 cup** whole

*** artificially sweetened**
**** unsweetened**

Other foods containing carbohydrate

Sweets	**Combination foods**
They are of poor nutritional value so its best to choose them occasionally for a treat!	The following foods contain a variety of ingredients
Each of the following is approximately 1 carbohydrate (15 gram) serving:*	**Each of the following is approximately 1 carbohydrate (15 gram) serving:***
Cake (no icing), **2 inch sq**	Bean soup, **1/2 cup**
Chocolate milk, **1/2 cup**	Beef stew, **1 cup**
Jelly /Jam, **1 Tbsp**	Chili with beans, **1 cup**
Gingersnaps, **3**	Lasagna, **1 cup or 8 oz**
Ice cream no sugar added, **1/2 cup**	Macaroni and Cheese, **3/4 cup or 3 oz**
Pudding sugar free, **1/2 cup**	Pizza cheese thin crust, **1/8 of 10 inch pie**
Pudding regular, **1/4 cup**	Spaghetti with tomato sauce, **1/2 cup**
Sugar table or powdered, **1 Tbsp**	**Combination/Fast Foods**
Syrup light, **2 Tbsp**	Big Mac, ® **1/3 of 1 whole**
Syrup regular, **1 Tbsp**	Cheeseburger, 1/2 **burger**
Vanilla wafers, **5**	Subway sandwich, ® **1/3 of 6 inch sub**
	Most fast foods are high in kcalories, sodium and fat 😐

***** Please read the food label on all prepared products for exact information on the **total number of carbohydrate grams** contained in 1 serving.

How do you figure out your daily carbohydrate consumption? A good start is to keep records of your daily meals and snacks. Include all food and beverages and record **portion sizes,** e.g., 1 cup, $^1/_2$ cup, 2 slices, etc. This will help when working out the number of carbohydrates **you need** each day

Foods that do not contain carbohydrates:

Meats, meat substitutes

Meats and meat substitutes are rich in protein. If you don't exceed the recommended portion size, they have very little effect on your blood sugar levels. Choose lean meats to cut down on saturated fat and kcalories.

Recommended types and serving sizes are listed below:

Meats	**Meat Substitutes**
One serving = **3 oz cooked:**	Serving sizes are listed below:
Chicken, Turkey breast no skin	Low fat cheese, e.g. Mozzarella **3 oz**
Fish or Shellfish	Cottage cheese, $^3/_4$ **cup**
Beef eye of round	*Eggs **(1–2)** or egg whites **(3)**
Tuna fresh or canned in water	Tofu non fat, $^1/_2$ **cup**

***Eggs yolks are high in cholesterol. Limit 3 per week.**

Fats

Like meats, **fats** have very little effect on your blood sugar levels. However, if you eat excessive amounts, you will likely gain weight. Also, saturated fats may raise your blood cholesterol levels. Try to limit saturated fats and instead use healthier unsaturated fats.

Recommended types and serving sizes are listed below

Unsaturated Fats ☺	**Saturated Fats** ☹
Oils: canola, olive, peanut, **1 tsp**	Butter, Lard, **1 tsp**
*Soft margarine / Mayonnaise, **1 tsp**	Bacon, **1 slice**
Nuts, **6–10**	Cream cheese, **1 Tbsp**
Avocado, **1/8 of 1 whole**	Sour cream, **2 Tbsp**

***Look for margarines labeled "No Trans Fat"**

How much protein and fat do you need per day? Each person has different needs!
An **approximate** recommendation is:

- 2 servings of meat or meat substitute per day.
- 2–3 servings of fat per day.

Sample Meal Plan for carbohydrate counting

Please note that each person has individual needs. This is purely an example!

Breakfast	Food / Beverage	Carb Grams	Carb Servings
	3/4 cup Branflakes	15	1
	1/2 banana	15	1
	1 cup 1% milk	15	1
	Tea or coffee	0	0
Total		**45**	**3**
Lunch	**Food / Beverage**		
	2 slices wholegrain bread	30	2
	1 tsp mayonnaise	0	0
	Lettuce, tomato, celery	0	0
	3 oz tuna canned in water	0	0
	1 small orange	15	1
Total		**45**	**3**
Evening Meal	**Food / Beverage**		
	3 oz grilled chicken	0	0
	1/2 cup pinto beans	15	1
	1/3 cup cooked rice	15	1
	Large mixed salad	0	0
	1 Tbsp oil / vinegar	0	0
	1 1/4 cup strawberries	15	1
Total		**45**	**3**
Snack	**Food / Beverage**		
	1 cup 1% milk	15	1
	3 Graham crackers	15	1
Total		**30**	**2**
Daily Total		**Carb grams**	**Carb servings**
Meals		**135**	**9**
Snack		**30**	**2**
Grand Total		**165**	**11**

FOOD LABELS

When carb counting, take a step by step approach to reading labels

Make a note of:

- **Serving size**
- **Total carbohydrate grams All carbs including sugar, other starches, and dietary fiber, are contained in total carbohydrate grams.**

When label reading, 12–18 grams carbohydrate counts as 1 carb serving
In each of the following examples, the total carbohydrate grams counts as 1 serving:

Wholegrain bread

Nutrition Facts
Serving size: 1 slice
Kcalories: 70
Total fat 1 g
Sat fat 0 g
Total carbohydrate 13 g
Dietary fiber 2 g
Sugar 1 g
Protein 3 g

Unsweetened frozen pineapple

Nutrition Facts
Serving size: $^1/_2$ cup
Kcalories: 70
Total fat 0 g
Cholesterol 0 mg
Total carbohydrate 16 g
Dietary fiber 1 g
Sugar 13 g
Protein less than 1 g

Skim milk

Nutrition Facts
Serving size: 1 cup
Kcalories: 86
Total fat 0 g
Cholesterol 4 mg
Total carbohydrate 12 g
Dietary fiber 0 g
Sugar 11 g
Protein 8 g

Please continue reading for information on the fiber rule! This shows how you can reduce your total carbohydrate intake by eating high fiber foods!

The Fiber Rule

- **As previously mentioned, all carbs including sugar, other starches, and dietary fiber, are contained in total carbohydrate grams.**
- **Sugar and other starches convert to glucose in your body and will raise your blood sugar levels.**
- **Fiber is not digested in your body so it will not raise your blood sugar levels.**
- **If the fiber content of the food is greater than 5 grams, you may deduct this amount from the total carbohydrate grams.**

- **The following example shows you how to use the fiber rule**

High Fiber Cereal

Nutrition Facts
Serving size: 2/3 cup
Kcalories: 90
Total fat 1 g
Saturated fat 0 g
Cholesterol 70 mg
Total carbohydrate 25 g
Dietary fiber 9 g
Sugar 6 g
Protein 2 g

- **Subtract the dietary fiber from the total carbohydrate to find out how many carbs are in this product. See below:**

Total Carbohydrate 25

Fiber $\frac{-9}{16}$

Total carbohydrate = 16 grams for 2/3 cup of this cereal.

16 grams = 1 carbohydrate serving

Check out the labels and choose high fiber foods! ☺

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8

Diabetes and Exercise

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INTRODUCTION

While everyone can benefit from exercise, those who have diabetes derive even more benefit than most other people. Many people are aware of the benefits of exercise, but have difficulty incorporating physical activity into their lifestyles. The goal of this chapter is to review and discuss the practical aspects of using exercise to prevent and manage diabetes.

BENEFITS OF EXERCISE IN PEOPLE WITH OR AT RISK FOR DIABETES

Diabetes Prevention

Lack of exercise is one of the strongest predictors of the development of type 2 diabetes. Many studies have shown a protective effect of physical activity, and this protection appears to be stronger in those at highest risk: individuals who are obese and have a strong family history of diabetes. The mechanisms of diabetes prevention through exercise are thought to be similar to those at work to improve diabetes control in people who already have the disease. These mechanisms are reviewed below.

Blood Glucose Control

One goal of diabetes management is to control the blood glucose level, which will help to prevent or delay long-term complications such as blindness, neuropathy, and kidney failure, and will decrease cardiovascular risk. Exercise has been shown to be as effective at lowering the blood glucose level as many oral hypoglycemic medications. The reason that exercise is such an effective tool in the management of diabetes is that it can lower blood glucose in the absence of insulin action. Those who are insulin resistant, such as the vast majority of people with type 2 diabetes, have a decreased response to insulin action, thus the ability to lower blood glucose independent of insulin is important. At the cellular and molecular level, defective insulin signaling causes insulin resistance. In other words, insulin resistance is the result of defects in the way certain molecules communicate to enable glucose uptake into muscle and fat cells via glucose transporter

proteins. Exercise is an effective treatment for insulin resistance because muscle contraction enables the signaling molecules to communicate properly and cause glucose uptake into muscle cells without insulin action. Thus, a person with type 2 diabetes, who has poor insulin action due to insulin resistance, can lower his/her blood glucose level by exercising.

The acute effects of exercise can result in lower blood glucose levels for up to 48–72 hours after the bout of exercise is completed. Although these are short-term effects, regular physical activity can result in an overall decrease in the insulin-resistant state—the earliest major metabolic defect in type 2 diabetes. Those with type 1 diabetes benefit from glucose lowering ability as well, although in general the risks of hypoglycemia are increased relative to those with type 2 diabetes (see "Risks of Exercise" section).

Insulin Sensitivity

Type 2 diabetes accounts for the vast majority of all diabetes cases worldwide. By definition, people with this disease are insulin resistant, meaning that insulin action is inefficient. Physical training (regular exercise) has been shown to decrease body fat, fat cell size, and blood insulin levels. Regular exercise also results in higher levels of the glucose transporter proteins in muscle cells, without which glucose is unable to enter cells to be metabolized. All of these mechanisms act to improve the body's sensitivity to insulin, and these benefits persist as long as exercise is performed regularly. Because of these effects, regular exercise can result in a decreased requirement for exogenous insulin or other diabetes medication.

Weight Control

Most people with type 2 diabetes are overweight, and weight loss and/or prevention of weight gain is important for long-term diabetes management. Although it is possible to lose weight without exercise, studies show that it is more difficult. Exercise increases the body's energy expenditure, and may help to prevent the decreased metabolic rate that often accompanies weight loss, which can lead to regain of lost weight.

Blood Pressure

About 70% of people with all types of diabetes have hypertension, and blood pressure can be a stronger risk factor than blood glucose level for some of the major diabetes complications (such as cardiovascular disease). Blood pressure control must be one of the priorities for diabetes management. Regular exercise is associated with lower systolic and diastolic blood pressures, independent of other effects of training, such as weight loss. According to the National Institutes of Health, regular aerobic exercise has been shown to reduce resting blood pressure in people who have hypertension by an average of 11 points (systolic) and 9 points (diastolic).

Depression

Research suggests that over 50% of people with diabetes also suffer from depression, although it is not yet known whether this comorbidity is related to biochemical or psychosocial issues. Depression can severely interfere with the multiple self-management aspects of a diabetes treatment regimen; therefore, controlling depression is critical to the control of diabetes in patients who suffer from both. Studies have demonstrated that regular physical activity can work at least as well as any other treatment for mild to moderate depression. Research in animals and humans indicate that exercise alters neurotransmitters that control emotion, can stimulate the parasympathetic nervous system, and improve the ability of the body to tolerate stress and to meet changing demands. Exercise also has definite cognitive effects; it has been shown to improve self-perception, providing a sense of personal mastery and positive self-regard. It also reduces negative thinking. These cognitive changes can be critical to a

person's ability to control a chronic disease such as diabetes.

Lipids

Since diabetes is a disease of not only carbohydrate, but also fat and protein metabolism, it is not surprising that the majority of people with diabetes have disturbances in lipid metabolism that result in dyslipidemia. Because dyslipidemia is a strong risk factor for the development of cardiovascular disease, and because people with diabetes are already at very high risk, every effort must be made to normalize serum lipids. Although most people will likely require medication to treat dyslipidemia to target levels, exercise can be a useful adjunct to medications along with proper adjustments in nutritional intake. Studies have shown that exercise can help to lower triglyceride levels and raise high-density lipoproteins (HDL—cholesterol), two changes that are necessary in most patients with type 2 diabetes. Exercise has also been shown to change body composition, so that visceral fat stores ("central adiposity") are decreased relative to subcutaneous fat. Visceral fat has been implicated as a major cause of the metabolic syndrome, and therefore decreasing the depot of this type of fat results not only in improved insulin sensitivity, but also might decrease cardiovascular risk in a number of other ways, such as by improving lipid profiles and prothrombotic characteristics of the metabolic syndrome.

GOALS OF EXERCISE

The overall goal of an exercise program is to achieve the health benefits described above. Other goals include improving flexibility, increasing muscular strength and endurance, improving cardiorespiratory function and aerobic endurance, and reducing or maintaining body weight with appropriate levels of bone, muscle, and body fat. These are all important goals, leading to increased functional capacity, improved quality of life, and contributing to health outcomes. A program that encourages improvement in each of these areas is generally recommended. As noted above, research has shown that disease risk factors, e.g., fasting glucose, insulin, lipids, and blood pressure, can be improved with moderate amounts of exercise. Achieving an adequate level of weekly energy expenditure is key and has led to public health recommendations for weekly levels of exercise. Any physical activity that contributes to increased daily energy expenditure can be beneficial for weight control, lowering body fat, and improving glucose regulation. Improvements in other fitness components, such as flexibility, muscular strength, and aerobic endurance, require more specific types and intensity of exercise.

Public Health Recommendations

Research has shown that even modest levels of physical activity have significant health benefits if done on a regular basis. Guidelines from the U.S. Centers for Disease Control and Prevention, endorsed by the American College of Sports Medicine and the American Heart Association recommend 30 minutes or more of moderate intensity exercise accumulated on most days of the week (Pate *et al*., 1995, pp. 402–407). Moderate intensity is defined as an exercise heart rate in the range of 45–85% of maximum heart rate. This level of exercise corresponds to about 150 minutes per week and 700–1,000 cal of energy expenditure per week depending on frequency and intensity of exertion. Recent research suggests that several short bouts (∼10 minutes) of exercise spaced throughout the day may be as beneficial as one sustained bout, as long as ∼30 minutes of exercise is accumulated over the course of the day (Pate *et al*., 1995; DeBusk *et al*., 1990). Thus, the guidelines emphasize accumulating the recommended minutes of exercise most days. Physical activity in chores such as sweeping, raking, shoveling, and similar activities is also beneficial, adding to daily energy expenditure, as does other strategies like taking the stairs

rather than the elevator and parking a few blocks from one's destination and walking the final distance. However, they can be difficult to track and are recommended as an adjunct, not a replacement, for planned exercise.

Planned Exercise

Planned exercise is any physical activity done explicitly for the purpose of achieving a given health and fitness objective. The type, intensity, duration, and location of activity are planned to contribute to the desired results. The range of activities is broad, from a 30-minute walk with a friend to increase energy expenditure, to a bout of weight lifting to improve muscular strength. We distinguish planned activity from more informal strategies since planning, scheduling, and logging activity improves awareness and ensures progress toward exercise goals. Sample physical activity planners and a log are given in the Appendix.

Weight Control

While both moderate caloric restriction and increased energy expenditure are recommended for weight loss, an increased level of daily physical activity is the best predictor of sustained weight loss. Rhythmical aerobic activities that engage large muscle groups, such as walking, rowing, cycling, and swimming, and that can be sustained for several minutes or more are generally best suited for increasing energy expenditure. These represent the most common activities prescribed for improving aerobic capacity and metabolic risk factors. The CDC guidelines represent an ideal goal for overweight individuals beginning an exercise program. For some obese individuals, this level of activity can be quite challenging, although it is more tolerable if shorter more frequent bouts of exercise are prescribed. Research has shown that individuals who are most successful at losing weight and keeping it off expend 1,500–2,000 cal or more in weekly exercise (Wing and Hill, 2001). This is more than recommended in the CDC guidelines and represents a useful long-term goal as fitness improves. This level of exercise represents roughly 15–20 miles of walking per week for an average weight individual.

Aerobic Endurance

Aerobic endurance supports the ability to sustain repetitive dynamic activities that require large muscle group involvement and elevated breathing and heart rates, such as brisk walking, jogging, swimming, rowing, and cycling. Also referred to as cardiovascular fitness and aerobic fitness, it relates to the ability of the circulatory and respiratory systems to supply oxygen during sustained physical activity. A treadmill or cycle ergometer exercise test of maximum oxygen consumption (max $\dot{V}O_2$ test) is considered the best measure of cardiovascular fitness, although field tests such as the 1-mile run or walk reflect aerobic fitness. Moderate intensity aerobic activities require significant energy expenditure, contribute to weight management, improve cardiac function and cardiovascular and muscular efficiency, lower blood pressure, and improve glucose metabolism.

Muscle Strength

Adequate levels of muscle strength are important for daily function. Muscle loss with aging and reduced muscle strength contribute to inactivity, physical impairment, lower resting energy expenditure, risk of weight gain, impaired glucose tolerance, and bone loss. While walking, swimming, and similar aerobic activities are essential for enhancing cardiorespiratory endurance, they have a modest effect at best on lean mass and muscle strength. Muscle strength is best improved through weight lifting and other types of resistance exercise. Persons with hypertension, nephropathy, neuropathy, or retinopathy should consult their physician before beginning resistance exercise since elevations in blood pressure may put them at risk.

Flexibility

Poor flexibility is associated with joint stiffness and low back pain. Flexibility can be readily improved with a regular routine of static stretches. Improving flexibility may help with stiffness and protect against injury during exercise.

RISKS OF EXERCISE IN PEOPLE WITH DIABETES

For most people with diabetes, or at risk for the development of the disease, the benefits of exercise far outweigh the risks. However, some precautions must be taken when making exercise recommendations in this high-risk population.

Exercise Assessments

Prior to recommending exercise to a patient with diabetes, a careful medical history and physical examination should be done with a focus on the symptoms and signs of disease affecting the heart and blood vessels, eyes, kidneys, feet, and nervous system.

According to the American Diabetes Association's 2004 Clinical Practice Recommendations, an exercise stress test is recommended for people who meet the following criteria:

- Age >35 years,
- Age >25 years, and
  - Type 2 diabetes of >10 years' duration
  - Type 1 diabetes of >15 years' duration.
- Presence of any additional risk factor for coronary artery disease,
- Presence of microvascular disease (proliferative retinopathy or nephropathy, including microalbuminuria),
- Peripheral vascular disease, and
- Autonomic neuropathy.

Although these criteria may seem conservative, and most adults with diabetes would meet at least one, it is important to acknowledge that this high-risk population requires careful screening for the presence of complications that may be worsened by the exercise program. In patients planning to participate in low-intensity forms of physical activity such as walking, clinical judgment may be used in deciding whether to recommend an exercise stress test.

Complications in addition to cardiovascular disease that are potentially worsened by exercise include (and are not limited to) diabetic retinopathy and neuropathy. Patients who have proliferative diabetic retinopathy should avoid weight lifting and other physical activity that involves straining, jarring, or Valsalva-like maneuvers. Patients with diabetes who are interested in strength training or body building programs must receive approval from their eye care professional prior to their participation.

Hypoglycemia

It is important for the clinician to realize that not all patients with diabetes are at risk for hypoglycemia (low blood glucose). Many patients with type 2 diabetes are able to control blood glucose levels without the use of medications that increase insulin levels, and thus do not experience insulin-induced hypoglycemia. In contrast, patients with type 1 diabetes must rely on exogenous insulin, and therefore are by definition at risk for hypoglycemia.

Hypoglycemia occurs in people with diabetes as a result of a mismatch between the amount of insulin required to promote adequate glucose uptake into cells (under present and potentially changing conditions) and the amount of insulin action during the same time period. Because sulfonylurea medications act by increasing insulin release from the pancreas, patients taking these drugs can experience the same mismatch of insulin need and insulin availability. Patients with diabetes are often in the difficult situation of wanting to normalize their glucose levels for prevention of complications and experiencing more hypoglycemia when they improve glycemic

control. Hypoglycemia is very common in such situations.

In part, it is difficult to predict and "standardize" the amount of glucose entering the bloodstream (dietary carbohydrate, endogenous glucose production) and the amount exiting the bloodstream by means other than insulin (exercise). As discussed earlier, exercise promotes the transport of glucose out of the bloodstream and into muscle cells aside from insulin action, thus resulting in a lowering of blood glucose levels in addition to that caused by insulin. The amount of glucose lowering depends upon not only the duration of the activity, but also on the intensity. The timing of physical activity also may be important in those who use medications that have a "peak action" such as intermediate-acting insulin. Because of the many variables involved, exercise-induced hypoglycemia can be a common, unpredictable, and dangerous complication of their diabetes.

As mentioned earlier, all types of insulin have the potential to cause the side effect of hypoglycemia. In addition, all medications that act to increase blood insulin levels can also cause hypoglycemia. These include sulfonylureas and combination medications containing sulfonylureas (Table 8.1).

TABLE 8.1. Medications that Increase Blood Insulin Levels

Generic name	Brand name
Newer (second generation), more likely used	
Glyburide	Diaβeta, Micronase, Glynase
Glipizide	Glucotrol XL
Glimepiride	Amaryl
Older (first generation), less likely used	
Chlorpropamide	Diabenese
Tolazamide	Tolinase
Tolbutamide	Orinase
Combination drugs containing sulfonylureas	
Glyburide and Metformin	Glucovance
Glipizide and Metformin	Metaglip

TABLE 8.2. Medications that Increase Pancreatic Insulin Release

Generic name	Brand name
Repaglinide	Prandin
Miglitol	Glyset

In addition to sulfonylureas, other drugs work by increasing insulin release from the pancreas and also can potentially cause hypoglycemia. However, these drugs are very short-acting and should be taken only with carbohydrate-containing meals. Patient education regarding the actions of medications should significantly reduce the side effect of hypoglycemia (Table 8.2)

EXERCISE RECOMMENDATIONS

Exercise prescriptions consider frequency, duration, intensity, and types of exercise (Table 8.3). Together, these variables determine total energy expenditure and the type of adaptation (e.g., muscle strength versus endurance) that can be expected.

Frequency

Some form of exercise can be done on most if not all days of the week. Low-to-moderate intensity aerobic exercise can be done on a daily basis without undue stress. More intense aerobic activity should be followed by less intense exercise or a rest day to ensure adequate recovery. Stretching exercises are safe to do every day. Strengthening exercises require a rest day between workouts. Research has shown significant improvements in muscle strength and bone mineral density with two days of weight training per week. Thus, two and not more than three weight training sessions per week are recommended.

Intensity

Moderate intensity aerobic exercise is defined as an aerobic activity that elicits a heart rate of approximately 45–85% of

TABLE 8.3. Example of Exercise Prescription Focused on Major Fitness Components

Goals	Improve major fitness components: aerobic endurance, muscular strength and endurance, flexibility, body weight and composition.
	Energy expenditure: ≥700–1,500 cal per week
Mode	Matched to goal (fitness component) and participant interest
	Aerobic endurance → rhythmical, large muscle group activity that elevates heart rate and respiration.
	Muscle strength and endurance → resistance exercise
	Flexibility → static stretching
	Body weight/composition → energy expenditure
Frequency	Overall: 5–7 days per week
	Aerobic endurance → 4–7 days per week
	Muscle strength and endurance → 2–3 days per week
	Flexibility → 5–7 days per week
	Body weight/composition → 5–7 days per week
Intensity	Aerobic endurance → 50–85% of max HR
	Muscle strength endurance → loads that allow 8–12 repetitions; final rep is challenging to complete
	Flexibility → hold for 15–30 seconds, at point just before discomfort
Duration	Overall: accumulate ≥30 minutes per day; 10–60 minutes per session, depending on goal, mode and fitness level.
	Aerobic endurance → 10–60 minutes per session
	Muscle strength and endurance → 30–60 minutes per session
	Flexibility → 10–15 minutes per session
	Body weight/composition → ≥30 minutes per day

maximum heart rate. This is roughly equivalent to brisk walking or easy jogging (4–6 mph). Most individuals are able to carry on a conversation during moderate intensity exercise, which is a good practical guide. Loads that can be lifted 8–12 times are considered moderate loads during weight lifting exercise.

Duration

Total exercise of 30–60 minutes per day is sufficient to achieve most exercise goals. Shorter bouts of 10 minutes each have been shown to have substantial benefit, as long as about 30 minutes are accumulated over the course of the day. Weight training sessions typically last 30–60 minutes. This amount of time is needed to exercise all major muscle groups and for adequate rest between sets. Only active time should be counted toward the weekly minute's goal.

Type

It is important to match the type of activity with the desired goal. Rhythmical aerobic activities, which engage large amounts of musculature, such as walking, jogging, swimming, and cycling, and which can be sustained for at least several minutes, generally elicit the greatest energy expenditure. Regular aerobic activity improves cardiorespiratory function, muscular endurance, and contributes to weight reduction and reduced body fat. Weight training and other forms of resistance exercise (e.g., cycle ergometers and rowing machines with adjustable levels of resistance) are necessary to improve muscle strength. Resistance exercise also contributes to energy expenditure, although potentially less than aerobic activity because of its intermittent nature with frequent rest intervals between sets. Stretching exercises must be performed to improve flexibility.

Energy Expenditure

The Diabetes Prevention Program's (DPP), *Lifestyle Change Program*, clearly showed exercise, along with healthy eating and modest weight reduction (∼7% of body weight), can dramatically reduce the risk of type 2 diabetes in individuals with impaired

glucose tolerance (DPP, 2002). The DPP exercise goal of 700 cal of energy expenditure in moderate intensity exercise was chosen because it is feasible for most individuals to attain. This goal corresponds to approximately 150 minutes of physical activity similar in intensity to brisk walking. Participants were encouraged to distribute their activity throughout the week with a minimum frequency of three times per week, with at least 10 minutes per session. A maximum of 75 minutes of strength training could be applied toward the total 150 minutes weekly activity goal.

Walking versus Other Activities

Many adults choose walking as their primary mode of exercise because it requires no special equipment, other than a good pair of walking shoes, and can be done just about anywhere. A beginner's walking plan is given in the Appendix. Other activities, equivalent to brisk walking, such as aerobic dance, bicycle riding, swimming (laps), and skating, can be equally effective for increasing weekly energy expenditure. Any safe, enjoyable activity that requires large muscle activity should be encouraged.

Flexibility

Approximately 10 minutes of static stretching exercises are recommended 3–7 days per week. Stretching is best done after light-to-moderate aerobic activity when the body temperature is slightly increased and the muscles are warmed. Stretching during cooldown is the recommended time. Upper and lower body stretches of all major muscle groups should be done. Static stretches that slowly elongate the muscle are recommended, along with holding the stretched position just before the point of discomfort. Specific stretches should be chosen in collaboration with a physical therapist or exercise specialist, considering past injury, joint laxity, or other imbalances, so as to not exacerbate existing conditions. Ballistic movements should be avoided.

Progression

A conservative progression encourages increasing frequency followed by duration and intensity. For previously inactive individuals, 3 days of exercise per week, of up to 30 minutes per day, is a good beginning. A minimum of 10 minutes per session is recommended. An additional day per week is added until the participant is exercising 5 or more days per week. Once the exercise "habit" is established, increasing duration in not more than 30 minutes increments per week over 5 weeks is recommended until the 150 minutes per week goal is reached. A total weekly energy expenditure of 700 cal, roughly equivalent to 150 minutes per week of moderate intensity exercise, is considered feasible and sustainable, and has been shown to be sufficient to produce improvements in weight, glucose, insulin sensitivity, and overall health. This is considered the minimum amount of weekly exercise. Successful long-term maintenance of weight loss has been associated with approximately 1,500–2,000 cal of energy expenditure per week, or roughly 15–20 miles of brisk walking (or the equivalent activity) per week. This level of exercise represents a long-term goal, to be undertaken once the minimum has been successfully maintained for ~3 months. This gives adequate time to improve fitness and establish a base from which more intense exercise can be safely undertaken. The increased energy expenditure can be accomplished by gradually increasing duration or intensity of exercise. For many individuals, there is limited time for exercise, so gradually increasing intensity (speed of walking for jogging) becomes the most feasible way to increase energy expenditure for individuals who are willing and able, without excessive time demands.

Static stretching can be done every day. No more than 5–10 minutes is needed to perform 4–5 stretches that stretch each major muscle group. Each stretch should be held for 15–30 seconds. Assisted stretching procedures like proprioceptive neuromuscular facilitation may facilitate greater improvements

in flexibility, but should be performed with care by trained partners, physical therapists, or sports medicine personnel.

Strength training is recommended 2–3 days per week. No more than 2–3 sets of 8–12 repetitions with the major muscle groups are needed to increase muscle strength and muscle mass. A typical progression is to begin with loads that can be lifted 8 times and increase repetitions over several sessions until 12 repetitions are achieved. The load is then increased by 2–10 lbs (depending on the muscle group), repetitions decreased to 8, and the cycle repeated.

Group Exercise Classes

Group exercise classes are beneficial for individuals who enjoy the camaraderie of exercising with other individuals, and they provide an opportunity for persons with lower self-efficacy to learn from leaders and more experienced classmates. Group classes allow facilities to provide instruction, motivation, and guidance to participants at a relatively low cost. However, they must be designed in a manner that is consistent with the specific goals and objectives of the participants, which can be challenging if the group is very diverse. Instructors must be knowledgeable about health risk factors, be able to conduct appropriate screenings, and modify programs for special needs. Instructors must hold appropriate certifications from nationally recognized organizations, such as the American College of Sports Medicine's Group Exercise Leader Certification.

Participants must have undergone appropriate screening and instructors must review and consider screening results for all class members when designing the class. Ideally, a group of individuals would start the class and progress together, although in community and clinical settings, this is often not feasible. The leader must be aware of each participant's fitness level, and the class must be structured so that participants can exercise at an appropriate intensity. Offering beginning, intermediate, and more advanced classes is an advantage, so participants may be grouped by fitness and experience.

Health and fitness facilities often offer a menu of classes that emphasize a particular fitness component, e.g., traditional aerobics classes, and aerobics classes that use equipment such as steps and bikes designed to improve cardiovascular fitness; weight training classes to improve muscle strength; and yoga and stretching classes to improve flexibility. For individuals without medical contraindications and who are interested, enrolling in "specialty" classes is enjoyable, motivating, and beneficial. Alternatively, classes can be structured to improve multiple fitness components. Typically, light-to-moderate aerobic activity for warm-up is followed by more vigorous aerobic and resistance exercise for improving aerobic endurance and muscle strength. Stretching for flexibility is done during a cooldown period following the more vigorous portion of the session. In the group setting when all individuals are performing the same exercise, caution in selecting appropriate exercises for all ages, disabilities, and skill levels is crucial. When selecting exercises appropriate for the group, the following evaluation is recommended; a yes answer to all questions is required to maximize participants' safety.

- Is the exercise safe for all participants based on age and health status?
- If the exercise is safe, are the participants able to perform the exercise properly?
- Is this exercise an effective way to increase flexibility, strength, coordination, balance, or cardiovascular endurance?

ACSM's *Resource Manual for Guidelines for Exercise Testing and Prescription* contains a detailed list of common high-risk exercises and recommendations for alternative exercises (American College of Sports Medicine, 2001). Finally, all facilities should have a written emergency plan for medical complications, and exercise class leaders must be familiar with them and certified in CPR and first aid. The Active Living Leadership, a national project supported by the Robert Wood Johnson Foundation, has recently launched

an online calculator (see "Resources" section) that can be used to estimate the financial cost of physical inactivity. This tool is useful for demonstrating to individuals and employers the costs of inactivity, the savings associated with becoming more active, and may be motivational.

MOTIVATING PEOPLE TO EXERCISE

The greatest challenge of any behavioral intervention is supporting patients in their goal of sustaining the new behavior until it is incorporated into their daily routine and becomes a way of life. According to the CDC, fewer than 50% of adults engage in the recommended amount of exercise, and about 25% of adults report no leisure time physical activity. In today's hectic world, with the demands of job, spouse, children, friends, and other obligations, there is little time left for exercise and other leisure pursuits, or so it seems. Perceived time constraints are probably the most cited barrier to regular activity, and inactive individuals need help restructuring their priorities. Frequent stress may contribute to depression, lethargy, and little enthusiasm for physical activity. Others may lack confidence that they can exercise or be fearful of injury, and some confuse fatigue with pain and injury. Still others set unrealistic goals and become discouraged when they are not met, or take on "too much too soon", and experience excessive soreness or injury. Even before an exercise program is begun, it is imperative that these issues be addressed. Too often, patients are told they should get more activity without instruction on how, or are given a prescription or sent to a gym without addressing psychosocial concerns. Lacking an adequate support system, it is understandable why they fail.

Participants need to know what they can and cannot safely do, and they need to be taught the difference between fatigue and undue soreness. Realistic goals (short- and long-term) and a realistic progression linked to those goals must be established. Perceived barriers to exercise must be identified and addressed, and the importance of planning, scheduling, and monitoring activity must be discussed. Appropriate forms for planning and logging activity should be given to the participant.

These issues can best be addressed one-on-one with a counselor or any other trained personnel. They also can be addressed in a group setting, led by a facilitator, as long as a nonjudgmental, supportive environment is maintained. The key is for individuals to self-identify challenges and personal solutions, although hearing other people's challenges and solutions can be insightful, and problem-solving with the group is often helpful. Individualization and enjoyment are keys to long-term motivation.

Participating in a variety of fun activities is motivational for many individuals; others are creatures of habit and prefer to stick with one activity. Finally, an appropriate support system is essential. For some persons, the opportunity for social interaction is attractive, and exercising with a buddy or group is motivational. Others view exercise as an opportunity for much-needed "solitude," and need understanding and support from others to reprioritize and take personal time. Some people need help in identifying their interests and exercise "personalities," and encouragement to ask for the support they need from friends and family. It is important to recognize that life challenges are constantly changing. Thus, psychosocial issues impacting on exercise and other healthful lifestyle behaviors should be revisited often and strategies revised right along with traditional prescription variables such as frequency, intensity, duration, and mode of exercise.

Creating Readiness and Stages of Change

People are more likely to adopt and sustain healthy behavior when they are ready to change. The Transtheoretical Model of Behavior Change (Prochaska and DiClementi) postulates people move through a series of stages while adopting and sustaining a new

behavior. The stages are precontemplation (no intent and no exercise), contemplation (intent, but no exercise), preparation (intent and occasional exercise), action (regular exercise), and maintenance (exercising for 6 months or more). Progression through these stages can be facilitated by targeted strategies. For example, individuals in precontemplation and contemplation may be helped by receiving information on the health benefits of exercise, instructions from a person of authority (health care provider), interactions with role models (in person, or through audio or videotapes), and through examination of previous attempts that may reveal ways to encourage adoption in a future attempt. Incentives and disincentives are important antecedents for health behavior change. Incentives should be built into the program and outweigh disincentives. Reducing disincentives, such as exercising at an inconvenient time, an unappealing place, or an unenjoyable activity, is very important. Goal setting is also an important part of the adoption phase. Asking participants to list goals and identify areas where assistance is needed may be effective in encouraging change.

Once a behavior is adopted, other factors determine maintenance. Behavior that is satisfying (reinforcing) or reduces discomfort is likely to be maintained. Four strategies have proved useful in enhancing maintenance: (1) monitoring (e.g., keeping logs) and feedback of change; (2) reinforcement—making the activity as satisfying as possible; (3) anticipating relapse or interruptions (relapse prevention); and (4) making a formal commitment (contract). Monitoring may take the form of self-reports, diaries, or physiological testing. Monitoring forms can be used together with exercise staff to determine progress and for problem-solving. Reinforcement may take many forms—social and symbolic reinforcers include attention, praise, money, and awards. It is important to recognize that reinforcers are idiosyncratic, and the particular reinforcers must be appealing to the participant. Relapse prevention may be especially important. Upon initiation of a program, participants should be encouraged to monitor exercise, identify clear signals for relapse, such as actual or anticipated reduction frequency, and develop written strategies to deal with situations that interrupt exercise, such as illness, injury, and changes in schedule.

ASSESSMENT

The recommended screening procedures before beginning exercise in patients at risk or with diabetes are given below. In addition to the usual medical screening, evaluation of activity history, self-efficacy for exercise, exercise barriers, motivation, social support, and readiness for activity are useful for developing strategies for adoption and maintenance of exercise.

Medical Screening

Screening is required prior to recommending individual exercise programs. For newly diagnosed patients or those without up-to-date medical records, a history and physical examination are required, including diabetes evaluation, evaluation of retinopathy, neuropathy, and nephropathy, cardiovascular evaluation, serum lipid profile, and an exercise ECG in patients with known or suspected CAD. Specific recommendations are given in Table 8.4.

The Physical Activity Readiness Questionnaire (PAR-Q)

The PAR-Q was developed to identify people who may need a medical evaluation prior to beginning an exercise program. This questionnaire would be appropriate for community prevention programs that include healthy people as well as those with chronic health challenges. “Translation, reproduction, and use in its entirety” are encouraged by the developers, the British Columbia Ministry of Health. The document can be found online at: http://www.nsa-norva.navy.mil/mwr/Physical%20Activity%20Readiness%20Questionnaire.pdf.

TABLE 8.4. Recommended Screening Procedures Before Beginning Exercise[a]

History of physical examination for those new diagnosed or without up-to-date records
Review all systems
Identification of medical problems (e.g., asthma, arthritis, and orthopedic limitations)
Diabetes evaluation
Glycosylated hemoglobin (HbA_1)
Ophthalmoscopic examination (retinopathy)
Neurological examination (neuropathy)
Nephrological evaluation (microalbumin or protein in urine)
Nutritional status evaluation (underweight, overweight)
Cardiovascular evaluation
Blood pressure
Peripheral pulses
Bruits
12-lead electrocardiogram
Serum lipid profile (total cholesterol, triglycerides, HDL, and LDL cholesterol)
Exercise ECG in patients with known or suspected CAD (for IDDM, those over 30 years of age or diabetes of longer than 15 years' duration; for NIDDM, those over 35 years of age)

[a] From Campaigne (2001, pp. 227–284).

Physical Activity History

Knowing a person's activity history, including their activity successes and failures, is helpful in planning their activity program. This can be assessed informally by asking what activities they enjoy, whether they prefer group or individual activities, team, dual or individual sports, their skill level and confidence, and frequency of participation. It is useful to assess at least the past 6–12 months history. A number of physical activity questionnaires have been developed, and many are reviewed in *A Collection of Physical Activity Questionnaires for Health-Related Research* (Pereira *et al*., 1997). The book by Montoye and colleagues is another helpful resource (Montoye *et al*., 1996). A checklist of common activities, which assesses typical frequency and duration of participation is useful for the purpose described.

Readiness for Change

Informally, a participant's readiness to undertake an exercise program can be assessed by asking him/her to rate on a 10-point scale his/her readiness to adopt and sustain an exercise program (1 = not ready, 10 = very ready). More formally, the Exercise Stages of Change questionnaire can be administered. The participants are asked to consider five statements regarding their exercise intent and recent history, and indicate which statement is true for them. Knowledge of the participant's readiness can help focus efforts designed to encourage behavior change. For more information on the Transtheoretical Model and Stages of Change, see the article by Marcus and Simkin (1994).

Exercise Perceived Barriers

Perceived barriers to exercise are assessed with questions surveying the demands on the participant's time, motivation, family obligations, health, and interest in exercise. Identification of potential barriers is the first step in developing a plan for removing barriers and sustaining compliance. The questionnaire is available in the article by Steinhardt and Dishman (1989).

Exercise Intrinsic Motivation

The Exercise Intrinsic Motivation questionnaire addresses interest in physical activity, enjoyment, perceived skill, and anxiety during physical activity. Along with perceived barriers, knowledge of intrinsic motivation aids in planning programs to enhance

compliance. The questionnaire can be found in the article by McAuley *et al*. (1989).

Exercise Self-efficacy

The exercise self-efficacy questionnaire assesses a person's confidence that they can stick with an exercise program when confronted with various situations and challenges. Individuals with low self-efficacy are at risk for poor compliance and may benefit from more frequent monitoring and social support. Realistic goals must be set, so they experience early success and build confidence. Exercising with a more experienced "buddy" also may help them build confidence (Sallis *et al*., 1988; Sallis *et al.*, 1987).

A flow chart summarizing steps for screening, exercise prescription, and promoting adoption and maintenance of regular activity is given in Figure 8.1. Exercise prescription guidelines are summarized in Table 8.3 and recommended screening procedures before beginning exercise are summarized in Table 8.4.

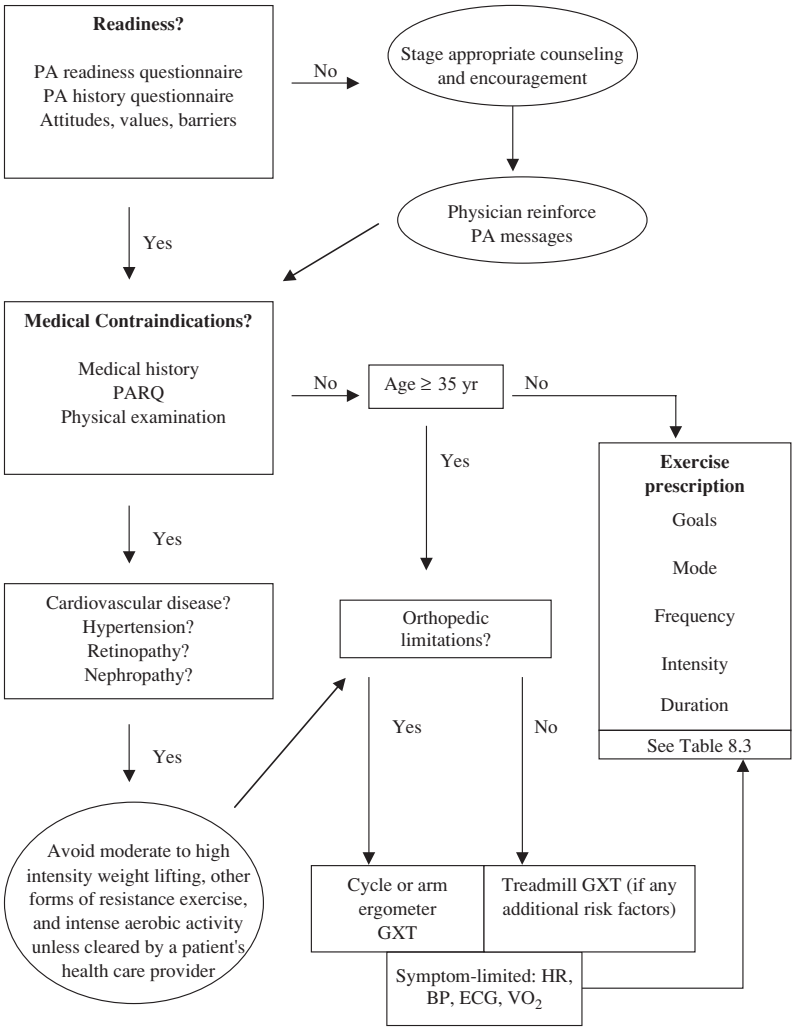

FIGURE 8.1. Steps for promoting and prescribing exercise. PA = physical activity, PAR-Q = physical activity readiness-questionnaire, GXT = graded exercise test.

APPENDICES

Walking Planner

Weekly goals: _____ minutes/ _____ steps

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
1	Duration	Duration	Duration	Duration	Duration	Duration	Duration
	Location	Location	Location	Location	Location	Location	Location
	Time	Time	Time	Time	Time	Time	Time
	# Steps	# Steps	# Steps	# Steps	# Steps	# Steps	# Steps
2	Duration	Duration	Duration	Duration	Duration	Duration	Duration
	Location	Location	Location	Location	Location	Location	Location
	Time	Time	Time	Time	Time	Time	Time
	# Steps	# Steps	# Steps	# Steps	# Steps	# Steps	# Steps
3	Duration	Duration	Duration	Duration	Duration	Duration	Duration
	Location	Location	Location	Location	Location	Location	Location
	Time	Time	Time	Time	Time	Time	Time
	# Steps	# Steps	# Steps	# Steps	# Steps	# Steps	# Steps
4	Duration	Duration	Duration	Duration	Duration	Duration	Duration
	Location	Location	Location	Location	Location	Location	Location
	Time	Time	Time	Time	Time	Time	Time
	# Steps	# Steps	# Steps	# Steps	# Steps	# Steps	# Steps
Daily Total Min							
Daily Total Steps							

Week's totals	Minutes	Steps

Note. In the Total steps boxes, write steps for the entire day.

Physical Activity Planner

Name: _____
Month: _____
Week's goals: Time _____ Minutes
Calories _____ cal

No

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
AM	Activity 1	Activity 1	Activity 1	Activity 1	Activity 1	Activity 1	Activity 1
	Duration	Duration	Duration	Duration	Duration	Duration	Duration
	Location	Location	Location	Location	Location	Location	Location
	Time	Time	Time	Time	Time	Time	Time
	Calories	Calories	Calories	Calories	Calories	Calories	Calories
AM	Activity 1	Activity 1	Activity 1	Activity 1	Activity 1	Activity 1	Activity 1
	Duration	Duration	Duration	Duration	Duration	Duration	Duration
	Location	Location	Location	Location	Location	Location	Location
	Time	Time	Time	Time	Time	Time	Time
	Calories	Calories	Calories	Calories	Calories	Calories	Calories
AM PM	Activity 1	Activity 1	Activity 1	Activity 1	Activity 1	Activity 1	Activity 1
	Duration	Duration	Duration	Duration	Duration	Duration	Duration
	Location	Location	Location	Location	Location	Location	Location
	Time	Time	Time	Time	Time	Time	Time
	Calories	Calories	Calories	Calories	Calories	Calories	Calories
TOTALS (CAL)							

Week's total

Important questions to consider while building your physical activity plan:

What physical activities do I enjoy?
What physical activities can I realistically engage in this week?
Can I engage in those activities safely (e.g., right shoes, hydration, etc.)?
How much activity do I need to meet my energy expenditure goal for this week?
How much rest should I get between activity days/sessions?
Can I involve anyone else in my physical activity Action Plan? Do I want to?

Physical Activity Log

Name: _____

Date	Time of Day	Description of Physical Activity (type, intensity, etc.)	Duration (minutes)	Comments
8/16/00	7:30 AM	Brisk walk, 3.5 mph	40	Felt great; try some jogging next time
8/17/00	4:00 PM	Swimming, leisurely	30	With Janet, bring water bottle

Notes: _____

_____

_____

_____

Beginner's Twelve Week Walking Schedule

This beginner's program is designed to get previously inactive persons *in the habit* and walking 60 minutes in 12 weeks. Warm-up and cooldown are included in the scheduled minutes. Consistency is the key to creating a new habit, even if initially the minutes must be reduced. Listen to your body and adjust accordingly. This schedule is meant as a guide. The starting point may be too strenuous or too light. Try to keep your easy and harder days in the same order. It is natural to feel a little tired or have a few aches when beginning a fitness program. However, if you are "worn out" or have pain, add a rest day. If the pain continues, see a physician.

	Sun	Mon	Tue	Wed	Thu	Fri	Sat
Week 1	15 min	15	20	15	20	15	20
Week 2	15 min	20	20	15	20	15	25
Week 3	15 min	25	20	15	25	20	25
Week 4	20 min	30	20	20	25	20	30
Week 5	20 min	30	30	20	30	20	35
Week 6	25 min	30	30	25	30	25	40
Week 7	25 min	30	40	30	30	30	40
Week 8	25 min	30	40	30	30	30	40
Week 9	30 min	40	40	30	40	40	50
Week 10	30 min	40	50	30	50	40	50
Week 11	40 min	40	50	40	50	40	50
Week 12	40 min	40	60	40	60	40	60

Resources

1. *American Diabetes Association (ADA):* The ADA provides information to people with diabetes, health care professionals, and the general public. A variety of programs targeted to preventing diabetes and its complications in high-risk populations are available for implementation in communities.

   a. Home page: www.diabetes.org

   b. Exercise information for patients: http://www.diabetes.org/weightloss-and-exercise/exercise/overview.jsp

   c. Small Steps, Big Rewards Program: The ADA and the National Diabetes Education Program (NDEP) have designed a national awareness campaign to target people at risk for type 2 diabetes. The campaign will create awareness that type 2 diabetes can be prevented through modest lifestyle changes and losing about 5–7% of body weight (translation of the DPP results into practice). A walking kit with pedometer (step counter) is available for purchase through the following web site: http://store.diabetes.org/adabooks/product.asp?pfid=922&WTLPromo=EXERCISE_book_smallsteps

   d. [d.] Diabetes Risk Test: A questionnaire developed to evaluate the risk of having or developing Type 2 Diabetes. Useful for health fairs or community health screenings.

   e. African American Programs: http://www.diabetes.org/community programs-and-localevents/africanamericans.jsp

   f. Latino Programs: http://www.diabetes.org/communityprograms-and-localevents/latinos.jsp

   g. Native American Programs: http://www.diabetes.org/community programs-and-localevents/ nativeamericans.jsp

2. *Diabetes Exercise and Sports Association:* http://www.diabetes-exercise.org/index.asp

3. *National Center for Bicycling and Walking:* The mission of this organization is to create bicycle-friendly and walkable communities. The website includes valuable information that can be applied to any community, including assessment tools: http://www.bikewalk.org/index.htm

4. *Centers For Disease Control Exercise Recommendations:* http://www.cdc.gov/nccdphp/dnpa/ physical/recommendations

5. *NIDDK: Information on Physical Activity and Weight Control:* http://www.niddk.nih.gov/health/nutrit/pubs/physact.htm

6. *Active Living Leadership* (http://www.activelivingleadership.org), physical inactivity cost calculator (http://www.activelivingleadership.org/ costcalc.htm)

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9

Living Well with Diabetes

An Approach to Behavioral Health Issues

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INTRODUCTION

Effective management is critical when you are living with a chronic condition like diabetes, a condition for the most part that is not curable. In order for this management to be effective, it needs to be as comprehensive as possible. This chapter will offer health care providers a comprehensive approach to helping individuals cope with chronic illnesses such as diabetes.

A THREE-PRONGED APPROACH TO COMPREHENSIVE MANAGEMENT

Sotile (1996) describes three main components for overall chronic care self-management: medical, behavioral, and emotional. To help remember this comprehensive approach to managing diabetes, it is helpful to think of a three-legged stool metaphor.

Medical Management

The first leg of the stool is effective medical management. Most patients think that effective medical management means taking medications as prescribed, seeing a physician or provider regularly, and perhaps, having a quality relationship with their physician or provider that allows them to ask questions and get the information they need. They are correct in thinking that these are essential aspects of effective medical management. But some people try to manage their diabetes with just medical management. This dimension of management is critically important but if it is the only way that a patient tries to manage their diabetes, then it is like having a one-legged stool. A one-legged stool can be effective, such as one used for milking cows, however, it does not offer solid support and, therefore, its effectiveness is limited.

Behavioral Management

The second leg of the stool is effective behavioral management. Behavioral

management includes diet patterns, physical activity levels, compliance, whether or not the patient tests and documents blood glucose levels regularly, whether or not they smoke, how well they understand and use diabetic equipment, whether or not they check their feet daily, etc. People with diabetes who take into consideration effective behavioral management along with effective medical management do much better than those who just try to manage their diabetes medically.

Emotional Management

The third leg of the stool is effective emotional management, which involves understanding and being able to deal effectively with the most common emotional reactions of living with diabetes.

COMMON EMOTIONAL REACTIONS

A common emotional reaction when first diagnosed with diabetes is *shock*. Even patients whose entire family has diabetes react with shock when they are diagnosed with diabetes because they felt immune to getting it or they thought they were living a healthy lifestyle that would prevent them from getting it.

Another initial emotional response can be *fear* or *uncertainty*. When first diagnosed, patients will often feel very uncertain about their future. They ask themselves what the disease means to them and wonder what changes they will have to make or how else it will affect them. Combined with these questions, there also might be a lot of fear, both of the unknown and of what will happen to them. Some will face their own mortality or the prospect of dealing with complications. Perhaps they will think about their relatives or friends who have lost limbs or have gone blind.

When working with a patient who has been recently diagnosed with diabetes, it is important to ask them sometime early in the process what their initial reactions were to the diagnosis. The patient's initial reaction will allow the health care provider to learn about the patient's understanding of diabetes, what their perspective of diabetes is, and whether or not they have had any family member or friends who have had diabetes. It is especially important in the Hispanic or Mexican American cultures to ask whether any relatives or friends have had it. They almost always will have relatives or friends who have diabetes and, based on this experience, they will have a certain perspective about the disease. Some of these perspectives will be positive or contribute positively toward their self-management of the diabetes. For example, a patient might talk about an aunt who lost her leg and is now on dialysis and that what they learned from this was that it is important to manage diabetes well to avoid such complications. These patients might, therefore, be more motivated to control their blood glucose levels.

Other perspectives might make it more difficult for patients to learn to cope with their diabetes. Another patient might describe similar kind of concerns (i.e., a relative dealing with complications) and see that as the inevitable road that they will have to travel.

Often when patients are initially diagnosed with diabetes, health care professionals overwhelm them with information about monitoring blood sugars, diet and exercise, or about lifestyle changes they have to make. Not enough time is dedicated to finding out their view of the illness, which ultimately shapes their response to self-management issues. Reviewing these common emotional reactions provides an opportunity to hear about the patient's individual perspective. These early discussions also can be very effective in a group context. As one patient describes their emotions, other patients identify with them, which can lead to a useful discussion about emotions and reactions that is really initiated and sustained by the patients themselves. During these discussions, patients practice skills that ultimately will contribute to their effective management of the chronic condition.

Another common emotional reaction at diagnosis and in the continuing struggle to live well with diabetes is *anger*. The answers of patients or group of patients as to why they are angry will usually go in one of two directions. Patients might say that they are angry at themselves because they knew that they were at risk for diabetes but they did not do the things that they knew they should have done to prevent it. Or they might be angry at the reality of getting the diagnosis because they feel they had been doing the right things to avoid diabetes. There is often a high level of frustration simply with the fact of having to learn so much new information and having to make adjustments in so many areas.

The reactions of family members also should be discussed. Often family members will not have an initial reaction of anger but as the situation progresses, they too can experience frustration, anger, and fear as they have to make changes too. For example, a spouse who does all the cooking and grocery shopping and who does not have diabetes might feel frustrated at having to make significant changes for the person who has diabetes.

Another common emotion is *anxiety*. Often people are very anxious about whether they will be able to make the needed adjustments in their lifestyles. They will also have anxiety about being able to continue the type of work that they are doing or whether they will be able to afford the medical costs related to controlling their diabetes.

Another common emotional reaction that typically occurs further down the road after initial diagnosis is *depression.* We will elaborate on depression further in this chapter.

EMOTIONAL CONTINUUM

Although these emotional reactions are present initially, many of these emotions actually manifest themselves on a continuum. The fear continuum can range from a small amount of anxiety to being paralyzed with the fear. The anger continuum can range from a small amount of frustration with the lifestyle changes that are needed to a paralyzing anger or bitterness toward these changes and an outright refusal to make them. The depression continuum can range from feeling down or discouraged at certain times to being clinically depressed.

Continuum

Fear

Anxiety——————————Paralyzing fear

Anger

Frustration——————————Bitterness

Depression

Sadness, discouragement } ——————— { Clinically depressed

Depression

It seems that no matter how hopeful and optimistic a patient is when they begin the trek of dealing with diabetes, eventually everyone gets discouraged at some point in managing and controlling it because it is a chronic condition and has to be dealt with over time. It is important to introduce patients to this fact fairly early in the process just to help them normalize this reaction. Knowing that depression is a natural reaction to diabetes will help some get through it.

Other patients may need additional help getting out of a depression. It is important to address depression because there is really good evidence that people with chronic conditions, such as diabetes, who also get clinically depressed, have a much harder time controlling and managing their diabetes.

At Marana Health Center, we routinely screen for depression. Any patient with diabetes is given a PHQ-9 depression screen (Spitzer, Kroenke and Williams, 1999), a widely used depression screening in primary care.

If depression is diagnosed, then we follow the guidelines established for treating depression in primary care that were part of the McArthur study (The Macarthur Initiative on depression & Primary Care at Dartmouth &

Duke, 2003). Depending on the PHQ-9 score, we might decide to follow a watchful waiting protocol to see how the patient responds, adjusts, and deals with it and then reassess in a month. Or we may decide to start the patient on antidepressant medications immediately with frequent follow-up. It is important to realize that some level of depression or depressive feelings is common and to manage this along with the diabetes is crucial.

In addition, there needs to be ongoing assessment of both depressive feelings and the other common emotions because a patient can do very well managing the emotions at one point in living with their diabetes but experience significant problems with these emotions at another point in their lives. For example, I worked with a 46-year-old Hispanic female who had diabetes for about 18 years. She had worked very hard to manage her diabetes well and not let it interfere in her life in any way. She got an infection in her foot and was hospitalized for 1 week. After returning home, the infection got worse, she had to be rehospitalized and ended up spending another 5 weeks in the hospital. She almost lost her leg and did loose her job. She was completely recovered by the time I saw her at Marana Health Center but was now struggling with emotions she had never experienced before related to her diabetes—fear and discouragement. Patients need to be aware that managing the emotional part is just as important as managing the medical part of diabetes.

Managing Stress

Other aspects of effective emotional management include understanding and managing stress, learning how to relax and refuel, managing personality based coping patterns, nurturing family teamwork, and controlling cognitions or thought patterns. These five components of effective emotional management come from Dr. Wayne Sotile and are explained more fully and completely in his book, *Psychosocial Interventions for Cardiopulmonary Patients* (1996).

Both patients and health providers who work with patients with diabetes should consider the three-legged stool metaphor and at every opportunity bring up questions or offer information related to each leg of the stool: effective medical, behavioral, and emotional management. These three legs are always interacting and the people who live well with diabetes over the long haul have learned to manage diabetes in each of these three ways.

Building a Foundation

In addition to the three types of effective management of diabetes, there are the three foundation stones for living well with a chronic illness, such as diabetes. This is another discussion that is often very effective in a group context because of the interaction that it sparks among patients with diabetes. This discussion is most effective in a group where there is a range of patients in terms of the amount of time that they have been dealing with their diabetes.

Awareness, Acceptance, and Action

The three foundation stones that are useful in living well with diabetes are (three A's): awareness, acceptance, and action. First of all, patients with diabetes need to be aware of as much information as possible regarding diabetes. Normally providers are very good at giving the patient information. This should include information about the chronic quality of diabetes and how that affects a person differently than a disease that is curable. At this point, it is important to get the patient's perspective on what chronic means and how the chronic quality of the illness affects a person physically, emotionally, mentally, and in relationships. It is also important for patients to have awareness about the uncertain quality of diabetes and to know that, even when it is managed well, certain things beyond their control can happen. They also need to have awareness of the healing systems of the human body and

how it functions as an integrated system in which you cannot separate the mind from the body in terms of dealing with a chronic disease. Patients tend to be very open to receiving information, but as health providers we often feel that by giving the information we have done enough. However, the reality is that information does not change anyone by itself. It can be the beginning of a change, but it is also important to talk about acceptance, the second foundation stone.

When asking patients how they react to the word "acceptance," a health care professional will usually get a few different reactions. Some can be very negative. For example, some patients might say that they will never accept having this illness. Upon further exploration, the health professional might learn that, for this person, acceptance means "giving into it" or "giving up." Acceptance would contradict their personal goal of overcoming the disease. Other reactions include trying to live like they do not have diabetes (i.e., pretending to not have it) or denying that they have it. Denial eventually is very problematic for the patient because diabetes cannot be beat simply by force of will. Usually, the person who tries to live like they do not have it crashes hard. Eventually they get to the point, they have a melt down, or get extremely sick and then are faced with dealing with the reality of the illness.

Two types of people who do not do well with diabetes are those who give up when they get the diagnosis and those who try to live like it really is not true. An approach is to talk them about acceptance as a victory that has two parts. The first part is accepting the reality of the illness. The patient says to themselves "all this information I've gotten applies to me and it is true for me." The second part is accepting that they have power to respond to the information and to make a difference with the disease.

Awareness and acceptance leads to action, the third foundation stone. At this point, patients have the information available to them, they have accepted the reality of the disease, and that the information they have received is relevant to them. They then put this information into action. They are now willing to start making changes in the way they eat and are willing to start monitoring their blood sugars regularly. They are also willing to muster all of their personal resources and to start doing things in all of the realms of what it means to be a human being. These realms include the mental, emotional, and spiritual aspects of a person. They are willing to start taking action to add to the body's natural resources and responses by doing things that increase the healing response and encourage wholeness.

Building a Framework

A foundation is not a house, so the next step is to talk to patients about building a framework on the foundation. The discussion about the foundation stones and the framework can also be done effectively in a group context. Group sizes can range from three to eight people in order to be effective in dealing with the issues that come up with emotional management. More and more community health centers are using group classes for patients with diabetes, during which time they discuss effective emotional management.

As the discussion of building a framework on the foundation stones unfolds, patients are encouraged to cultivate certain senses or states. When asking patients what the word "cultivates" means, the responses usually have an agricultural connotation. For example, they will use terms like "to turn up the soil," "to expose to light," "to irrigate," "to weed," and so on. Many descriptions imply a very active process. To cultivate is a very active ongoing process, and the process and end result is very helpful, which is a perfect description of what a patient with diabetes wants to do with certain states or senses.

Patients are encouraged to cultivate a greater sense of relaxation. And for most patients, this is a difficult one to incorporate into their lives especially because for many with

diabetes their lives get busier as they do the things necessary to manage the illness. Discussing ways to include and cultivate a greater ability to relax physiologically also will cultivate more peace of mind. Since there seems to be an increased level of anxiety associated with living with diabetes or other chronic illnesses, cultivating peace of mind becomes important.

Cultivating a greater sense of control is important especially for the patients who experience living with diabetes feel like their life is starting to spin out of their control. Anything that can give them a greater sense of control will help them manage their diabetes and control their emotional reactions of living with it. Patients also are encouraged to cultivate hope and joy. Often when a person starts dealing with a chronic illness, it is an opportunity to start discussing some of the larger issues in life. Spiritual issues might become more important with patients. Patients are especially encouraged to continue to do things that are fun for them and make them laugh. Often people have to stop doing things, especially around food, that were pleasurable to them and it is important to find other ways to experience joy.

Patients are also encouraged to cultivate connections. Dealing with diabetes can often narrow a person's involvement with others. Perhaps they stop going out to eat or to have pizza and beer with a group of friends because they do not want to deal with the issues affecting their blood sugars or having to explain to them about their newly diagnosed condition. As a result of diabetes, their lives can become more confined or restricted. Patients need to know that it is important to continue cultivating connections with others. One of the advantages of discussing this in a group context is the new friendships that can develop.

Creativity is another topic that patients are encouraged to cultivate. When they are faced with doing new things and thinking about things in new ways, they can use this as an opportunity to do things they have never done before. Patients are encouraged to start experiencing or exploring new things to broaden their experiences. Patients are also encouraged to cultivate the spiritual aspects of what it means to be fully human and this might include seeking God or developing faith. Some patients pray or have others pray for them. Others find ways to serve others even in the midst of their struggles with diabetes.

Spirituality may be about finding ways to love others. An older Mexican American woman, who comes to the Marana Health Center, lives alone and feels that attitude is one of the most crucial aspects in managing her diabetes. What helps her continue to have a positive attitude about her own health is volunteering three to five times a week at the senior center in Marana. Helping others takes her mind off herself. It also made her realize that many people have it worse than she does. Doing this motivates her to continue to take good care of her diabetes. She also finds real pleasure and enjoyment in taking care of her dogs, and that motivates her to do the things that she needs to do for herself so that she will be able to be with them and take care of them.

As mentioned earlier, these issues can be dealt very effectively in a group context, but most patients with diabetes probably will not spend a lot time within a group context. It is possible to bring these issues up in small ways as health providers have an ongoing relationship with their patients. Over time, discussions with patients are opportunities to bring up the three types of effective management, the foundation stones, and the states to cultivate. Patients are encouraged to continue on a path of managing and controlling their diabetes when health care providers tie together medical, behavioral, and emotional management.

As a health care professional continues to work with patients with diabetes, they can provide them with incremental information about effective emotional management. This can happen either in a group context or individually.

The next component of effective emotional management includes providing the patient with information about understanding and managing stress, making a connection between stress and physiology. When they get this connection, they can then see how it relates to their blood sugars or their blood pressure and the other issues that affect diabetes.

Health care professionals should also show the connection between stress and coping energy, describing the warning signs they should see when their coping energy is getting low. This energy is the one they need to cope well with things including their diabetes and the other issues that are ongoing in their life. At the same time, patients should be shown that to understand and manage stress, they need to learn to relax and refuel.

Another dimension that becomes critical in effective emotional management and can be seen over time when working with patients with diabetes is their personality-based coping pattern or style. This style will have a major impact on the way they approach the management of their diabetes and how effective they are with managing their diabetes. It is important for patients to be more aware of their particular pattern and to recognize the pitfalls associated with that pattern when they are living with a chronic condition. They should also begin to work on changing parts of their pattern. Dr. Wayne Sotile gives detailed information on these coping styles and describes the most common coping styles and the pitfalls of each style when living with a chronic illness. This information is useful for framing how to make suggestions to patients with diabetes in terms of certain behavioral changes, and how to support them in the changes that they are making.

Discussing these coping styles or patterns can lead naturally to a discussion of nurturing family teamwork. It is important to emphasize with patients having diabetes that diabetes is not just an individual disease, it affects the entire family. And like any chronic condition it can tear down relationships over time unless individuals and family members are doing things to make sure that this does not happen. The tearing down of relationships can happen in small increments, but because the condition is chronic, over time these small separations can result in a large separation between family members or the people with which they are most intimately involved.

It is basically true that the more connected, understood, and supported a person feels, the better they do in managing their diabetes. So it is important to acknowledge and identify the types of support needed for encouragement and to practice openness and intimacy. These issues certainly include the issue of independence versus dependence, of change of roles, of change of lifestyles, and of uncertain future. Often, it is important for the health care provider to bring up these issues as family members might be reluctant to bring them up because they do not want the patient with the diabetes to feel guilty or get angry with them. Sometimes family members and friends are afraid if they bring up certain issues about living with diabetes and how it affects them that it might look like they do not really care about the patient.

CONCLUSION

The most effective management of diabetes will always involve medical, behavioral, and emotional components—a three-legged stool. Health care providers have a crucial role in helping patients with diabetes manage the emotional component. From dealing with common emotions to managing stress and nurturing family teamwork, the health care provider can consistently and gently help the patient along the path of living well with their diabetes.

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10

Planning for Sick Days, Surgery, and Travel

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Diabetes control can be adversely affected by stressful situations related to physical or emotional distress. Health care providers must be able to advise patients with diabetes who become ill with infections, injuries, or other ailments that complicate their diabetes management routine and cause hyperglycemia.

Definition of a sick day: A sick day could be caused by a variety of situations, from a common cold to a broken bone to a death in the family. If the patient is thrown off of his/her usual diabetes management routine, or experiences persistent hyperglycemia despite self-management techniques that usually maintain glucose control, he or she is having a sick day.

RISKS ASSOCIATED WITH CONCURRENT ILLNESS

The most critical complication of concurrent illness is diabetic ketoacidosis (DKA). Although DKA usually does not occur in those with type 2 diabetes, studies in recent years indicate that it does occur more than was once thought in younger people and in people of color who have type 2 diabetes. DKA is present in the patient who is producing ketones and has a blood pH below normal. Ketones are produced when the body is unable to metabolize carbohydrate for energy. This situation is caused by insulin levels that are insufficient to promote glucose transport inside cells where its metabolism occurs. Therefore, since DKA is caused by insulin deficiency, it can usually be prevented by adequate insulin administration.

Another life-threatening complication is called hyperglycemic hyperosmolar nonketotic syndrome (HHNK), also called hyperosmolar nonketotic hyperglycemia (HONK). In this situation, which is most commonly found in elderly people with type 2 diabetes, severe hyperglycemia and dehydration occur in the absence of ketone production.

Both DKA and HHNK are life-threatening situations. Preparing patients to safely and effectively manage sick days ahead of time can mean the difference between life and death.

PATIENT RECOMMENDATIONS FOR NUTRITIONAL INTAKE AND MEDICATION ADJUSTMENT

Type 1 Diabetes

Insulin Adjustment

The most common trigger for DKA is the omission of insulin. Health care providers have consistently taught patients that they must eat after taking their insulin. Patients can misinterpret this information, and omit their insulin if they know they are unable to eat due to illness. It is important to explain to patients that their long-acting (basal) insulin is required even if they are not eating. Most patients with type 1 diabetes are now on peakless basal insulin analogs (such as insulin glargine) that do not cause hypoglycemia during fasting (if appropriately dosed). Those patients who are on a basal/bolus insulin regimen should understand that the basal insulin has no relationship to food intake, and their bolus (short-acting) insulin is meant to cover meals and to correct hyperglycemia when it occurs. Patients who are taking older basal insulins may experience hypoglycemia during the insulin's peak time when they are fasting or unable to eat. Regular insulin, which is still used by some patients to cover meals, is actually closer to an intermediate-acting than a short-acting insulin. The short-acting insulin analogs (such as lispro or aspart) are more effective for meal coverage and for correcting hyperglycemia than is regular insulin. In the event that patients are not eating, basal insulin should be continued, and regular insulin and the short-acting analogs should be used only to correct hyperglycemia.

Other Medications

Antiemetics. Vomiting is a very potent trigger for DKA, and can also be a symptom of DKA. In any case, if vomiting persists the patient will almost certainly decompensate and require a hospital admission. Thus, it is crucial to attempt to prevent or stop vomiting in patients with diabetes. Antiemetic suppositories are a practical treatment for nausea, and can be called in to the pharmacy if the patient complains of nausea and/or vomiting. Patients who have had recurring DKA associated with vomiting should have an active prescription for antiemetics at all times.

Nutritional Recommendations

To prevent or limit dehydration and electrolyte imbalance, it is important for food and/or fluid intake to continue. In general, patients should be encouraged to drink 4–6 ounces of noncaloric fluids every 30 minutes. Carbohydrate (sugar) intake is also important, and a goal of 50 g every 4 hours will simulate typical meals. Foods and fluids that may be used to replace usual meals include:

- Sports drinks
- Crackers
- Jell-o (*not* sugar-free)
- Soup
- Applesauce
- Bananas
- Fruit juice
- Soft drinks (*not* sugar-free)

Type 2 Diabetes

Medication Adjustment

Patient taking oral medications to treat diabetes should continue to take them. If they are nauseated and unable to eat solid food, they may have to temporarily omit their metformin, since it can exacerbate nausea if taken on an empty stomach. Insulin secretagogues such as glyburide and glipizide should be taken to maximize the patient's ability to secrete insulin during the illness. This insulin production is necessary and is similar to the exogenous basal insulin discussed in type 1 diabetes. Therefore, patients should not omit these medications even if they are not eating.

Patients with type 2 diabetes who are taking insulin should be advised as if they have type 1 diabetes—always take the basal insulin

even if unable to eat; take extra short-acting insulin if necessary.

Nutritional Recommendations

Nutritional recommendations during sick days for those with type 2 diabetes are similar to those for type 1.

SURGERY AND OTHER MEDICAL PROCEDURES

Surgery certainly qualifies as extreme stress, and as such promotes a physiological response similar to a sick day, and usually more extreme. Medical procedures such as vascular studies or endoscopies usually require special preparations that disrupt the patient's usual routine and may or may not alter medication requirements. Risks of surgery include severe hyperglycemia, fluid and electrolyte imbalance, hypoglycemia, and DKA.

Patients with diabetes should also be prepared for other challenges associated with hospitalization, such as receiving appropriate nutrition. Despite current, evidence-based of nutritional recommendations for patients with diabetes provided by the American Diabetes Association and others, most hospital food service departments continue to provide meals according to calorie level, or "no sugar (sucrose) added" limits, not carbohydrate content. Patients who are managing their total carbohydrate intake may be frustrated with the high carbohydrate meals they receive in the hospital. In some situations, a regular diet would be more beneficial to patients who know how to estimate their own carbohydrate intake.

PATIENT RECOMMENDATIONS FOR THE PERIOPERATIVE PERIOD

Ideally, a patient with diabetes who is scheduled for surgery should discuss their perioperative management with the diabetes care provider prior to the surgical preparation. Often, patients receive insufficient or inaccurate recommendations from the anesthesia and/or operative team. Many times older patients with type 1 diabetes are assumed to have type 2, and are thought to be safe temporarily without basal insulin. Iatrogenic DKA is fairly common due to omission of insulin during the perioperative period. In contrast, if hospital professionals have a poor understanding of the differences in insulin requirements between insulin-resistant patients with type 2 diabetes (very large doses) and insulin-sensitive type 1 patients (sometimes very small doses), all patients with diabetes might receive similar insulin doses for the same blood sugar level. This is seen in the outmoded "sliding scale" insulin orders using regular insulin, which is not recommended.

Type 1 Diabetes

- Patients should never be advised to omit a dose of basal insulin. If the basal insulin is NPH or Lente, due to the potential for hypoglycemia during the peak action, the dose may be adjusted:
    - If NPO:
        - If basal insulin is glargine or another peakless insulin, do not change the dose. This insulin should already be adjusted to fasting glucose levels.
        - If basal insulin is NPH or Lente, give the usual night time dose; decrease the morning dose by 30%.
        - Use short-acting insulin only to correct hyperglycemia (if the patient does not have individualized instructions, 15% of total daily dose 4 to 6 hours apart is a good starting point).
    - If on clear liquids:
        - No change in the basal insulin.
        - Use short-acting insulin to correct hyperglycemia (as above).
        - Recommend a combination of carbohydrate-free and carbohydrate-containing beverages, aiming for 50 g to replace one meal.

Type 2 Diabetes

If the patient takes oral diabetes medication, they should continue to take it until a strict NPO situation is necessary. If a potential exists for renal compromise during or after the procedure, metformin should be discontinued until after a postprocedure creatinine level less than 1.4 mg/dl. Patients who take insulin should be given the same insulin-adjustment guidelines as type 1 patients (discussed above).

Travel

Patients with diabetes are able to safely travel as long as a few precautions are taken. High and low blood sugars can occur due to changes in meal timing and content. Medication adjustments may be necessary for a minority of travelers. In order to control diabetes during travel, patients must have adequate monitoring supplies, medications, and knowledge regarding the foods that will be available and a method of estimating carbohydrate content.

Foot Care

Travel often includes using public transportation, sightseeing, and other activities that cause more wear and tear than usual on already vulnerable feet. Foot problems during travel are so common that a new term has been coined by the podiatry community—"Diabetic Holiday Foot Syndrome." Patients with diabetes should be prepared to walk more than they usually do in a typical day. Encourage travelers to wear athletic or other walking shoes, to limit friction on skin by wearing socks, to examine feet frequently (especially in the middle of the day to detect early problems), and to carry supplies for minor foot problems such as blisters or abrasions. Patients with neuropathy will not be able to detect early skin problems and must actively seek them by examining their feet frequently.

Packing

Regardless of the mode of travel, people with diabetes should have the following items in a "carry-on" bag, easily accessible:

- all the insulin and syringes you will need for the trip
- all oral medications (an extra supply is a good idea)
- blood glucose testing supplies (include extra batteries for your glucose meter)
- urine ketone strips if using an insulin pump or history of DKA
- other medications or medical supplies, such as glucagon, antidiarrhea medication, antibiotic ointment, antinausea drugs
- personal ID and diabetes identity card
- a well-wrapped, air-tight snack pack of crackers with cheese or peanut butter, a juice box, and some form of sugar (hard candy or glucose tablets) to treat low blood glucose.

Airline Security

The American Diabetes Association has worked closely with the Transportation Security Administration to ensure that people with diabetes are treated fairly in light of recent increases in airport security. A full set of recommendations can be found at www.diabetes.org. In general:

- Notify the security screener that you have diabetes and are carrying your supplies with you.
- Make sure your insulin vials, insulin pens, jet injectors, and insulin pump are accompanied by a professionally printed pharmaceutical label identifying the medication (insulin), which is usually on the outside of the box.
- Lancets, blood glucose meters, blood glucose test strips can be carried through the security checkpoint.
- Notify screeners if you are wearing an insulin pump, and request that they visually inspect the pump rather than removing it from your body.

- Advise screeners if you experience symptoms of a low blood glucose level and are in need of medical assistance.
- The above protocol applies only to travel within the 50 United States and is subject to change. International passengers should consult their individual air carriers for applicable international regulations.

Dealing with Time Zone Changes

Time zone changes are not usually problematic unless the change increases the risk of hypoglycemia. The risk of hypoglycemia is increased if insulin is taken and carbohydrate is not consumed during the time the insulin peaks. People taking oral agents, basal/bolus insulin, or using insulin pumps typically do not need to make major adjustments during travel. Those who take premixed insulin, intermediate-acting insulin, or a combination of intermediate-acting and short-acting insulins may need to make some adjustments.

Adjusting Insulin for Travel

Newer insulins have made travel much less of a burden for insulin-treated diabetes. If a peakless basal insulin is used, the timing of the injection need not be changed since it has no relationship to food intake. If the patient expects to be asleep during the time of the usual injection, the time could safely be adjusted by up to 2 hours per day until reaching a convenient local time to take the injection. Depending on the length of the trip and the difference in time zone, another option would be to premeasure the insulin and keep the syringe at the bedside, set an alarm and take the injection at the same time as at home. Short-acting insulin should be taken to cover meals and correct hyperglycemia as usual.

Older basal and premixed insulins are more difficult to adjust, since they do influence meal times. The more time zones the patient crosses, the more complicated the adjustment will be. In general, traveling East shortens the day, and less insulin may be needed. Traveling West lengthens the day, and more insulin (additional injections) may be needed. In general, patients will be safe taking the usual dose the morning of travel, if two daily injections are taken, the larger dose is usually (not always) taken in the morning, to control meal-related glucose excursions during the day. When traveling to another time zone, the patient should be advised to take the usual dose the morning of travel, and to adjust amounts the rest of the day. For example, if traveling West, take half the evening dose with a meal at the usual (home) time, and the remaining half with another meal at the local dinner time.

It should be apparent that the basal/bolus regimen is less complicated and people who travel extensively should be offered this regimen if they are still taking intermediate-acting or premixed insulin.

SUMMARY

Sick days, surgery, and travel are situations in which routines are disrupted. Careful planning can help avoid diabetes complications during these challenging times.

PATIENT GUIDE TO SICK DAY MANAGEMENT

Type 1 Diabetes

What is a sick day? Any day that you are not feeling well, having trouble eating your usual meals, or are experiencing a medical procedure or extreme emotional upset.

Why are sick days important? Diabetes is affected not only by what you eat and the insulin you take, but also by other hormones in the body. Hormones that work against insulin usually increase during illness or stress, causing the insulin you take to work less effectively. This is why illness and stress cause the blood sugar to rise. Diabetic ketoacidosis is a severe, life-threatening complication of diabetes that commonly occurs during illness or severe stress. This develops due to a lack of adequate insulin to fight the stress-related hormones.

What can I do? The *MOST* important thing you can do during a sick day is to take your insulin. Even if you cannot eat, your body needs at least the insulin you take during a usual day, maybe even more. You should adjust your insulin as follows:

- Identify your longest-acting insulin. This is probably either glargine (Lantus), NPH, or Lente. Take your usual dose of this insulin, the same number of times during the day.
- Identify your shortest-acting insulin. This is probably lispro (Humalog), aspart (Novolog), or regular insulin. If you are not eating, do not take your usual doses of the short-acting insulin. Take the short-acting insulin as follows:
    - Add together your total daily dose of all insulin.
    - How many units of long-acting and short-acting insulin do I take in a typical day? _____ units
    - Figure out 15% of this number (with a calculator, multiply your total daily dose × 0.15). If the result is a fraction, round up to the nearest unit. This is your "sick day dose".
    - My "sick day dose" is:_____ units of short-acting insulin.
    - When blood sugar is over 150 mg/dl, take this dose of short-acting insulin, at least 4 hours apart.

What should I eat? If you are able to, eat the way you usually do. If you are unable to eat normally, it is important to make sure you get enough fluid and carbohydrate (sugar).

- Drink 4–6 ounces (4 ounces is half a cup) of fluid without calories every 30 minutes. This fluid could include water, unsweetened hot or cold tea, or diet soft-drinks. This fluid is important to prevent dehydration.
- Eat or drink 50 g of carbohydrate every 4 hours. To find the carbohydrate content in food/fluids, look at the nutritional label. Note the serving size, and the total carbohydrate. For example, one can of (non-diet) soda contains 12 ounces and 43 g of carbohydrate. This carbohydrate (sugar) will provide you with energy to fight your illness, and help to prevent low blood sugar.

What else should I do during a sick day?

- Check your urine for ketones. When the body produces ketones (detectable in the urine) and your blood sugar is high, it means you are not taking enough insulin to stay in control during your illness.
    - If you have ketone strips, make sure they are not expired
    - If you do not have ketone strips, get some at the pharmacy (available without a prescription)
    - Check your urine for ketones several times daily while you are sick. If you are taking enough insulin and fluids, ketone levels should not be more than "small"

- Call your diabetes care provider (primary care physician, nurse practitioner, or diabetes educator) if:
    - You vomit (throw up) even once; ask for an antinausea medication. Suppositories work best if you are having trouble keeping food down. A prescription may need to be called in to your pharmacy. This could prevent a hospital stay.
    - You have an obvious infection. You may need an antibiotic.
    - Your illness lasts longer than 2 days
    - Your blood sugar is over 400 mg/dl, two times in a row, after you have taken your sick day dose of insulin and it should have had an effect.
    - You have "moderate" to "large" amounts of ketones in your urine and a blood sugar over 200 mg/dl for more than 8 hours, even after taking your sick day dose of insulin.
    - You feel very sick or are in pain.
    - You have abdominal pain, shortness of breath or trouble breathing, your family notices a fruity odor in your breath, or you become extremely sleepy or woozy.

Your diabetes care provider is:
Name: _____
Office number: _____
Emergency contact information: _____
_____
_____

PATIENT GUIDE TO SICK DAY MANAGEMENT

Type 2 Diabetes

What is a sick day? Any day that you are not feeling well, having trouble eating your usual meals, or are experiencing a medical procedure or extreme emotional upset.

Why are sick days important? Diabetes is affected not only by what you eat and the insulin you take, but also by other hormones in the body. Hormones that work against insulin usually increase during illness or stress, causing the insulin you take to work less effectively. This is why illness and stress cause the blood sugar to rise. Severe high blood sugar requiring hospitalization can occur if proper care is not taken during illness.

What can I do? When you are sick, even if you are unable to eat normally, you must take your diabetes medication. If you take only pills for your diabetes, you need these even if you are unable to eat. Metformin (Glucophage), a common diabetes medication, can cause stomach upset if not taken with meals. If this happens to you, stop taking the metformin until you are able to eat again.

If you take insulin (either alone or in combination with diabetes pills), you still need to take it while you are sick. Even if you can not eat, your body needs at least the insulin you take during a usual day, maybe even more. You should adjust your insulin as follows:

- Identify your longest-acting insulin. This is probably either glargine (Lantus), NPH, or Lente. Take your usual dose of this insulin, the same number of times during the day.
- Identify your shortest-acting insulin. This is probably either lispro (Humalog), aspart (Novolog), or regular insulin. If you are not eating, do not take your usual doses of the short-acting insulin. Take the short-acting insulin as follows:
    - Add together your total daily dose of all insulin.
    - How many units of long-acting and short-acting insulin do I take in a typical day? _____ units
    - Figure out 15% of this number (with a calculator, multiply your total daily dose × 0.15). If the result is a fraction, round up to the nearest unit. This is your "sick day dose".
    - My "sick day dose" is: _____ units of short-acting insulin.
    - When blood sugar is over 150 mg/dl, take this dose of short-acting insulin, at least 4 hours apart.

What should I eat? If you are able to, eat the way you usually do. If you are unable to eat normally, it is important to make sure you get enough fluid and carbohydrate (sugar).

- Drink 4–6 ounces (4 ounces is half a cup) of fluid without calories every 30 minutes. This fluid could include water, unsweetened hot or cold tea, or diet soft-drinks. This fluid is important to prevent dehydration.
- Eat or drink 50 g of carbohydrate every 4 hours. To find the carbohydrate content in food/fluids, look at the nutritional label. Note the serving size, and the total carbohydrate. For example, one can of (non-diet) soda contains 12 ounces and 43 g of carbohydrate. This carbohydrate (sugar) will provide you with energy to fight your illness, and help to prevent low blood sugar.

What else should I do during a sick day?

- If you normally take insulin, check your urine for ketones. When the body produces ketones (detectable in the urine) and your blood sugar is high, it means you are not taking enough insulin to stay in control during your illness.

- If you have ketone strips, make sure they are not expired
- If you do not have ketone strips, get some at the pharmacy (available without a prescription)
- Check your urine for ketones several times daily while you are sick. If you are taking enough insulin and fluids, ketone levels should not be more than "small"

- Call your diabetes care provider (primary care physician, nurse practitioner, or diabetes educator) if:
  - You vomit (throw up) even once; ask for an antinausea medication. Suppositories work best if you are having trouble keeping food down. A prescription may need to be called in to your pharmacy. This could prevent a hospital stay.
  - You have an obvious infection. You may need an antibiotic.
  - Your illness lasts longer than 2 days
  - Your blood sugar is over 400 mg/dl, two times in a row, after you have taken your sick day dose of insulin and it should have had an effect.
  - You have "moderate" to "large" amounts of ketones in your urine and a blood sugar over 200 mg/dl for more than 8 hours, even after taking your sick day dose of insulin.
  - You feel very sick or are in pain.
  - You have abdominal pain, shortness of breath or trouble breathing, your family notices a fruity odor in your breath, or you become extremely sleepy or woozy.

Your diabetes care provider is:
Name: _____
Office number: _____
Emergency contact information: _____

11

Self-Management

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INTRODUCTION

Never before have health care professionals had at their disposal the variety and efficacy of medications. Sulfonylureas, once the mainstay of type 2 diabetes mellitus management, have now been joined by many new medications that reduce insulin resistance and inhibit hepatic glucose production. Today's glucose monitoring systems are less painful and patients have an endless choice of foods specifically produced for people with diabetes. Insurance companies even will reimburse patients who regularly exercise by offering discount memberships to health clubs. Despite the advances in medicine and technology, too many patients have HbA1cs over 8%. Complications of renal failure, amputations, and vascular diseases continue to plague persons with diabetes. Regardless of how advanced the science of diabetes management is, positive health outcomes will not occur without effective strategies to encourage patients to self-manage more effectively.

Self-management efforts are a priority for today's health care team. Demonstration projects funded by the Center for Medicare and Medicaid (CMS) have turned their efforts to a "pay for performance" strategy rewarding providers with higher reimbursements for achieving positive health outcomes in chronic care management. In the managed care arena, pay-for-performance models have been launched in several of the Blue Cross plans in California and Michigan and also within Aetna. "Rather than monitoring physician groups on the basis of traditional cost controls and utilization management, Pay for Performance (P4P), the revised bonus evaluation process, monitors for improving the quality of care given to HMO patients using health outcomes and patient satisfaction information from a number of clinical and service categories, according to the Blue Cross of California" (www.healthsourcesonline.com/edu/payper.htm, 2004).

In order to move to this next level of health care reimbursement, health care team members must prepare themselves to not only know how to measure their outcomes but they also must learn new skills. Health care providers should ask themselves . . .

– How do I motivate patients to be "self-managers?"

– What kind of skills do I, as a health care provider, need to learn so that I can teach and empower my patients to become "self-managers?"

– How do I do this in my 12-minute office visit?

– Can I do it more efficiently as a team?

These are not easy questions to answer. Empowering patients to be in charge of their health is a complex process of knowledge and skill-building coupled with problem solving and coping skills to deal with day-to-day issues. Even more challenging is that in order to motivate a person to self-manage his diabetes mellitus effectively, the provider must know the patient as an individual. What motivates one person may not motivate another. This can be a baffling challenge for both patients and providers. In essence, the health care team and patient must be armed with a "menu" of strategies to approach self-management.

This chapter will identify elements of self-management behavior goals recommended by the American Association of Diabetes Educators (AADE) and provide an overview of adult learning principles, key theoretical perspectives, and application models being utilized in today's chronic care self-management frameworks. This chapter also will offer the reader a number of self-management tools that can be adapted to any setting.

DIABETES SELF-MANAGEMENT EDUCATION GOALS

The American Association of Diabetes Educators has outlined seven self-care behaviors as the Diabetes Self-Management Education Core Outcomes Measurements. These behaviors are:

1. Being active: physical activity (exercise)
2. Eating
3. Medication taking
4. Monitoring blood glucose
5. Problem solving especially for blood glucose and low levels, and sick days
6. Reducing risks of diabetes complications
7. Living with diabetes (psychosocial adaptation) (Mulcahy *et al*., 2003, p. 768).

Any type of diabetes program should weave these seven behaviors into individual and group self-management efforts. The AADE offers a comprehensive framework for the diabetes educator to assess, intervene, and evaluate these behaviors. For a complete technical review, the reader can obtain a copy of the standards from The Diabetes Educator, September/October 2003 issue authored by Mulcahy *et al*. (2003)

ADULT LEARNING PRINCIPLES

To begin a self-management program, the basics of adult learning must be reviewed. Beebe and O'Donnell identify five principles that are applied to diabetes self-management education:

– Self-directed learning enhances autonomy

– Adults must feel a need to know

– Problem-oriented learning is more acceptable

– Incorporating life experiences enhances motivation

– Active participation is essential for behavior change (Beebe and O'Donnell, 2001, p. 381).

Example. Utilization of these five principles can be exemplified through the ongoing relationship of one particular patient, Mr. J.L., a 45-year-old Hispanic man with type 2 diabetes. Mr. L's HbA1c is 8.7%. He lives alone and eats all of his meals at three different church base shelters everyday. He is asked to come in weekly to the clinic and see the nurse practitioner to review the type of food he has eaten at the shelters. He and his nurse practitioner together identify the foods and fluids he eats. They talk about food choices in food quality and quantity, such as choosing a small

glass of orange juice instead of a fruit drink, using a small quantity of pancake syrup only, and a pass up on the toast and jam are also offered. In addition, he is advised to walk after every meal to increase carbohydrate utilization. Further insight is encouraged by asking him how much fatigue he had the day when he ate excess of carbohydrates.

Beebe and O'Donnell add that these principles regarding self-management education are also applicable to children with diabetes. However, they note that additional interventions on coping skills and decreasing parent–child conflict also must be incorporated.

Another aspect to consider is that adult learners have different learning styles. Hartman (1995) identifies four major styles:

Concrete. This is an individual who wants things presented in a clear, structural, and orderly sequence. This person wants to know what is expected and what are the goals and objectives.

Experiential. This individual learns through direct practical instructions. This person learns by doing—physical objects are important.

Abstract. This individual is the most challenging, because they want to know "why" about everything. They need other references/research.

Cooperative. This individual learns best in groups.

While applying diabetes self-management education to the adult learner, the educator must be creative and able to assess quickly what type of learner the person is and what tools can be utilized to meet his/her learning style. For example, the concrete learners will benefit with the patient diabetes MAP (see Figure 11.1) and pocket passport. They can see exactly what is expected of them in their self-management process.

The experiential learners will learn by monitoring their blood sugar levels and seeing the changes over time. The abstract learners may need a textbook and web sites to satisfy their need for more information. The cooperative learners will learn better in a group class where they can participate with others.

The Center for Case Management expands on the Adult Learning principles through their Levels of Patient Education Outcome Attainment (Henry and Zander, 2001). In this model, the educator identifies a patient's educational competency level by cognitive, psychomotor, and belief domains. This model integrates Lamb and Stempel's (1994) case management work on "insider–expert" with the educator role and defines the teaching/helping process in three steps:

1. As an educator, you bond with the patient around the crises (such as newly diagnosed with diabetes or having to start on insulin injections). The educator helps the patient to learn the meaning of the illness and their hope.
2. The educator begins to work with the patient, helping them think differently about themselves and their situation.
3. Eventually, the educator assists the patient in changing by experimenting with new behaviors, accepting help, and moving into self-care as much as possible.

This model opens the health care provider to a different relationship with the patient, in some cases, the educator/provider serves as an "expert" for the patient when the patient needs new information and, at other times, the educator is an "insider" for the patient when they need support and encouragement. Table 11.1 illustrates how a provider can evaluate their success in being the "insider–expert" with their patients' achievement with self-management.

LITERACY

Literacy is another aspect to consider when addressing self-management. Too often, providers assume that the patient can read and/or write, or are medically literate. Therefore, assessing literacy is critical but difficult. In most cases, patients are embarrassed to admit they cannot read or write. Or they nod their head when the provider is explaining about laboratory results in medical terminology. In some cases, patients may bring someone else with them to the visit to mask their literacy. In order to address these literacy

Patient Diabetes MAP

Patient Name:_____ **Date:**_____
Primary Care Provider:_____ Phone:_____
Diabetes Nurse Educator:_____ Phone:_____
Dietician:_____ Phone:_____

Your Health Care Team	A team of doctors, nurses and dieticians are working together to evaluate and treat your diabetes.
Self-Management:	The following activities are important for you to do as part of your own are management:
Blood Sugar	☐ Check your blood sugar _____ times a day before meals and record the results.
Meal Plan	☐ Follow the individual meal plan that has been developed by you and dietician. Please make appointment with Dietician. Appointment Time:_____
Exercise	☐ Follow the exercise prescription given to you. _____
Medication	☐ Take your diabetes medicine regularly as prescribed.
Testing:	You and your health care team will work together to keep your:
Weight	☐ Weight near the target weight decided on by you and your dietician. Goals sets: _____
Blood Sugar	☐ Blood Sugar between 80 and 120 before meals and 2 hrs after meals below 145.
HgbAlc	☐ HgbAlc checked every three months. ☐ HgbAlc at or below 7%.
Blood Pressure	☐ Blood pressure at or below 130/80.
Cholesterol	☐ LDL Cholesterol at or below 100 mg/dl
Urine Protein	☐ Urine for protein annually
Prevention:	In order to notice any important changes in your condition: ☐ Have an annual dilated eye exam. ☐ Check your feet daily and have them checked regularly by your physician. ☐ Report any infection or illness for prompt treatment. ☐ Do not smoke. If you are smoking start a smoking cessation plan. ☐ Control stress in whatever healthy ways work best for you (no drugs or alcohol please). ☐ Others: _____
Education:	☐ 1. type of Diabetes _____ ☐ 2. Glucose monitor given _____ ☐ 3. Patient given instruction on how to use glucose monitor. ☐ 4. Patient able to demonstrate Finger stick technique and Blood testing. ☐ 5. Hyperglycemia, causes, and treatments. ☐ 6. Hypoglycemia, causes, and treatments. ☐ 7. See a diabetes educator (nurse and/or dietician) for basic diabetes education. _____ ☐ 8. After that initial visit, follow-up education will be scheduled as needed

Signature of Educator _____Date: _____

Source: St. Elizabeth of Hungary Clinic, 2002

FIGURE 11.1. Patient Diabetes MAP.

issues, Schillinger (2000) suggests the following methods for providers and health educators to work with their patients:

(1) *Use qualitative jargon rather than technical or lay jargon*. In other words, describe a measurement in terms of how much or how often. Be careful not to use the words "good" or "bad" without qualifying. For example, when discussing diet with a patient who had high cholesterol, the patient said that he had heard that peanuts and walnuts were a good fat, so he ate them regularly and in large quantities. The patient truly believed that he was making a healthy choice. When the provider

TABLE 11.1. Levels of Patient Education Outcome Attainment Model

Competency level	Cognitive domain	Psychomotor domain	Value/Belief
Beginner	Knowledge	Perceptions and set	Receives
	Repeats	*Reads*	*Pays attention*
Intermediate	Comprehension	Guided Response	Responds
	Defines	*Reviews with*	*Comments*
Advanced	Application	Mechanistic	Values
	Describes	*Uses*	*Plans*
		Performs	
		Completes	
Expert	Analysis	Complex Overt	Organizes
	Evaluates	*Adjusts, Adapts*	*Commits*

Source: Used with permission: The Center for Case Management, Inc. 1991.

explained that nuts are still a fat and must be eaten in limited quantities, the patient was surprised, but very willing to reduce his intake before starting on medications. This patient was a high school math teacher, but had limited medical literacy.

(2) *Use the interactive communication loop*. Schillinger (2000) describes a circular methodology that asks patients to repeat the instructions or have them explain their disease process or health problem back to the provider or educator. This gives the provider a better understanding of what area needs to be restated or explained. After the provider evaluates where the patient is in their level of recall and understanding, then the provider offers another explanation and has the patient again recall the instructions or explain.

Example. Mr. J.L., who was previously mentioned, is illiterate but can copy numbers from his glucometer to his log book. He cannot write down his food intake but can understand pictures of food and beverages, which he circles on a picture log. He then can visibly see the relationship of the foods he ate with subsequent blood sugar readings. The practitioner reviews the log and assesses the patient's level of comprehension from both the qualitative and disease integration standpoint.

THEORETICAL PERSPECTIVES ON BEHAVIOR CHANGE

When looking at self-management, many health care team members lump success in relation to the person's willingness to comply or adhere to self-care advice given. But it is not that easy. Kristeller and Rodin (1984) differentiate between a three-staged model of treatment: compliance, adherence, and maintenance (self-management). They summarize that compliance is the greatest level of dependency on the health care system, adherence is an intermittent dependency, while self-management is the demonstration of maximum of independence on the system.

Theoretical models approach self-management through constructs that investigate cognitive capabilities, literacy levels, gender differences, cultural belief systems, attitudes, behavioral change components, and social support systems. Not only is it an issue of learning new behaviors, but in many cases, old patterns must be unlearned (Beebe and O'Donnell, 2001). This section describes common models that are currently being applied in adult self-management training and what has been shown to work. One thing for sure, it is not an easy issue of just compliance to advice.

Health Belief Model

The Health Belief Model (Becker, 1974) offers a framework for the health care team to gain an all encompassing perspective related to the individual's perceptions, sociodemographics, external cues, and likelihood to

take action. This model discusses the interrelationship that occurs in a person's health belief and how the provider must take into account when assessing these multidimensional aspects needed for a patient to become a "self-manager." The following description of each component is described with examples.

Individual perceptions address two concepts: (1) susceptibility and (2) seriousness. Assessing how a person views their own level of susceptibility to an illness, and their own lived experience with the seriousness of the illness helps shape the person's willingness and readiness to take action of some type. For example, a patient who has had a family member with diabetes and renal complications or a serious infection on their foot that eventually lead to an amputation will help enhance the individual's perception of seriousness. If they have had several close family members with diabetes, they most likely will perceive their own risk of getting diabetes some day.

Sociodemographics are another critical feature of this model. Lower income individuals do not seek preventive health care and tend to have a higher rate of chronic illnesses, such as diabetes, high blood pressure, etc. Cultural influences and beliefs also play an important role in prevention and chronic illness actions. It is important to assess the person's cultural beliefs and actions and understand how to adapt interventions into the person's belief systems. For example, the diabetes team considered combining a nutrition group class for Asian Pacific patients. However, when it was explored more thoroughly, it was identified that each culture holds very separate food preferences, which may be contradictory to the other and insulting. For example, one from Asian Pacific culture may eat red meat while another may not. Therefore, trying to encourage this patient to attend a group nutrition class will only distance the person from care. Instead, a more personalized approach through a one-on-one format may be more appropriate.

Finally, other demographics such as educational level must be recognized. Individuals who have a higher educational level tend to have a greater rate of health insurance (www.covertheuninsuredweek.org). This translates into better practices for health prevention and early detection for those with health insurance.

TABLE 11.2. Cues to Action

Family members	Most cultures
Church bulletins, clergy	Most cultures
Community Health Workers: promotoras and community health representatives[a]	Mexican American, Native Americans, African Americans
TV advertisements on language specific stations	Mexican American
Radio stations for specific cultures	Mexican American, Asian-Pacific,
Newspapers for specific cultures	Most cultures
Grocery store flyers (language specific)	
Workplace flyers (paycheck stuffers)	

[a] Community Health Workers have become more and more important in the areas of self-management.
Source: Please refer to "Chapter 20" for a more comprehensive discussion on the background, training, and utilization of the CHW.

Cues to action portray a multitude of cultural vehicles related to their values and belief systems. For example, in the Mexican American culture, novellas (soap operas) are a popular form of entertainment and can be used as an educational vehicle. Other popular forms of cues to action are provided in Table 11.2.

Likelihood to take action weighs the benefits to the barriers while adapting a self-management practice. In other words, is the cost or time to perform a new behavior perceived as more of a barrier or a benefit for that individual and/or their family. For example, if a person is asked to start monitoring their blood glucose daily, it is important to assess if the patient has the financial means to pay for the glucometer strips and whether the person has the time to perform the test as recommended by the provider. The skill-building

effort also may be looked at as a barrier and not a benefit.

Example. One nurse practitioner (NP) teaches her patients who do not have insurance to test daily as follows: First day, the patient will do a prebreakfast measurement. The next day, the patient will check their blood sugar 2 hours after lunch. The third day, the patient will do a reading before bedtime. Of course, the NP instructs the person to take a reading if they experience unusual symptoms.

Transtheoretical Theory (Readiness for Change)

One of the more widely applied models today is Prochaska and DeClementi's Readiness for Change Model (1992). Initially applied to addictive behaviors, this model has been utilized with many other behavioral change efforts, such as weight management, smoking cessation, and chronic care management.

The success of this model is threefold:

1. The health care provider can easily assess the person's level of readiness by identifying their stage of change.
2. The health care provider can then match an intervention modality keeping in mind the person's culture and literacy level.
3. The health care provider engages in a collaborative process with the person to identify barriers and level of confidence to begin a self-management practice.

The stages of change and typical characteristics are illustrated in Table 11.3. Suggested interventions are offered with each stage.

Here are a few examples of applying the stages of change theory to patients with diabetes.

TABLE 11.3. Motivating Behavior Change

Stage	Attitude	Typical characteristics	Intervention tools
Precontemplation	"Never"	Not planning to change in the near future. Uninformed or under-informed about the risks; often labeled as resistant or unmotivated	Build awareness Screenings for blood Sugar Health fairs Computerized health Risk appraisals
Contemplation	"Someday"	Consider changing their habits in the near future. Some awareness of risks; often labeled as procrastinators or ambivalent.	Give more information through brochures, books, web sites
Preparation	"Soon"	Planning to take action within the next 30 days. May have made unsuccessful attempts to change.	Set Goals Develop a wellness plan
Action	"Now"	Actively changing their habits. May not consistently carry out new behaviors.	Give logs such as blood sugar logs, diet logs, exercise logs Health care provider must give review and give feedback[a]
Maintenance	"Forever"	Have maintained new behaviors for 6 months. Not tempted to return to old habits.	Refer to support groups Have patient return for regular (i.e., monthly, quarterly, etc.) check ups Develop relapse Prevention plan

[a] Motivating Behavior Change: Modified from Take the First Step Heart Health Resource. General Mills Bell Institute of Health and Nutrition.

– *Precontemplation stage*: Elicit from them symptoms like blurred vision or fatigue and discuss the relationship of these symptoms to hyperglycemia.

– *Contemplation stage*: Discuss how elevated blood glucose levels damage the lining of small blood vessels and utilize props from brochures or a video.

– *Preparation stage*: Set a goal of two servings of fresh vegetables and two servings of fresh fruit per day.

– *Action*: Ask the patient to fax or call the provider with their weekly blood sugar log.

– *Maintenance*: Set a goal with the patient to come for quarterly diabetes visits to review HbA1c results, weight, blood sugar, and exercise logs.

Dr. Scott Gee, a pediatrician and medical director for Prevention and Health Information in Kaiser's in Oakland, CA, suggests two tools: communication guidelines to promote health behavior change, and talking with patients about diabetes management key strategies: patient choice, matching readiness, and promoting self-care. Providers and educators can use these tools as guides to assess individuals and families based on their level of readiness plan and help them develop a plan to move in self-management adherence (Figures 11.2 and 11.3).

Self-Efficacy

Self-efficacy is a theory that describes a person's evaluation of his or her capacity to manage stressful or problematic situations (Bandura, 1982). Successful self-management depends on the person believing that the behavior change will improve the situation (outcome expectancy). The person also must believe that he can make the behavior change (Bandura, 1982). When working with a patient with diabetes mellitus, help him set realistic goals.

For example, discuss the goals of increasing the intake of three vegetables servings a day and decreasing 1–2 servings of starch each day. Then ask the patient if they feel this is possible for them to do for the next 2 weeks. Using a scale of 1–10, with 1 being not very confident and 10 being very confident, ask the patient how they would rate their level of confidence or capability in accomplishing these goals. If the patient says 4, ask what would help them raise it to a 7 or 8. As the provider, you may need to help the patient redefine the goal to achieve a higher level of confidence. Figure 11.4 is an example of a self-management tool that providers can use with patients (www.improvingchroniccare.org).

Putting Theory into Practice

Chronic Care Model: Self-Management Component

Putting these theories into practice is a process of integrating many of the constructs described here and fitting them into a working rubric. Without question, there are a number of internal and external variables that must be considered. The Chronic Care Model discussed in Chapter 6 offers a methodology to assess an organization's ability to effectively manage chronic care. The model addresses six elements for chronic care management: community linkages, health system, self-management support, clinical information systems, delivery system design, and decision support (Wagner, 1998). The 2002 Health Disparities Collaborative Training Manual provides a checklist for health care organizations in relation to examining the six elements of the Chronic Care Model. The manual recommends the following self-management review. Does your organization:

- Use diabetes self-management tools that are based on evidence of effectiveness.
- Set and document self-management goals collaboratively with patients.
- Train providers on how to help patients with self-management goals.
- Follow-up and monitor self-management goals.
- Use group visits to support self-management.
- Tap community resources to achieve self-management goals.

Developing a program that incorporates these self-management objectives into practice will begin to address the patient–provider interaction. Effectiveness will then be measured through health status changes and satisfaction rates of patients and providers.

CHRONIC DISEASE SELF-MANAGEMENT PROGRAM

The Chronic Disease Self-Management Program (CDSMP) was designed at the Stanford Patient Education Research Center (Sobel & Lorig, 2002). This program utilizes

BRIEF NEGOTIATION
Behavior Change Counseling for Diabetes Management

Communication Guidelines to Promote Health Behavior Change

Ask Permission

- *Would you be willing to spend a few minutes discussing your diabetes management?*
- *Would you be interested in discussing ways to manage your diabetes?*

Share Clinical Results (optional)

- *I have your recent test results, would you like to look at them together?*
- *What is your understanding of A1C? (educate as needed)*
- *Your A1C is 8.9%.*
- *The target A1C for diabetes control is 7.0%.*
- Ask for the patient's interpretation: *What do you make of this?*
- Add your own interpretation or advice as needed AFTER eliciting the patient's/parent's response

Offer Options

- *There are a number of ways to manage your diabetes. They include:*
  - Healthy Eating
  - Physical Activity
  - Medication
  - Home Blood Sugar Monitoring
- *Is there one of these you'd like to discuss further today? Or perhaps you have another idea that isn't listed here.*

Assess Readiness

0	1	2	3	4	5	6	7	8	9	10

- *On a scale from 0 to 10, how ready are you to consider [**option chosen above**]*
- Straight question: *Why a 5?*
- Backward question: *Why a 5 and not a 3?*
- Forward question: *What would it take to move you from a 5 to a 7?*

FIGURE 11.2. Communication guidelines to promote health behavior change. (*Source*: Used with permission, Kaiser Permanente, Oakland, CA 2003.)

BRIEF NEGOTIATION
Behavior Change Counseling for Diabetes Management

Explore Ambivalence

Step 1: Ask a pair of questions to help the patient explore the pros and cons of the issue

- What are the things you like about____? ***AND:***
- What are the things you don't like about_____?

OR

- What are the advantages of keeping things just as they are_____? ***AND:***
- What are the advantages of making a change_____?

Step 2:

- Summarize Ambivalence
- Ask: Did I get it all? / Did I get it right?

Tailor the Invention

Stage of Readiness	Key Questions
Not Ready 0 – 3 • Raise Awareness • Elicit Change Talk • Advise and Encourage	• *Would you be interested in knowing more about managing your diabetes?* • *How can I help?* • *What might need to be different for you to consider a change in the future?*
Unsure 4 – 6 • Evaluate Ambivalence • Elicit Change Talk • Build Readiness	• *Where does that leave you now?* • *What do you see as your next steps?* • *What are you thinking/ feeling at this point?* • *Where does _____fit into your future?*
Ready 7 – 10 • Strengthen Commitment • Elicit Change Talk • Facilitate Action Planning	• *Why is this important to you now?* • *What are your ideas for making this work?* • *What might get in the way?* • *How might you work around the barriers?* • *How confident are you in your ability to carry out your plan?* • *How will you know you've reached your goal?* • *How might you reward yourself along the way?*

Close

- Summarize
- Show Appreciation/Acknowledge willingness to discuss change
- Offer advice, emphasize choice, express confidence
- Confirm next steps
- Arrange for follow up

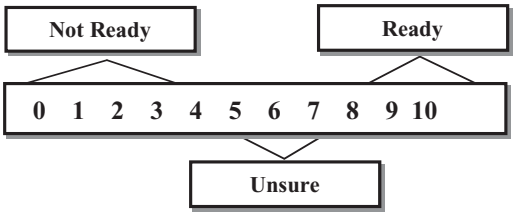
FIGURE 11.2. (*continued*)

Talking with Patients About Diabetes Management
Key Strategies: patient choice, matching readiness and promoting self care

Research supports that patient choice and matching your intervention with patient readiness promotes successful self care. Eliciting patient perspectives highlights strengths and barriers that allow you to swiftly focus on what is most important to the patient. "Matching" your intervention can decrease frustration in talking about behavior change.

Invest in the Beginning

- Ask Permission
  "Would you be willing to spend a few minutes discussing your diabetes management?"
- Assess Readiness
  "We've talked a little about your diabetes and how important healthy eating can be. On a scale from 0 to 10, how ready are you to begin making some changes in how you eat?"
- Customize Your Approach Based on Readiness



Stage of Readiness/Goals	Key Questions
Not Ready 0 – 3 • Raise Awareness • Advise and Encourage	→ Would you be interested in knowing more about diabetes and your health? → How can I help?
Unsure 4 – 6 • Evaluate Ambivalence • Build Readiness	→ What might be the pros and cons of making a change? → What do you see as your next steps? → What are you thinking/feeling at this point?
Ready 7 – 10 • Strengthen Commitment • Facilitate Action Planning	→ What are your ideas for increasing physical activity? → What might get in the way? → How might you work around the barriers? → How confident are you in your ability to carry out your plan?

Invest in the End

- Show appreciation for patient's willingness to discuss diabetes
- Express Confidence
  "I strongly encourage you to begin a regular exercise program. Physical activity is one of the best things you can do to successfully manage your diabetes. I recognize that the choice to exercise is entirely yours. I am confident that if you decide to begin a physical activity program, you can find a way to do it."
- Confirm next steps
- Arrange for Follow Up

FIGURE 11.3. Key strategies while talking with patients about diabetes management. (*Source*: Used with permission, Kaiser Permanente, Oakland, CA 2003.)

Self-Management Support Tool

Health Changes Plan

Organization:_____

Name:_____ Date:_____

Phone:_____

The health change I want to make is (be very specific: What, When, How, Where, How Often):

My goal for the next month is:

The steps I will take to achieve my goal are:

The things that could make it difficult to achieve my goal include:

My plan for overcoming these difficulties includes:

Support/resources I will need to achieve my goal include:

My confidence that I can achieve my goal: (scale of 1–10 with 1 being not confident at all, 10 being extremely confident)
1 2 3 4 5 6 7 8 9 10

Review Data:_____ with_____

Source: www.improvingchroniccare.org

FIGURE 11.4. Self-management support tool.

lay leaders to facilitate weekly programs that train others on how to live with a chronic illness, regardless of the disease. This program has been very successful throughout the country and is being quickly adopted. The topics cover a wide range of behavioral, informational, and knowledge components, such as an overview of self-management, relaxation and cognitive symptom management, fatigue management, advanced directives, depression, informing the health care team. These are just a few, for more information on the CDSMP, visit the Stanford University Web site at www.stanford.edu/group/perc/cdsmp.html.

INCENTIVE PROGRAMS

Incentives are a method to motivate people to improve adherence to self-management behaviors. Incentives range from discount vouchers on services, food or supplies to "give aways" such as water bottles, pedometers, or T-shirts. These tend to be successful when matching them appropriately with the patient population. For example, one clinic received a grant and funded a glucometer strip incentive program for their patients who were uninsured. Patients were enrolled into an incentive program when they agreed to participate by signing a self-management agreement to test their blood sugars at least three times a week and bring their logs in monthly and review them with the nurse. In return they would pay only $5/bottle for their strips every month.

Over 80 people enrolled, but less than half participated regularly. The program was successful for those who were ready (in the action stage) and/or had a good handle on monitoring and recording their blood sugar levels. However, many patients did not return monthly because they were at different stages of readiness. Patients either did not feel they

needed to check their blood sugars because they were feeling fine, or they needed more intensive follow-up on how to complete the blood sugar logs. The greatest level of adherence in performing regular blood sugars was seen in the gestational diabetes group. This was expected since they were motivated to have a healthy baby and scheduled for regular weekly or biweekly visits.

Other incentive programs that have been received positively focus on coupons to grocery stores or health clubs for regular attendance to diabetes education classes. Today, many diabetes self-management programs provide an incentive program in the initial stages. It is when the more intensive education program ends and the patient must then transition to the long-term regime of regular follow-up visits with the provider—the desire is that the patient and the provider will be able to maintain an incentive-driven interaction. At these visits, it is critical that the provider review the self-management logs and provide feedback. That feedback will lead the provider to help the patient develop new self-management goals that can then be the internalized incentive for the patient. This is the direction of proactive health care.

Special note. Diabetes education can be provided by a variety of people, in a variety of settings. Explaining a nutrition label to someone with diabetes, regardless of the credentials of the person teaching or the location of the encounter, is diabetes education. Comprehensive diabetes education is typically provided by formal programs employing certified diabetes educators (CDEs). Health care professionals experienced in diabetes education may be eligible to become certified as diabetes educators through the National Certification Board for Diabetes Educators (NCBDE—see www.ncbde.org). Comprehensive diabetes education programs may be eligible for recognition by the American Diabetes Association (required by some payors for reimbursement). ADA-recognized programs must meet the National Standards for Diabetes Self-Management Education, published in Diabetes Care, 27:S143, 2004, and available at www.diabetes.org. Diabetes is a worldwide epidemic and education is a key component to its management. Education that provides accurate and useful information to people affected by diabetes is extremely valuable, and should be provided by all who are willing and able to reach communities at-risk.

CONCLUSION

Self-management abilities are constantly being challenged by internal and external forces. This chapter gives the health care team a number of evidence-based options that can be applied within individual or group interactions. With the onset of the pay-for-performance models, self-management skills cannot be viewed as a one-time approach—it is an ongoing process of trial and learning among providers, patients, and families. Just as patients are learning new ways of living through better self-management—so must the health care providers learn new ways of motivating and teaching their patients how to be better self-managers.

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12

The Diabetic Foot

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INTRODUCTION

The diabetic foot and its associated pedal manifestations have been well documented and, when left untreated, pose potentially limb-threatening complications. Foot ulcerations in people with diabetes represent the most common cause of nontraumatic lower extremity amputation in the industrialized world. Individuals with diabetes mellitus run a 15–46 times higher risk of a lower extremity amputation than those without diabetes (Harris, 1998). Likewise, complications associated with the foot account for the most frequent reason for hospitalization in the patients with diabetes, and account for up to 25% of all diabetic admissions in the United States (Harris, 1998). A number of studies have shown that the vast majority of diabetic foot complications resulting in an amputation begin with the formation of a skin ulcer. Among the many risk factors identified as reasons for foot ulcerations, the most common single precursor to lower extremity (foot and/or leg) amputation are reduced/impaired response to infection(s), peripheral neuropathy, vascular disease, abnormal foot pressures, minor trauma, foot deformity, limited joint mobility, and a history of past ulceration and/or amputation, which have shown to be related in the repetitive minor trauma associated with a diabetic foot ulceration (Frykberg *et al*., 1998).

Figure 12.1 represents an illustration summarizing the various pathways, contributing factors, and a cycle of occurrence leading to a diabetic foot ulceration most often seen in this patient population.

DIABETIC AMPUTATION AT A GLANCE

- Amputation is 15 times more likely in people with diabetes.
- 50% have contra-lateral amputation within 3–5 years.
- 3-year mortality rate of 20–50%.

The foot is often thought of as a mirror of systemic disease and, in diabetes, it is the place where early manifestations of the disease may be initially present. Not all diabetic foot complications can be prevented, but it may be possible to reduce their incidence with a program designed with a multidisciplinary

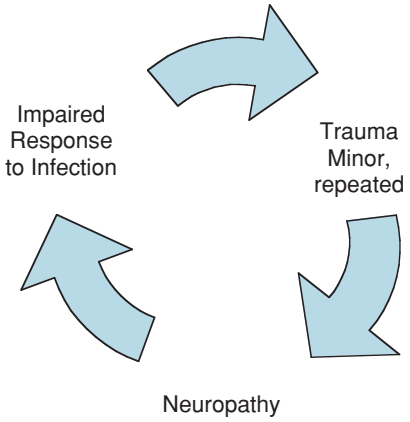

FIGURE 12.1. Cycle of pathways leading to ulceration.

team to manage the disease itself. The program should combine the management and then prevention of the complications, a program of early detection of risk factors, and a course of appropriate treatment. When implemented, many of these ulcers and perhaps up to 85% of amputations may be prevented.

The goal of this chapter is to review, discuss, and provide guidelines for a comprehensive foot exam and to manage the diabetic foot in diverse clinical settings.

BEGINNING WITH A COMPREHENSIVE FOOT EXAMINATION

The importance of building a strong foundation of care for a patient with diabetes begins with a comprehensive foot and lower extremity examination. Several studies have found that in a primary care clinic setting, foot examinations are infrequently performed during a patient's routine office visit, and, if performed, these examinations are often not documented well (Pham *et al*., 2000). In the case of hospitalized patients with diabetes, their feet also may be inadequately evaluated (Pham *et al.*, 2000). There is not just one aspect of the care being rendered that result in these statistics; unfortunately, there may be a number of factors, all contributing to a missed opportunity to address patients' foot care needs.

Family physicians, their staff, and additional medical care providers who come in contact with a patient with diabetes can and should play a pivotal role in early diagnosis of complications associated with the lower extremity and feet. What are the components of a comprehensive foot examination? In response to this question, the following suggestions are proposed, based on possible roles each member of the multidisciplinary team may play.

First, there are a number of terms and/or definitions mentioned during the course of the forthcoming discussion that one should become familiar with for both the examination and treatment aspects to care.

Diabetic foot. The foot of a patient with diabetes, which has the potential risk of pathologic consequences, including infection, ulceration, and/or destruction of deep tissues associated with neurological abnormalities, various degrees of peripheral vascular disease, and/or metabolic complications of diabetes in the lower limb (based upon the World Health Organization [WHO] definition) (Alberti *et al*., 1999).

Diabetes type 1. Formerly called insulin-dependent diabetes mellitus (IDDM). This describes an autoimmune disease of younger patients with a lack of insulin production causing hyperglycemia and a tendency toward ketosis.

Diabetes type 2. A metabolic disorder resulting from the body's inability to produce enough or properly utilize insulin. Formally called noninsulin-dependent diabetes mellitus (NIDDM), these patients also have hyperglycemia but are not as prone to ketosis.

Epidemiology. The study of occurrence and distribution of disease.

Incidence. The rate at which new cases of disease occur with a specific time period.

LEAP. Lower Extremity Amputation Prevention program.

Neuropathy. Nerve dysfunction affecting sensory, motor, and/or autonomic fibers

with varying degrees of impairment, symptoms, and/or signs.

Diabetic peripheral neuropathy. Presence of symptoms and/or signs of peripheral nerve dysfunction in people with diabetes after the exclusion of other causes.

LOPS. Loss of protective sensation describes the progression of neuropathy in the diabetic foot to the point that the foot is at risk for ulceration.

Intrinsic minus foot. A neuropathic foot with intrinsic muscle wasting and associated claw toe deformities.

Ischemia. The impairment of blood flow secondary to an obstruction or constriction of arterial inflow.

Infection. Invasion and multiplication within body tissues by organisms such as bacteria, fungi, or yeast, with or without the clinical manifestation of disease.

Ulceration (ulcer). A partial or full-thickness defect in the skin that may extend to subcuticular tissue, tendon, muscle, bone, or joint.

Amputation. The complete or partial removal of a limb or body appendage by surgical or traumatic means.

Charcot foot (Arthropathy, osteoarthropathy, neuroarthropathy). Noninfectious destruction of bone and joint associated with neuropathy.

A PROCESS OF CARE

When a patient with diabetes arrives for examination, there are a number of diagnosis and treatment objectives that a multidisciplinary team should achieve. These include: (1) appropriate screening and examination, (2) early recognition and treatment of diabetic foot complications, (3) prevention of ulceration and recurrence (particularly if the patient has a past history), and (4) most importantly, patient self-management education. The goal of treatment should be to maintain the patient as an ambulatory, productive member of society.

The many and common risk factors for amputation can be identified based on specific aspects of the history of the patient and a systematic examination of the foot. Those risk factors for lower extremity amputation include peripheral neuropathy, structural foot deformity, ulceration, infection, and peripheral vascular disease.

All patients with diabetes who seek treatment with any health care practitioner require inspection of both feet at each visit and should receive a comprehensive examination no less than once a year. For those patients who demonstrate diabetic foot-related complaints, a detailed evaluation should be performed more frequently.

DIAGNOSIS AND EVALUATION

In evaluating the diabetic foot, a workup of the patient's general medical history (Abbott *et al*., 1998), physical findings, and any results from necessary diagnostic testing and/or procedures coupled with a thorough medical and foot history and examination should be performed.

PATIENT HISTORY

The foot examination is initiated by interviewing the patient and reviewing both their past medical and specific diabetic foot conditions. The collection of this medical history should consist of the information offered in Table 12.1.

CLINICAL EXAMINATION

A clinical examination should be performed systematically so as not to overlook any significant and important aspects of an active medical condition. After the patient and his or her extremities have been acutely evaluated, key components of the foot examination should be performed. Many of the

TABLE 12.1. Diabetic Patient History Checklist

Patient's general history	Foot-specific history	Wound/ulcer history
Diabetes disease duration	General	Location
Glycemic control and management	Daily activity	Duration of wound/ulcer
Cardiovascular, renal and ophthalmic, dental evaluations	Current footwear	Inciting event or trauma
Other co-morbidities	Any chemical exposures	Recurrences
Current treating physicians	Callus formation	Infections
Social habits such as alcohol/tobacco	Deformities	Hospitalizations
Current medications	Previous foot surgery	Wound care/off loading methods
Allergies	Neuropathy symptoms	Patient's compliance/wound response
Previous hospitalizations and surgeries	Ischemic symptoms	Interference with wound care/family or social problems for patient
Previous medical treatments to the feet		Previous foot trauma or surgery
Previous or most recent laboratory studies, vascular, radiological studies . . .		Edema—unilateral versus Bilateral
		Previous or active Charcot joint treatment to date

possible conditions to examine are presented in a bulleted format below. Each bulleted item represents an important component of what should be included in a comprehensive foot examination or a significant finding that should be noted, based on evidence that indicates likely predictors for ulceration.

Vascular Examination

- Palpation of pulses (dorsalis pedis, posterior tibial, popliteal, femoral)
- Subpapillary venous plexus filling time (normal $\leq$3 seconds)
- Venous filling time (normal $\leq$20 seconds)
- Color changes:
  - Cyanosis
  - Dependent rubor
  - Erythema
- Presence of edema
- Temperature gradient
- Changes to the skin possibly indicating ischemia:
  - Skin atrophy
  - Nail changes
  - Distribution of pedal hair—decreased or absent

Neurologic Examination

- Vibration perception:
  - Turning fork 128 cps
- Semmes–Weinstein 10 g monofilament
- Light touch: cotton wool
- Two-point discrimination
- Pain: pinprick
- Temperature perception: hot and cold
- Deep tendon reflexes ankle, knee
- Babinski test

Musculoskeletal Examination

- Biomechanical abnormalities: foot deformities
  - Hammertoes
  - Bunion (s) or Tailor's Bunion(s)
  - Flat or high-arched feet
  - Charcot deformities
  - Amputations
  - Limited joint motion
- Gait evaluation
- Muscle strength testing:
  - Passive and active, nonweight-bearing and weight-bearing
  - Foot drop
  - Atrophy-intrinsic muscle atrophy
- Plantar pressure assessment:
  - Computerized devices
  - Harris ink mat

Dermatologic Examination

- Skin appearance:
  - Color or discoloration of skin, texture, turgor, quality, dry skin

- Calluses: discoloration—sublesion hemorrhage
- Fissures (especially posterior heels)
- Nail appearance
  - Onychomycosis, dystrophic, atrophy, hypertrophy
    - Paronychia
- Ulceration, gangrene, infection (note location, size depth, infection status, etc.)
- Tinea pedis

Footwear Examination

- Type of shoe
- Fit—breakdown of shoes inside and outside the shoe
- Foreign bodies
- Insoles, custom orthoses.

Once this detailed/comprehensive examination of the diabetic foot has been completed, the patient can then be placed in a classification representative of their individual accumulative risk category. By using a risk classification system, the physician is able to design a treatment plan that may be able to help reduce the patient from a high-risk category to the lowest risk level, thus leading to the prevention of an amputation.

There have been several risk stratification schemes that have been proposed and developed, which assign different weights in important risk factors for ulceration, although no system has been universally adopted that can or may predict ulceration.

An often used treatment base is the diabetic foot system developed at the University of Texas San Antonio by Dr.'s Armstrong, Lavery and Harkless (Armstrong and Lavery, 1998). This treatment approach provides a clear, descriptive classification system that may be used by all participants on a multidisciplinary team. This includes the patient as the center of the treatment team once they have been given the tools to participate fully in their care and management of any complications that may arise over the years. A much simpler, but frequently used system accepted by the International Working Group, is given in Table 12.2 (IWGDF International Consensus of the Diabetic Foot, 1999; Frykberg *et al*., 1999).

TABLE 12.2. Risk Categorization System

Category	Risk profile	Frequency of evaluation
0	No neuropathy	Annual
1	Neuropathy	Semi-annual
2	Neuropathy, PVD, and/or deformity	Quarterly
3	Previous ulcer or amputation	Monthly–quarterly

Source: American College of Foot and Ankle Surgeons, International Working Group on the Diabetic Foot (1999).

In the primary care setting, based on the risk, patients with risk level 1 or above should be referred to a Podiatric physician for further detailed workup, such as obtaining Ankle Brachial Indices, or Doppler segmental pressures and wave form analysis. Also, the identification of plantar foot pressures may require evaluation for fabrication of custom foot orthoses and/or extra-depth shoes. Podiatric physicians, due to their unique education, knowledge of biomechanics, and foot anatomy, are well suited to care for diabetic foot ulcers and prevent these complications that place the patient at highest risk of amputation. Limb salvage procedures are well worth the time and energy involved, based on the high morbidity rate of those patients having undergone an amputation. Patient quality-of-life is an important component that should be considered when discussing the possible need for an amputation, as it is clear that patients appreciate the physician who tries hard to first save their foot, rather than bluntly offering amputation as the only viable treatment procedure. Prevention is the goal we must all strive toward, and with a well-organized system for examination and follow-up, we can now treat our patients with intention rather than by addressing opportunities as they arise—that is, treating patients only when they have complications. This comprehensive plan allows the practitioner to be proactive, and not just reactive.

TABLE 12.3. Risk Factors for Lower Extremity Amputation in the Diabetic Foot

Absence of protective sensation due to peripheral neuropathy
Arterial insufficiency
Foot deformity and callus formation resulting in focal areas of high pressure
Autonomic neuropathy causing decreased sweating and dry, fissured skin
Limited joint mobility
Obesity
Impaired vision
Poor glucose control leading to impaired wound healing
Poor footwear that causes skin breakdown or inadequately protects the skin from high pressure and shear forces
History of foot ulcer of lower extremity amputation

The following list of risk factors is provided to consider helping clinicians in a multidisciplinary team, to help direct care, and to educate patients during their examination, in order to allow patients to develop behaviors that will aide in prevention and to decrease risk factors for lower extremity amputations in patients with diabetes (Table 12.3).

CONCLUSION

If we adhere to a systematic regimen of diagnosis and classification of risk factors for each individual patient while utilizing the multidisciplinary team approach that facilitates appropriate treatment of complications, this may ultimately lead to a reduction in both complications as well as lower extremity amputations as they relate to diabetes.

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III

Special Care Issues

13

Prediabetes

A Risky Prodrome to Diabetes

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INTRODUCTION

Prediabetes is the most fascinating and confusing area of the diabetes continuum. Fascinating because this is probably the phase of the condition in which the biggest difference can be made in preventing complications and thereby sparing human suffering and health care expense; confusing because of the various synonymous or overlapping labels and conditions.

Metabolic syndrome, syndrome X, cardiovascular dysmetabolic syndrome, prediabetes, insulin resistance, impaired glucose tolerance, impaired fasting glucose, polycystic ovary syndrome, dyslipidemia, gestational diabetes. These are all terms that are used to define or describe patients in a "prodromal phase" of diabetes. The overlapping of these conditions has led to some interesting and powerful clinical interventions, as well as some basic "grandmother wisdom," that have been helpful in the day-to-day care of patients. For instance, my grandmother used to tell us as children, "You'd better be careful about using too much sugar in your iced tea, or you could end up with diabetes."

With our current understanding of the priming of the insulin production mechanism, and development of insulin resistance, that was a pretty good advice. The discovery recently that increasing exercise and reducing high glycemic index foods in the diet can be potent treatments for insulin resistance has given strong scientific verification to my grandmother's advice. Some of our newer diabetes medications can also be used to prevent diabetes through overcoming insulin resistance at the cellular level (NIDDK, 2001).

A functional definition of prediabetes comes from William Cefalu, "a clinical state in which a normal or elevated insulin level produces an impaired biological response" (Leahy *et al.*, 2000).

ETIOLOGY THEORIES

The idea that insulin resistance was involved in the causing diabetes is not new,

however, the potential for preventing the progression of prediabetes to the full blown condition of diabetes is recent and somewhat exciting, particularly in the current era of "diabetes as epidemic." The genetic underpinnings of diabetes remain beyond the scope of current medical or scientific alteration, and clearly play a part in the predisposition toward diabetes. But, the obvious links between obesity and inactivity, obesity and high caloric diets (over-eating), and obesity and diabetes, taken together with the compelling evidence that weight loss, increased activity, and dietary modifications can prevent development of the disease, give us new information about the etiology of prediabetes. This same series of relationships also helps explain why the incidence of diabetes is increasing at such an alarming rate.

What is additionally compelling is the evidence that the hyperinsulinemic state either leads to or is at least strongly associated with a group of risk factors for cardiovascular disease including atherosclerotic vascular disease, hypertension, central obesity, dyslipidemia, and increased thrombotic state (Leahy *et al*., 2000).

CONTROVERSIES IN DIAGNOSING AND TREATING PREDIABETES

The definition and clinical diagnosis is not yet clearly defined in practical terms. The scientific community uses the euglycemic clamp for research purposes to define prediabetes, but this is not very useful for clinical practice. Plasma insulin levels, whether measured fasting (100–125) or postprandial (140–160), are predictors of the risk of developing diabetes (CDC-IR, Diabetes Care, 1998) and therefore serve as markers for prediabetes. Another interesting method is an index popularized by Harold Lebovitz called the Homeostasis Model Assessment for Insulin Resistance (otherwise referred to as HOMA-IR) index, which is calculated from the relationship between fasting plasma glucose and fasting plasma insulin (Lebovitz, 2001). In our clinical practice, we have found the fasting insulin level to be a cost effective and practical screening tool.

So now that we have identified those patients likely to have prediabetes, how do we treat them? The evidence that came out soon after the release of metformin in this country, which showed a potent effect on prevention of progression of prediabetes to diabetes, was very exciting; however it involved the off-label use of the medication (DPP, NIDDK, 2001). It was a bit daunting, to say the least, to contemplate the informed consent process that would be involved in following this research guideline. Happily, soon afterward came the evidence that diet and exercise were even more potent derailers of the progression to diabetes, so with the help of our nutritionist and diabetic educators, and some community groups interested in exercise modeling, we have the beginning of a diabetes prevention program.

PREVENTION

With the evidence that caloric and particularly simple carbohydrate restriction, teamed up with increased activity (diet and exercise), are potent interventions for our patients with prediabetes; and the circumstantial evidence of increasing diabetes in parallel with increasing obesity in the United States, the general approach to the prevention of diabetes is straightforward. The difficulty lies in the facilitation of our patients' decision making processes to commit to the necessary self-management goals.

Prevention of this common and increasing condition of prediabetes and the fully established disease that follows requires basic lifestyle changes. This is quite difficult in the context of our present day culture

of fast-food, mobility, separation of people from natural support groups, and the relentless advertising of unhealthy foods and beverages. Today's health professionals and educators are well served to work in teams and be familiar with practical decision-making facilitation techniques.

Our experience in treating patients with diabetes sheds light on the necessary steps for those with prediabetes in order to avoid progression to diabetes and its attendant complications. The screening of all new patients to our practice, and the stratification into risk groups helps to identify those in need of fasting insulin levels. Those with elevated insulin levels are then offered the same team approach as our diabetic patients, namely, group education, individual education, and continued tracking and reinforcement through primary care provider visits. We use a modified version of our chronic disease (diabetes) flow-sheet to track and treat our patients with prediabetes in a uniform and comprehensive manner (see Figure 13.1). The patient's willingness to make change, assessing the importance of change in the patients mind, and the patient's confidence to carry out the selected goals also play an important role in the facilitation of change (Davis, 2003). Our program is new and so experience is limited, but these seem the most likely interventions to have some effect.

The Secretary of Health and Human Services estimates there are about 16 million people with prediabetes and most are unaware of the condition. Given that these people are at 50% greater risk of developing cardiovascular disease than the general population, there is a virtual gold-mine of opportunity to save health care costs as well as reduce morbidity and mortality by discovering and intervening early in the continuum (DPP, NIDDK, 2001). There is a multiplier effect that comes into play because of a whole cluster of diseases and conditions that hover around prediabetes, and so the quest for future health care providers becomes reducing the burden of suffering and health care costs through the identification and treatment of prediabetes.

APPLICATIONS

We are often preoccupied with the adult population who come to health centers for care, but prevention programs would be far from effective if they do not include the nation's children. While administrators are beginning to address nutrition issues in current school lunch programs and campus vending machines, physical education programs and curricular requirements continue to dwindle, and thus contribute to the current problems of childhood obesity and diabetes. Involvement in school health and physical education programs will be vital to the overall long-term success of any diabetes prevention effort.

Outreach programs for community screening of populations at high risk are another important component of prevention of diabetes. Health fairs, churches, and other neighborhood events and festivals are important considerations for additional effort in order to find those at high risk who do not frequent health centers.

The use of the chronic disease management model has been helpful for developing effective programs at our health center and the sharing of experiences through the Arizona Diabetes Collaborative has helped to identify "best practices" and overcome barriers in a more productive way.

CONCLUSION

The condition of prediabetes represents the immediate threshold to the disease diabetes mellitus, but actually is only an identifiable point on the continuum from those people at low risk of death and complications to those at the very highest risk. The effort required to

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High Risk/Pre-Diabetes Quality Indicators: Clinical

Patient: _____ DOB: _____

MR# _____ Provider: _____

		Frequency	Baseline	6 mo	1 year	18 mo	2 year
	Date/Initials						
Assessment	Serum Insulin <17	q-visit					
	Blood Pressure ≤ 140/90	q-visit					
	Height	q-visit					
	Weight	q-visit					
	Body Mass Index (BMI)	q-visit					
Lab	Chol/TG < 200/200	Annual					
	HDL/LDL > 45/<100	Annual					
	Bun/Creatinine	Annual					
Interventions	Ace Inhibitor Y or N						
	Statin Y or N						
	ASA Y or N						
	Vaccines Specify (ie. flue, pneumonia, etc)						
PE	Full Physical Exam Y or N	Annual					
Self Care	Meal Plan S or SMER						
	Physical Activity 4x/week						
	Tobacco Cessation S or SMER						
	Medication S or SMER						

S= Satisfactory SME= Self-Management Education Referral Re=referred C=Completed

This flow sheet indicates recommended services to be provided in the continuing care of persons with pre-diabetes. Document values where indicated. Any discussions with patients or significant others should be documented in the "notes" section in date order.

Signature	initials	Signature	initials

FIGURE 13.1. High risk/prediabetes quality indicators.

identify prediabetes and intervene at an earlier stage in the continuum is justified by consideration of the expense, both in health care costs and human suffering, involved in the treatment of diabetes and its attendant cardiovascular and microvascular complications.

The challenges for health professionals and educators are several: to develop effective screening and outreach strategies for finding those at greatest risk; to continue discovering the most efficient ways of facilitating behavior change in individual and small group settings; to help obviate the prevalent unhealthy forces on our nation's adults and children; and to help overcome barriers to everyone receiving appropriate and affordable health care and prevention services.

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14

Gestational Diabetes

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INTRODUCTION

Before the availability of insulin in the early 1920s, pregnant women with diabetes faced very high maternal and perinatal mortality rates. Pregnancy was therefore not recommended in patients with diabetes. Today, with the advent of insulin, these mortality rate increases have been virtually eliminated, so that pregnancy should no longer be discouraged in a young woman with diabetes.

DEFINITIONS AND PREVALENCE

In general, diabetes mellitus is classified according to two broad etiopathogenic categories as type 1 or type 2 (National Diabetes Data Group [NDDG], 1979).

Owing to the heterogeneity of disorders causing hyperglycemia, the NDDG and the World Health Organization (WHO) Expert Committee on Diabetes in 1985 included Gestational Diabetes separately into one of its various distinct types (NDDG, 1979; World Health Organization, 1985).

The American Diabetes Association (ADA) Expert Committee on the Diagnosis and Classification of Diabetes Mellitus recognizes that the degree of hyperglycemia reflects the severity of the underlying metabolic process and its treatment more than the nature of the process itself. Thus, for a clinician and patient, it is less important to label the particular type of diabetes than it is to understand the pathogenesis of the hyperglycemia and to treat it effectively (American Diabetes Association, 2003).

Gestational diabetes mellitus (GDM) is defined as any degree of glucose intolerance with onset or first recognition during pregnancy. This definition applies irrespective of whether insulin or diet is used for treatment or whether the condition persists after pregnancy. It does not exclude the possibility that unrecognized glucose intolerance may have antedated or begun concomitantly with the pregnancy (American College of Obstetricians and Gynecologists [ACOG], 1994).

According to the ADA Expert Committee, 6 weeks or more after pregnancy ends, the patient should be reclassified into one of the following categories: (1) diabetes, (2) impaired fasting glucose (IFG), (3) impaired glucose tolerance (IGT), or (4) normoglycemia. In the majority GDM cases, glucose

TABLE 14.1. White's Classification of Diabetes Mellitus in Pregnancy

Class	Age of onset	Duration	Vascular disease	Treatment
A-1[a]	Any	Any	No	Diet only
A-2[b]	Any	Any	No	Insulin
B	>20	<10	No	Insulin
C	10–19	10–19	No	Insulin
D	≤10 or	≥20 or	Benign retinopathy	Insulin
F	Any	Any	Nephropathy	Insulin
R	Any	Any	Proliferative retinopathy	Insulin
H	Any	Any	Coronary artery disease	Insulin
T	Any	Any	Renal transplant	Insulin

[a]Fasting blood sugar (FBS) <105 and postprandial blood sugar (PPBS) <120 mg/dl.
[b]FBS ≥105 and PPBS ≥120 mg/dl.
Class E "Calcification of pelvic vessels"—no longer used.
Source: Modified from American College of Obstetricians and Gynecologists (2001).

regulation will return to normal after delivery (ADA, 2003).

Approximately 0.3% of pregnancies in the United States occur in women with preexisting diabetes mellitus (Buchanan, 1995), and 2–3% more are complicated by gestational diabetes (Coustan *et al*., 1989). GDM represents the majority of all pregnancies complicated by diabetes. Gestational diabetes, therefore, is most likely to be encountered by every health professional caring for pregnant women (Coustan, 2003).

Table 14.1 illustrates a classification based on the presence of vascular disease adapted from Priscilla White. This classification did not include the category "Gestational Diabetes."

MATERNAL AND FETAL COMPLICATIONS

Gestational diabetes, and especially its association with obesity and advanced maternal age increases the likelihood of developing hypertension during the pregnancy. In nonobese younger women, preeclampsia and cesarean delivery seem to be the most common associations. The incidence of diabetes later in life is seemingly more common as well in patients with GDM (ACOG, 1994).

Babies of women with GDM are more frequently macrosomic, and more commonly found to have hyperbilirrubinemia, as well as long-term obesity and diabetes. Shoulder dystocia, operative delivery, and birth trauma also are seen more frequently (ACOG, 1994).

Maternal mortality has decreased dramatically after the advent of insulin, but it is still considered to be higher than the average obstetric population.

Fetal mortality associated with diabetic ketoacidosis (DKA) is higher during the later weeks of pregnancy. Increasing insulin resistance as pregnancy progresses produces increased risk of DKA in the second half of pregnancy. This may be true at lower glucose levels and requires close follow-up and aggressive management (Coustan, 2003).

Hypoglycemia also can affect pregnant patients managed with insulin, and it is therefore important to counsel patients as to early symptoms and management of this condition.

Nephropathy can complicate pregnancies associated with diabetes. Proteinuria of ≥300 mg/day can complicate both type 1 and type 2 diabetes. Hypertension and retinopathy usually are present when nephropathy is detected. Significant proteinuria may make the diagnosis of hypertensive disorders of pregnancy quite difficult. Most patients who develop marked proteinuria during pregnancy revert to their prepregnancy renal status after delivery.

Diabetic nephropathy, in turn, can cause higher perinatal mortality, preterm induction

and delivery, preeclampsia, severe anemia, intrauterine growth restriction, and fetal distress (Coustan, 2003).

Diabetic retinopathy results from the damage to retinal arterioles and capillaries. In its earlier stages (background retinopathy), microaneurysms, vessel obstruction, cotton wool spots, hard exudates, small retinal hemorrhage, and venous microvascular anomalies may occur. Vision is only affected if there is macular edema or ischemia in background retinopathy. About 15–20% of individuals with diabetes may have changes consistent with background retinopathy at 5 years and about 90% after 15 years. In proliferative diabetic retinopathy, neovascularization occurs in response to retinal ischemia. This leads to hemorrhage, scarring, and contraction of the vitreous humor, causing retinal detachment, and visual loss. This process can be prevented by laser photocoagulation and tight metabolic control. Whether pregnancy exerts an adverse effect on retinopathy is still controversial at the present time (Coustan, 2003).

Neuropathy in pregnant patients with diabetes can be present in the form of visceral or autonomic neuropathy causing symptoms such as persistent pain, nausea and vomiting, early satiety and fullness, which can actually be due to gastroparesis. Less commonly excessive postural pressure changes, and absence of normal respiratory variation in the heart rate can indicate cardiovascular involvement. Peripheral neuropathies are manifested in the form of paresthesias, most often in the lower extremities. More severe forms lead to skin ulceration and ischemia that requires amputation (Coustan, 2003).

Hypertension has been seen to occur in the presence or absence of nephropathy in diabetic gravidas, and it may be as high as 30% in patients with known vascular disease (Coustan, 2003).

Urinary tract infections are more common in patients with diabetes. Pyelonephritis can complicate up to 3% of patients with preexisting diabetes. Such an event, if left untreated can precipitate DKA in a pregnant patient.

Hydramnios, or excessive amniotic fluid, complicates about 2% of gestational diabetic pregnancies. The cause is currently unknown, and its presence is associated with an increased risk for congenital malformations, premature labor, and maternal respiratory restriction. In spite of these problems, it is distinctly unusual for diabetes-associated hydramnios to require therapeutic amniocentesis (Coustan, 2003).

Placental Problems

The placenta is responsible for fetal gas exchange, nutrition, waste removal, hormone production, and release into both the maternal and fetal circulations. Any or all of these functions may be affected by diabetes, particularly by the vascular disease present in women with long-standing diabetes. Placentas from mothers with diabetes weigh more and are larger than those from mothers without diabetes, with cellular hyperplasia dominating over hypertrophy, and may in fact compete with the fetus for oxygen and nutrients. In the presence of maternal vascular disease, the placentas may be smaller, rather than larger, than those of mothers without diabetes. Both premature senescence and immaturity of chorionic villi have been described in placentas of mothers with diabetes (Coustan, 2003).

Perinatal Mortality

Although perinatal mortality is now similar to normal pregnancies due to the modern coordinated maternal–fetal care, it may still be a problem in patients who have long-standing hyperglycemia and vascular involvement.

Both fetal and neonatal deaths occurred with increased frequency in diabetic pregnancies before the advent of modern management methods. The cause of fetal death remains incompletely understood. Maternal DKA, associated with a 50–90% fetal mortality rate (Golde, 1991), is currently rare among

appropriately treated women with diabetes (Coustan, 2003).

There appears to be a clear association between suboptimal metabolic control and perinatal death. Animal studies suggest that fetal insulinemia brought about by maternal hyperglycemia may cause fetal hypoxemia and lactic acidosis and, in extreme cases, fetal death (Coustan, 2003). Likewise, the infusion of large amounts of glucose-containing solutions to pregnant women has been associated with fetal acidosis (Kenepp *et al*., 1982; Lawrence 1982). It thus seems likely that maternal hyperglycemia is at least partially the cause of the increased fetal death rate among diabetic pregnancies.

Perinatal mortality consists of both fetal and neonatal deaths. Although fetal death probably is directly related to metabolic derangement in diabetic pregnancies (described above), neonatal deaths appear to be caused more indirectly. In the past, the threat of fetal death has prompted attempts of early delivery. Thus, prematurity and its sequelae increased the neonatal death rate.

In addition, infants of poorly controlled mothers with diabetes are more likely to develop respiratory distress syndrome (RDS) at a given gestational age than infants of mothers without diabetes. And adequate control of glycemia seems to exert a protective effect in infants of mothers with diabetes (Karlsson and Kjellmer, 1972; Robert *et al*., 1976).

Congenital Anomalies

A good percentage of perinatal mortality and morbidity is related to congenital anomalies. Infants of mothers with diabetes are three times more likely than infants in the general population to manifest all types of birth defects (Cousins, 1983). Cardiac, neural tube, and skeletal defects are most common, but a particular set of anomalies affecting the lower half of the body, the caudal regression syndrome (congenital malformation characterized by the association of hypo- or agenesis of the lower extremity of the spine with genitourinary and anorectal anomalies) is highly specific for diabetic pregnancy (Coustan, 2003).

All structural birth defects seen in infants of mothers with diabetes occurred by the 8th week of gestation. Most women do not seek prenatal care before this time. In animal studies, hyperglycemia can induce congenital anomalies during this period of organogenesis (from the 5th to 9th week of gestation) (Sadler, 1981; Buchanan *et al*., 1994).

There is an association between the level of glycosylated hemoglobin and congenital anomalies in the offspring (Leslie *et al.*, 1978; Miller *et al*., 1981). Such an association is the basis for recommending adequate prepregnancy metabolic control in patients with preexisting diabetes with a concomitant decrease in the incidence of congenital anomalies from 7% to 2–3% as in the baseline population (Fuhrmann *et al*., 1984).

Macrosomia is defined as a specific birth weight (i.e., 4,000 or 4,500 g) or as a relative weight for gestational age (i.e., 90th, 95th, or 97.5th percentile). The latter designation is more scientifically correct as a premature baby may be macrosomic for its age.

Macrosomia is considerably more prevalent among offspring of women with diabetes versus nondiabetic pregnancies. This is true for gestational diabetes as well as preexisting diabetes (ACOG, 1994; ACOG, 2001). Macrosomic infants of mothers with diabetes are at risk for shoulder dystocia at the time of delivery because typically they have increased body fat but not head or brain size. This causes their shoulders to be abnormally broad in relation to their head size. The incidence of shoulder dystocia for diabetic mothers remains elevated even when corrected for birth weight (Langer *et al*., 1991).

Fetal Hypoglycemia

At birth, the maternal glucose contribution to the fetus is interrupted and, given the state of hyperinsulinemia in the neonate, hypoglycemia may occur.

Hypoglycemia (or blood sugar of less than 35 mg/dl at term, or less than 25 mg/dl

in a preterm infant) is more commonly associated with maternal hyperglycemia and infusion of intravenous glucose fluids during labor (Lawrence *et al*., 1982). It usually occurs during the first 60–90 minutes of life, and is often asymptomatic. On the other hand, symptoms may include irritability, apneic spells, tachypnea, hypotonia, shakiness and, at the extreme, convulsions. If hypoglycemia does not occur early in the neonatal period, it is unlikely to show up later. Early institution of oral feeding may be helpful in preventing hypoglycemia. Hypoglycemia, which is promptly treated generally, is not associated with adverse sequelae (Coustan, 2003).

Neonatal Respiratory Problems

Respiratory distress syndrome, as well as other forms of neonatal respiratory distress, occurs with increased frequency in infants of mothers with diabetes. Before elective induction of labor, amniocentesis and phosphatidylglycerol determination is indicated to establish fetal lung maturity. Good metabolic control during pregnancy seems to minimize the incidence of RDS.

Other Neonatal Problems

Additional neonatal problems in the neonatal period are polycythemia, hyperviscosity, hyperbilirrubinemia, and hypocalcemia. Thrombocytopenia is more common as well. Umbilical venous pH also was significantly lower than in controls, although still within the normal range. Transient cardiac dysfunction, presumably due to increased thickness of the intraventricular septum, has been reported in neonates of mothers with diabetes even when metabolic control was reported to be good during pregnancy (Coustan, 2003).

Growth and Development

Obesity may be a problem during childhood and adolescence in the offspring of mothers with diabetes. But in a particular study involving Pima Indians, cultural factors also may play a role. Intellectual development during the neonatal and later periods has been found to be inversely correlated between hyperglycemia and ketonemia during the second trimester.

Animal studies and studies in human populations (after corrections for genetic factors) have demonstrated that exposure to hyperglycemia can cause gestational diabetes in female offsprings for up to two generations (Coustan, 2003).

CURRENT SCREENING AND DIAGNOSIS OF GESTATIONAL DIABETES

In spite of the absence of data that universal screening for GDM in pregnant women may not confer a benefit to the population as a whole, in the United States the 50-g, 1-hour laboratory screening has become and probably should continue to be widely used. There seems to be a lack of evidence that fasting improves the accuracy of the screening test and, in fact, fasting may pose significant logistical problems. A 50-g, glucose load in 150 ml of solution is therefore administered orally without regard to the time elapsed since the last meal (ACOG, 2001).

The threshold value recommended by the American Diabetic Association is 130 mg/dl. Increasing the threshold to 140 mg/dl has been used in the past to increase the specificity of the test. Currently, either thresholds are considered acceptable (ACOG, 2001).

Screening is traditionally recommended between 24 and 28 weeks of gestation in normal patients, because studies have demonstrated that GDM is more prevalent with advancing gestation. However, in patients with traditional historic risk factors, screening early in pregnancy is preferable. Also, performing a full 3-hour, 100-g oral test instead of a 1-hour test may allow earlier detection and intervention. Historical risk factors include:

1. Previous adverse pregnancy outcomes associated with GDM.
2. Previous history of GDM.
3. Family history of DM (first-degree relative).
4. Glycosuria.
5. Previous delivery of a >4,000 g baby.
6. History of polyhydramnios.
7. Obesity.
8. History of child with congenital anomalies.
9. Maternal age greater than 30 years.
10. Member of an ethnic group with an increased risk for the development of type 2 diabetes (examples of high-risk ethnic groups include women of Hispanic, African American, Native American, South or East Asian, or Pacific Islands ancestry).
11. Previous history of abnormal glucose tolerance (Coustan, 2003; ACOG, 2001).

The specific diagnostic test recommended by the ADA is the 100-g, 3-hour oral glucose tolerance test (GTT) and it consists of a 100-g glucose oral challenge. This is administered after an overnight fast of 8–14 hours, and after 3 days of an unrestricted diet containing at least 150 g of carbohydrate per day. The diet preparation is important to induce an adequate insulin response during the test. A positive diagnosis requires that two or more thresholds be met or exceeded. Patients should not smoke before the test and should remain seated during the test (NDDG, 1979; ADA, 2003; Coustan, 2003; ACOG, 2001).

Table 14.2 illustrates two sets of diagnostic criteria adapted from the original O'Sullivan and Mahan values after laboratories switched from whole blood samples to plasma or serum samples. There are no data from clinical trials to determine which is superior.

Patients with only one abnormal value have been demonstrated to manifest increased risk and morbidity associated with GDM. The relationship between carbohydrate metabolism and such problems is a continuum and no threshold will identify all patients at risk.

Monitoring Blood Glucose in a Woman with Gestational Diabetes

The modern management of diabetes during pregnancy relies on patient's self-monitoring of glucose levels. The use of test strips for blood and read by a reflectance meter seems to be the most practical and economical way of monitoring blood glucose.

It is a common practice to monitor blood glucose levels four times daily during pregnancy. It is recommended that the patient record an initial fasting blood glucose and then 1- or 2-hour postprandials after every main meal. Macrosomia has been found significantly more likely if 1-hour postprandial blood sugars exceed 130 mg/dl. Postprandial blood sugars seem to be more predictive of fetal macrosomia than fasting ones. Unlike macrosomia, maternal mortality has not yet been shown to be affected by adhering to this threshold. Table 14.3 illustrates blood sugar level goals for pregnant women with GDM.

TABLE 14.2. Diagnostic Criteria for Gestational Diabetes

	Plasma or serum glucose level		Plasma level	
	Carpenter/coustan conversion		National Diabetes Data Group conversion	
	mg/dl	mmol/l	mg/dl	mmol/l
Fasting	95	5.3	105	5.8
One hour	180	10	190	10.6
Two hours	155	8.6	165	9.2
Three hours	140	7.8	145	8.0

Source: American Diabetes Association (2003).

TABLE 14.3. Goals of Treatment in Gestational Diabetes

Times of testing	Goals (mg/dl)
Fasting	60–100
2-hour postbreakfast	70–120
2-hour postlunch	70–120
2-hour postdinner	70–120

Source: Coustan (2003).

MANAGEMENT OF DIABETES IN PREGNANCY

Diet in the Treatment of Diabetes in Pregnancy

A pregnant woman with diabetes should have normal, stable glucose levels and avoid ketosis, but at the same time achieve adequate nutrition and weight gain. Nutritional counseling should be done if possible by a registered dietitian. A diet should be prescribed based on weight and height. A 30 cal/kg per day based on prepregnant body weight for nonobese individuals is recommended by the ADA. For obese individuals (body mass index >30), a moderate caloric restriction (30–33% so as to prevent starvation ketosis) seems to decrease the incidence of fetal macrosomia (ACOG, 2001).

Insulin in the Treatment of Diabetes in Pregnancy

Based mostly on management of pregnant women with preexisting diabetes, it is a common practice to add insulin if medical nutrition therapy does not maintain fasting plasma glucose below 105 mg/dl or 2-hour postprandial values below 120 mg/dl or both. However, based on pregnancy outcome studies concerning fetal macrosomia, there is reason to start insulin for patients with fasting blood sugar greater than 95 mg/dl. Furthermore, the concept of "prophylactic insulin" administration to women with gestational diabetes, regardless of fasting blood sugar levels, seems to derive from ultrasound studies that showed an even further reduction in the incidence of fetal macrosomia (Coustan, 2003).

At the present time, it is recommended that women with GDM be given diet therapy for a period of 2 weeks if initial fasting blood sugars are under 95 mg/dl. If the patient initially or after 2 weeks presents blood sugars above 95 mg/dl, insulin should be considered (Coustan, 2003; ACOG, 2001).

Exercise in the Treatment of Gestational Diabetes

Exercise can help achieve weight reduction and improve glucose metabolism, and may help in the prevention of fetal macrosomia. Exercise programs should be encouraged during pregnancy (ACOG, 2001).

Oral Antidiabetic Agents in the Treatment of Gestational Diabetes

The sulfonylureas, first used for treatment of type 2 diabetes, crosses the placenta and could stimulate the fetal pancreas, leading to fetal hyperinsulinemia. Glyburide has been compared to insulin in patients with gestational diabetes, showing similar glucose control, as well as outcomes such as rates of cesarean delivery, preeclampsia, macrosomia, and neonatal hypoglycemia. Furthermore, glyburide could not be detected in the fetus. More data are needed to support recommendations for the newer oral agents such as metformin (Coustan, 2003).

FETAL ASSESSMENT IN THE TREATMENT OF GESTATIONAL DIABETES

Antepartum testing is recommended for patients with preexisting diabetes. Commonly used are: (1) fetal kick counts starting at 28 weeks (the patient documents fetal movements every day, which should exceed a

predetermined standard), and (2) nonstress testing or NST (which consists of fetal monitoring to look for fetal movement and fetal heart accelerations associated with it) twice per week with ultrasound assessment of amniotic fluid volume (Coustan, 2003; ACOG, 2001).

Biophysical profile is done with ultrasound weekly to document fetal movement, breathing, tone and amniotic fluid volume, or amniotic fluid index (AFI). This test is usually performed once or twice weekly. A Contraction Stress Test (CST), which requires intravenous fluids and oxytocin and involves hospital and nursing care, is used in some centers according to local practice (ACOG, 2001).

Ultrasound is used to estimate fetal weight in patients with suspected macrosomia prior to delivery although it has not been shown to be superior to clinical estimates. Expected ranges of error during the second trimester can be as high as 500 g (ACOG, 1997; ACOG, 2000). A "Level II" or "targeted" ultrasound study is usually performed in the second trimester to look for fetal anomalies (Coustan, 2003).

Laboratory and Ancillary Testing in the Management of Diabetes in Pregnancy

In addition to routine prenatal laboratory tests, women with diabetes during pregnancy, and especially those with preexisting diabetes, should undergo kidney function tests (24-hour collection for creatinine clearance and protein) and HbA1c at regular intervals, monthly or bimonthly, depending on control. Consultation with the ophthalmologist for retina assessment is indicated in the women with preexisting diabetes. Urine cultures should be performed to detect asymptomatic bacteriuria every month or two months to prevent UTI, which could progress to pyelonephritis. Electrocardiography should be obtained in diabetic women with vascular disease or longstanding diabetes.

The management of diabetes in pregnancy usually requires a team of perinatologists, obstetricians, neonatologists, nutritionists, endocrinologists, and additional specialists as required among others maintaining constant and open communication (Coustan, 2003; ACOG, 2001).

DELIVERY

Delivery can be accomplished at 40 weeks in patients with good control. In women with GDM, there is no evidence to support an induction before term. When control is less optimal, or in patients with preexisting diabetes, or when there are risk factors such as hypertension or previous stillbirth, delivery by induction should be accomplished at 38–39 weeks of gestation or sooner, depending on the severity of the complication.

Amniocentesis, to document fetal lung maturity, is usually recommended at $\leq$38 weeks of gestation due to the more frequent incidence of RDS in patients with diabetes.

Cesarean delivery rates are more frequent in patients with GDM compared to mothers without GDM. This difference does not appear to be related to fetal macrosomia. It is likely that caregivers tend to perform more cesarean sections to prevent shoulder dystocia at delivery. The incidence of shoulder dystocia is increased in pregnant patients with diabetes. It is therefore reasonable to recommend elective delivery by cesarean section if a particular threshold of fetal weight is exceeded, such as when the estimated fetal weight is 4,500 g or greater. When the estimated weight is 4,000–4,500 g, additional factors such as the patient's past delivery history, clinical pelvimetry, and the progress of labor may be helpful to consider in determining mode of delivery (ACOG, 2001; ACOG, 1997; ACOG, 2000).

Metabolic Management During Labor

During labor, it is essential to maintain maternal euglycemia (60–120 mg/dl), and at the same time prevent ketosis, hypoglycemia, and fetal acidosis. Frequent monitoring of

TABLE 14.4. Criteria for the Diagnosis of Diabetes Mellitus in the Nonpregnant State

Normal values	Impaired fasting glucose or impaired glucose tolerance	Diabetes mellitus
FPG <110 mg/dl 75-g, 2-hour OGTT 2-hour PG <140 mg/dl	FPG 110–125 mg/dl 75-g, 2-hour OGTT 2-hour PG 140–199 mg/dl	FPG ≥126 mg/dl 75-g, 2-hour OGTT 2-hour PG ≥200 mg/dl symptoms of diabetes and PG (without regard to time since last meal) ≥200 mg/dl

Abbreviations: FPG, fasting plasma glucose; OGTT, oral glucose tolerance test; PG, plasma glucose. The diagnosis of diabetes mellitus should be confirmed on a separate day by any of these three tests.
Source: American Diabetes Association (2003).

blood sugar is therefore essential (every 1–2 hours). Simultaneous infusions of intravenous glucose and insulin are therefore common. If the patient is scheduled for an elective cesarean section, intravenous fluids of normal saline can be given prior to the procedure. Immediately after the procedure, a dextrose infusion can be started to prevent starvation ketosis.

After delivery, insulin requirements usually fall to prepregnancy levels. During this time, blood sugar control should not be as strict and blood sugar levels may be allowed to rise to 150–200 mg/dl without untoward short-term effects. Insulin doses may be started at 1/3–1/2 of the predelivery amounts and adjusted according to the blood sugar levels (Coustan, 2003).

POSTPARTUM SCREENING

Gestational diabetes in women poses an increased risk of development of diabetes later in life. This is particularly true of populations who do not have access to screening and who have a high prevalence of type 2 diabetes. It is therefore appropriate to screen these patients for diabetes annually with their first screen in the postpartum period. Table 14.4 illustrates the diagnosis criteria for diabetes mellitus. There are no long-term follow-up studies documenting its benefit (Coustan, 2003).

The use of fasting plasma glucose to diagnose diabetes after delivery is less cumbersome than the oral GTT but the ACOG believes the oral GTT will more accurately identify those women who now have impaired glucose tolerance after delivery. This is thought to be important in counseling patients in regards to subsequent glucose control before their next pregnancy (ACOG, 2001).

Contraception and Prepregnancy Counseling

To minimize the incidence of congenital anomalies, adequate contraception counseling and medical follow-up are highly recommended in women with diabetes so that pregnancy is not unintentional. Contraceptive methods of virtually all types can be used in patients with diabetes. Progestational agents like levonorgestrel implants may require closer glucose monitoring (ACOG, 2001).

Prepregnancy counseling usually involves reassessment of current diet and further diet counseling, discontinuation of oral antidiabetic agents, folic acid supplementation, basal kidney and retina assessments, and institution of insulin and glucose monitoring regimens to achieve tighter control. Use of glycohemoglobin every 2–3 months can document improvement in average glucose levels. Exercise and weight reduction are usually encouraged (Coustan, 2003; ACOG, 2001).

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15

Chronic Kidney Disease

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This chapter will examine the mechanisms of chronic kidney disease (CKD) and diabetes, natural history, and potential therapies available. Diabetes accounts for more than 40% of the individuals currently seeking dialysis and transplant (U.S. Renal Data System, 2003). Current estimates are that 40 million Americans have or have the potential to develop diabetes mellitus (Coresh *et al.*, 2003). Chronic kidney disease develops in 10–15% of people with type 2 diabetes and approximately 40% of people with type 1 diabetes.

OVERVIEW OF RENAL PHYSIOLOGY

The kidneys are retroperitoneal organs that weigh approximately 150 g (1/3 lb) each (see Figure 15.1). Each kidney contains approximately 1.5 million glomeruli that are the most basic functional unit of the kidney. Chronic kidney disease results in the loss of glomeruli, such that when the total number of remaining glomeruli reaches 300,000, dialysis and transplantation are often needed to sustain life. The basic function of the kidney is to cleanse the body of unwanted metabolic waste products and control the fluid and electrolyte balance of the body. This function is usually measured in terms of glomerular filtration rate (GFR). Glomerular filtration rate may be thought of as a rough percentage of renal function and is usually expressed in terms of milliliter per minute (i.e., 80 ml/minute is roughly 80% of normal kidney function). Blood is delivered to the kidneys by the renal arteries and taken away by the renal veins. Glomerular filtration rate in adults is normally 100–120 ml/minute or 150 l/day. This literally means that the kidneys filter 150 l of blood per day and sort out the desirable from the undesirable substances. The undesirable substances then end up in urine that is expelled (cleared) from the body via bladder emptying. We commonly measure the clearance of a substance from the body as a way of estimating GFR. For example, insulin clearance is felt to be the gold standard for measuring GFR, but is difficult to do and is no longer used in clinical medicine (National Kidney Foundation, K/DOQI, Guideline 4 for CKD). Iothalamate clearance is a radioactive substance that can very accurately estimate GFR, but generates low-level radioactivity,

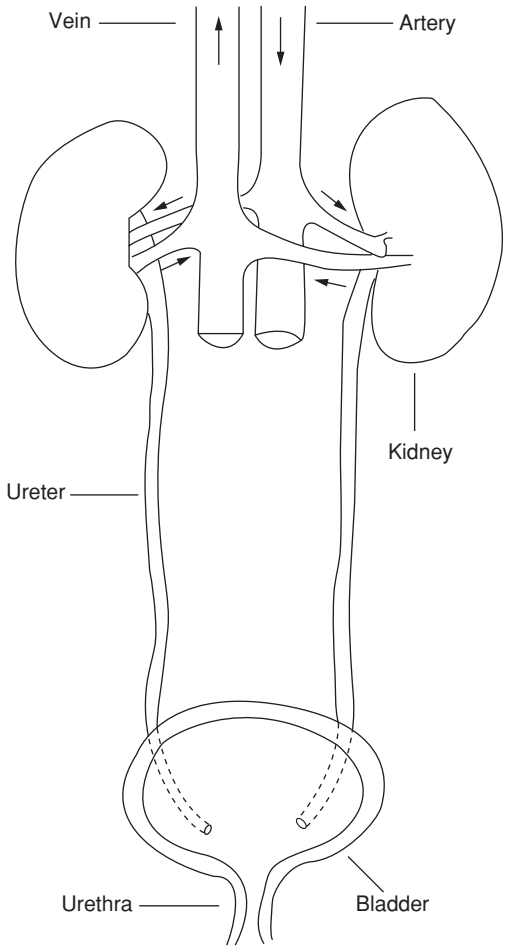

FIGURE 15.1. The vascular anatomy and structures of the kidney and urinary tract. These structures lie in the retroperitoneal area. The large vein on the left is the vena cava and the artery on the right is the aorta (Used with the permission of the National Kidney Foundation).

which is difficult to dispose of, and hence not commonly performed. Much more common clearance tests that are performed are creatinine clearance and urea clearance. Creatinine clearance overestimates GFR and urea clearance underestimates GFR (especially at low levels of GFR) and are commonly averaged to yield a more accurate estimate of GFR that is clinically useful and also gives information about protein catabolism (see below). The Modified Diet in Renal Disease (MDRD) study (Klahr *et al.*, 1994) developed an equation that has been validated to iothalamate clearance and uses age, sex, weight, height, race, serum albumin, serum creatinine, and BUN to calculate a GFR. This equation can be accessed at http://nephron.com/cgi-bin/MDRD.cgi.

The basic structure of the kidney consists of nephron (see Figure 15.2) that can be viewed as a series of structures involved in clearance. The blood delivered to the nephron is filtered by the glomerulus, fluid then passes through the tubules where important substances are either reclaimed or excreted into the final urine. The tubules are also important

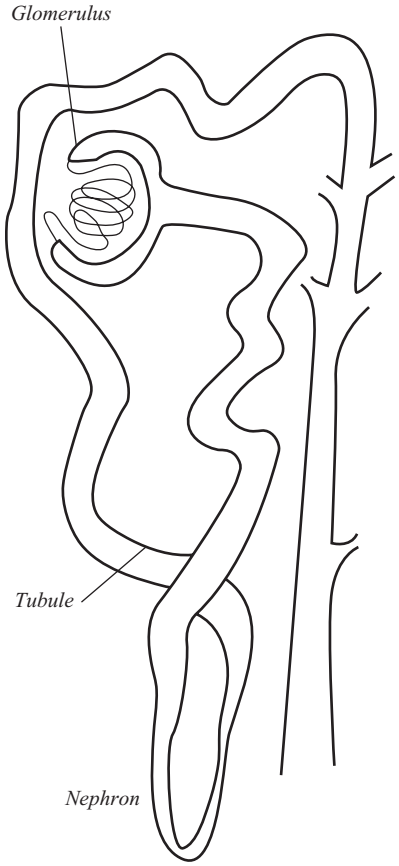

FIGURE 15.2. A schematic representation of the nephron. Each nephron consists of an artery bringing blood to the glomerulus, and the vessel taking blood away from the glomerulus. Blood is filtered into the tubule where the process of sorting out unwanted wastes and reclaiming important chemicals and fluids occur (Used with permission of the National Kidney Foundation).

in excretion of acids, production of hormones such as vitamin D, erythropoietin, and renin. The tubules also adjust the final amount of water that ends up in the urine. The kidney is also responsible for breaking down insulin and helping to regulate blood sugar. The kidney breaks down and excretes other hormones such as parathyroid hormone (PTH) and does the same activity for many drugs. As the urine is finally produced, it flows into a collecting duct that sends the urine into the ureter and finally into the bladder for final elimination. All these complex functions are affected by CKD.

NATIONAL KIDNEY FOUNDATION K/DOQI GUIDELINES

The National Kidney Foundation (NKF) has published guidelines covering many aspects of CKD (NKF, K/DOQI, 2000, 2002, 2003*a,b*). These guidelines can be accessed via the NKF Web site at www.kidney.org.

Chronic kidney disease is defined as an abnormality of kidney structure or function with or without alterations in GFR that are present for more than 3 months. In addition, anytime GFR is less than

TABLE 15.1. Stages and Prevalence of Chronic Kidney Disease

			Prevalence[a]	
Stage	**Description**	**GFR (ml/minute)**	**Population (1,000's)**	**(%)**
1	Kidney damage with normal or increased GFR	≥ 90	5,900	3.3
2	Kidney damage with mild decrease in GFR	60–89	5,300	3.0
3	Moderate decrease in GFR	30–59	7,600	4.3
4	Severe decrease in GFR	15–30	400	0.2
5	Kidney failure	<15 or dialysis	300	0.1

[a] Data for Stages 1–4 from NHANES III (1988–1994). Population of 177 million with age ≥20 years. Data for Stage 5 from USRDS (1998) includes approximately 230,000 patients treated by dialysis, and assumes 70,000 additional patients not on dialysis. GFR estimated from serum creatinine using the MDRD Study equation (see text). Stages 1 and 2 kidney damage based on abnormal spot albumin-to-creatinine ratio.
Source: Based on data developed by the National Kidney Foundation (NKF, K/DOQI, 2002).

60 cc/minutes per 1.73 m^2 and is present for more than 3 months, CKD is present. The NKF has developed a staging system based on GFR that includes descriptive characteristics of CKD and actions to be taken with each level of kidney disease (see Table 15.1).

Specific guidelines have been published regarding nutritional management, anemia management, management of dyslipidemias, and management of bone and mineral metabolism for CKD. There are also guidelines under development for management of cardiovascular disease and hypertension.

NATURAL HISTORY OF DIABETES MELLITUS, TYPE 1

Type 1 diabetes mellitus (diabetes) is the result of an absolute lack of insulin production by the body. This disease is covered in "Chapter 6", so this chapter will only deal with the pertinent features seen in diabetic kidney disease.

The earliest form of CKD seen in type 1 diabetes is microalbuminuria (see Figure 15.3). After approximately 5 years of diabetes, small amounts of albumin begin appearing in the urine (Mogensen, 1987; American Diabetes Association, 2002a). Special laboratory testing is necessary to detect small amounts of albumin in the urine. The most commonly performed test is a radioimmunoassay of the albumin in the urine. A colorimetric assay for albumin in the urine is also available. Normal amounts of albumin in the urine are less than 20 μg/mg of creatinine (also expressed as milligram per gram of creatinine) or less than 20 μg/minute if a 24-hour collection is performed. Microalbuminuria is said to be present when excretion is greater than 30 μg/mg of creatinine. Overt albuminuria (overt proteinuria) is said to be present when excretion exceeds 300 μg/mg of creatinine. Overt albuminuria can be detected by routine urine testing such as with a urine dipstick without resorting to specialized testing. Microalbuminuria begins when GFR is in the normal range and would qualify as Stage 1 CKD under the NKF classification system (NKF, K/DOQI, 2002). Overt proteinuria commonly begins between 5 and 10 years of type 1 diabetes.

At approximately 10 years of type 1 diabetes, GFR begins to decline and several

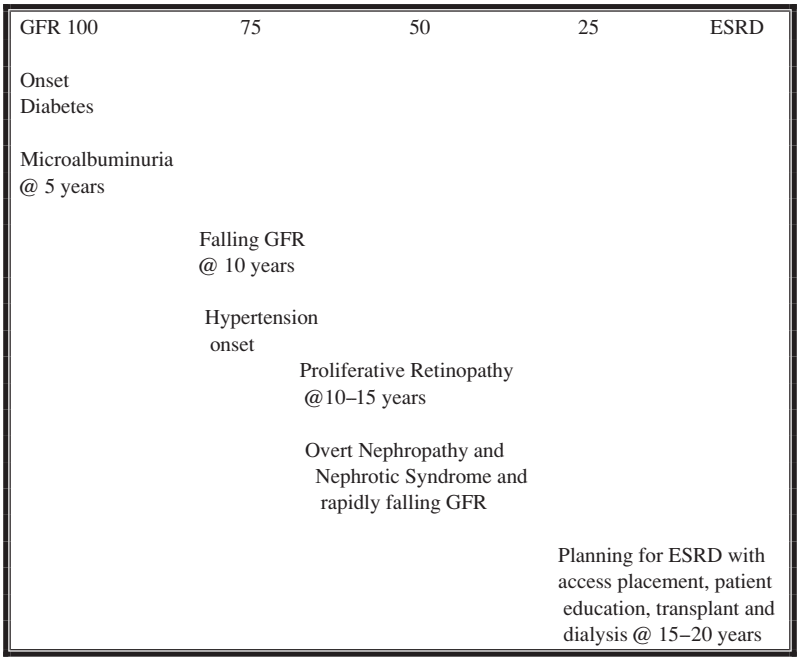

FIGURE 15.3. Natural history of diabetic nephropathy, type 1.

important pathophysiologic changes occur. Hypertension begins to develop. Retinopathy usually occurs in the 10–15-year time frame. The need for laser treatment of proliferative diabetic retinopathy commonly occurs in the same time frame as well. The combination of proteinuria, retinopathy, and diabetic peripheral neuropathy is commonly referred to as a diabetic triopathy and is particularly characteristic of progressive CKD in persons with type 1 diabetes. Accelerated hypertension is seen during the same time frame, hence retinopathy also can be complicated by hypertensive changes as well as diabetic changes.

A rapid fall in GFR is seen in the 15–20-year interval, such that most people with type 1 diabetes with CKD will require dialysis or transplant therapy within 5 years of the diagnosis of typical diabetic nephropathy. Diabetic nephropathy is characterized by severe hypertension, overt proteinuria, and declining GFR. Nephrotic syndrome may be seen in diabetic nephropathy and is a combination of more than 3.5 g of proteinuria per 24 hours (urine protein to creatinine ratio of greater than 3.5 on a spot specimen), hypoalbuminemia, and elevated serum cholesterol. The syndrome of diabetic nephropathy seen without diabetic retinopathy should cause some concern that the CKD may be the result of some other kidney disease rather than true diabetic nephropathy. A kidney biopsy may be the only way to differentiate other forms of kidney disease from typical diabetic nephropathy.

Dialysis and transplant are commonly considered when GFR is below 15 ml/minute. Placement of an arteriovenous fistula is recommended when the GFR falls in the 15–30 ml/minute range (NKF, K/DOQI, 2000, 2002). The arteriovenous fistula will facilitate management at later stages of the illness and requires 6 months or more to become developed enough to use for dialysis access. Planning for transplantation should

also be started during the same time frame. Please see Management of End Stage Renal Disease (ESRD) for further discussion on this topic.

NATURAL HISTORY OF DIABETES MELLITUS, TYPE 2

Type 2 diabetes is a disease that results from resistance to the actions of insulin in the body. Normal and even high concentrations of insulin may be available but the body does not respond normally to glucose loads and the activity of the insulin is impaired at the cellular level. This type of diabetes is often genetically transmitted in families. This chapter will deal with the myriad manifestations of CKD in persons with type 2 diabetes.

In contrast to type 1 diabetes, a patient with type 2 diabetes appears to have many other metabolic complications that result in a very different picture of CKD. The sequence of events depicted in Figure 15.3 is also true for type 2 diabetes but the time frame is not as predictable (ADA, 2002a.). Hence, microalbuminuria progressing to overt proteinuria, acceleration of hypertension, retinopathy, and progressive decline in GFR characterize diabetic nephropathy in persons with type 2 diabetes, but the timeline is not as predictable as we see in persons with type 1 diabetes. There are a number of reasons for this.

The person with type 2 diabetes frequently has other preexisting disease that may contribute to CKD. Such diseases as hypertension frequently predate the onset of proteinuria in persons with type 2 diabetes and may result in kidney damage. Hyperlipidemia is commonly seen in type 2 diabetes prior to the onset of CKD, but in type 1 diabetes, hyperlipidemia is not common until after the onset of overt proteinuria or nephrotic syndrome (ADA, 2002a.).

The metabolic syndrome is the combination of insulin resistance, dyslipidemia, hypertension, and obesity (Scott, 2003). Many of these patients have a genetic predisposition to develop type 2 diabetes. They have a high incidence of atherosclerotic vascular complications, including coronary heart disease, atherosclerotic nephrosclerosis, and resultant CKD. Hence, in type 2 diabetes, CKD may result from nephrosclerosis, renal artery stenosis secondary to atherosclerotic vascular disease, and hypertensive nephrosclerosis. Typical diabetic nephropathy may then develop in the setting of any one or all of these diseases. This makes the timeline for the development of CKD in type 2 diabetes very unpredictable.

End stage renal disease progresses over time and dialysis or transplant therapy is necessary when the GFR reaches Stage 5 (less than 15 ml/minute). In type 2 diabetes, atherosclerotic vascular and cardiac disease, hypertensive heart and vascular disease, and obesity all contribute to the morbidity and mortality commonly seen in this population with Stages 4 and 5 CKD. The creation of arteriovenous fistula access is also complicated in this population because of these preexisting and comorbid conditions.

DIAGNOSTIC EVALUATION OF CKD

The most important aspect in the diagnostic evaluation of CKD in diabetes is a careful history and physical examination. This will yield an accurate diagnosis and also provide information about complications of diabetes including hypertension, peripheral neuropathy, retinopathy, peripheral vascular disease, and the possibility of renal artery disease. Family history can give clues as to the genetics involved and provide information about hypertension, heart disease, hyperlipidemia, and ESRD as risk factors for the development of CKD. Certain ethnic populations with predisposition to diabetes are known to be at particularly high risk for the development of CKD including black race, Hispanic, Pacific Islander, and American Indian (NKF, KEEP, 2003).

The next step in the evaluation of CKD is to measure kidney function and look for signs of kidney damage. A GFR calculation can be done using the MDRD calculation noted above. Urine should be measured for microalbumin or overt proteinuria. This can be done with an individual (spot) urine sample or a 24-hour collection. The patient's GFR should be staged using the NKF's CKD system. This staging system then gives the patient recommendations for actions to be taken at each level of GFR. This will help to prepare the patient for dealing with ESRD, should therapy be necessary.

Patients should undergo testing to include a chemistry panel that includes BUN, creatinine, sodium, potassium, albumin, bicarbonate, calcium, and phosphate levels. A PTH level should be done in patients with Stages 3–5 CKD to assess secondary hyperparathyroidism (NKF, K/DOQI, 2003b.). A complete blood count should be done, which includes a hemoglobin and a hematocrit to evaluate for anemia of CKD. With GFRs below 60 ml/minute, anemia would be anticipated. A lipid panel should be done to look for the characteristics of the nephrotic syndrome, metabolic syndrome, and risk factors for coronary artery and peripheral vascular disease. HbA1c should be measured to assess metabolic control of diabetes and establish prognosis for progression of CKD. A 24-hour urine collection can be used to measure GFR and when urea clearance and protein are measured, one also can determine normalized protein catabolic rate (nPCR) that can provide information about nutritional status and dietary protein requirements (NKF, K/DOQI, 2000, Nutrition Guidelines). A subjective global assessment also can be used to evaluate nutritional status and assist in the dietary management of the diabetic with CKD (NKF, K/DOQI, 2000, Nutrition Guidelines).

Neurology testing, including monofilament testing, will provide valuable information regarding risks to the patient with diabetes and CKD. Typical diabetic triopathy includes diabetic peripheral neuropathy but also may include other forms of diabetic neurological injury including gastroenteropathy (including gastroparesis and diabetic diarrhea), autonomic neuropathy with orthostatic hypotension, mononeuropathy with individual muscle paresis, painful peripheral neuropathy, radiculopathy, and abnormalities of sweat gland control including postgustatory sweating. CKD is commonly seen in the setting of diabetic neuropathy.

When CKD is seen in diabetes and especially in type 2 diabetes, the possibility of renal artery disease and other forms of CKD, other than diabetic nephropathy, have to be considered. Auscultation for renal artery bruits, Doppler ultrasounds of the kidney, magnetic resonance imaging, nuclear medicine scanning with or without captopril and CT angiograms may be used to try and detect renal artery disease in appropriate clinical circumstances. A renal ultrasound should be done in almost all cases of CKD in the patient with diabetes and should look for reversible factors including obstruction, the presence of two kidneys, size of the kidneys, and echotexture of the kidneys. Incidental mass lesions are occasionally discovered during screening ultrasound of the kidneys and need to be evaluated appropriately. Typical diabetic nephropathy results in large kidneys seen on ultrasound, whereas diseases such as hypertensive and atherosclerotic nephrosclerosis typically result in smaller than normal kidneys with increased echo-texture (suggestive of scarring and loss of water content). Valuable information commonly derived from ultrasound also includes obstruction of the urinary tract at any level from the prostate to the renal pelvis. Obstruction is a reversible cause of CKD and should be sought in all cases.

TREATMENT CONSIDERATIONS IN CKD

Once the diagnosis of CKD is made in a person with diabetes, the most important treatment considerations are based on the

stage of CKD. Specifically, levels of GFR and proteinuria will guide therapy. Dietary management includes the diabetic diet as recommended by the American Diabetes Association (ADA, 2002b.). In addition, diets such as the Dietary Approaches to Stop Hypertension (DASH diet) are also recommended as lifestyle modifications in the treatment of hypertension and diabetic kidney disease (Sacks *et al.*, 2001; Chobanian *et al.*, 2003). Protein restriction and restriction of phosphorus in the diet has been advocated by some based on small studies (ADA, 2002b.), but no prospective randomized trials have been carried out in diabetic nephropathy of sufficient size to make a strong recommendation. The control of diabetes with an HbA1c in the range of 6.0–6.5 has been shown to treat and reverse microalbuminuria and prevent the progression of diabetic nephropathy (Diabetes Control and Complications Trial Research Group, 2003).

Antihypertensive therapy is the key to therapy of diabetic nephropathy. The Joint National Committee Report on Prevention, Detection, and Treatment of High Blood Pressure (Chobanian *et al.*, 2003) currently recommends treatment of diabetic CKD to a target of 130/80. There have been suggestions that diabetic CKD, especially with proteinuria in excess of 1 g per 24 hours, should be treated to a lower target of 125/75 (Bakris *et al.*, 2000). The control of hypertension frequently requires multiple drug therapy to achieve these targets. Studies have suggested that an average of 3–4 drugs may be required in these individuals to achieve this type of control (Chobanian *et al.*, 2003).

The choice of agents in antihypertensive is also of critical importance. Type 1 diabetic nephropathy has been shown to respond to angiotensin converting enzyme inhibitor (ACE-I) therapy (Lewis *et al.*, 1993). In contrast, type 2 diabetic nephropathy has been shown to respond favorably to angiotensin receptor blockers (ARBs) (Lewis *et al.*, 2001; Brenner *et al.*, 2001; Parving *et al.*, 2001). Please see Table 15.2 for examples of ACE-I and ARB agents used in diabetic nephropathy. These agents have been shown to slow the progression of diabetic nephropathy and in some cases have been able to reverse microalbuminuria to normal levels of albumin excretion in the urine. Therapy should be initiated as soon as microalbuminuria is detected, regardless of the level of blood pressure. Hence, ACE-I and ARB therapy should be initiated in Stage 1 CKD found in patients with either type 1 or type 2 diabetic nephropathy. Recent studies have suggested a synergistic effect of the combination of ACE-I with an ARB in the treatment of proteinuria associated with both non-diabetic and diabetic nephropathy (Campbell *et al.*, 2003; Jacobsen *et al.*, 2003). This combination results in a significantly greater fall in proteinuria than with either agent alone. Hence, if either agent is incompletely effective in reaching target blood pressure or decreasing proteinuria, the other agent could be added to try and achieve these goals.

The recent ALLHAT trial demonstrated that thiazide therapy decreases mortality and morbidity of hypertensive patients, including patients with diabetes mellitus (ALLHAT Collaborative Research Group, 2002). Hence, the addition of thiazide therapy such as hydrochlorothiazide and chlorthalidone (see Table 15.2) to the ACE-I and ARB agents would be the next reasonable addition in an attempt to reach a goal blood pressure in diabetic nephropathy. These agents are effective in Stages 1–3 CKD associated with diabetes, but are not effective with GFRs below 30 ml/minute. The thiazide diuretic metolazone is not only effective with GFRs below 30 ml/minute, but also results in significant complications including gout from hyperuricemia, hypokalemia, and hypomagnesemia. If a diuretic is needed with Stage 3 or greater CKD, loop diuretics such as furosemide, torsemide, or bumetanide (see Table 15.2) should be used. Loop diuretics can also cause hypokalemia, hypomagnesemia, and gout. The combination of ACE-I or ARBs with diuretics frequently avoids the complication of hypokalemia. ACE-I and ARB agents may cause hyperkalemia and diuretics will

TABLE 15.2. Selected Antihypertensive Drugs

Drug class	Generic names	Trade names
ACE-inhibitors	Captopril, enalapril, lisinopril, fosinopril, moexipril, perindopril, quinapril, ramipril, and trandolapril	Capoten, Vasotec, Prinivil, Zestril, Monopril, Univasc, Aceon, Accupril, Altace, and Mavik
ARBs	Candesartan, irbesartan, olmesartan, losartan, valsartan, telmisartan, and eposartan	Atacand, Avapro, Benicar, Cozaar, Diovan, Micardis, and Teveten
Diuretics	Bumetanide, furosemide, torsemide, hydrochlorothiazide, chlorthalidone, methylclorthiazide, indapamide, metolazone, spironolactone, amiloride, triamterene, and eplerenone	Bumex, Lasix, Demadex, Hydrodiuril, Hygroton, Enduron, Lozol, Mykrox, Zaroxlyn, Aldactone, Midamor, Dyrenium, and Inspra
Beta-blockers	Acebutolol, atenolol, betaxolol, bisoprolol, carteolol, carvedilol, labetalol, metoprolol, naldolol, pindolol, propranolol, and timolol	Sectral, Tenormin, Kerlone, Zebeta, Cartrol, Coreg, Trandate, Normodyne, Lopressor, Toprol, Corgard, Visken, Inderal, and Blocadren
Calcium channel blockers dihydropyridines	Nifedipine, nicardipine, isradipine, amlodipine, felodipine, and nisoldipine	Adalat, Procardia, Cardene, Dynacirc, Norvasc, Plendil, and Sular
Nondihydropyridines	Diltiazem and verapamil	Cardiazem, Dilacor, Cartia, Calan, and Isoptin
Other agents useful in treating hypertension and diabetic nephropathy	Terazosin and doxazosin minoxidil and hydralazine clonidine and guanfacine	Hytrin and Cardura Loniten and Apresoline Catapres and Tenex

counter this tendency. Virtually, all cases of CKDs are associated with volume expansion; hence low-salt diets and diuretics should be used appropriately to control volume in diabetic nephropathy. Thiazolidinedione-type diabetic drugs, such as rosiglitazone (Avandia) or pioglitazone (Actos), are known to be salt retaining and may cause exacerbation of congestive heart failure. Patients with type 2 diabetes mellitus taking diuretic medication will experience antagonism by using thiazolidinedione-type drugs.

All calcium channel blockers are not equal when it comes to hypertension treatment in diabetic nephropathy. Calcium channel blockers can be roughly divided into dihydropyridines and nondihydropyridines (see Table 15.2). The dihydropyridines are effective antihypertensive agents but have been shown to worsen proteinuria with monotherapy (Hoelscher and Bakris, 1994) and when compared to ACE-I and ARB agents are clearly inferior (Lewis *et al.*, 2001). The nondihydropyridines such as diltiazem and verapamil, in contrast, have been shown to decrease proteinuria in diabetic renal disease (Parving *et al.*, 1997; Bakris *et al.*, 1998). Hence, the nondihydropyridines may be additive therapy or alternatives to ACE-I or ARB agents in patients with contraindications or intolerance of such drugs. Dihydropyridines should probably be reserved for add-on therapy in patients not achieving target blood pressure with ACE-I and/or ARB with diuretic therapy. These agents would be third-level agents behind ACE-I, ARB, and diuretic therapy. Calcium channel blockers are more expensive than the first or second line therapies for diabetic nephropathy, and this fact limits their usefulness in therapy.

Beta-blockers are useful as antihypertensive agents but have some problems in people

with diabetes that needs to be considered. Beta-blockers have been shown to reduce mortality in essential hypertension and reduce cardiovascular mortality in patients with coronary heart disease (Chobanian *et al.*, 2003). In people with diabetes, especially those taking insulin, hypoglycemic unawareness may be a problem. In other words, patients may not "feel" the adrenalin rush from low blood sugar if beta-blockers are administered. Beta-blockers may cause hyperkalemia that will complicate management in the person with diabetes already prone to high serum potassium levels either from the underlying diabetic nephropathy or as a complication of ACE-I therapy. Beta-blockers will be helpful in the patient with diabetic nephropathy and known cardiovascular disease. Current targets for hypertension control (130/80) will require 3–4 drugs for control (Hansson *et al.*, 1998; Adler *et al.*, 2000) and beta-blockers may be very effective in the properly selected patient population with CKD and diabetes.

Other agents (see Table 15.2) should be used in diabetic nephropathy as needed to achieve target blood pressure. These agents include peripheral alpha adrenergic drugs such as terazosin, doxazosin, combination adrenergic drugs such as labetalol, central alpha drugs such as clonidine and guanfacine, and vasodilators such as hydralazine and minoxidil. Potassium sparing diuretics such as triamterene, spironolactone, and eplerenone should have very limited use in diabetic CKD because of the common tendency to hyperkalemia in these patients.

Referral to other health care providers will help in the management of the myriad problems associated with diabetic nephropathy. Early referral to a dietitian with experience in diabetic CKD is important (NKF, K/DOQI, 2000). These diets are frequently very complicated and require experience in listening to the patient and their dietary preferences. After review of dietary preferences, taking into consideration stage of CKD and assessment of 24-hour urine for nitrogen excretion and nPCR, the renal dietitian can appropriately adjust the diet to the requirements for diabetic nephropathy and hypertension control. Hyperlipidemia is a significant risk factor for progression of CKD (NKF, K/DOQI, 2003a) and requires dietary management as well as drug therapy. Recent evidence suggests that CKD is a risk equivalent to established coronary heart disease in the therapy of hyperlipidemia. Current recommendations for CKD include targeting total cholesterol to less than 200, LDL cholesterol to less than 100, and non-HDL cholesterol to less than 130. Ophthalmology referral is necessary because of the known association of proliferative diabetic retinopathy with diabetic nephropathy. Referral to a neurologist may be necessary to establish the nature and type of diabetic polyneuropathy. Regular programs for exercise and weight control are essential parts of lifestyle modifications for successful treatment of hypertension and maintenance of general health in patients with diabetic nephropathy.

As patients progress to Stage 3 and greater degrees of CKD, progressive acidosis may be seen. This is usually demonstrated by serum bicarbonate concentrations less than 22 mEq/l. Systemic acidosis leads to excess protein catabolism, osteoporosis, hyperkalemia, and fatigue. Treatment is advocated to maintain a bicarbonate concentration above 22 mEq/l and usually involves sodium bicarbonate either in tablet form or as baking soda. The sodium load associated with sodium bicarbonate administration can be a problem for hypertension and volume control, but it is generally felt that the sodium load can be managed and the benefits of treatment outweigh the risk (NKF, K/DOQI, 2000).

Secondary hyperparathyroidism is a common accompaniment of CKD in the diabetic. Recently published guidelines are available from the NKF (NKF, K/DOQI, 2003b). Generally, PTH should be measured in any patient with Stage 3 or greater CKD. Dietary phosphorus restriction of 800–1000 mg may be appropriate for patients with Stage 3 CKD or greater. Phosphate binders such as

lanthanum, calcium carbonate, calcium acetate, and sevelamer may be necessary to maintain phosphorus levels between 2.7 and 4.6 mg/dl. Vitamin D therapy may be necessary if significant hyperparathyroidism persists despite adequate control of serum phosphorus and calcium concentrations.

END STAGE RENAL DISEASE

Patients with Stages 4 and 5 CKD and diabetes should be referred for appropriate nephrologic care (NKF, K/DOQI, 2002). Stage 3 CKD could be referred, if necessary, to establish a diagnosis or therapy that is ineffective or in question. Hypertension, which has not been successfully treated to target, should also be referred for consultation. Primary arteriovenous fistula should be placed when patients reach Stage 4 CKD. Competent vascular surgeons should place arteriovenous fistula. Many studies indicate that the more experience a vascular surgeon has, the more likely that arteriovenous fistula will be successful (NKF, K/DOQI, 2000). Vein mapping should be done prior to placement of the fistula. Forearm fistula are preferred over upper arm fistula and brachiobasilic fistula can be successful but frequently require translocation to more superficial tissues over the biceps muscle to allow easier access for dialysis. Currently, less than 30% of fistulas nationwide are primary AV fistula, but the NKF and the Center for Medicare and Medicaid Services (CMS) have set a goal of more than 50% primary AV fistulas in new patients with ESRD by 2010 (USRDS, 2003; Centers for Disease Control, Health People 2010 Objectives Database, 2003 Update). Preservation of the cephalic vein over the forearm and avoiding intravenous needle insertion into this very critical vein in people with diabetes at risk for CKD is essential. Education of nurses and other professionals who place intravenous access devices about this critical vein will help to achieve the goal of more than 50% AV fistulas in this high-risk diabetic population. Avoiding subclavian central access cannulation also will be important in avoiding central venous stenosis as a complication of upper arm AV access. Placement of pacemaker leads in the central veins also complicate upper arm AV access procedures and may result in arm edema and venous hypertension.

Formal patient education regarding ESRD should begin at Stage 3 CKD. Most programs deal with at least six topics of discussion: (1) anatomy and physiology of the kidney; (2) hemodialysis; (3) peritoneal dialysis; (4) transplantation; (5) diet; and (6) insurance and psychosocial issues. The NKF offers a program known as "People Like Us Live" that provides patients with videos and discussion about each of these topics. Several other programs are available commercially (Baxter Health Care and others) and are often offered by local dialysis facilities or dialysis providers. There is currently legislation pending in Congress to fund predialysis education under Medicare much the same as is currently reimbursed under Medicare for dietary education and for diabetic education. Early referral to a nephrologist when patients reach Stage 3 CKD is advocated so that this early education can begin. Patients should be counseled about modality choice. Modalities that should be considered for patients contemplating ESRD include hemodialysis, both home and in-center, peritoneal dialysis, and transplantation. In diabetes, options for transplantation include cadaveric kidney transplants, living donor transplants, and pancreas–kidney transplants for people with type 1 diabetes. Living donor transplants may include living related donors (such as brothers and sisters) or living unrelated donors (such as spouse, significant other, or other altruistic individual). Patients who have ESRD education are more likely to elect home therapies such as peritoneal dialysis or home hemodialysis (Gomez *et al.*, 1999). Transplant evaluation is generally performed with Stages 4 and 5 CKD. Recent experience has demonstrated that patients who undergo transplant without spending time on dialysis have better long-term

survival than patients who are on dialysis and then are transplanted (Kasiske *et al.*, 2002). This form of transplantation is known as preemptive transplantation and is only possible with early referral to a nephrologist or a transplant center.

POSTTRANSPLANT CONSIDERATIONS FOR DIABETES MELLITUS

The most common drugs used for immunosuppression after a kidney transplant are steroids, azothiaprine (Imuran), cyclosporine (Neoral, Sandimmune, and Gengraf), tacrolimus (Prograf), sirolimus (Rapamune), and mycophenolate mofetil (Cell Cept). Each of these agents may result in particular problems for the diabetic transplant recipient. Steroids may cause insulin resistance and poor glycemic control, weight gain, osteoporosis, hyperlipidemia, and worsening hypertension. Several recent immunosuppressive protocols have been developed that avoid or limit use of steroids in an effort to reduce these posttransplant complications. Azothioprine does not have any particular complications in a person with diabetes but has been replaced by mycophenolate mofetil in most recent protocols. Mycophenolate mofetil frequently causes gastrointestinal symptoms including nausea, vomiting, and diarrhea that may already be a problem related to diabetic gastroenteropathy. Cyclosporine may cause worsening hypertension and may induce some resistance to insulin. Tacrolimus commonly causes glucose intolerance and insulin resistance in peoples with diabetes after transplantation. Sirolimus is associated with posttransplant hyperlipidemia and frequently interferes with wound healing. Both of these problems already plague people with diabetes. All of these agents suppress the immune system and may lead to infectious complications that are already common in diabetes.

The management of the diabetic posttransplantation is dependent upon the type of transplant that was performed. People with type 1 diabetes will obviously require insulin management if only a kidney transplant is performed. The target for glycemic control remains an HbA1c of 6.0–6.5 range. If simultaneous pancreas and kidney transplantation is successfully performed, then insulin will no longer be needed. Some receive a kidney transplant and then seek a pancreas transplant at a later date; however, recent reports have questioned this practice (Venstrom *et al.*, 2003). Pancreas transplantation in type 1 diabetes may reverse some of the complications of diabetes including peripheral neuropathy and may prevent recurrent diabetic nephropathy. The patient may, however, experience worsening of retinopathy and gastroenteropathy in the early posttransplant course. People with type 2 diabetics are not candidates for pancreas transplants.

The most common cause of death posttransplant is infection in the first 6 months, but thereafter cardiovascular complications are the most common cause of morbidity and mortality later in the posttransplant course. Careful management of risk factors for cardiovascular disease is necessary. Total cholesterol should be targeted less than 200 mg/dl, LDL cholesterol should be less than 100, and non-HDL cholesterol should be less than 130 (NKF, K/DOQI, 2003a). Triglyceride levels should be targeted less than 500 mg/dl. Diet should reflect caloric needs and emphasize weight control. Exercise is mandatory to prevent the weight gain commonly seen after transplantation. Use of drugs for lipid control must take into consideration the immunosuppressive drugs that are being used in order to avoid interactions. Many of the statins must be used cautiously or not at all in patients taking cyclosporine and tacrolimus so as to avoid myopathy and rhabdomyolysis. Niacin may worsen glycemic control and cause hyperuricemia and gout. Fibrates may also be associated with myopathy in transplant recipients, especially when given with statin drugs.

Secondary hyperparathyroidism, especially when poorly controlled in the

pretransplant period, may become tertiary hyperparathyroidism after kidney transplantation with the return of full vitamin D metabolism in the new kidney. This will result in hypophosphatemia, hypercalcemia, hypercalcuria, and stone disease. If the parathyroid glands do not diminish in size and function with time after transplant, parathyroidectomy after transplantation is occasionally necessary to prevent complications. Calcium stones may obstruct the urinary system causing acute renal failure, rather than pain, in the denervated kidney transplant. Hypophosphatemia, hypomagnesemia, and hypercalcemia may be seen for other reasons including steroids, diuretics, and other drugs given to the posttransplant patient. Attention to calcium and other mineral metabolism will help to prevent osteopenia and osteoporosis in the posttransplant patient. Measurement of bone mineral density by techniques such as dual energy X-ray absorptiometry scanning at least every 2 years will screen for these diseases and permit appropriate therapy.

While rejection remains the serious concern in the early transplant period, other kidney diseases such as CMV infection, BK virus infection, obstruction of the ureter or bladder, pyelonephritis, lymphocoel, and drug toxicity all remain causes of transplant dysfunction. Careful observation and frequent drug monitoring are necessary in the early transplant period. Glycemic control with insulin and oral hypoglycemic (for type 2 diabetes) are necessary to prevent recurrent disease in the kidney transplant. Rarely, other forms of primary glomerulonephritis may occur in the posttransplant kidney in patients with diabetes.

Health care maintenance in the transplant recipient is the same as would be taken for any other diabetic patient, except for some minor changes. Live virus vaccines should not be used in the posttransplant patient, and this includes the newest nasal live virus influenza vaccines. Families of transplant patients also should not receive live virus vaccinations, if those viruses are shed after vaccination. Annual flu shots and pneumococcal vaccination every 5 years are recommended. Tetanus and diphtheria vaccinations every 10 years are recommended. Regular visits for appropriate screening examinations should be undertaken, including rectal exams, pap and pelvic examinations, and appropriate colorectal cancer screenings are advocated. Dental care should be continued and appropriate antibiotic prophylaxis should be prescribed for patients with fistulas and other intravascular devices that warrant treatment according to the American Heart Association guidelines (American Heart Association, 1997). Prior to transplantation, patients undergo extensive screening examinations and should have a baseline examination for most organ systems available in their pretransplant records for comparison.

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16

Caring for the Uninsured and Diabetes

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Quite possibly the greatest public health problem to date is the lack of health insurance for an estimated 43.6 million Americans, approximately 15% of the population. The number of uninsured is estimated to grow 1.5 million per year. During the past 2 years, some 75 million went without insurance (Groman, 2003; Kaiser Family Foundation [KFF], 2003a). Approximately 80% of uninsured Americans are children and working adults (KFF, 2003b). Rising premiums, co-payments, and deductibles make it increasingly unlikely for many to afford health insurance in the future. Recently, we have seen a 12.7% increase in insurance premiums, which is quadruple the rate of inflation (Gabel, 2001). Uninsured patients pay $26.4 billion in out-of-pocket expenses for health care and receive $98.9 billion in care; $35 billion of it uncompensated (comes from predominantly federal and state programs). These numbers illustrate how the uninsured not only pay a great toll for their care or lack of care, but also how health care costs exact a great toll from the taxpayers as a whole (Volunteers in Health Care [VIH], 2004).

There are 18.2 million people in the United States, or 6.3% of the population, who have diabetes. While an estimated 13 million have been diagnosed with diabetes, 5.2 million people (or nearly one-third) are unaware that they have the disease (American Diabetes Association, 2004). Lack of health insurance has important health consequences for persons with diabetes. Inability to obtain necessary care endangers the health of people with diabetes and has increasingly been shown to result in higher costs for the nation (Institute of Medicine [IOM], 2001, 2002; Reed and Tu, 2002).

Nearly 40% of uninsured adults skipped a recommended medical test or treatment, and 20% say they have needed but not received care for a serious problem in the past year. Uninsured Americans have been found to be up to four times as likely as insured patients to require both hospitalizations and emergency hospital care for conditions that could be avoided, like pneumonia and uncontrolled diabetes.

Both uninsured adults and children are less likely to receive preventive care (American College of Physicians, 1999; KFF, 2000b). Studies show that 25% of adults with diabetes who were uninsured for a year or more went without a checkup for 2 years, compared to 5% of adults with diabetes who were insured (IOM, 2002). Uninsured people

with diabetes are also less likely to receive regular eye and foot exams (IOM, 2002) and less likely to have an HbA1c less than or equal to 9.5% (Saaddine *et al.*, 2002). Uninsured people with diabetes are more likely to use the emergency room for care, more likely to be admitted, less likely to be identified with a primary care physician, and less likely to follow-up with a physician (Wilson and Sharma, 1995; Oster and Bindman, 2003). This results in greater costs to the patient and the nation for uncompensated care.

The truth is that lack of health insurance is a predictor of ill health, resulting in a 10–15% higher mortality rate, and in earnings of 10–30% less because of poor health (KFF, 2002a). One study estimates that more than 18,000 adults die each year in the United States because of the lack of health insurance (IOM, 2002).

COMMON MYTHS AND FACTS REGARDING THE UNINSURED

The following are myths and facts regarding the uninsured in the United States (*Source:* KFF, 2003b; Ayanian *et al.*, 2000; Bell, 2000; VIH, 2004):

Myth: People without insurance have adequate access to health care.

Fact: Numerous studies confirm that not having health insurance reduces your access to preventive, primary, and specialty care. People without insurance are more likely to live sicker and die younger.

Myth: Medicaid covers all poor people.

Fact: Only 41% of the poor are covered by Medicaid, which does not cover 26% of poor children, 40% of poor women, and 50% of poor men.

Myth: Most uninsured are poor, unemployed minorities.

Fact: Most uninsured Americans are employed and Caucasian (Bell, 2000, available at www.amsa.org). About 80% live in families where at least one person works and 80% are American citizens. The uninsured can be found at every income level: 64% are at <200% of Federal Poverty Level (FPL), 16% are between 200% and 299% of FPL, and 19% are at or above 300% of the FPL. However, it is important to note that people of lower socioeconomic status, rural populations, and some racial and ethnic minorities are disproportionately represented among those who are uninsured.

Myth: Everyone has access to care through the emergency room.

Fact: Emergency rooms (ER) are the most expensive and inefficient way to deliver primary care. Diabetes is a chronic condition that is well treated through prevention and education that, for good reason, should not be done in the ER setting. There is now a growing national problem of emergency room overcrowding partly due to people inappropriately using the ER as their main source of care. Despite this perception of a "safety net," uninsured adults continue to demonstrate poor or fair health and are not getting the needed medical care.

Myth: Women and children are most likely to be uninsured.

Fact: Young men are at greatest risk. Low-income women are more likely to qualify for Medicaid, which covers pregnant women and heads of single-parent families, who are usually women. Most uninsured are adults: 40% are 19–34 years old, 31% are 36–54 years old, and 21% are under 19 years old. Children are less likely to be uninsured than adults. Medicaid has less restrictive criteria for children than it does for adults. Medicaid only covers adults who are disabled, pregnant, elderly, or who take care of dependent children. The federal Children's Health Insurance Program covers children above Medicaid income eligibility limits, but cuts off those in families earning more than 200 of the FPL.

Myth: Most people without health insurance have chosen to be uninsured.

Fact: Only 7% of uninsured adults reported that they were uninsured by choice or because they did not believe in health insurance. Families and individuals who are uninsured face a hard choice. For many, health insurance premiums and fee-for-service payments are simply not possible.

Myth: Even if there is a problem, nothing can be done about it.

Fact: Many people are doing something about it in their offices, from donating free care, researching free prescription medications, volunteering, and getting involved in organizing care. One study estimates that 69% of private practice

internists provide charity care and 55% of employee internists provide charity care (Fairbrother *et al.*, 2003). There are 750 Federally Qualified Community Health Centers with 3,200 sites. Together these sites provide health care to 10 million patients, 39% of whom are uninsured. There are approximately 1,000 free clinics in the United States, offering health care to approximately 3 million uninsured patients per year. There should be greater efforts on a state and national level to understand why the uninsured have greater unmet health needs and to address how to improve our health systems, including assessing whether we need to increase the "safety nets" or whether there should be a complete overhaul.

Diabetes is a chronic disease that is largely self-managed. This presents a great challenge and opportunity for those involved in the care of the disease. Relatively modest lifestyle changes have been shown to both prevent the onset of diabetes and control the symptoms and complications.

For many reasons, medicine in America continues to be lopsided with more effort and resources being spent on treatment and fewer resources dedicated to prevention and health promotion education. It is imperative that the care of an uninsured person with diabetes starts with addressing lifestyle issues, specifically obesity and inactivity. While prevention usually requires more than taking another pill, it is a much healthier and economical approach. In terms of cost to the patient, many prevention and education strategies can reap great improvements with little personal outlay.

Often the lack of health insurance is only one of the many barriers an uninsured person with diabetes faces in obtaining quality health care. The physician or other health care professional needs to take into account "the big picture," including ethnicity, culture, language, illness world view, religion, alternative lifestyles, transportation, illiteracy, and family structure (Management Sciences for Health, 2003). Many of these issues have been touched on in other chapters of this book, but some issues will be revisited here.

For an individual health practitioner to provide good cost-effective care to the uninsured patients with diabetes two things are essential:

(1) *Current working knowledge of diabetes care.* The knowledge of risk factors, and thus prevention, is critical in any program or practice because the cost of prevention (whether through vaccines for influenza and pneumonia or aspirin and ace-inhibitors for cardiac and renal complications) is exponentially less than the cure for preventable complications requiring hospitalizations and aggressive treatments. Any provider must be thoroughly familiar with guidelines and practice current medicine. Some guidelines can be found in the 2004 Clinical Practice Recommendations for Diabetes (available at http://care.diabetesjournals.org/content/vol27/suppl_1/) at the National Guidelines Clearinghouse (see www.guideline.gov), and at the American Association of Clinical Endocrinologists (see www.aace.com/clin/guidelines/diabetes_2002.pdf). Doing so will actually cost the patient less over the life of their illness.

(2) *Commitment to work with the uninsured patient*. This includes a willingness to research options and flexibility to learn from patients what works for them. Most people will pay for what they understand to be valuable. The challenge lies in making the care not only affordable but also valuable; that is, taking time to find out what the patient values. The start of caring is moving beyond the label of "noncompliant patient" when a treatment plan is not followed and understanding why a patient did not come for a visit or take a medicine. Most patients, if listened to, will have a rational reason for not doing what the doctor wanted. This is often difficult for physicians who have a different value hierarchy than their patients. It is helpful to view the care of people with diabetes as a relationship that requires trust and to know that this trust often takes time to establish. Many uninsured patients, for a variety of reasons, have come to distrust, dislike or avoid doctors, hospitals, and medical systems. Some of it is due to the obvious reason that they cannot afford care. Some of it is due to the way they have been treated or mistreated. Many of the studies alluded to earlier in this chapter showing worse outcomes and inadequate levels of care for the uninsured are no

surprise to those who have been working with the uninsured.

Perhaps the first and most obvious place to start is to help a person with diabetes with the cost of medicines, since they all will at some point in their lives be on some medication (Montemayor, 2002). There are inescapable costs associated with the diabetes care. Estimates range from $1,000 to $5,000 per year, depending on the intensity of medications and visits. A common drug combination of aspirin, statin, sulfonylurea, ace-inhibitor, and metformin or thiazidalone can easily cost more than $100 per month (Walgreen's, 2004). This estimate is for a 1-month supply of daily Aspirin 81 mg, daily Lipitor 10 mg, daily Lisinopril 20 mg, twice-daily Glyburide 5 mg, and twice-daily Metformin 500 mg. Often, the costs of medications create a financial burden that many simply cannot bear and they end up not taking them. Quarterly doctor visits, laboratory tests, annual specialty care (ophthalmology, podiatry, endocrinology, nephrology, and cardiology), and classes with a diabetes educator or dietician, while part of an optimal care plan, are usually out of reach for the uninsured. In some recently diagnosed cases, it may be that the patient has never needed or wanted health insurance previously. Helping them find affordable health insurance should be a first priority (ADA, 2004; National Institutes for Health, 2003).

The following is a practical list of things that my colleagues and I have found can help decrease the cost of medications for a person with diabetes. Many of these may require a little research, but I have found willing partners in my patients when their dollars are at stake. Most patients do not know that there may be many options for a particular medicine and not just the only one prescribed.

(1) Prescribe generic medicines whenever possible. Savings can easily be 50%.

(2) Often prescribing #100 pills at a time will be less than #30 with 3 refills. I have found this to be true with hydrochlorothiazide.

(3) Tell patients to call different pharmacies for pricing. Pharmacies buy in bulk and the prices can literally change day by day.

(4) If possible, use the cheapest in a class of medicine. There is a 15-fold difference in starting doses of captopril and fosinopril (Walgreen's, 2004). Both are ACE-inhibitors commonly used in the treatment of hypertension or proteinuria for people with diabetes.

(5) If you do not know the cheapest class, write two or three prescriptions. Then ask the patient to do the research, fill the cheapest, and return or destroy the other unfilled prescriptions.

(6) "Pill splitting" or cutting a 100 mg pill in half with the intended purpose of using 50 mg/day. This has been shown to be safe with atorvastatin, pravastatin, and lisinopril, among others (Stafford and Randall, 2002). In general, if the pill is scored (see PDR color atlas), it can be split. Some health plans even mandate this as a cost-saving measure.

(7) Only use samples as a "bridge" to something else or for short-term indications. Sample medicines are usually quite costly if they are to be purchased. In the long run, getting a patient's sugar or blood pressure stabilized on an expensive medicine will end up costing them more.

(8) Occasionally, it can be cheaper to prescribe a combination form rather than two separately. For example, prescribing 70/30 insulin rather than Regular and NPH or Caduet rather than amlodipine and atorvastatin can be cheaper. However, prescribing combination forms is not always cheaper and should be researched.

(9) Patients living near an international border will often go to Mexico or Canada to buy cheaper medicines. There is a lot of news and politics surrounding this, but it is likely safer to get prescription medications somewhere than not at all (Pugh, 2003). Let patients know the options and let them decide whether or not they will pursue this.

(10) For patients with Internet access, they can go online and order medications from Canadian pharmacies. The state of Minnesota even maintains a website (www.MinnesotaRx.com) to help its employees.

(11) Almost all pharmaceutical companies have programs that will provide qualified applicants with three months of free medicines (ADA, 2004b). Every company has a different set of qualifications, income limits, and forms. This can be quite cumbersome for the patient and the physician at times. In a clinic where I worked, we found

we were processing 3–500 of these applications per month. Since almost none of our patients had access to the Internet, our nurses were doing all this work. We instituted a small fee per application to cover the cost of paper and time. We made it clear to the patients that this was our fee and not the pharmaceutical company's and that it covered the service of application. They were free to apply themselves. Patients were more than happy to pay a token to get three months of free medicines. I have found the best source to be a centralized website (www.RxAssist.org) that lists all the medications available, and has forms for each pharmaceutical company that can be printed and sent in.

(12) Early initiation of insulin. This may not only be a good idea in the course of their disease, but also could be cheaper. By the time a person with diabetes is on three oral medicines for diabetes near maximum doses (sulfonylurea, metformin, and a thiazolidine), they are easily spending $200 per month for medicines. It will be much cheaper to use insulin in place of one or all of these medicines.

(13) Tell patients to buy a glucometer with the cheapest test strips NOT the cheapest glucometer. After a few months they will thank you.

In the office or clinic, there are many systems and changes that can benefit the uninsured person with diabetes. One model for cost-effective care that has shown promise is the class or group-visit (Clancey *et al.*, 2003). There are several ways to structure group visits. In an effort to get all patients screened and educated who were either new patients with existing diabetes or patients with newly diagnosed diabetes, one clinic held a "diabetes day" each month (Zasworsky, personal communication, February 11, 2004. Two groups (English and Spanish) would rotate through four services (ophthalmology, podiatry, diabetes nurse education, and registered dietician) that were brought into the clinic. In this way, the patients would only have one "visit" to the clinic and yet receive multiple services.

Networking with community partners and agencies can help access resources, such as specialty/consults, education, exercise facilities, etc. Many communities have health centers or volunteer clinics that may be a source of local expertise for accessing services in that area (community health centers by zip code can be found at http://ask.hrsa.gov/pc/ and volunteer clinics can be found at http://www.volunteersinhealthcare.org/links.htm or http://www.vimi.org/). If providing care for uninsured patients is too difficult in your office, volunteering at a free clinic or similar facility can provide much-needed services.

Annual eye exams are an important part of diabetes care. Asking a local ophthalmologist/optometrist to donate a few screening exams per year is a way to start. The American Optometric Association has a program called Vision USA that provides free eye exams annually (American Optometric Association, 2004). Some community health centers have retinal cameras and with "store and forward" features can do dilated eye exams any time and send the images to an ophthalmologist later for reading. Unite for Sight (www.uniteforsight.org/) is a national nonprofit organization that develops sustainable solutions to reduce eye health disparities. Each of their 25 chapters works with local community infrastructures to improve access to health programs.

There also are organizations that provide financial assistance for people who need prosthetic care (Amputee Coalition, 2004; Easter Seals, 2004; Prosthetics for Diabetes Foundation, 2004) or wheelchairs (Wheelchair Foundation, 2004).

In conclusion, we have a growing problem in this country that involves not just the lack of equal access to care but the resultant growing inequalities in health. Diabetes magnifies the consequences of being uninsured because it is a chronic progressive illness. While having a national health plan (providing universal health coverage) alone is not sufficient to reach the desired outcome of good health for all, it would be undoubtedly the most essential step in decreasing health care disparities in this country.

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17

Disease Management in Rural Populations

Can it be Done?

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INTRODUCTION

Rural health care providers must cope with various challenges that far exceed recognized, conventional concerns such as financing, controlling costs, and ensuring proper medical care. The provision of health care in rural populations is additionally complicated by limited number of health care providers, higher rates of uninsured, longer distances to travel for treatment, and fewer community resources to supply and support health care (Bierman and Clancy, 1999; Keefover *et al*., 1996; Noonan, 1997; Aadalen, 1998; Moscovice and Rosenblatt, 2000; Dalton, 2001; Welch *et al*., 2002; Beaulieu *et al*., 2003). In order to address rural access problems, federal and state health agencies have implemented a variety of programs, including Federally Qualified Health Centers (FQHCs), Critical Access Hospitals (CAHs), Rural Assistance Center (RAC), Rural Health Clinics (RHCs), and state sponsored Rural Development Councils (Kozma, 1998; Diamond, 1999; Rawlings-Sekunda *et al*., 2001 June; Welch *et al*., 2002; Foote, 2003). Despite the intent of these programs to provide and improve health care in rural locations, limited access to health care by rural populations continues as a significant concern.

Recently state and federal health agencies have encouraged managed care and fee-for-service plans to implement disease management (DM) services. However, DM may present formidable organizational challenges and a mix of benefits and costs for rural health care systems and their patients. This chapter will report on six organizations that have successfully instituted chronic DM in rural areas.

Background

Conditions in rural America often bring unique and difficult challenges to those residing in this environment. However, rural life may be especially formidable for persons with chronic diseases such as diabetes, congestive heart failure, chronic obstructive pulmonary disease, depression, and asthma because of the scarcity of health providers and services in nonurban settings (Gamm

et al., 2003; Moscovice and Rosenblatt, 2000; Bolin *et al*., 2003; Call *et al*., 2000). Rural Americans are as culturally, racially, and ethnically diverse as the topography of landscape where they live (Rosenblatt, 2002). For instance, the rural population in North Dakota may be quite different from rural residents of the Pacific Northwest or Southeastern United States. Conditions in the rural Northeast are distinct from those found in the rural Southwest. Regional differences in customs and ethnography, and indigenous characteristics handed down through multiple generations of families and cultural groups create hardships in health care delivery that may be quite magnified in rural areas. Recent and past migration patterns to various parts of our Nation's rural areas reflect homesteaders and workers seeking both land and/or work opportunities. These diverse and complex demographic features amplify the challenges that occur in instituting and developing DM programs in rural locations (McGrath *et al*., 1990).

As our nation's infrastructure has changed to accommodate more service-oriented industries, the agrarian economies of many rural areas have receded. Employees in rural locations often receive wages fixed at or near poverty level, and these workers are not as likely to be offered access to health insurance even if they are employed regularly (Coburn *et al*., 1999). Consequently, many rural working families living just above poverty levels may be uninsured (Waitzken *et al*., 2002), and thus have greatly reduced access to health care services.

Other issues common to rural areas include ethical challenges that may arise in providing health services to residents in small communities. Frequently, the health care professional's work life and personal life overlap in his/her interaction with patients. This presents a situation that may cause confidentiality and privacy predicaments, as well as conflict of interest problems when medical personnel and patients are faced with shared decision-making situations (Nelson, 2004). In sum, a host of geographic, economic, cultural, and ethical challenges may confront health care providers when addressing the needs of chronically ill patients residing in rural America.

The Rural Chronic Disease Management Research Project

In September 2001, the Southwest Rural Health Research Center (Texas A&M—HSC School of Rural Public Health) initiated a 3-year study analyzing health plans and health systems providing chronic DM services to rural and underserved populations, titled "Chronic Disease Management in Rural and Underserved Areas: Patient Responses and Outcomes." To conduct this study, the project team initially undertook site visits to five health plans that had agreed to participate, and later visited a sixth DM program serving the uninsured. The health plans participating in this study are listed in Table 17.1.

These site visits revealed a wide range of chronic diseases being managed formally by rural health plans, including (1) diabetes, (2) congestive heart failure, (3) chronic obstructive pulmonary disease, (4) asthma, (5) depression, (6) hypertension, (7) osteoporosis, (8) tobacco cessation, and (9) prenatal case management. Figure 17.1 shows the specific chronic DM services being offered through the six rural health care systems participating in the study.

TABLE 17.1. Health Plans Participating in the Chronic Disease Management in Rural Areas Research Project

Carle Clinic Health Plan (Champaign-Urbana, IL)
Marshfield Clinic (Marshfield, WI)
Geisinger Clinic (Danville, PA)
Scott and White Clinic (Temple, TX)
The Health Plan of the Upper Ohio Valley (St. Clairsville, OH)
St. Elizabeth of Hungary program for the uninsured (Tucson, AZ)

Diseases Addressed by DM in the Rural Systems

Diseases Addressed	IDS1	IDS2	IDS3	IDS4	OTH1	OTH2
Diabetes	X	X	X	X	X	X
CHF and related	X		X-O	X-O	X	
COPD	X		X-O	X		
Asthma	X	X				
Depression		X-O		X		
Other	X	X		X		

X=offered; O=outsourced

FIGURE 17.1. Diseases addressed by DM in the rural systems.

Survey of Health Plan Leaders

Following site visits to each location, the research team prepared and mailed a self-administered survey to key DM leaders (physicians, nurse/case managers, and administrators) at each of the six health care facilities. A total of 315 surveys were mailed, and 71 usable surveys returned. Of the 71 survey responses, 15% came from DM administrators, 45% of the replies were sent from DM nurses, and 40% of the returns arrived from DM physicians.

An examination of survey responses revealed the DM program identified most frequently was diabetes (N = 57), followed by congestive heart failure (N = 37), chronic obstructive pulmonary disease (N = 33), asthma (N = 32), depression (N = 15), and hypertension (N = 13). Four other DM programs were mentioned, but to a lesser degree: tobacco cessation (N = 8), osteoporosis (N = 5), prenatal (N = 2), and case management (N = 1).

The number and type of chronic diseases mentioned by respondents reflect the chronic disease burden shouldered in the particular area served by each health plan. According to key DM physicians, nurses, and administrators, a large percentage of patient visits pertain to the five most prominent chronic diseases or conditions indicated in the survey. Diabetes was ranked highest among all chronic diseases or conditions, and accounted for nearly 50% of all patient visits. After diabetes, the next four most common chronic diseases resulting in patient visits were: congestive heart failure, chronic obstructive pulmonary disease, asthma, and depression (Table 17.2).

TABLE 17.2. Chronic Diseases Responsible for Greatest Percentage of Patient Visits in Health Plans Serving Rural and Underserved Patient Populations

Chronic disease	Percentage of patient visits (mean%)	Percent of patients being treated for condition (mean%)	Overall percent of patients with this diagnosis (mean%)
Diabetes	45	48	38
Depression	20	12	12
Chronic Obstructive Pulmonary disease	20	21	20
Congestive heart failure	17.4	35	18

Source: Chronic Disease Management in Rural Areas Survey, 2002.

According to respondent estimates, 38% of all patients under their care are being treated for diabetes, while 24% exhibit depression and 20% experience chronic obstructive pulmonary disease (Table 17.2). Respondents were also asked to estimate the percentage of their patients being treated for each disease or condition *and* who are participants in their DM program. Diabetes was again listed the condition treated most frequently (48%), followed by congestive heart failure (35%), and chronic obstructive pulmonary disease (21%) (Table 17.2). Although diabetes accounted for the largest number of patient visits, depression was responsible for proportionally more patient visits and congestive heart failure for fewer visits than one would expect, according to their proportions among all DM patients. Survey respondents noted a large number of their patients who evidence two or more chronic diseases, making case management more difficult and complicated to perform in such situations.

Challenges of Providing DM in Rural and Underserved Areas

Historically, DM has been a phenomenon or model of health care utilized most often in urban settings. DM is frequently promoted by large health plans interested in quickly and efficiently reaching significant numbers of enrollees to reduce health care costs while improving treatment outcomes. Not surprisingly, most studies suggest that DM-related activities, and preventive care generally, are less prevalent among provider organizations located in rural areas (Vaughn *et al.*, 2002; Dennis and Pallotta, 2001).

Survey information from the *Rural Chronic Disease Management Research Study* (2003) was instrumental in identifying effective health plan strategies available for building or initiating DM programs with rural populations. DM fills a void in providing unique and valuable service to patients in rural areas, where there are often fewer acute care facilities, a smaller health care workforce is present, and available medical equipment is of less sophisticated quality (Bolin *et al.*, 2003; Coon and Zulkowski, 2002; Call *et al.*, 2000). Indeed, the benefits of DM for rural populations are perhaps more significant than for nonrural populations, given the restraints of travel time for rural patients and scarcity of rural health care providers. Case studies about three programs effectively providing DM in rural and underserved areas are discussed in "Part 5" of this book.

Survey respondents identified successful initiatives for instituting DM in rural areas, nevertheless many constraints or "impediments" to success were also identified. For example, respondents estimated that from 37% to 45% of patients active within their respective DM programs *do not* comply with DM program instructions or guidelines a majority of the time. These impediments to DM are identified in Table 17.3.

Most of the impediments listed in Table 17.3 refer to conditions that may apply to DM patients residing in urban and rural areas. That is, lack of motivation and denial, insufficient attention to diet and exercise, and lack of understanding may be found among patients living anywhere. It is possible, however, that other impediments may be more commonplace among rural patients in light of rural conditions mentioned earlier. Drug cost may be higher in small rural pharmacies and less affordable to rural patients. Health

TABLE 17.3. General Factors or "Impediments" to Patient Compliance with DM Guidelines

Impediments to patients' compliance
Attitudes—lack of motivation, denial
Behaviors—lifestyle, diet, exercise
Knowledge—lack of understanding
Financial—drug costs, financial means
Treatment—complexity, no provider support
Mental state—depression, nerves
Setting—transportation, distance, weather

Source: Bolin, Gamm, Zunigh (2003). Chronic Disease Management in Rural Areas: Year-2 Report.

care provider support may be less available, depression may be as prevalent or more so but less often treated, and distance concerns that are compounded by lack of transportation or inclement weather may be more prevalent among rural residents.

When queried more specifically to provide reasons for rural patients' noncompliance with DM, respondents identified factors ranging from cost of drugs, lack of physician support, and patient's denial of disease. Impediments to DM specific to "rurality" were such factors as limited health resources, travel barriers, or lack of transportation and social conditions such as unemployment and poverty. Table 17.4 lists disadvantages, of a rural nature associated with DM programs, which were identified by the survey respondents.

The extent of patient noncompliance with DM was significant. The fact that between 37% and 45% of patients active within the six participating DM programs *do not* comply with DM guidelines, a majority of the time bears additional attention. However, it is not clear what the rate of noncompliance is for nonrural patients—an area worth investigating. Respondents estimated that the rate of noncompliance for congestive heart failure was 37%, diabetes 38%, chronic obstructive pulmonary disease 42%, asthma 43%, and depression 45%. In follow-up questions, respondents were asked to identify factors that affected patients' failure to comply with DM program instructions. The following factors (Table 17.5) were listed as affecting patient's compliance with DM.

TABLE 17.4. Specific Rural Disadvantages Associated with Disease Management Programs

Limited health resources
Lack of urgent care facilities
Reduced access to health resources (e.g., labs or pharmacies)
Limited access to specialty care
Physician compliance in rural areas
Rural doctors or nurses sometimes have less training
Overlapping relationships between work life and personal life
Travel barriers and transportation
Increased time for DM nurses to drive to rural locations
Winter travel limitations to/from rural locations
Difficulty with transportation to clinic
Social conditions
Patients less likely to participate in screenings or fairs
Rural prevalence of young, single mothers
Poverty and/or cannot afford health care
Lack of phone or phone failure
Rural employment increases morbidity or injuries
Employment lay-offs initiate lack of insurance
Conflict of interest

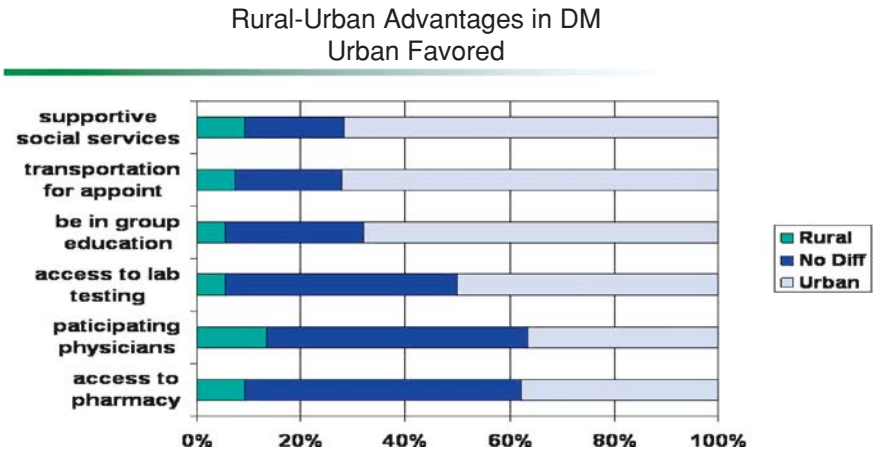
TABLE 17.5. Factors Affecting Patients' Compliance with Disease Management

- Prohibitive cost of drugs
- Inability to make lifestyle changes
- Inability to understand program instructions
- Lack of physician support
- Co-morbidities
- Denial of disease
- Distance to clinic
- Lack of family support

When asked to compare urban versus rural advantages and disadvantages to DM across 14 participation and compliance items presented in the survey, over 50% of the respondents saw no difference between rural and urban patients on 5 of 14 items that might affect participation in DM programs. However, on six items, the ratio of respondents noting an urban advantage over a rural advantage ranged from nearly 3:1 (pharmacy) to more than 10:1 (social services & transportation). These areas of "relative rural disadvantage" include rural patient's comparatively poor access to supportive social services and lack of transportation to appointments, laboratory services, pharmacy services, and scheduled group DM activities. Table 17.6 provides a representation of factors perceived as favoring urban over rural patients' participation in DM programs.

Moreover, many of the survey respondents view rural patients as less likely to obtain access to a physician who provides DM services. In three areas, there appears to be little difference between responses indicated by rural and urban patients, or less

TABLE 17.6. Factors Favoring Urban Patients

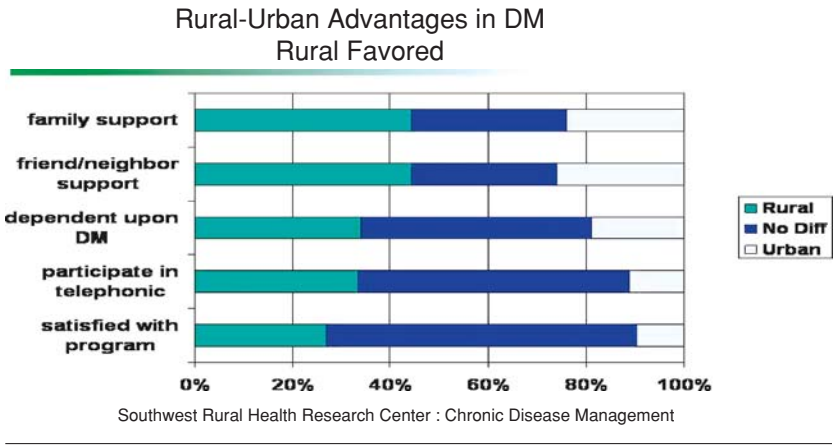


consensus offered by respondents regarding which group of patients is advantaged (Table 17.7).

Considering the five elements where there appears to be an advantage for rural patients, for only one element is there as much as a 3:1 ratio of response. Slightly under one-half (45%) of respondents identified an advantage for rural patients in the form of friends' and neighbors' support in DM and family support in DM. One-third of the respondents noted a relative advantage for rural patients in their participation in telephonic case management and patient dependence on the availability of a DM program. Finally, a modest advantage is accorded more frequently to rural patients than to urban patients on the element of satisfaction with the DM program.

There is substantial agreement about the types of disadvantages that rural patients face when compared to patients in urban settings. Both on-site interviews with DM leaders and

TABLE 17.7. Rural-Urban Advantages in DM



survey responses from these leaders, physicians, and DM staff members underscore similar challenges for rural patients. Rural patients are viewed as disadvantaged relative to urban patients on access to transportation, laboratory services, supportive social services, and pharmacy services. They may be less likely to have a physician who participates in DM. Likewise, with respect to travel and transportation challenges for rural patients, DM programs can help reduce both frequency and costs associated with patient visits to distant health care facilities or to emergency rooms. Most of the social conditions that are deemed to present disadvantages for rural patients, although not directly addressable by DM programs, may underscore the importance of the availability of timely, accessible DM programs.

A majority of respondents viewed rural DM patients as having some advantage in participation in telephone case management, experiencing the support of friends and neighbors in DM, receiving family backing in DM, recognizing advantages offered by DM, and being satisfied with DM. It appears that rural patients may be at a relative disadvantage in being able to comply with DM activities, yet the responses suggest, too, that rural patients may find DM activities more important. It seems likely that the DM connection may substitute on occasion for a rural patient's travel to a distant provider on matters that can be responded to over the phone. Such connections may offer immediate response or may be forwarded by the DM staff member to the physician and then communicated back by the physician or the DM staff member to the rural patient.

Some differences, yet unexplored, may be attributed to cultural features found in particular rural populations and/or the level of cultural recognition demonstrated by the provider/educator. For example, cultural differences in rural Native American, Hispanic, or African American populations may place greater importance on family, religion, or the beliefs of elders within the extended family (Berger, 1998; Saha *et al*., 1999; Kim and Kwok, 1998). Moreover, the quality of provider–patient communication at all points along the DM continuum is contingent upon the patients' ability to understand directions and instructions, which, when possible, should be delivered in the patient's native language. Providers tend to overestimate patients' understanding of treatment plans. Thus, steps should be taken to improve communication and understanding between patients and health care workers when their primary language and cultural heritage are not shared (Calkins *et al*., 1997).

Future Potential and Promise of DM in Rural Health Care

The ability of disease management to help control health care costs and contain health insurance expenditures for rural employers makes the cost-saving potential of DM more substantive with rural populations where employee numbers tend to be smaller and hourly wages lower (Sidorov *et al*., 2002; Bolin and Gamm, 2003; Weiners and Harris, 2003). The positive impact of DM on health care utilization and quality, as well, may be particularly important to rural populations. Given a paucity of health care providers in rural areas, combined with greater travel distances to specialized facilities and providers for treatment of chronic diseases, the rural chronically ill may gain greater benefits from DM than patients who are more proximate to health resources. Uninsured and underinsured populations, and the providers who serve them, may stand to benefit greatly from DM programs. Such programs offer patient education and care coordination that can help control a disease and reduce acute care needs of patients, thus reducing associated nonreimbursed costs that would otherwise be shouldered by the providers.

DM program respondents are overwhelmingly confident that DM improves the quality of patient care. DM's contribution to health care quality is reflected in research

reports from the systems (health plan or clinic) and in published high satisfaction levels with DM activities on the part of patients (e.g., as reflected in HEDIS). Although survey respondents are likely to see at least a moderate contribution of DM to the financial benefit of the clinic, agreement on this is not as strong as it is for DM contributions to care quality. Nonetheless, at least *two* of the systems have published papers that point to significant financial savings associated with DM programs (Sidorov *et al*., 2001). Such findings suggest that information on both clinical outcomes and financial outcomes should be communicated frequently to physicians, clinic leaders, and others engaged in or potentially involved with DM. Also, there is need for more widespread discussion of possible strategic benefits of a DM program for health plans and provider organizations. The study also found that nearly three-quarters (73%) of physicians, nurses, and administrators responding to the study believe that diabetes DM was "very important," with another 22% of the respondents stating that diabetes DM was "important." Thus, 95% of respondents regarded diabetes DM to be important patient health care. That is, an effective DM program may enable a health plan to better manage higher-risk employer populations, Medicaid populations, or Medicare risk contract enrollees. Benefits of this type can simultaneously serve the interests of health plans and providers and increase access to care among rural populations.

Use of Established Clinical Guidelines and Protocol in Rural DM

The models of diabetes DM employed by the plans participating in this study rely on national standards and quality indicators as their programs' benchmarks. Survey responses suggested that health systems are satisfactorily carrying out DM using established, recognized quality indicators for diabetes, congestive heart failure, chronic obstructive pulmonary disease, and asthma (among other diseases). These health plans are achieving success in reducing patient morbidity, and improving patients' overall health by employing the chronic DM model across a variety of populations, including uninsured, private pay, and Medicare.

A prominent finding from the survey was the extent to which health plans tended to rely more on nurses for patient monitoring and education, as well as the support and delivery of DM services. This is an important finding, and when considered in light of the success of these programs, exploration of state-by-state differences in licensing restrictions that might prevent nurses from carrying out DM monitoring and delivery of services is warranted. Government agencies, foundations, health plans, and providers would benefit through supporting research to identify methods for nonphysicians to provide DM monitoring and services in order to assure the greatest possible participation in DM.

INFORMATION SYSTEMS AND DATA LIMITATIONS IN RURAL AREAS

Close monitoring of patients' clinical conditions require the rapid flow of information among team members. This may require technological means for remote monitoring, especially in rural DM programs. In a congestive heart failure DM program instituted by NYLCare Health Plans of New York, the following informatics tasks were considered essential:

> (a) evaluation of the patient population for all high-risk, high-volume conditions that would benefit through DM;
>
> (b) identification of national consensus guidelines;
>
> (c) identification of patients with the target illnesses, with stratification;
>
> (d) creation of a database to store and manage data;
>
> (e) establishment of a communication system to store and manage the patient data;

(f) establishment of a communication system to educate and monitor patients; and

(g) implementation of appropriate analytical systems to evaluate the impact of DM (Roglieri *et al*., 1997).

Sophisticated electronic information systems devoted to DM programs have been developed and utilized in many of the systems participating in the study. In two of the integrated delivery systems, DM nurses have access to electronic medical records (EMRs) as well. DM participants value the latter arrangement, supporting rapid and continuous communication between the DM nurse and physician, regarding DM patients. At the same time, there remain opportunities for integrating or regularly querying DM information systems and EMRs to generate reports of DM contributions on an ongoing basis.

BUY OR BUILD? PLANNING/ IMPLEMENTATION/ SUSTAINABILITY OF DM PROGRAMS

The decision to "buy or build" a DM program must be addressed by health plans serving rural and underserved populations by carefully attending to clinical and business issues. In the most general sense, the buy or build decision may rest with how DM is viewed by the health plan or provider organization. Is DM perceived as a discrete or special product or service employed to control costs and improve outcomes beyond what providers and health plans do, or is DM seen as an integral part of reengineering the processes of care that are supported by health plans and providers? If DM is viewed as a detached or unconventional service, then buy–build decisions may be determined largely by whether a better DM product and performance can be provided more efficiently internally versus doing so through outsourcing. If, in contrast, DM services are viewed as natural parts of what providers and/or health plans seek to accomplish, and the day-to-day working relationships and information sharing between activities of DM staff and staff of providers and/or health plans is the dominant concern, then building such a system may be more attractive.

Within the context of this broader decision, a number of other factors may influence the decision of whether or not to buy or build a DM program. If providers are currently committed to clinical protocols for addressing chronic diseases, then there are in-house clinical champions of DM and there is in-house expertise on what goes into a DM program. Thus, a build strategy is supported. If one or two of these elements are lacking, then such circumstances may encourage a more scrutinized consideration of the buy decision. Also, if there is a shortage of RNs in the region served by the provider or health plan sponsors of a DM program, then a buy decision may be supported. Moreover, if a health plan, for example, is financially challenged and needs to capture DM-related cost savings among chronically ill enrollees, then a buy decision is once more suggested. In making the buy decision, of course, consideration should be given to the time and expertise that the rural plan or provider must allocate to negotiating the initial DM contract and monitoring performance to ensure that expectations are being met.

There are, of course, variants of or midpoints between the build–buy options. DM companies can be contracted to help build a DM program (via a consultant relationship or turnkey arrangement). Or, the build or buy decision may be modified over time. One health plan in the study built its own diabetes DM program, but "bought" or outsourced CHF and COPD DM when it launched DM efforts in early 2000. Later, all programs were brought "in-house" and managed successfully by the plan's own cadre of DM trained nurses who were responsible for specific DM programs.

The pros and cons of homegrown, outsourced, and mixed. DM program are identified in Table 17.8.

TABLE 17.8. "Buying or Building" DM Programs in Rural and Underserved Patient Populations

Program type	Pros	Cons
Homegrown	Key personnel from the health plan are involved from the start.	It takes longer to plan and implement a DM program when designing it from the ground up.
	Existing human resources can be used at no significant additional cost. This provides more experienced and highly trained nurses a career ladder, and opens up entry level health care jobs in a rural community.	The potential overlapping of work and life relationships occurs due to small available labor market.
	No loss of control or patient contact. DM workers are more likely to be familiar with the culture of the patient population.	Increased chance of conflicts of interest because of shared decision-making process and relationship boundaries.
	The DM program can be customized to local comorbidities including the degree of mental health services needs.	May have to build transportation services as part of the in-house DM program due to lack of reliable transportation in rural community.
Outsourced	Faster initiation of DM program. Outsourcing may cut support and personnel costs.	Higher front-end costs. Inability to manage change or content. Awkward patient care and technology interfaces.
	There is a rural advantage in patient participation in telephone case management, making outsourced DM strategically a better choice.	Some DM companies treat only one or two diseases, & thus may not treat co-morbid conditions.
	The patient may be more responsive to telephone DM than to providers who are their neighbors.	Costs associated with contracting and monitoring activities.
	It may be possible to negotiate a financial incentive to be shared with physicians who choose to participate in DM activities.	Distant relationship, initially, between DM company and health care organization.
Mixed	Homegrown disease plans may feel most comfortable, rewarding, and educational to providers.	Awkward interface between patient care and DM-provider technology.
	Outsourcing of diseases may prove most difficult or time consuming.	Difficult integration with other program applications.
	Build DM program depending on existing professional skill set, worker availability, and interest.	Potential challenges with caring for patients with co-morbidities.

It is not clear how much the decision to "buy" or "build" rests on the nonrural or rural status of health plans, providers, and target patients. It may be that rural health plans and provider groups will have relatively less technological expertise to support building homegrown DM programs. At the same time, they may be less able to afford the loss of growing resources for DM that might migrate to external DM companies. Just as proximity and familiarity of local DM staff with rural patients may support the success of DM it may be the case that some rural patients desiring privacy may prefer to interact with out-of-area DM staff contacting them by phone.

There are advocates for each approach to DM development. Tamara Lewis, medical director for community health and prevention at

Intermountain Health care in Salt Lake City, observes: "If you're going to change a system, you have to do it internally." An outsource DM company sometimes finds it difficult to define what it is and is not supposed to be managing. Because many DM guidelines and protocols are well established DM can be developed locally (homegrown) relatively easily and shaped into a valuable tool for controlling costs and improving patient health and overall satisfaction with health care across varied populations.

Another "pro-building" sentiment asserts that "an outside company can really only educate patients and monitor their compliance. It is still up to providers to care for and manage the patient. That is where gaps begin to exist with outside programs." (http://www.managedcaremag.com/archives/0001/0001.dmpac.doc_op.html).

At the same time, there is a rapidly growing outsourcing movement supported by an increasing number of DM companies, some operated by large pharmaceutical firms. Both Medicaid and Medicare programs appear to be looking toward such companies to demonstrate cost savings and quality improvement in care for the chronically ill.

The six DM programs that participated in the Rural Chronic Disease Management Study had all developed "homegrown" DM programs. The most successful programs appointed advanced degree nurses at the helm in the design of DM programs, working closely with physician leaders, and in charge of, or copartnering responsibility for, day-to-day operations. These programs have also instituted information systems and ongoing data collection procedures in order to establish benchmarks and monitor patient care quality.

Building the management structure and information systems necessary for an in-house DM program could also help rural heath plans and/or providers to participate in other government supported and incentivized quality initiatives such as the quality indicators reporting initiative offered through the Centers for Medicare and Medicaid Services as part of The Medicare Modernization Act of 2003 (CMS, 2004). DM and quality reporting are both initiatives that help health care providers work toward assuring and improving the quality of care. At this point, CMS has identified three conditions with 10 appropriate quality measures that can be reported by participating hospitals. These three conditions include acute myocardial infarction, heart failure, and pneumonia. The opportunity to merge quality indicator reporting and DM into one overall quality program that is built from within the rural health plan and hospital simultaneously should be considered by rural health care provider networks. The DM initiative can be structured in a way to offer incentives to the participating physicians, the quality indicator initiative will provide for improved reimbursement rates for the hospital, while the health plan benefits from the results associated with reduced acute care utilization rates and therefore reduced cost of care.

CONCLUSIONS

Many rural residents find it difficult to access appropriate or timely care. Age, poverty, and lack of insurance or Medicare supplemental insurance may reduce their ability to self-manage chronic illness. Travel distances and shortages of care providers and ancillary health services such as pharmacy and laboratory access create additional barriers to care. DM services are all the more critical to rural chronically ill patients, who may need to rely more fully on DM resources to help manage their condition rather than making frequent visits to providers.

Based primarily on recent research focused in six health systems serving rural populations, we have described how such systems have gone about ensuring the availability of DM services to their patients. Diabetes, CHF, and COPD DM programs were most often in place across these systems. Patients with diabetes account for the largest number of patients supported by DM. Depression

appears to require more DM patient visits and CHF patient fewer in relation to their proportions among those served by DM programs in the six systems. Disadvantages for rural patients identified by DM caregivers in these systems appear in several forms—less access to supportive health services (laboratory, pharmacy, and participating physicians), poverty, lack of a phone, lack of transportation, and poor weather, and travel conditions. At the same time, rural patients may have a relative advantage over others in family and neighbor support and desire to participate in DM.

For rural health plans and providers, participation in DM programs involves a number of considerations. There is evidence that DM saves costs and improves health care quality. The success of DM, however, is heavily dependent upon access to supportive information systems, acceptance and adoption of clinical protocols and guidelines for chronic disease, and careful consideration of multiple criteria in deciding which chronic diseases to address. An additional key decision for the rural health plan or provider group is whether to build a DM program or buy one from an external vendor. A major part of this decision rests on whether DM is viewed as a discrete and separate service or whether it is viewed as an integral part of a health plan's or provider group's day-to-day work. At the same time, there are a number of other factors to consider in this decision making, such as provider commitment to clinical protocols and guidelines for chronic disease, and the availability of a clinical champion and in-house expertise. Other factors are important to the decision-making process, such as the local availability of RNs and DM-related incentives to providers and plans provided by employers and Medicare and Medicaid programs.

There is ample evidence that rural health systems can deliver effective DM services to rural patients. It remains to be seen how fully the needs of rural patients for chronic DM will be met by multiple payers—government and nongovernment—rural health systems, and DM programs—locally owned and administered or provided by outside firms.

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18

Caring for the Border Communities

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Few would argue that the behavioral regimen required for diabetes management is for many a drastic and challenging change in lifestyle. As we have seen in this book, the demands upon diet, physical activity, medication regimen, and clinical attendance require that patients obtain and practice multiple skills. Individual self-management is the focus for controlling diabetes complications, however, the larger environmental context will either support or hinder the ability of people with diabetes to adopt and maintain self-management behaviors (Jack *et al*., 1999). This chapter will describe the specific challenges to those living with diabetes in border communities and will recommend some core elements of diabetes outreach and education programs that have proven successful in this environment. In addition, the chapter will explore strategies for addressing broader environmental influences on diabetes prevention and self-management.

U.S.–MEXICO BORDER ENVIRONMENT

The U.S.–Mexico border environment is shaped by five overlying factors, which in turn serve to complicate a person's ability to follow diabetes self-management recommendations.

(1) *Poverty.* Approximately 30% of the population on the U.S. side of the border live in poverty. Of the 25 U.S. counties on the border, 3 are among the 10 poorest in the nation and 21 are designated by the Federal Government as economically distressed (HRSA, 2000).

(2) *Growth.* At the same time, the border is experiencing rapid population growth compared to other parts of the country. According to the U.S. Census, 2000, 2 of the 10 fastest growing cities, Yuma, AZ and McAllen-Edinburgh-Mission, TX, are located on the U.S. side of the border, and border communities will double in size over the next 30 years (U.S. Census, 2000).

(3) *Young population*. The age distribution on the border is contributing to the rapid population growth. Approximately 25% of the border population is under 15 years of age (PAHO, 2000).

(4) *Shared infrastructure*. The U.S.–Mexico border is a line drawn on the sand; however, communities on both sides of the line share the same water, the same air, and many of the same services. U.S. and Mexican citizens alike cross the line to visit relatives, shop, access health care, and purchase medication.

(5) *Militarization*. In spite of a bicultural and binational community, U.S.–Mexico border

residents are living in an increasingly militarized environment. In 2002, there were 9,500 border patrol agents working in the region (Cañizo, 2004), nine times as many as were allocated to the U.S.–Canadian border, which is twice as long. In addition to ground patrol, efforts to control illegal immigration include electronic sensors, night vision scopes, aircraft, and most visibly, the construction of a steel wall. The environment of low-intensity conflict increases the psychological stress of people living within the community.

Clearly, people with diabetes on the U.S.–Mexico border are living in unique surroundings. The rapidly growing population coupled with extreme levels of poverty exacerbate the inadequate infrastructure, and ensuing environmental concerns. While the border environment offers the unique experience of shared culture flowing both north and south, the growing presence of uniformed and armed patrol leads to escalating levels of intimidation and fear, which impacts one's ability to access medical and other services. Although the population is relatively young, the morbidity and mortality related to diabetes is inordinately high. A person with diabetes must overcome numerous challenges in order to access, interpret, and apply information regarding how to control the disease.

This chapter focuses on the U.S.–Mexico border because of the enormous impact of diabetes in border communities. The U.S.–Canada border has a different scenario. Residents on both sides of this border share comparable language and culture, socioeconomic status, population growth rate and age distribution, as well as infrastructure. A stark difference between the two borders is that Canada is considerably less militarized. Because of these characteristics, the U.S.–Canada border seems physically and psychologically invisible. One interesting similarity is the increasing trend of U.S. residents crossing both borders to obtain more affordable prescription drugs.

DIABETES ON THE U.S.–MEXICO BORDER

The impact of diabetes on the U.S.–Mexico border is devastating. Diabetes was the fourth leading cause of death among Mexican communities on the border between 1995 and 1997 (Anonymous, PAHO, 2000), and the diabetes mortality rate in the border region is nearly 50% higher than in the rest of the country (ADA, 1996). Everyone that you speak to in a border community will have a family member who has or who has died from diabetes. While the population is young, the occurrence of type 2 diabetes among Mexican American children is being diagnosed at an increasingly younger age (ADA, 2000).

The epidemic proportion of diabetes is related to the border characteristics outlined above because these contribute to and aggravate an environment in which it is difficult to prevent or control diabetes. The most glaring issue is that the region is highly medically underserved. If the U.S.–Mexico border region were a state it would rank last in access to health care. More than 30% of the Hispanic population is uninsured (HRSA, 1999), a rate twice as high in the rest of the country. Lack of insurance, the seasonal nature of employment for farmworkers, and fear and discrimination related to immigration make it difficult for Mexicans living in border areas to establish a regular source of care (Ruiz-Beltran and Kamau, 2001). The fact that residents frequently cross over to Mexico to access medical services makes it difficult for physicians to provide consistent diabetes treatment. Studies document that up to 40% of residents in border communities in the United States go to Mexico to utilize physician health care services (Landeck and Garza, 2000; Marcias and Morales, 2001).

A second issue is that the border environment creates specific challenges to diabetes self-management. Border residents who are not eligible for Medicaid programs can rarely

afford diabetes medications, making it difficult for them to comply with their medical regimen. Those who have insurance often do not have pharmaceutical coverage and people with diabetes frequently must decide whether to buy food or medication. Diabetes patients resort to cutting pills in half or attempt to self-regulate medication based upon how they are feeling. While diabetes programs may make glucose monitors available, there are few resources to cover the costs of strips.

Following recommendations related to diet and physical activity are also problematic. The presence of lifestyle related risk factors for diabetes and diabetes-related complications (sedentary lifestyle, poor nutrition) is 5–10 times higher in U.S.–Mexico border communities than in the rest of the country. While some of these behaviors can be attributed to individual characteristics, it must be recognized that the environment does not support engagement in healthy lifestyles. Border towns have very little infrastructure for recreational areas and parks; even sidewalks to facilitate walking are scarce. Issues such as uneven pavement, lighting, and wild dogs challenge even the more motivated individuals. With respect to nutrition, it is difficult to access healthy foods such as fresh fruits and vegetables, which are high-priced and often unavailable. Many of the health messages, ubiquitous in mainstream, urban areas, do not reach these marginalized communities.

A third issue is related to the social support network that might facilitate diabetes self-management and care. There is a perception that Hispanic families are close knit and available to one another. In many cases, although family ties may be strong, elderly people with diabetes are isolated within the border communities. Extended family members may live in Mexico, and the economic and social reality has resulted in children moving to urban areas. As residents age and begin to have more health issues, it is more difficult for them to travel to visit relatives and they may become increasingly isolated and depressed.

Finally, all of these issues coalesce to impact the health perspective of people living on the border. This health perspective also is influenced by language and sociocultural factors. First of all, there is a dearth of very basic information about diabetes. Many health providers are not bilingual, and formal, culturally competent diabetes education in Spanish is often not available. Second, the issue of health care access leads many people to feel that if they do contract a disease there will be very little they can do to treat it, so they will be better off not knowing. A fair amount has been written about this phenomenon under the term "*fatalismo"* or fatalism (Antshel, 2002, 435–449), however, a better term might be "realism" given the challenges and barriers identified in this article.

Four issues are thus identified as related to the extreme prevalence of diabetes and the high level of morbidity and mortality attributed to the disease as (1) access to health care, (2) difficulty in engaging in healthy lifestyle, (3) lack of social support, and (4) health perspective. The next section will present the elements of a successful diabetes outreach and education model and provide descriptions of how this model has been adapted to fit the characteristics of existing border communities in the Arizona–Sonora region.

DIABETES OUTREACH AND EDUCATION PROGRAMS ON THE U.S.–MEXICO BORDER

In talking about diabetes education, it is important to reiterate that programs that address individual diabetes self-management in a vacuum will have difficulty creating sustainable changes among their participants. While people need access to information and support for diabetes management, the broader structural and societal issues must be addressed for them to practice difficult behavior

changes. The final section of this chapter will offer some suggestions on how to work for a supportive environment.

A review of the literature indicates that diabetes education is an effective means to change patient self-management behaviors (Peyrot, 1999; Brown and Hanis, 1999) and greater understanding of diabetes has been correlated with greater blood glucose control (Dalewitz *et al*., 2000). In 1998, community agencies in Nogales, Arizona developed a diabetes education and outreach model in response to the growing threat of diabetes in the community. This program successfully documented decreases in random blood glucose, weight, and blood pressure among program participants. Since that time, four additional border communities in Arizona in South Yuma County, Tucson Southside and Ajo in Pima County, and Cochise County, have adapted the model to fit their specific needs and have documented significant decrease in HbA1c levels over a 6-month period. While the models differ across sites, program evaluation has identified several key elements to success.

(1) *Provide basic diabetes education.* Demographic data on program participants revealed that the majority had been living with diabetes for 15 or more years and had never had access to formal diabetes education. This program uses a culturally competent, straightforward curriculum that employs a variety of teaching methods to cover the definition of diabetes, nutrition, physical activity, diabetes complications, and foot and eye care. The general format of the classes includes five 2-hour classes held once a week for five weeks. Graduation parties mark completion of the program. Evaluation of class participation revealed that providing a close-ended series of classes assisted participants in developing a group identity and in completing the program.

(2) *Include peer outreach and education.* This successful model depended upon use of community health outreach workers, or *promotoras*, to provide outreach, assist participants in incorporating self-management behaviors into their lifestyle, and conduct ongoing support and follow-up. The essential nature of *promotoras* is clear from evaluation of these programs that indicate:

- *Promotoras* significantly improve completion of the diabetes classes. A program that had included *promotora* follow-up achieved an 80% completion rate compared to 35% in a program without that support.
- *Promotoras* address a broad range of participant needs that would be impossible to otherwise provide. Participants said that the *promotoras* provided support, motivated them, reminded them to attend classes, reinforced information on diabetes, provided transportation to the classes, and ran support groups. The impact of the *promotora* was summarized by one participant in the following way:

> "*To know that they are keeping an eye on me, to know simply that they're conscious, just the fact of asking me how I'm doing really helps."*

- *Promotoras* were also crucial in helping participants understand and adopt self-management behaviors. Program participants described the support of the promotoras as transformative because they could depend upon them to be available and to help them apply the information they had learned. An obvious example is in learning to self-monitor glucose; the *promotoras* conducted home visits to help participants use their monitors. As one woman explained,

> *"Without the promotoras I would not have changed anything."*

To be successful, it is important that the *promotoras* not be engaged within the more traditional health educator or case management role, but rather that they have the flexibility to respond to the multiple needs of program participants in innovative ways. (For information on initiating a community health worker program, contact the Arizona Community Health Outreach Worker Association or the Prevention Resource Center at the University of Arizona Mel and End Zuckerman College of Public Health.)

(3) *Ensure that diabetes education is linked to clinical care.* In a local provider survey, health care providers in Nogales acknowledged that, given time constraints, it is difficult to provide adequate diabetes education to their patients. Recognizing this reality, physicians are nonetheless skeptical of the accuracy and effectiveness of education provided through other venues. From the outset of the program, it is vital to create relationships with

physicians by informing that the resource is available to their patients.

Another strategy to link education and clinical care utilized within this model is to have the *promotoras* refer participants to clinical examinations and advocate for them within the health system. One community health center places a note in the patient file regarding the completion of diabetes education. Another program sends a follow-up letter to doctors who referred patients with acknowledgement of attendance or lack of attendance, education received, and results of clinical tests given as part of the classes.

(4) *Address issues related to health care access*. Clinical targets cannot be reached without consistent clinical care and a diabetes education program on the border should address this issue with participants as they enter the program. Although many are not eligible for insurance, there are some individuals who are not aware that they qualify for assistance, and diabetes programs can be essential in connecting them to consistent medical care. The education program also must stress the importance of regular medical care and creating a relationship with a provider. Two communities have adopted the use of a diabetes card to track clinical visits when patients cross the border to access medical care.

(5) *Address access to medication*. Hand in hand with the issue of a consistent source of care, a diabetes program must address access to medication. It is unlikely that a program will have the resources to provide medication, but a program can help participants apply for special programs or can obtain samples from pharmaceutical companies. This also is an issue that can be addressed on the political plane, which will be discussed at the end of this chapter.

(6) *Consider alternatives to Certified Diabetes Educators*. While certified diabetes educators are always preferred to present the classes, unfortunately there are very few of them, especially bilingual, in marginalized communities. Some programs have included a training component to help local health care workers to gain certification. Evaluation of this model demonstrated, however, that with back up and support from a medical professional, *promotoras* can deliver the diabetes curriculum and obtain similar results to those achieved by certified diabetes educators.

(7) *Provide clinical examinations as part of the program*. Health information from program participants indicated that many could not recall a past eye examination. In many cases eye exams are not covered by medical insurance. The communities utilizing this model found resources to provide this service, either through physicians volunteering their time or through complementary grant programs.

(8) *Include patient empowerment*. Empowering people with diabetes to be proactive with respect to their clinical care continues to be a challenge for these programs. This issue is particularly acute on the border because many people cross back and forth for care and there is no consistent record of treatment. The program in Nogales created a diabetes empowerment card that includes documentation of clinical visits, medications, class attendance, and personal goals. While the card is popular with program participants, infrastructure within the medical community has not been created to ensure that the cards are viewed and filled out by physicians.

(9) *Conduct program evaluation for sustainability*. Each of the five Arizona border communities employing this diabetes model are committed to program evaluation, although it demands additional resources. Evaluation is essential to help programs improve their services and to document changes in health outcomes. Perhaps more important, sustainability is much more likely when a community program can demonstrate that it has made a difference in the health of people with diabetes. These programs were originally grant funded, and of the three communities who have expended their grant, all three are sustaining their program in some fashion.

PROGRAM CASE STUDIES

This section will briefly describe how the diabetes model is being applied in three Arizona border communities in Nogales, South Yuma County, and Southside Tucson. The strengths and challenges of the programs also will be presented.

Nogales, Arizona

The diabetes outreach and education model was created in this community in 1998, and the program itself represented one of the

first collaborative efforts between its two major health providers: a small hospital and a community health center. One of the greatest strengths of the program is the participation of a bicultural certified diabetes educator who also is a family nurse practitioner. This offered a far greater measure of patient case management than could be provided through other programs. This program also helped to define the role of the *promotora* and identified the need for flexibility.

The education classes were based upon the idea that the program would provide weekly classes and that there always would be an open door to community members. One of the lessons learned during the course of the program is that participants will be more likely to graduate if they are part of a cohort of participants with whom they can identify and draw support. While the open door policy remained in place, more emphasis is now placed on completing the full series of classes within a specific time frame.

Implementation of this program also has revealed the importance of the link between clinical care and the education program. It was well into the program that physicians began regularly referring their patients to the classes, but feedback to the physicians has still not been incorporated. The strategy of having physician offices forward patient HbA1c results to document participant progress proved to be unrealistic and is no longer feasible under HIPAA guidelines. In response, this program developed a diabetes empowerment card to encourage patient—provider communication.

South Yuma County, Arizona

This program also was the catalyst for collaboration between the community health center and the regional hospital, and it benefited from the lessons learned from the Nogales program. The most successful aspect of this program was the resources committed to *promotoras.* Aware of the need to conduct extensive outreach to the farmworker community, this program funded four *promotoras*, each of whom had the responsibility for a certain "caseload" of participants. The program developed a protocol for *promotora* contact and follow-up so that all the participants received a base level of support. Of course, many participants sought out additional contact and assistance so support was not equal across participants.

The Yuma program also managed to more successfully link the program to clinical care. Housed within the community health center, it was the first prevention/education program to be delivered and thus the coordinator of the program also had access to patient records. When HbA1cs were indicated, the coordinator was able to order the test through the clinic. The *promotoras* were successful in calling participants and helping them schedule appointments. While the *promotoras* were from an outside community-based agency, they were given an office in the clinic so that program participants could access them when they made a clinical visit. Through the hospital, the program also accessed local physicians to provide eye and foot exams for free. It also incorporated the exams as a class activity to maximize the number of people that received the service.

The challenge for this program has been in sustaining the program within the clinic environment. The clinic has hired a *promotora* to provide the classes with their patients; however, the capacity to support participants to the level offered previously is difficult. Fortunately, the clinic continues to collaborate with a community-based program to provide support for diabetes care, which enhances the level of support for participants.

Tucson Southside, Arizona

This program is funded through a nonprofit hospital and is unique in that it serves a large urban area. While the program benefits by having access to a broader scope of resources than in rural communities, the need is overwhelming. The program is responding by holding classes in various sites in the community. Each site is in close proximity

to a health care provider and since the program has successfully created a relationship with each provider, the physicians are regularly referring their patients to the classes. The *promotoras* follow up on the referrals by providing personal invitations to join the classes and the physicians receive a letter stating whether or not the patient participated in the program, what classes they attended, and the results of health measures (weight, blood pressure, random blood glucose, and HbA1c).

To facilitate regular physical activity, each participant is provided with a free pass to the local community center walking track, which is inside and air-conditioned. The program is attempting to form volunteer walking clubs to encourage use of the passes. However, since not all participants are close to this site, other resources for walking are currently being developed. This program also has incorporated a grocery store tour to assist participants in identifying diabetes-friendly foods and teaching them to read labels.

PROGRAM OUTCOMES

These programs collected substantial data, both qualitative and quantitative, which provide rich descriptions about the impact of the programs, both on quality of life and health status. The major outcomes in participant behaviors that have been reported across programs include:

- increase in regular glucose monitoring;
- increase in regular checking of feet;
- increase in adherence to diabetes diet; and
- increased physical activity.

Behavioral changes have also resulted in improved health status. While the data being collected across sites varies, results demonstrate:

- significant decrease in random blood glucose that is maintained over 6-month follow-up.
- decrease in diastolic and systolic blood pressure, although significance varies across sites.
- trend toward weight loss.
- significant decrease in HbA1c at 6-month follow-up at the two sites that collected this measure.

Of equal importance are the improvements in basic quality of life described by participants up to one year after graduating from the program.

- The perception of diabetes changed from one dominated by fear, depression and futility to an understanding of the disease and awareness that it is incurable but controllable.
- Participants feel healthier both physically and emotionally.
- Participants feel that there is support in the community and are less isolated.
- In general, participants feel more supported by their family members.

The actual words of program participants underline the enormous need for diabetes education and support in marginalized communities, and the tremendous impact it can have on health and quality of life.

"This program really helps us know we can live with diabetes and enjoy our life."

"Now it is sickness that is tremendous, and not tremendous. Tremendous because of the consequences, but not so tremendous because you can control it."

"I am grateful, if I had not gone to the classes I don't know how I would be doing. They opened my eyes to the consequences; what diabetes is."

"I believed that a diabetic had to stop eating everything, but you can eat everything in moderation."

"Before controlling my diabetes my feet were always asleep, I was really tired. Now I feel good."

CREATING ENVIRONMENTAL CHANGE

Those people with diabetes living on the border who have been fortunate enough to access diabetes education programs still must confront an environment unfavorable to self-management. Programs serving people with diabetes are most aware of the environmental issues facing their clients and can advocate for policy level change.

Two of the communities utilizing this diabetes model also had funding to mobilize a community response to issues related to nutrition and physical activity. As part of a larger initiative, these programs were involved in forming coalitions with the purpose of shaping and implementing policy necessary to support positive changes in lifestyle factors important to the management of diabetes. A key element of their success is that they included decision makers and program practitioners from health care providers, schools, local and county government, community organizations, and the media in the process.

The coalitions focused on issues such as the availability and promotion of healthy foods in grocery stores and the creation of infrastructure to support physical activity. Their successes include:

- Allocation of funds to construct local parks.
- Green areas incorporated into local plans for growth.
- Collaboration with local supermarkets to promote healthy foods.
- The construction of major walking trails.
- Vending machines removed from schools.

It requires a combination of qualities for a community coalition to be successful. In the case of these coalitions, they had several ingredients. First, decision makers were included at the table as the ones who have the power to make policy changes. Second, the groups had a strong sense of purpose; addressing the burden of diabetes resonates strongly among border residents. Third, the coalitions achieved both organizational and grassroots energy and commitment. Many of the coalition priorities were proposed by decision makers, but only occurred because *promotoras* were able to involve the broader community in supporting it. Fourth, the coalitions had an engine that drove them toward policy. It is easy for groups to focus on program related issues, such as raising awareness and providing services. Those running programs should understand that a policy-focused coalition is an opportunity to think how to change the very environment that makes the success of their programs so difficult.

These communities had additional funding to support a policy effort, but the members were volunteers, and a coalition with the qualities outlined above can have notable impact in creating environmental change simply by leveraging existing resources. A program in any marginalized community that is thinking about providing diabetes outreach and education should consider how to include a broader perspective in their effort and creating sustainable change.

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Utilizing Community Health Advisors in Diabetes Care Management

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Community health advisors (CHAs) are community members who work almost exclusively in community settings and serve as connections between health care consumers, providers, and health care organizations. These individuals are an integral part of the health care team and can be instrumental in the success of community diabetes care management programs. This chapter describes the history and background of community health workers, the evolution of their role in the health care system, the current training and development available, and their role in a community diabetes care management program.

WHO ARE COMMUNITY HEALTH ADVISORS?

Community health advisors are workers who live in the community they serve, are selected by that community, are accountable to the community, receive a short defined training, and are not necessarily attached to any formal organization (World Health Organization, 1987). Community health advisors have promoted health and advocacy among groups that have traditionally lacked access to adequate health care. Community health advisors are effective cultural mediators in reducing barriers to care, improving access to the health care system, providing education for their clients, and providing emotional and resource support (CDC, 1994).

Upon review of the literature, community health advisors are referred to as lay health workers, promotores, community health workers, and health aides. The history of the community health advisor began with the Indian Health Service in 1955 with the introduction of the community health representative program (Indian Health Services website, 2003; www.ihs.gov/nonmedicalprograms/chr). In the 1960s, community health advisors were used to reach people in underserved communities with health promotion and disease screening programs. This type of worker has been used throughout the world for all types of roles such as teachers, health care providers when none are available, and community leaders. The role of the community health advisor in

the United States has varied in popularity, but has been most utilized in rural and remote communities. Only in the last 10 years has the community health advisor been a popular strategy in urban and minority communities. Today, Meister (1992) estimates that there are over 12,500 community health advisors in the United States in both paid and unpaid positions.

The role of the community health advisor varies in different geographic regions, communities, and populations and continues to evolve in response to today's health care environment. Community health advisors are seen as teachers, mentors, advocates, and community activists. In 1998, a national survey was completed of community health advisors that yielded some validated roles for further study (Rosenthal, 1998). These roles include cultural mediation, informal counseling and social support, providing cultural health education, advocating for individual and community needs, assuring that people receive services they need, building individual and community capacity, and providing direct services. In addition, the Center for Public Awareness (1999), describes several global functions for community health advisors, which include decreasing health care costs, increasing health care access, strengthening the local economy, and strengthening the family and community. However, there is currently no strong consensus about the role of the community health advisor and the effectiveness of various aspects of the role.

WHAT DO WE KNOW ABOUT THE EFFECTIVENESS OF COMMUNITY HEALTH ADVISORS?

In 2002, Swider completed a comprehensive data-based literature review on the effectiveness of community health advisors. Of the studies reviewed, most were descriptive in nature and differed in the definitions of the community advisor role. It is difficult to assess what aspects of the community health advisor role were measured in relation to the outcomes. The studies also utilized community health advisors with various populations, ranging from high-risk pregnant women to children with asthma to patients with diabetes. Lastly, most data were self-report, therefore, rending application to other communities and populations weak. However, despite the difficulties with current study methodologies, all the articles supported that community health advisors are strong in reaching and serving the underserved and those hard to reach. Additional data suggest that the use of community health advisors to impact behavioral change requires many hours of face-to-face time with the patient (Swider, 2002).

From the literature review of a total of 19 studies, which met Swider's inclusion criteria (2002), three of the studies described interventions with minority, low income, patients with chronic illnesses. In two of the studies, hypertensive patients increased significantly in keeping their follow-up appointments after contact from a community health advisor (Bone *et al*., 1989). The third study was a randomized clinical trial that focused on a group of people newly diagnosed with diabetes who attended a nurse-led diabetes education class. All the patients who completed the classes showed significant improvement in knowledge, self-care, and hemoglobin A1c levels regardless of the community health advisor intervention being present or not. However, those patients who received a community health advisor intervention demonstrated a higher rate of completion of the classes. Thus, the community health advisors played a notable role in improving patient participation rates, thereby improving the knowledge, self-care and clinical indicator of HbA1c. The study limitation is the use of the convenience sample and the patient self-report data (Corkery *et al*., 1997). The Border Health Strategic Initiative, an additional research project funded on the Arizona border provided individualized support to patients with diabetes. This program

demonstrated a significant reduction of 0.5% in HbA1c results 3 months after classes. The self-report measures of regular exercise, glucose monitoring, foot self-exam, and knowledge of HbA1c also was significant at 0.001. The population with the community health advisor intervention yielded better class attendance as well as clinical outcomes. The community health advisor's presence at educational classes provided the value of social support (Meister, 2003).

From these few studies investigating the role of community health advisors in working with patients with chronic disease, we then try to identify the attributes that make community health advisors most effective with patients with chronic illness. With the goal of using community health advisors to optimize a patient's health status as well as their self-management skills, the attributes for effective use of community health advisors would include help with access to care, advocacy, cultural education, and support. Glasgow and Osteen (1992) found that changes in the knowledge and attitudes of patients with diabetes are not sufficient to change self-management behaviors. The presence of self-efficacy is critical to the self-regulation of motivation (Bandura, 1977). The presence of self-efficacy may possibly be developed with the social support provided by the community health advisor.

HOW ARE COMMUNITY HEALTH ADVISORS TRAINED AND WHAT EDUCATION IS AVAILABLE FOR THEM?

Historically, the community health advisor has had "on the job" training in response to the needs presented by the client or the community being served. With the continued utilization and proliferation of community health advisors, the questions of education, training, and competencies have been raised. Since many community health advisors are employed through grants and volunteering, the role has been operationalized in many forms and styles. In addition, as community health advisors transition from various grant funded programs, their roles evolve and expand.

An early need identified was the need to transition from "on the job" training to a postsecondary responsive curriculum. The earliest postsecondary certification program was developed with the U.S. Department of Education and a partnership between San Francisco State University and the City College of San Francisco in 1995 (University of Arizona, 2002). This certification program was known as the Community Health Worker Initiative and consisted of a 17-credit basic curriculum. The program was urban-based and defined competencies and performance standards within the curriculum. A secondary gain of this initial certification program was the development of an employment market for community health workers.

The University of Arizona followed with a successfully funded program called Project Jump Start, which was funded by the U.S Department of Education and Health Resources and Services Agency (HRSA) in 1998. This initiative focused on rural, underserved, and border populations and developed a 16-credit basic certificate program that detailed core competencies for community health workers. The curriculum was validated by employed community health workers and their employers. The University of Arizona program has continued to collaborate with many community colleges across the United States to assess, implement, and evaluate this core curriculum (University of Arizona, 2002).

The University of Arizona Jump Start curriculum is available in a guidebook, which details six modules that can be used in concert with community colleges or as stand-alone continuing education for community health workers. This guidebook includes instructions, suggested learning activities, and recommendations based upon the Arizona experience in helping community health workers achieve core competencies. See "Appendix"

for full community health worker's curriculum. The modules included are:

1. Primary Health Care and Human Services: The Community Health Worker's World of Work.
2. Communication skills: Obtaining, Developing, and Providing Information.
3. Advocacy: The Role of the Community Health Worker within a Larger System of Primary Care and Human Services.
4. Community Health Education, Culturally Appropriate Health Education, Health Promotion Information, and Disease Prevention Competencies.
5. Capacity Building: Motivating Individuals and Groups to Action.
6. Service Skills and Responsibilities: Employment/Work Skills, Legal Responsibilities, Organizational Skills, and Interpersonal Skills.

In addition, modules 7–10 were developed in response to educational needs identified by community health workers working with diabetic patients.*

7. Diabetes and Current Research.
8. Diabetes, Nutrition, and Exercise.
9. Diabetes and Medications.
10. Diabetes Complications and Self-Care.

From these funded projects, the objectives for postsecondary education of community health workers becomes apparent and are currently embraced by partners across the United States (Proulx, 2004). These objectives include:

1. Establish opportunities and recognition for community health workers through a new entry point in postsecondary education.
2. Validate and give credit for core competence through assessment of prior learning and direct experience.
3. Design responsive postsecondary programs that recognize the indigenous nature of the community health worker and the nontraditional characteristics of these students.
4. Establish curriculum standards and flexible delivery of training that meets student/worker and employer needs.
5. Produce a cohort of model programs of excellence.

The national working group spearheaded by the University of Arizona is currently working on career education and training tracks for community health workers comprising preparatory training, field work experience, and academic course work. The current interest from a national perspective in the education and development of core competencies for community health workers is a strong positive movement toward the support of this community position; however, the need for public policy to follow and match this effort cannot be unaddressed.

WHAT ABOUT THE DEVELOPMENT OF ADVOCACY FOR COMMUNITY HEALTH WORKERS AND PUBLIC POLICY?

As aforementioned, all the education, training, and core competency achievement is essential, but if the employment market is not available and consistent, community health workers will not achieve their optimal levels of effectiveness in improving the health status of clients and communities. The development of advocacy and public policy is critical.

The case study of the ongoing evolution of the Arizona Community Health Outreach Worker (AzCHOW) can be reviewed as a model for other groups of community health advisors. In May 2001, community health advisors in Arizona identified the need for an organization that would support and recognize their work. AzCHOW, which comprises community health advisors, provides an opportunity for a collective voice for educating policy makers, finding methods of becoming financially sustainable and expanding their professional standing in Arizona (Collyer, 2004). To date, the organization has provided public policy education for their members, completed incorporation as a nonprofit organization, written a member newsletter and sponsored an advocacy day at the Arizona Legislature. The group has provided valuable education for legislators on the funding discussion of Arizona Health Start, the only state funded community health advisor program in the state of Arizona (Collyer, 2004).

The organization of this grassroots group of community health advisors can help to support education, substantiate the role in terms of presentation of case studies and best practices, and provide assistance in educating policymakers on the important role of community health advisors in the current health care delivery system. However, the need also is apparent to collect quality data that illustrate the value community health advisors bring to health outcomes for patients and communities.

WHAT ARE THE NEXT STEPS FOR THE DEVELOPMENT OF THE COMMUNITY HEALTH ADVISOR IN THE CARE OF PATIENTS WITH DIABETES?

The pertinent literature review illustrates the beginnings of the data management around best practices and clinical outcomes for patients with community health advisor interventions. However, we still can see many barriers to the development of public policy and financial allocations within the health care system to support these roles. Some of the areas for consideration when designing chronic care models utilizing community health workers are:

1. How do we design the care to assure the ability to measure the effectiveness of the community health worker? Can we look at populations with and without the community health worker intervention? Will we be able to see the value of social support in improving patient participation, clinical indicators, cost benefit, and other variables?
2. How do we communicate these findings to policy makers and health care payers to influence a portion of the health care dollar allocation to fund community health workers?
3. How do we reach consensus on the performance measures for community health workers when working with a specific chronic disease and/or population?

The case study, described below, models the use of community health advisors in the continuing care of a high-risk diabetic population and highlights many of the findings from the literature as well as the support for the next step questions posed above.

In summary, the role of the community health advisor is established in our communities as valuable. The role should strengthen as models of best practices and quality data are collected and disseminated. These data identify and support the value of the community health advisor from a clinical outcome perspective as well as from the cost benefit implications for the care of patients with diabetes.

CASE STUDY

The Role of the Promotora in the Continuing Health Care Model

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One of the greatest gaps in health care delivery and those that need health care is the high rate of “no shows” or patients who do not keep their scheduled medical appointments. The percentage of “no shows” can range from 40% to 60% or even higher on any given day. This high no-show rate results in a loss of health care dollars, resources, and continuity of patient care. As the population of the United States grows more diverse, the demand for affordable and accessible health care becomes paramount. Unaddressed barriers to care, such as language, transportation, cost and culture, are becoming all too familiar.

In the uninsured or "working poor" populations, patients do not keep appointments for many different reasons, mostly socioeconomic and family responsibilities. Many of the patients seen in Continuing Care Clinics are over 50 and assume care for their school-age grandchildren, while others, are taking care of aging parents. Their day-to-day care of grandchildren and aging parents take priority over medical appointments. Other reasons patients miss their appointments include:

1. Preventive care is not a priority
2. Family emergencies dictate their daily agenda
3. They cannot get off work or afford to take time away from work
4. Lack of transportation
5. Traveling across the border to see relatives
6. Lack of funds to pay for appointment
7. They forget the appointment

Promotoras or Lay Health Educators bridge the gap between patients and the medical staff. After appointments are made, promotoras make phone calls, usually in the evenings when employed patients are home from work, to remind them of their appointments. It is more effective to call three or four days before the appointment and again the day before the appointment. Even with two or more reminder calls, many patients find it difficult to keep their appointments because of unforeseen family situations or transportation problems that frequently happen on the day of the appointment. During reminder calls, the promotoras encourage patients to keep their appointments and to take care of themselves so they can take care of their families.

A common challenge that exists is motivating patients to self-manage their diabetes. In fact, many patients are not familiar with the idea of goal-setting or self-management. During their medical visit, patients are taught that behavior changes such as healthy eating, activity, monitoring of blood glucose, and stress management can have a positive effect on their blood glucose levels and diabetes. Patients frequently tell us that these changes are very difficult to make and hard to sustain. Some studies show that patients forget 50% of what the doctor told them before they even get to their car. The promotoras bridge the gap by making follow-up phone calls weekly or monthly to assess how patients are doing with their self-management goals and to provide encouragement. The patients keep an empowerment log to be reviewed by their doctor, dietician, or nurse during their next visit to the clinic. The phone calls made by promotoras have been positively received.

The promotora serve as a vital link between clinic staff and the patient population. They help patients overcome barriers of language and culture. They also help patients overcome barriers of transportation, care giving, money, and other socioeconomic factors that prevent them from health care.

APPENDIX

Training Curriculum

The core curriculum designed to train Community Health Workers comprises six modules as a basic training. The competencies or performance abilities that the promotores should have and use in their direct service roles and then a specific curriculum can be designed to work with a specific population such as people with diabetes. Field work in the

community is integrated with each module allowing for practice, growth, and discussion.

Module I—Primary Health Care and Human Services: The Community Health Worker's World of Work

Core competency statement: Upon completion of this module, the community health worker will be able to describe primary health care delivery, principles of health promotion and disease prevention, basic human service needs, and how to assess these needs in a community.

Objectives

- Explain the principal components of primary health care and human services and the history of these fields of work.
- Explain principles of health promotion and disease prevention.
- Use health and human services terminology and case finding assessment techniques.
- Prepare reports, activity logs, home visit forms, and related documentation of the community health workers service in the community.

Module II—Communication Skills: Obtaining, Developing, and Providing Information

Core competency statement: Upon completion of this module, the community health worker will be able to network effectively to research and obtain primary health care and human service information, and impart this information orally and in writing to the members of the community being served.

Objectives

- Access information through health and human service agencies and providers as appropriate, and as applied within the community-based agency or setting in which the community health worker performs work/service.
- Use facility-specific guidelines and methods for sharing information.
- Assess ability of others to understand and adapt communication to meet individual needs, including paraphrasing and/or translating and imparting information with a sensitivity to multicultural and multilingual needs.
- Transmit information to health and human service providers/agencies, including formal and informal observations, environmental conditions, treatment and care plan progress, and unusual client occurrences or risks, while protecting the confidentiality of this information to assure that people access needed services.
- Demonstrate communication skills, including listening, rapport and trust building, perception and values clarification, respect and empathy.

Module III—Advocacy: The Role of the Community Health Worker within a Larger System of Primary Care and Human Services

Core competency statement: Upon completion of this module, the community health worker will be able to network effectively to serve in an advocacy role to address individual and community needs.

Objectives

- Describe and impart to community members the wide range of health care and human services available, how reimbursement affects delivery, and how to access services.
- Serving as culture mediator, educate providers/agencies of care and services about cultures and practice/beliefs in the community and how changes in provider attitudes, services and practice approaches, and materials can promote favorable outcomes.

Module IV—Community Health Education, Culturally Appropriate Health Education, Health Promotion Information, and Disease Prevention Competencies

Core competency statement: Upon completion of this module, the community health

worker will be able to provide culturally appropriate information and make health education, health promotion, and disease prevention accessible to a community through various methods of distribution.

Objectives

- Through a needs assessment, plan and lead health promotion activities, selecting appropriate education and public health resources, and evaluate the outcomes of these activities.
- Educate about preventive health screenings and health promotion practices.
- Promote healthy lifestyle practices and encourage clients to manage and reduce health risk factors.
- Teach concepts of health promotion and disease prevention using the public health model and public health resources in groups, one-on-one, and during home visits.

Module V—Capacity Building: Motivating Individuals and Groups to Action

Core competency statement: Upon completion of this module, the community health worker will be able to develop and use networks and coalitions to help communities build their capacity to care for themselves and to use informal counseling and social support to build the health of the community.

Objectives

- Help people identify assets, strengths, and resources to empower clients and to mobilize the community to solve their own problems and address their own needs, including creating and using good support materials and networking.
- Network and develop coalitions to address client needs for food, clothing, housing, and hygiene services.
- Provide informal group counseling and social support, including forming and leading support groups.
- Build client and community capacities to protect and improve health and bring about community participation.

Module VI—Service Skills and Responsibilities: Employment/Work Skills, Legal Responsibilities, Organizational Skills, and Interpersonal Skills

Core competency statement: Upon completion of this module, the community health workers will be able to exhibit interpersonal qualities and skills necessary to promote teamwork, respect for diversity, individual self-esteem, and community mobilization.

Objectives

- Exhibit interpersonal skills as a peer to meet people where they are and to build a trusting relationship.
- Exhibit friendliness, sociability, confidence, professional conduct, and appearance; demonstrate time management skills and organizational abilities.
- Exhibit qualities of being patient, open-minded/nonjudgmental, motivated, and self-directed.

**Supplemented Population Specific Modules*

Module VII—Diabetes and Current Research

Core competency statement: Upon completion of this module, the community health worker will be able to identify the normal functioning of the body and the changes as a result of diabetes.

Objectives

- Identify the body's normal functioning without diabetes as well as the different types of diabetes and their impact on the body.
- Describe symptoms and treatment goals for type 2 diabetes.
- Learn the differences between low and high blood sugar and how to test blood sugars.
- Discuss the role of the family in the prevention and management of diabetes.

Module VIII—Diabetes, Nutrition, and Exercise

Core competency statement: Upon completion of this module, the community health worker will be able to identify the needed competency for healthy nutrition and optimal diabetes management.

Objectives

- Identify the various food groups and their role in the development of a meal plan.
- Construct a healthy meal plan being cognizant of sugar, fiber, sodium, and cholesterol.
- Discuss methods in which to assist and support patients in maintaining a diet conducive to diabetes management.
- Discuss various types of exercise, safe exercise recommendations, and the potential impact on diabetes management.

Module IX—Diabetes and Medications

Core competency statement: At the completion of this module, the community health worker will be able to identify various types of diabetes medications and their roles.

Objectives

- Identify the various classifications of prescription diabetes medications and their differences.
- Discuss the role of over-the-counter medications, vitamins, and herbs on diabetes management.
- Learn the potential role of nutrition and exercise and the use of various medications.

Module X—Diabetes Complications and Self-Care

Core competency statement: At the completion of the module, the community health worker will be able to identify potential complications from diabetes and preventive self-care interventions.

Objectives

- Identify the various body systems that may be damaged from poorly managed diabetes as well as the warning symptoms.
- Examine various self-care behaviors that may prevent or delay complications from diabetes.
- Identify various resources and organizations in the community that provide assistance and education to individuals and families with diabetes.
- Discuss the role of the community health worker in working with patients and families with diabetes.

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Complementary and Alternative Medicine in Diabetes

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Complementary medicine, also known as complementary and alternative medicine (CAM), alternative medicine, functional medicine, and integrative medicine, is re-emerging as one of the fastest growing fields in medicine today. A 1997–1998 national survey showed that 57% of individuals with diabetes reported using CAM therapies during that year; 35% used CAM specifically for their diabetes (Yeh *et al.*, 2002). Individuals with chronic disease often turn to CAM therapies as adjuncts to standard medical treatment. It is noteworthy, however, that approximately 40% of these patients do not discuss CAM therapies with their physicians. Of those who do report CAM use, only 35% of all self-reported supplements are documented in the patient's chart (Cohen *et al.*, 2002). Given that several herbs and supplements have properties that augment or attenuate pharmaceutical agents, a knowledge of CAM treatments for diabetes is imperative.

The list of modalities considered "CAM" is extensive. Included in this chapter are some of the major therapies of the Naturopathic medical system including lifestyle issues, nutritional supplements, and botanical medicine. Portions of other well-known and well-studied medical systems, such as Ayurveda and Chinese medicine, are included in the botanical section.

A basic tenet of most CAM medical systems views the individual as a whole: a somatic-psycho-social-emotional-spiritual being. To ignore or minimize these factors and treat simply the disease and its symptoms results in less than optimum care. It is the package of care, rather than the specific modality, that promotes healing and well-being.

LIFESTYLE

While diet and exercise are lifestyle choices that have obvious impact on diabetes (indeed, in most cases they can hardly be considered CAM), less apparent dietary topics and practices such as spirituality, social support, stress, and smoking can have profound effects on the disease and on the individual.

Diet

Standard dietary recommendations are well described. However, special mention needs to be made regarding fats and type 2 diabetes. In an extensive review, it was found that quality of fat was essential in glucose metabolism. Polyunsaturated fats and long-chain omega-3 fatty acids were found to be beneficial, while saturated fats and trans fats were detrimental to glucose metabolism and insulin resistance (Hu *et al.*, 2001). Indeed, some of the adverse effects of a high fat diet can be ameliorated with omega-3 fatty acids (Lichtenstein and Schwab, 2000), and an inverse relationship has been shown between vegetable fats and risk of diabetes (Lamson and Plaza, 2002a). It is important that the quality as well as the quantity of fats are addressed, as all fats are not created equal.

Cow's milk has been implicated in the development of type 1 diabetes. Elevated IgG antibodies to bovine serum albumin were found to average seven times higher in children with diabetes than their healthy counterparts. This, in conjunction with viral exposure, may lead to a cross reaction with the p69 surface cell antigen on beta cells, leading to release of interferon gamma and induction of the beta-cell surface antigen. While these results are controversial, it seems that breast milk should be favored over cow's milk, at least during the first six months of life (Head, 1997).

Smoking

Smoking, while deleterious on many counts, has particular influence on carbohydrate and lipid metabolism. In a group of insulin treated diabetics, smokers had a 15–20% higher insulin requirement and serum triglyceride concentration than their nonsmoking counterparts; this went as high as 30% in heavy smokers (Head, 1997). While complete abstinence appears to decrease insulin resistance, smoking cessation methods that employ nicotine (gums, patches) decrease insulin sensitivity. The degree of insulin resistance is correlated to the extent of nicotine used (Kelly, 2000). While encouraging patients to quit smoking is always recommended, care must be taken when prescribing patches and gums to aid this process.

Stress

Acute stress, associated with fight-or-flight response, is accompanied by clear and adaptive severe insulin resistance, quickly reversible with the removal of the stressor. Studies have shown, however, that psychosocial stress may be associated with continued insulin resistance (Kelly, 2000).

Cortisol, a major stress hormone, might contribute to insulin resistance by its tendency to oppose the action of insulin, however, the relationship remains unclear. Evidence suggests that consistently elevated levels of cortisol greatly inhibit nonhepatic glucose utilization (Kelly, 2000).

Social Support

Unlike other disease states, diabetes has a significant impact on the social unit of the patient, in addition to the patient themselves. Diet and exercise, the cornerstones of glucose control, will be affected by the support network of the individual. Change in the habits of people with diabetes will often be intimately tied, for better or worse, to the support of their families, colleagues, and health care systems.

A field test of a one-year program of education and support in Sweden, including ongoing counseling, examined 100 patients with type 2 diabetes. At the study onset, 51% of participants had HbA1c levels at or below 6.5%. After 12 months of education and counseling, 63% had HbA1c levels within this range. Interestingly, participants whose diabetes was diet controlled and rated their loneliness as high were more successful in lowering their HbA1c levels than their nonlonely counterparts (Sarkadi and Rosenqvist, 2001). This emphasizes the critical need for

social network (i.e., family) education, in conjunction with patient education.

Spirituality

Prayer and religious practice, a cornerstone of illness treatment for millennia, have been largely disregarded in modern medical practice. Recently, however, spirituality has been receiving attention as an adjunct to health care, particularly in the area of immune function. In diabetics, C-reactive protein (CRP—an acute inflammatory marker) levels are known to be higher than in nondiabetics. CRP has been tied to cardiovascular disease, a common sequelae of diabetes.

A recent cross-sectional survey of 556 diabetics examined attendance at religious services and CRP levels. Those who did not regularly attend religious service were more likely to have elevated CRP than those who attended religious services. After adjusting for demographic variables, health status, smoking, social support, mobility, and BMI, the association between religious attendance and CRP remained significant for respondents with diabetes (King *et al.*, 2002).

Conclusions

The psycho-social-emotional factors in diabetes can and should be addressed in caring for the individual. While maintenance of glycemic control is the ultimate goal, the well-being and quality of life of the patient must be addressed as well.

NUTRITIONAL SUPPLEMENTS

Several nutritional components have an effect on insulin resistance and diabetic control. Further, diet, along with medications, may affect micronutrient status in diabetic populations, leading to complications in their glucose control and in general health. Common vitamins, minerals, and nutrients that affect diabetes are discussed, as well as nutrient status affected by diabetes medications.

Vitamins

Vitamins are vital for life, and, ideally, should be maintained in adequate levels in the foods we eat. With over-farming and genetic modification of foods, the vitamin and mineral content today may not supply the nutrients of the foods past, or even meet what is necessary for optimal health. Add in fast foods, convenience foods, and high fat and sugar choices (some very cleverly disguised), and the ability to meet nutritional requirements becomes questionable.

A large longitudinal study found that adults who used vitamin supplements were 24% less likely to develop diabetes than those who did not. The protective effect of vitamins remained when adjusted for age, race or ethnicity, education, cigarette smoking, systolic blood pressure, use of antihypertensive medication, serum cholesterol, body mass index, exercise, alcohol consumption, fruit and vegetable intake, percent calories from fat, and total energy intake (Ford, 2001). Clearly, vitamins are an important part of health maintenance.

Vitamin B_3 (Niacin, Niacinamide, Nicotinamide)

Niacin plays an important role in fat, cholesterol, and carbohydrate metabolism. It is an essential component of the glucose-tolerance factor, giving it a key role in hypoglycemia and diabetes (Murray and Pizzorno, 1999). Niacin has been shown to be deficient in people with diabetes.

Niacinamide, a water-soluble amide of nicotinic acid, has been used successfully to prevent or delay the onset of type 1 diabetes, lowering the incidence from 15–20 per 100,000/year to 8 per 100,000/year. Treatment with high-dose niacinamide appears to delay rather than completely reverse disease development in those with preexisting type

1 diabetes. However, treatment of 'at risk' groups, in the majority of studies, shows promise in disease prevention (Anonymous, 2002b).

Lipid profiles in people with diabetes have been improved with niacin supplementation. Niacin has been shown to increase HDL, decrease triglycerides, and decrease LDL in patients with or without diabetes (Elam *et al.*, 2000). HbA1c levels remained unchanged in this study, however, another study found extended release niacin improved both HbA1c and lipid profile in diabetics (Pan *et al*., 2002).

Self-medication of high-dose niacin should be discouraged. Flushing, stomach irritation, and hepatic damage may occur with high doses (Murray and Pizzorno, 1999). In normal individuals, niacin has been known to cause insulin resistance (Head, 1997). Because of the capacity to disrupt blood sugar control, diabetics taking any form of niacin must monitor their glucose closely (Murray and Pizzorno, 1999).

Vitamin B_6 (Pyroxidine), B_{12} (Cobalamin), and Folic Acid (Folate)

Vitamins B_6 and B_{12} have been shown to be deficient in people with diabetes, especially those with diabetic neuropathy. Further, B_{12} absorption is reduced by metformin. B_6 prevents the glycosylation of proteins, and may be a safe treatment for gestational diabetes (Murray and Pizzorno, 1999). Studies have shown that folate, B_6, and B_{12} reduce homocysteine levels in diabetics (Aarsand and Carlsen, 1998; Chait *et al*., 1999).

Biotin

Biotin supplementation has been shown to enhance insulin sensitivity and increase the activity of glucokinase. Biotin significantly lowers fasting blood sugar and improves glucose control in both type 1 and type 2 diabetes. Insulin requirements must be monitored with high-dose biotin supplementation (Murray and Pizzorno, 1999).

Vitamin C (Ascorbic Acid)

Because the transport of vitamin C into cells is facilitated by insulin, it is often deficient in people with diabetes (Murray and Pizzorno, 1999). High doses of vitamin C have been found to inhibit aldose reductase, inhibiting the conversion of D-glucose to D-sorbitol, then to fructose. Left unchecked, sorbitol and fructose accumulate in cells, causing damage to glucose insensitive tissues: the eye lens, renal glomeruli, and peripheral nerves (Head, 1997), exacerbating many of the common complications of diabetes.

Vitamin E

Vitamin E appears to play a significant role in preventing diabetes. In a 4-year prospective study, a low plasma vitamin E was associated with a 3.9-fold increase in risk of diabetes. A 1 μmol/l decrement in serum vitamin E corresponded with a 22% increment in diabetes risk. Supplementation of vitamin E not only improves the action of insulin, but also has a number of beneficial effects that may prevent long-term complications of diabetes (Murray and Pizzorno, 1999).

Minerals

Like vitamins, minerals are essential to life, and theoretically should be available from foods. Since most multivitamins also contain minerals, it may be presumed that the decrease in diabetic incidence and complications seen with vitamin supplementation may include minerals as well. Several specific minerals, however, bear further mention.

Chromium

Trivalent chromium (Cr3) is a key constituent of glucose-tolerance factor, and deficiency has been linked to decreased glucose tolerance, increased serum insulin levels, and decreased number of insulin receptors

(Lamson and Plaza, 2002b). There is evidence that marginal chromium deficiency is common in the United States (Murray and Pizzorno, 1999).

Chromium is a part of a glucose/insulin system that maintains homeostatic control of blood glucose. Cr3 has also been shown to have a positive influence on individuals with no diabetic symptoms. Serum chromium levels in healthy individuals were found to be inversely related to insulin peaks in response to a glucose challenge. In people with diabetes, however, levels did not fluctuate with respect to insulin (Lamson and Plaza, 2002b).

Chromium deficiency has been associated with hyperglycemia in test animals as well as humans, and is reversible by supplementation. It is effective in treating various types of diabetes, including type 1 and 2, gestational, and steroid-induced. Treatment of type 2 diabetes with Cr3 has led to improvement in blood glucose, insulin, and HbA1c levels in a dose-dependent manner. Higher Cr3 doses also resulted in a decrease in cholesterol levels (Lamson and Plaza, 2002b).

While many studies show positive effects with chromium supplementation, the results are mixed. Further, some concern exists regarding high doses and renal dysfunction, including decreased thirst, fatigue, and urinary frequency. Other studies did not replicate this finding at the same dose; no changes in renal or hepatic function were found by laboratory testing (Lamson and Plaza, 2002b). The Drug-Induced Nutrient Depletion Handbook (Pelton *et al.*, 2001) states that side effects and toxicity with chromium supplementation are virtually nonexistent in humans.

Diets high in simple sugars increase urinary excretion of chromium, but show no change in absorption rates. Antacids have been found to decrease absorption (Lamson and Plaza, 2002b).

Magnesium

Hypomagnesemia is common in diabetes. Deficiency can potentially cause states of insulin resistance (Yeh *et al.*, Eisenberg, Kaptchuk, and Phillips, 2003), and supplementation may prevent some of the complications of diabetes such as retinopathy and heart disease (Murray and Pizzorno, 1999).

Magnesium levels are related to insulin resistance in type 1 and type 2 diabetes, as well as nondiabetics. Between 25% and 48% of type 2 diabetics have been shown to have low magnesium levels (Patrick, 2002).

The research on magnesium supplementation and glycemic control is mixed. Two trials showed a decrease in fasting plasma glucose and an increase in postprandial insulin. Three other trials did not show a change in blood glucose or HbA1c level (Yeh *et al.*, 2003). However, magnesium deficiency in people with diabetes is not under dispute. Given that magnesium toxicity is rare (Pelton *et al.*, 2001), it would seem wise to consider supplementation. Caution should be used, as high doses may cause diarrhea.

Potassium

A high potassium diet has several positive results for diabetes control: it yields improved insulin sensitivity, responsiveness, and secretion; it replaces potassium lost by exogenous insulin administration; and it reduces the risk of heart disease, atherosclerosis, and cancer (Murray and Pizzorno, 1999). A potassium-depleted diet was found to lead to insulin resistance at postreceptor sites, reversible when potassium was resupplied (Kelly, 2000).

Diet is the preferred method of increasing potassium intake, as supplementation with potassium salts can cause nausea, vomiting, diarrhea, and ulcers (Murray and Pizzorno, 1999). Further, kidney disease can result from potassium toxicity in people with diabetes, so supplementation other than dietary should be used with care.

Vanadium (Vanadyl Sulfate)

Vanadium is a trace mineral believed to regulate fasting blood sugar and improve

sensitivity to insulin (Kelly, 2000). It is thought to be insulin-mimetic, and upregulate insulin receptors (Yeh *et al*., 2003).

In three small studies, vanadium has been shown to decrease fasting blood sugar in people with diabetes; two of these also reported improvement in HbA1c and insulin sensitivity (Yeh *et al*., 2003). Beneficial effects remained after cessation of active treatment. No change in insulin sensitivity was found with supplementation in obese nondiabetics (Kelly, 2000).

Gastrointestinal discomfort was reported by many subjects, however, organically chelated vanadium compounds cause less irritation than vanadium salts (Yeh *et al*., 2003).

Zinc

Zinc is involved with the synthesis, secretion, and utilization of insulin. It also exerts a protective effect against beta-cell destruction. People with diabetes are prone to insulin depletion due to excess excretion, and zinc supplementation has been shown to improve insulin levels in both type 1 and type 2 diabetes (Murray and Pizzorno, 1999).

Nutrients

There are several nutritional components beyond vitamins and minerals that either have an affect, or are affected by diabetes. Further, oral hypoglycemics and insulin may deplete some of these essential nutrients, warranting supplementation.

Essential Fatty Acids

Essential fatty acids (EFA), including omega-3 (n-3), omega-6 gamma linoleic acid (GLA), eicosapentaenoic acid (EPA), and docosahexaenoic acid (DHA) have been studied extensively for their beneficial effects on cholesterol, triglycerides, blood pressure and cardiovascular disease, autoimmune disease, and inflammation (Murray and Pizzorno, 1999). Several compounds have been shown to be particularly relevant to diabetes, beyond their cardiovascular protective effects.

Diabetes, both human and experimental, has been associated with disturbances in EFA metabolism; in particular, the conversion of linoleic acid to GLA is inhibited. Linoleic acid shares functional similarities to potent insulin sensitizers, and has been shown to normalize impaired glucose tolerance and improved hyperinsulinemia in animal studies (Houseknecht *et al*., 1998). Gamma linoleic acid, however, is an important component of diabetic complications, particularly neuropathy. In a large multicenter trial, GLA supplementation was provided in the form of evening primrose oil to patients with diabetic neuropathy. Following 1 year of treatment, all symptoms of neuropathy improved (Head, 1997). Sources of GLA include evening primrose oil, borage oil, and black currant oil (Murray and Pizzorno, 1999).

Fish oils are an important source of long-chain n-3 fatty acids, EPA, and DHA. The ability of fish oil to enhance the rate of glycogen storage allows skeletal muscle to increase its uptake of glucose, even under conditions where fatty acid oxidation is accelerated. Fish oil enhances insulin secretion by incorporation of n-3 fatty acids into the plasma membrane. This reduces the concentration of amino acids in the plasma membrane, decreasing the production of prostaglandin 2 (PGE2) which, in turn, suppresses the production of cAMP, a well-known enhancer of glucose-induced insulin secretion. Consequently, fish oil enhances insulin secretion from beta cells, regulating blood sugar (Anonymous, 2000).

Fish oils have biological properties of potential relevance for the prevention of type 1 diabetes. One large case control study found that cod liver oil, given in the first year of life, was associated with significantly lower risk of type 1 diabetes (Stene *et al.*, 2003).

In type 2 diabetes, studies have shown mixed results. One study examined established type 2 diabetics, providing a diabetic

diet along with EPA and DHA supplements, or diet alone. Essential fatty acids supplementation resulted in significantly greater improvement in glycemic status, blood pressure, and lipid profiles, as well as reduction in measures of oxidative stress (Jain *et al.*, 2002). In other studies, supplementation with fish oils resulted in no change in either fasting serum insulin levels or insulin sensitivity, and one study found an increase in fasting blood glucose following fish oil intervention (Kelly, 2000). However, given the proven vascular benefits of EFAs, with careful monitoring supplementation may be indicated.

Medium chain triglycerides (MCTs) are a component of many foods, with coconut and palm oils being the dietary sources with the highest concentrations. In an inpatient setting, an experimental diet containing 78% of fat calories as MCTs (31% of total energy intake) increased glucose metabolism in patients with type 2 diabetes. In five outpatients with type 2 diabetes, an experimental diet containing 18% of calories from MCTs led to a slight reduction in postprandial blood sugar and no effect on fasting blood sugar. While promising, the role of MCTs in the management of diabetes remains to be decided (Anonymous, 2002a).

Blood lipid levels should be monitored when supplementing with EFAs. While the results are mixed, and several studies have shown improved lipid levels, but one study found an increase in cholesterol when supplementing people with type 1 diabetes with n-3 fatty acids (Head, 1997).

Alpha Lipoic Acid (Thioctic Acid)

Alpha lipoic acid (ALA) is a naturally occurring thiol, synthesized in the liver. It is a potent antioxidant, a cofactor in many enzymatic complexes, and may play a role in glucose oxidation (Yeh *et al*., 2003). Alpha lipoic acid has been shown to improve insulin resistance in a number of animal models, and experimental trials have indicated usefulness in insulin resistance, when delivered both parenterally and orally (Kelly, 2000).

Insulin sensitivity and glucose effectiveness following oral glucose-tolerance test was performed on lean and obese people with type 2 diabetes. Alpha lipoic acid treatment was associated with increased glucose effectiveness in both lean and obese groups, while higher insulin sensitivity and lower fasting glucose were significantly changed in lean subjects only (Konrad *et al.*, 1999). In another study, blood glucose levels following ALA supplementation were not changed, however changes in coagulation factors and marked lipid lowering were seen (Ford *et al.*, 2001).

A dosage study of ALA showed a mean increase of 27% in insulin-stimulated glucose disposal in treated subjects, with no significant differences between dosage levels. A relatively low dose, therefore, is sufficient to produce effects (Kelly, 2000).

Coenzyme Q_{10} (Ubiquinone)

Coenzyme Q_{10} (CoQ_{10}) is a cofactor in the mitochondrial electron transport chain. Because an adequate supply of energy is essential for the health of virtually all human tissues, CoQ_{10} is a vital nutrient (Gaby, 1996). Many recent studies have demonstrated the effectiveness of CoQ_{10} in maintaining cardiovascular health.

Several studies have explored the role of CoQ_{10} in diabetes. Administration of CoQ_7 (a nutritionally equivalent analog of CoQ_{10}) resulted in fasting blood sugar level declines of at least 30% in 31% of the patients (Gaby, 1996). A second study showed improvement in pain and paresthesias in diabetic neuropathy (Head, 1997). Several negative studies, however, have indicated that beneficial effects of CoQ_{10} administration may not be apparent in the short term (Lamson and Plaza, 2002a).

Many of the oral hypoglycemics and all of the lipid-lowering statins deplete CoQ_{10}. Given its known beneficial cardiovascular effects, and emerging effects on glucose

TABLE 20.1. Oral Hypoglycemics, Exogenous Insulin, and Nutrient Depletion (Pelton *et al*., 2001)

Hypoglycemic agent	Nutrient depleted	Potential effects
Acarbose (Precose) Acetohexamide (Dymelor) Glimepride (Amaryl) Glipizide (Glucotrol) Glyburide (Micronase) Tolazamide (Tolinase)	Coenzyme Q_{10}	Congestive heart failure, high blood pressure, angina, mitral valve prolapse, stroke, cardiac arrhythmias, cardiomyopathy, lack of energy, gingivitis, weakened immune system
Metformin (Glucophage)	Folic acid	↑ Homocysteine, megaloblastic anemia, headache, fatigue, hair loss, anorexia, insomnia, nausea, diarrhea, ↑ infections
	B_{12}	Fatigue, peripheral neuropathy, macrocytic anemia, confusion, depression, memory loss, poor blood clotting, dermatitis, anorexia, nausea, vomiting
Insulin	K^+	Cardiac arrhythmias, poor reflexes, weakness, fatigue, thirst, edema, constipation, dizziness, mental confusion, nervous disorders

control, supplementation in people with diabetes should be considered.

Conclusion

This list of nutritional supplements is not meant to be exhaustive. Several other substances, including beta carotene, calcium, manganese, L-carnitine, and glutathione, have shown promise in the treatment of diabetes.

The standard medications for glycemic control can and do influence nutritional status. Table 20.1 presents the most commonly prescribed diabetes medications, their effect on nutritional substances, and the potential consequences.

Botanical Medicine

There are literally thousands of herbal compounds available and beneficial for various health conditions. Most of the herbs described in this section have been used for centuries, and are just now beginning to be considered in mainstream medicine as options for diabetic control. As testing of botanicals increase, more use of the ancient treatments may be seen.

This section, like the nutritional supplements, cannot be considered exhaustive. The most rigorously studied herbs with the longest and most effective history of use are discussed, with contraindications and interactions presented in tabular form. A table with less well-studied, yet promising, treatments follows.

Bitter Melon (Momordica charantia)

Bitter melon is indigenous to tropical areas in Asia, India, South America, and Africa. It has been used widely in folk medicine as a treatment for diabetes (Murray and Pizzorno, 1999). Theoretical mechanisms of action include increased insulin secretion, tissue glucose uptake, liver muscle glycogen synthesis, glucose oxidation, and decreased hepatic gluconeogenesis (Yeh *et al*., 2003). The blood sugar lowering capabilities have been clearly established in clinical trials and experimental models (Murray and Pizzorno, 1999).

Charantin, an active component of bitter melon, is a more potent hypoglycemic agent than tolbutamide, a first generation sulfonylurea. It also contains an insulin-like polypeptide, structurally and pharmacologically

comparable to bovine insulin, which lowers blood sugar levels with fewer side effects than exogenous insulin injections (Head, 1997; Murray and Pizzorno, 1999).

Positive effects have been shown using bitter melon. One study showed 73% of people with type 2 diabetes had improved glucose tolerance with bitter melon juice. Another small study showed a 54% decrease in postprandial blood sugar and a 17% reduction in glycosylated hemoglobin with an aqueous extract (Dey *et al.*, 2002). No adverse effects have been reported in human studies (Yeh *et al*., 2003).

Bitter melon may have additive effects when taken with other glucose-lowering agents (Basch *et al*., 2003a). While capsules are available, the juice or extract form has been used in most studies. However, as the name implies, the juice is extremely bitter and may be difficult to make palatable (Murray and Pizzorno, 1999).

Bilberry (Vaccinium myrtillus)

Leaves of the bilberry plant were widely used for diabetic treatment before the availability of insulin. In addition, the berries, containing anthocyanidins, have beneficial effects on microvascular abnormalities common in diabetes (Dey *et al*., 2002).

Bilberry has been shown to lower plasma glucose and triglycerides in animals. In humans, it has been shown to improve retinopathy and normalization of collagen deposition (Head, 1997). Interestingly, a recent study of mulberry (*Morus indica* L.), another rich source of anthocyanidins, compared it to the standard antidiabetic medication glibenclamide. Patients with mulberry therapy significantly improved their glycemic control over those on glibenclamide treatment. Mulberry also significantly decreased serum total cholesterol (12%), triglycerides (16%), plasma free fatty acids (12%), LDL (23%), VLDL (17%), plasma peroxides (25%), and urinary peroxides (55%), while increasing HDL by 18%. Glibenclamide showed moderate improvement in glycemic control, but only had a significant effect on triglycerides (10%), and peroxides (15% plasma, 19% urine). Neither treatment affected HbA1c levels (Andallu *et al.*, 2001).

No side effects or contraindications are known with bilberry fruit. High doses and prolonged use of the leaves, however, may lead to chronic intoxication. This manifested in animals as cachexia, anemia, icterus, and excitation. Extremely high doses (1.5 g/kg per day) of the leaves over long periods could result in death (Blumenthal, 1998).

Fenugreek (Trigonella foenum-graecum)

Fenugreek is one of the oldest medicinal plants. Proposed mechanisms of action include delay of gastric emptying, slowing carbohydrate absorption, inhibition of glucose transport, increased erythrocyte insulin receptors, and modulation of peripheral glucose utilization (Yeh *et al*., 2003). In animal and several small human trials, fenugreek seeds have been found to lower fasting serum glucose levels, both acutely and chronically (Basch *et al*., 2003b).

In people with type 1 diabetes, ingestion of defatted fenugreek seed resulted in significant improvement in fasting blood sugar levels and glucose tolerance, as well as a 54% reduction in 24-hour urinary glucose excretion, and reductions in LDL, VLDL, and triglycerides (Murray and Pizzorno, 1999), indicating that fenugreek may aid with insulin secretion (Basch *et al*., 2003b).

Several small clinical trials have been conducted in type 2 diabetics. In one study, fenugreek-treated patients showed statistically significant mean improvements for glucose-tolerance test scores and serum-clearance rates of glucose (Basch *et al*., 2003b). In a series of two crossover studies, significant mean improvements were seen in the fasting blood glucose levels and glucose-tolerance test results in the fenugreek-treated patients, even though the dose of their standard antidiabetic medication (glibenclamide,

glipizide, or metformin) was reduced by 20% prior to the study period. The fenugreek patients also reported subjective improvements in polydipsia and polyuria (Basch *et al*., 2003b). In a study of newly diagnosed people with type 2 diabetes, however, the benefit of fenugreek seeds was not seen to be significantly different than diet and exercise (Basch *et al*., 2003b).

In their review of clinical trials, Yeh and colleagues found that whole raw seeds, extracted seed powder, gum isolate of seeds, and cooked whole seeds seemed to decrease postprandial glucose levels, while degummed seeds and cooked leaves did not (Yeh *et al*., 2003).

No adverse effects have been reported in clinical trials of fenugreek (Yeh *et al*., 2003), but interactions are possible due to decreased intestinal absorption. Hypoglycemic symptoms are to be expected, and should be monitored (Basch *et al*., 2003b).

Garlic and Onion (Allium sativa and Allium cepa)

Onions and garlic have demonstrated blood sugar lowering action in several studies. The active constituents are believed to be the sulfur containing compounds allyl propyl disulfide (APDS) and diallyl disulfide oxide (allicin) (Murray and Pizzorno, 1999). APDS may lower glucose levels by competing with insulin for inactivating sites in the liver, resulting in an increase of free insulin (Dey *et al*., 2002; Murray and Pizzorno, 1999).

In clinical trial, onion extracts reduced blood sugar levels in a dose dependent manner (Murray and Pizzorno, 1999). A second small study showed acute decrease in fasting blood glucose and increase in insulin, showing an insulin-mediating effect in nondiabetics (Yeh *et al*., 2003). Also in nondiabetics, using garlic was shown to decrease fasting serum glucose. Studies in diabetics, however, have been mixed (Yeh *et al*., 2003).

As well as potential hypoglycemic effects, garlic and onions have cardiovascular and immune enhancing qualities (Murray and Pizzorno, 1999), and are generally well tolerated. The use of these herbs in diabetes is valuable. Care is indicated with patients on anticoagulants.

Ginseng Species (Panax ginseng and Panax quinquefolius)

Ginseng root has been used for over 2,000 years for health promotion. Of the ginseng species, American ginseng (*P. quinquefolius*) and Asian ginseng (*P. ginseng*) are the most commonly used (Dey *et al*., 2002). Reported mechanisms of action include decreased rate of carbohydrate absorption into the portal hepatic circulation, increased glucose transport, and uptake mediated by nitric oxide, increased glycogen storage, and modulation of insulin secretion (Yeh *et al*., 2003).

There are several clinical trials that provide evidence for the hypoglycemic effects of ginseng. One study demonstrated a reduction in the levels of fasting blood glucose and HbA1c in type 2 diabetes when ginseng was taken before meals. The subjects also showed mood elevation, improved psychophysiological performance and physical activity, and reduced body weight (Dey *et al*., 2002).

In a second group of studies on ginseng and people with type 2 diabetes, ground American ginseng root in capsules of varying dosage were administered prior to an oral glucose challenge. Ginseng significantly affected postprandial glycemia, with significant interaction for area under the curve. Compared with placebo, all ginseng doses reduced glycemia, without significant effect as to time of administration (Vuksan *et al.*, 2000b). In a second similar study, people without diabetes were compared to those with type 2 diabetes. In nondiabetics, significant reductions in postprandial glucose were found only when the ginseng was taken 40 minutes prior to the challenge. In people with diabetes, however,

reductions in glucose were seen regardless of when ginseng was taken, either at challenge or before (Vuksan *et al*., 2000a).

Adverse effects for ginseng have been reported, and include nervousness and excitation. These generally diminish with increased use or dosage reduction. Ginseng may inhibit the effects of warfarin, and interact with the monoamine oxidase inhibitor phenelzine. Massive doses of ginseng may result in "ginseng abuse syndrome," characterized by hypertension, insomnia, hypertonia, and edema (Dey *et al*., 2002).

Gymnema (Gymnema sylvestre, Gumar)

Gymnema, an Ayurvedic herb, has been used for centuries as a treatment for diabetes. Gumar, the Hindi name, literally means "destroyer of sugar." Mechanism of action is unknown, but postulations include an increase in glucose uptake and utilization, increase in insulin release through cell permeability, increase in beta-cell number, and stimulation of beta-cell function (Yeh *et al*., 2003).

Chewing gymnema blocks the sensation of sweetness. Individuals who had gymnema extracts applied to their tongues prior to meals ate fewer calories compared to controls. This has not been shown with ingestion of capsules or tablets, however (Murray and Pizzorno, 1999).

In people with type 1 diabetes, supplementation with gymnema resulted in insulin requirements being decreased by one half, and reduced average blood glucose levels. HbA1c levels were reduced, but still remained higher than normal. Cholesterol and triglycerides were lowered significantly (Head, 1997). Gymnema appears to enhance the action of insulin in type 1 diabetes (Murray and Pizzorno, 1999).

In a study of 22 people with type 2 diabetes, gymnema taken along with their oral hypoglycemic drugs improved glucose control in all 22 participants. Further, 21 of the 22 were able to reduce their oral hypoglycemic medication dose considerably, and five were able to discontinue medication altogether and maintain glycemic control with gymnema alone (Dey *et al*., 2002).

Gymnema extract given to healthy volunteers does not produce any blood sugar lowering or hypoglycemic effects. No side effects have been noted (Murray and Pizzorno, 1999).

Soy (Phytoestrogens)

Phytoestrogens in general, and soy in particular, have been receiving increased attention of late due to substantial data that consumption of plant-based phytoestrogens have a beneficial impact on health. In diabetes, soy is thought to be beneficial both for glycemic control and for obesity, although the mechanism of action remains unclear (Bhathena and Velasquez, 2002).

In a recent study of postmenopausal women with diet-controlled type 2 diabetes, phytoestrogen supplementation resulted in significantly lower mean values for fasting insulin, insulin resistance, HbA1c, total cholesterol, LDL, cholesterol/HDL ratio, and free thyroxine. These results show that dietary supplementation with soy phytoestrogens favorably alter insulin resistance, glycemic control, and serum lipoproteins (Jayagopal *et al.*, 2002). A study examining a soybean-derived Touchi extract was tested against placebo in people with borderline type 2 diabetes. Initial fasting glucose and HbA1c gradually decreased, reaching statistical significance after 3 months. There were no complaints of side effects or abdominal distention (Fujita *et al*., 2001).

A review of the literature on soy and diabetes revealed that soy protein, along with soy fiber, decreased LDL, VLDL, total cholesterol, and triglycerides; decreased postprandial hyperglycemia with no effect on serum insulin; and improved glucose tolerance and glycated hemoglobin (Bhathena and Velasquez, 2002). While the number of studies is small, the results are promising.

TABLE 20.2. Interactions and Contraindications of Selected Herbs (Brinker, 2001)

Herb	Contraindications	Interactions
Bitter melon (*Momordica charantia*)	Pregnancy	Insulin, chlorpropamide
Bilberry (*Vaccinium myrtillus*)	None known	Warfarin and antiplatelet drugs
Fenugreek (*Trigonella foenum-graecum*)	Pregnancy	Insulin, cholesterol lowering drugs, may retard absorption of oral drugs, may interfere with warfarin
Garlic and onion (*Allium sativa* and *Allium cepa*)	Stomach inflammation, pregnancy, low thyroid, presurgery, acid reflux	Insulin, warfarin, indomethacin, dypiridamole, anticoagulants, may be protective against acetaminophen and isoprenaline toxicity
Ginseng species (*Panax ginseng* and *P. quinquefolius*)	Hypertension, acute asthma, acute infection, excessive menstruation, nosebleeds	Insulin, warfarin, caffeine, phenelzine, lithium, amitriptyline, potentiates amoxicillin and clavulanic acid, morphine, methamphetamine
Gymnema (*Gymnema sylvestre*, Gumar)	None known	Insulin, enhances glybenclamide and tolbutamide
Soy (Phytoestrogens)	Nontoxic goiter	Thyroxine in infants, estrogen replacement therapy

Drug–Herb Interactions

While generally well tolerated, many botanical substances react with other medications. Table 20.2 presents the contraindications and interactions of the botanicals discussed.

Less Well-Studied Beneficial Herbs

Table 20.3 provides botanical species that are not as well studied for their effects on diabetes, but have shown potential in at least one study.

Conclusion

A plethora of botanical substances exist that affect diabetes. Many of the lesser known herbs presented are from the Ayurvedic or Chinese medical systems, and have been used successfully in other countries with good results, but without the benefit of the rigorous scientific study required in the United States. As the world becomes smaller, more of these traditional medicines may become available.

Conclusions

It should be emphasized that while some of the most common modalities of CAM are presented, Naturopathic medicine, similar to Native American, Ayurvedic, or Chinese medical systems, does not operate solely by treating the disease. Instead, the emphasis is on treating the whole person. An individual with diabetes, for example, would likely receive some of the treatments outlined in this chapter. However, treatment would be individualized to that particular person, and other modalities such as homeopathy, counseling, acupuncture, bodywork (manipulation, hydrotherapy), and/or energy work (Reiki or another healing touch therapy) would be applied as well. It is precisely this individualization of treatment that make CAM medical systems so difficult to study in the reductionistic paradigm that guides current medical thinking. With time and understanding, however, medical systems rather than single treatments are beginning to be examined; it is hoped that this will continue in the future.

TABLE 20.3. Less Well-Studied Botanicals that May Benefit Diabetes

Herb	Effects	Reference
Aloe vera	↓ FBS and triglycerides in type 2 with or without standard anti-diabetic agents; hypoglycemic effects in type 2 and animal models; decreased FBS and HbA1c in type 2	Dey *et al*. (2002) and Yeh *et al*. (2003)
Salt bush (*Atriplex halimu*)	Improved blood glucose regulation and glucose tolerance in type 2; prevents diabetes in sand rats	Murray and Pizzorno (1999)
Konjac (*Amophophallus Konjac* C. koch)	Reduced plasma cholesterol, LDL, total: LDL ratio, fasting glucose in type 2 on oral hypoglycemics	Chen *et al.* (2003)
Cinnamon (*Cinnamomum cassia*)	Decrease serum glucose, triglycerides, cholesterol, LDL in type 2	Khan *et al.* (2003)
Ivy gourd (*Coccinia indica*)	Change in glycemic control better than conventional drug in type 2; blood glucose lowering in animals	Head (1997) and Yeh *et al*. (2003)
Horsetail (*Equisetum myriochaetum*)	Decreased blood glucose, no change in insulin following OGTT in type 2	Revilla *et al.* (2002)
Fig leaf (*Ficus carica*)	Decrease in postprandial glucose and insulin requirement in type 1; short- and long-term hypoglycemic effects in animals	Yeh *et al*. (2003)
Ginkgo biloba	Improves blood flow, thereby ↓ sequelae of diabetes	Murray and Pizzorno (1999)
Holy basil (*Ocimum sanctum*)	Positive effects on fasting and postprandial glucose in type 2; hypoglycemic effects in animal models	Yeh *et al*. (2003)
Nopal (*Opuntia streptacantha*)	Decreased fasting glucose and insulin levels in type 2; decrease postprandial glucose and HbA1c with synergistic effects with insulin in animal models	Yeh *et al*. (2003)
Oolong tea	Decreased concentration of plasma glucose and fructosamine in type 2 or hypoglycemics	Hosoda *et al*. (2003)
Psyllium (*Plantago ovata*)	↓ Total cholesterol, ↓ LDL, ↓ postprandial glucose rise	Anonymous (2002c)
Pterocarpus marsupium	Prevents beta-cell damage in rats; regenerates functional pancreatic bets-cells in animals	Murray and Pizzorno (1999)
Milk thistle (*Silibum marianum*)	Improved glycemic control in cirrhotic type 2 patients	Yeh *et al*. (2003)
Zygophyllum gaetulum	Short- and long-term reduction in blood glucose, normoglycemia without change in body weight in type 2	Jaouhari *et al.* (1999)

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21

Leading Edge Technologies Related to Diabetes Care

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This chapter will discuss two aspects of leading technologies for diabetes self-management: (1) patient self-management information systems, and (2) the use of telehealth networks to provide health promotion information to people with diabetes.

PATIENT SELF-MANAGEMENT INFORMATION SYSTEMS

People with either type 1 or type 2 diabetes need to manage at least three principal components of their daily life to achieve optimum diabetes self-management: (1) diet, (2) exercise, and (3) medications. Often there are other components in play, such as addressing how to get enough sleep, reduce stress, or carve enough time in their lives for spiritual or leisure activities.

There are a sundry of tools available in stores, bookstores, pharmacies, and on the Internet that can help patients with diabetes manage their disease and facilitate better blood glucose control. In general, the tools that are the most technical not only offer the most information and data to the patient, but are also more complicated to learn and use.

Glucometers

Glucometers are standard protocol for anyone who has been diagnosed with diabetes, whether it is type 1 or type 2. Glucometers vary immensely in size and in features. Some glucometers only offer a reading of the person's blood sugar level, date and time of day; while others can program events (such as stress), carbohydrates eaten, insulin boluses or medications taken, and exercise.

In addition, the more advanced glucometers offer graphs illustrating trends and averages of all results, by meals, by time of day, by exercise, and so forth. With some glucometers you can also program weight, height, HbA1c levels, blood pressure, etc.

Each individual with diabetes will have to determine how much control they want to have on their diabetes and select the tools they can use for self-management. If they consider

themselves technically literate, they will probably select a glucometer that will give them as much information as possible as well as one with the most number of programmable features.

Most glucometers (including LifeScan's OneTouch® and Boehringer's AccuChek® glucometers) offer free software that can be downloaded from their web sites. However, the patient will have to purchase a cable to download the information from the glucometer to their home computer. These cables are available for purchase on the glucometer maker's respective web sites. The software allows patients to create reports and charts to analyze trends in blood glucose levels and their relation to diet, exercise, and sometimes, other events such as stress.

The individuals with diabetes can then share this information with their health care professional to help tweak their treatment protocol. They also can print a report and provide a copy of this to their physician for their charts. Some physicians and health care professionals offer the cable and software on their office computers, so during a health visit, the patient can download it there and save money on purchasing the cables.

Areas of improvement for glucometers include:

- Less painful finger-sticks. Many people with diabetes will lessen the number of times they test their blood glucose levels because of the pain caused by finger-needle sticks. Some glucometers have improved on this by allowing a person to draw blood from a needle prick on the forearm or by requiring less blood for testing. However, there is still room for improvement. In addition, some companies have experimented with infrared (IR) glucometers with limited success.
- A foods database that offers nutritional information, including carbohydrate breakdown, calories, portion size, etc. The most advanced glucometers offer a place where a patient can manually input the number of carbohydrates, fats, calories, etc. Why not actually include this information in the glucometer? This would be extremely helpful to the individual with type 1 diabetes who needs to calculate a bolus based on amount of carbohydrates eaten.
- Ability to send information (glucose readings, especially) to a personal digital assistant (PDA) via IR, radio frequency (RF), or cable.

Personal Digital Assistants

In addition to self-management software available for PCs and Apple computers, there are hundreds of software available for PDAs. The biggest advantage of using a PDA is that it is more portable than a desktop computer or laptop.

A handy database to have on a PDA is one with nutritional information, such as BalanceLog™, which allows individuals to look up different foods and automatically inputs calories, carbohydrates, fats, protein, vitamins, calcium, iron, fiber, cholesterol, etc. This database even includes information for fast food restaurants. In addition, this software allows individuals to add new foods and allows them to track target weight, exercise levels, meals, and snacks. It is a handy tool for someone who wants to lose weight and start an exercise program. DiabetesPilot™ and GlucoPilot™ can also be used to track nutritional and exercise inputs as well as medications taken.

A quick search on the Internet will reveal more software for PDAs designed to track blood glucose levels in relation to exercise, medication, and diet. (A good source for this information is the web site www.diabetesnet.com.) Many of these software programs also will allow individuals to transfer information from the PDA to a PC/Macintosh version (via a quick synchronization process).

An area for improvement of PDA software is that there is yet a software program that combines both diabetes self-management information with a food database. A great program for individuals with diabetes who want to gain better control would include diet (with breakdown of nutritional information), exercise, medications taken, stress levels on a

scale, hours of sleep, and blood glucose levels. Being able to create reports and graphs with these variables would offer comprehensive information and facilitate better glucose control.

In addition, there is no commercially available software or cable that will allow a person to download their blood glucose levels from their glucometer into a PDA. This means that you have to manually enter blood glucose results into the PDA. For a short time, Handspring offered a glucometer expansion module for one of their PDAs. Once you inserted the module into the Handspring PDA, you could insert a Freestyle™ test strip. In this way, the PDA would convert into a glucometer. However, after Handspring was purchased by PalmPilot in 2003, the newer PDAs do not have the same expansion slot.

Manual Charts

For those individuals with diabetes, who do not feel technically literate or who cannot afford to purchase a computer or PDA, there is always the use of regular paper charts and forms to monitor self-management.

One of the most comprehensive manual charts (especially for people with type 1 diabetes) is My Other CheckBook™ (available at www.diabetesnet.com). Shaped similarly to a regular banking checkbook, this chart offers a place to write meals eaten (breakfast, lunch, dinner, and snacks), time eaten, carbohydrate content of meals and comments. Above this table, is a chart where one can write insulin doses taken, blood glucose level by time of day and activity levels by time of day and intensity (see Figure 21.1 for sample chart).

Free rudimentary charts also can be found on the Internet, especially at web sites of pharmaceuticals and manufacturers of glucometers. At the most basic level, manual charts should have a place to write the date, blood glucose levels obtained throughout the day, time of day of blood sugar test, foods (carbohydrates and calories) eaten, times of day meals and snacks were eaten, activity levels and time of day of activity, and medications taken.

Pedometers

In addition to following a healthy diet and maintaining a healthy weight, the U.S. Department of Health and Human Services recommends that all individuals walk at least 10,000 steps a day (between 4 and 5 miles) to be fit. Many people have taken this recommendation to heart and, as a result, pedometers have become popular.

Pedometers come in a variety of sizes and colors, and range from basic models that provide only a step count to advanced models that provide step counts, miles walked, and calories burned. The more advanced models even offer FM/AM radios or GPS tracking.

With some pedometers, like the ones offered by Sportsbrain™, you can download the number of daily or weekly steps taken to a website (see www.sportbrain.com). The website provides at-a-glance reports of steps taken, calories burned, average miles per hour walked, cheeseburgers burned, etc. The site also offers graphs of walks of 10 minutes or longer and logs these as a "SportActivities," providing time of day, calories burned, miles per hour walked, etc. In addition, you can join one or more online walk clubs and compare your performance with other members.

A word of caution about pedometers: they are not very accurate. An informal study of three pedometers worn on the same day yielded the following results:

	Pedometer A	Pedometer B	Pedometer C
Day 1	5,016	4,383	2,621
Day 2	2,007	2,811	2,002
Day 3	11,406	9,479	9,327

Most pedometers over-report steps because they count jiggles, including some that count steps when you are sitting in a car going over a bumpy road. Others are so sensitive

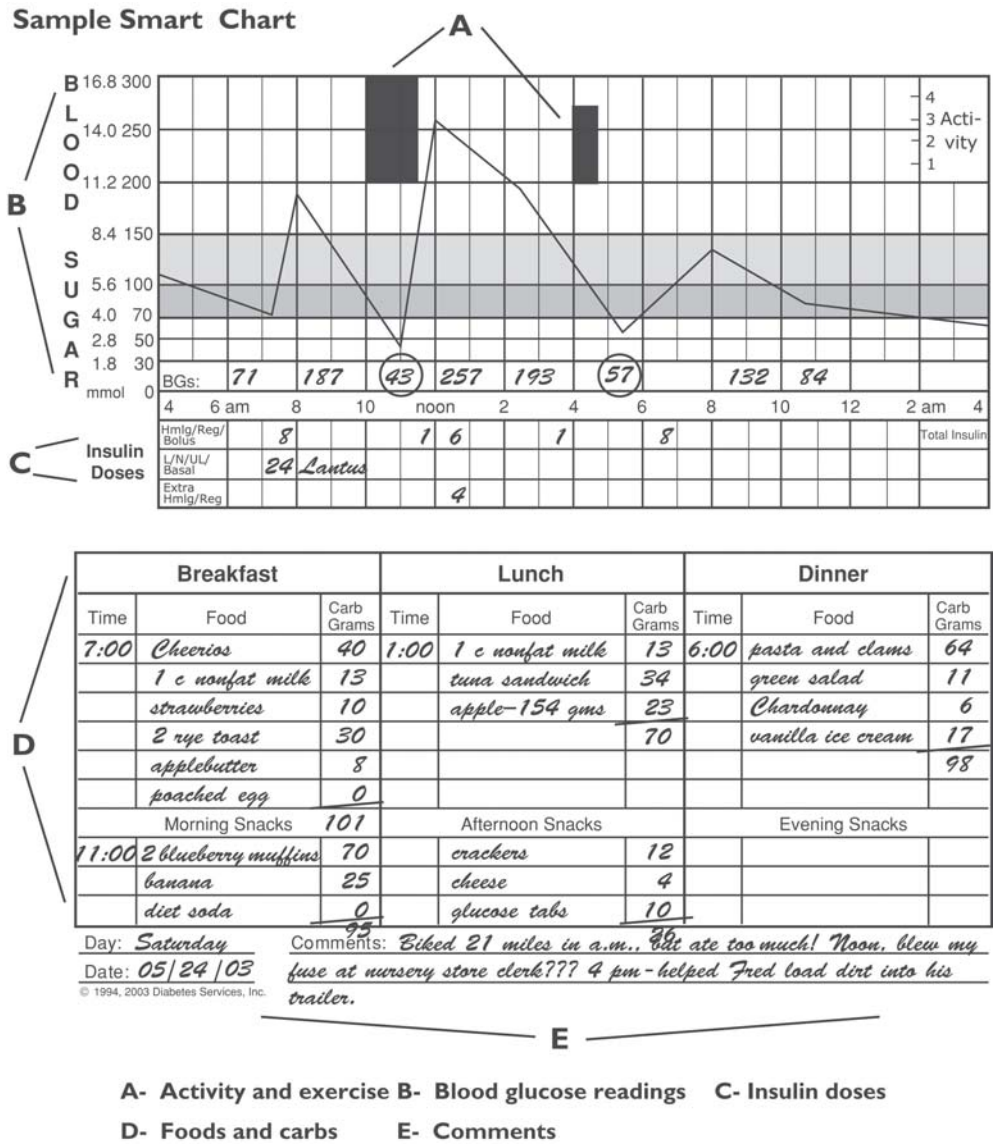

FIGURE 21.1. This comprehensive checkbook size charting system allows the user to see all the things that affect the glucose on one page.

they add steps when you simply open them to read the number of steps taken. Some manufacturers caution that steps will vary depending on where on the belt a pedometer is placed. An article written by a *Wall Street Journal* reporter noted that a 1–5% variance should be expected of pedometers (Bernstein, 2004).

An individual can get a general feel for the accuracy of steps taken by getting to know the pedometer. A good way to do this is to count 10 steps on a flat surface and then another 10 going up a set of stairs.

Despite their inaccuracy, using pedometers is still a fun way to keep track of walking. Purchasing pedometers for the whole family and initiating a friendly competition can be a fun and healthy activity. Most people who have diabetes can invite complications with

a sedentary lifestyle. Pedometers can help individuals ease back into an active lifestyle.

Heart Rate Monitors

Many people who lead sedentary lifestyles and who have tried to return to an active lifestyle have failed because they believed that to become fit you had to run yourself into the ground. The truth is that an individual does not have to feel pain to become fit again. In fact, being out of breath when you exercise is not a good practice.

For this reason, heart rate monitors can be extremely helpful for people while they exercise. When one knows one's maximum heart rate and keeps the heart rate between 70% and 85% of this rate while exercising, not only will exercise be more enjoyable, but it also will maximize the calorie burn and fat loss. "Chapter 9" of this book discusses in detail the benefits of exercise.

The best way to figure out the upper and lower limits for exercise is to take a cardio stress test and to specifically request the physician to provide the best heart rate range for fitness. A person also can come up with a ballpark of where these numbers should be by using the following formula:

1. Maximum heart rate = 220 – your age (e.g., if you are 45 years old: $220 - 45 = 175$. Hence your maximum heart rate is 175).
2. Multiply maximum heart rate by 70% to get the lower limit of your fitness zone (using the example above: $175 \times 0.70 = 122.5$; round up to 123 for lower limit).
3. Multiply maximum heart rate by 85% to get the higher limit of your fitness zone (using the example above: $175 \times 0.85 = 148.75$; round up to 149 for upper limit).

For example, a person is 45 years old (see example above), he or she will know that will gain maximum benefit from exercise by keeping their heart rate between 123 and 149 beats per minute.

Empowered with this knowledge, a person can join an aerobics class, for example, and using a heart rate monitor can do only the exercises that keeps the heart rate within this range. If one notice that the heart rate is at 147, one can decide not to do the arms in a part of the exercise or to shorten their stride to bring their heart rate down.

If a one does not have a heart rate monitor, one can find their pulse on their neck or wrist, count the number of heart beats in 10 seconds (and multiply by six) or 15 seconds (and multiply by four) to get the number of heart beats per minute.

If a person cannot find their pulse or hates doing the math while working out, another simple trick is to count out loud to 15. If the person takes two to three breaths while counting, they should be working within their heart rate limits. If they have to take more than three breaths, they are probably working too hard. If they only take one breath or they can breathe through their nose while exercising, they are not working hard enough.

Individuals should always consult with a physician before starting an exercise routine.

Emerging Technologies

Most emerging technologies related to diabetes self-management are driven by the needs of people with type 1 diabetes. However, people with any kind of diabetes (type 1, type 2, or gestational) can derive benefits from these technologies.

Insulin Pumps

Insulin pumps have been in various stages of development since the 1950s, but have recently gained tremendous popularity in people with type 1 diabetes. Pumps offer a continuous stream of insulin to the wearer that takes care of the glucose that is naturally released into the blood stream by the liver. This stream is called the basal rate and is programmed according to the physiological profile of the individual wearing the pump. Each patient figures out his or her own profile in the first few weeks of wearing the pump. In

addition, the pump user can self-administer a bolus of insulin to cover carbohydrates in a meal or to bring down a blood sugar that is too high. For a more detailed explanation of insulin and delivery systems, see "Chapter 7, Medication Management."

The single most important advantage of using a pump is that it uses only fast-acting insulin (typically Humalog®, but sometimes Regular® insulin), thereby minimizing the unpredictable hypoglycemic events caused by long-acting insulins, such as NPH®, Lente®, and Ultralente®. A disadvantage to insulin pumps is that, on average, users tend to gain weight, since the pump offers them the freedom of eating anything they want as long as they cover the carbohydrates in the meal.

Continuous Glucose Monitoring Systems

Because of its sometimes rapid onset and potentially lethal implications, one of the biggest concerns for a person with type 1 diabetes is hypoglycemia. Some people who maintain tight control of their glucose levels or who have too many hypoglycemic events develop a condition known as hypoglycemia unawareness. This condition can be dangerous because the telling symptoms of hypoglycemia (cold sweat, nervousness, pit in the stomach, keen vision, irritability, etc.) are not present. People who have hypoglycemia unawareness sometimes slip into unconsciousness or a seizure without feeling any warning symptoms. To counter this condition, physicians will tell some patients to back down from tight blood glucose control (if this is what is causing it). However, this does not take care of the hypoglycemic events that happen while sleeping or in the constantly variable lives of children with type 1 diabetes. The health industry has been furiously at work developing a continuing glucose monitoring system, but has yet to bring one to the market that is accurate and affordable.

Two products have been approved by the FDA, but both of them are still wrought with challenges. The first one is the GlucoWatch®, which is a watch-like device that has a transdermal sensor that tests blood sugar levels every 10 minutes. The device, which was developed by Cygnus uses an electrical charge to bring glucose levels to the surface of the skin where the sensor can measure it. It must be calibrated with a glucometer and takes about 4 hours to warm up every day. However, one advantage of this device is that it alarms if there has been a drop in blood glucose levels by 35% in the last hour or if it goes under a certain threshold.

The other product is the Sleep Sentry® Monitor, which is another watch-like device. Unlike the GlucoWatch, however, which measures blood glucose levels, this device measures two of the most common symptoms of hypoglycemia: sweat and a drop in skin temperature. Although this device provides many false alarms, measuring changes of temperature when bringing an arm out from under the covers, for example, or measuring sweat from other causes, it does provide some peace of mind.

For more information about either device or other emerging technologies, visit www.diabetesnet.com, a web site that is updated regularly.

TELEHEALTH

Tools that support individual self-management are important, however, tools to support patients in the learning process of how to be self-managers must also be considered. One method of support is through face-to-face visits with health care providers and educators. Another method of support is through telehealth avenues.

Telehealth is the removal of time and distance barriers to deliver health care services or related activities (American Nurses Association, 1997). The spectrum of telehealth includes telephones, computers, interactive video transmissions, direct links to health care instruments and transmission of images,

and teleconferencing by telephone or video (American Nurses Association [ANA], 1997). The term telemedicine refers to the delivery of medical specialties using telehealth technology, such as teleradiology, telepsychiatry, teleophthalmology, and telepathology. Telenursing has been applied to nursing specialties, such as primary nurse practitioner care, home care for wound assessment and patient monitoring, school nursing, psychiatric nursing, and case management.

In all of these telemedicine services, a patient is presented to a provider at another location via a camera and their interaction is usually transmitted through a T1 line (a special line that consists of 24 single digital telephone lines to enhance the clarity of the transmission) or via satellite. The image is transmitted in two ways: store and forward or real time.

Store and forward is when the image is taken, stored, and then transmitted (forwarded) for viewing at a later time. This is common for teleradiolgy, teledermatology, and telepathology. In the use of diabetes care, a nurse could take a picture of a leg ulcer with a digital camera and then e-mail the image to a wound specialist. Other uses would include monitoring blood glucoses with a special machine that forwards the data to an endocrinologist, who can then make changes to medications if needed. This information can be put in a graph to watch trends.

Real time is when the image is viewed live where the provider does a face-to-face patient visit. This could occur as a specialist visit, an educational visit, or a nutrition counseling visit. Depending on the type of visit, the transmission may occur through a T1 line exclusively—this is obviously imperative for clinical visits. Another method is to plug into a regular telephone line at the rural site for education or counseling—in this format, the transmission may not be as clear, but is less costly and more flexible for connections.

All of these telehealth methods can be deployed when caring for people with diabetes, particularly for those who live in rural settings. For example, the Arizona Diabetes Virtual Center of Excellence (ADVICE) is a comprehensive program for diabetes prevention, assessment, and management utilizing the Arizona Telemedicine Program Network. Partially supported by the Office for the Advancement of Telehealth (OAT), U.S. Department of Health and Human Services, Heath Resources and Services Administration (HRSA), ADVICE offers a unique delivery system for diabetes-related clinical services, professional and patient education, and research and community service. The program has been testing new methods of education and counseling services to rural areas.

However, two major features also being tested through the project are telediabetes classes and telenutrition counseling. The classes that are currently being taught to a group at a local clinic are also televised to a community setting in the rural community with the support of a community health worker—referred to as an "e-Promotora." This person has been trained to set up the special telephone that is equipped with a camera and video screen, which is plugged into a regular phone jack. People with diabetes in the rural community can gather at a community location such as a church or school and be active participants in the classes.

Telenutrition counseling utilizes the same configuration as the telediabetes classes but is done on a one-on-one format. Patients are referred by a rural provider and then seen by the nutritionist located in an urban clinic via a telemedicine connection at the rural site. The rural site could be the patient's home or community location. Again, the e-Promotora, armed with the equipment and a toolkit of nutrition tools that the nutritionist may use for the session, coordinates the visit and location. For more information on these and other telehealth opportunities visit the following web sites: http://telehealth.hrsa.gov/ or http://www.telemedicine.arizona.edu/ADVICE/.

SUMMARY

Innovations in technology have been making the lives of people simpler and better. Although some might argue that technology has had negative effects on health (e.g., televisions and cars have caused an increase in sedentary lifestyles), technology also can be used to improve people's health, raise their awareness of health issues, and facilitate health consultations with communities living in rural communities.

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IV

Business Issues

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Disease Management Research and Policy Initiatives

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INTRODUCTION—DISEASE MANAGEMENT RESEARCH, THE COST–QUALITY NEXUS, AND IMPLICATIONS FOR POLICY

The purpose of this chapter is to explore selected health policy issues emerging from recent research and documented experiences with disease management (DM) in the private and public sectors. More specifically, it will identify some of the precursors to DM and explore the increased reliance on and authoritative support of DM in America's public and private sector. Definitions of DM variously emphasize the role of the patient or informal caregiver, a closer relationship between patient and provider, guideline compliant care by providers, and implementation and evaluation of population-based approaches to improved care for those with targeted chronic diseases.[1] Health policy is defined here as a set of authoritative laws, regulations, and practices at national, state, or local levels that significantly impact the organization, delivery, or financing of health services.[2] At a more general societal level, health policy encompasses widely institutionalized and accepted practices in both the public, private, and voluntary sectors affecting access, cost, and quality of care. The chapter will conclude with a discussion of several key policy issues for future research in DM.

[1] Significant dependence is placed on the patient and informal caregivers, as is indicated in a definition offered by the Disease Management Association of America: "Disease Management is a system of coordinated healthcare interventions and communications for populations with conditions in which patient self-care efforts are significant." In part, DM is a response to recent studies suggesting that providers meet accepted standards of care for chronic illnesses only about half of the time McGlynn *et al*. (2003). A more encompassing definition of DM is "a systematic, population-based approach to identifying persons at risk, intervening with specific programs of care, and measuring clinical and other outcomes" Epstein and Sherwood (1996).

[2] This definition is closely aligned with a definition of governmental health policy as public policy pertaining to health and with public policy defined as "authoritative decisions made in the legislative, executive, or judicial branches of government that are intended to direct or influence the actions, behaviors, or decisions of others" Longest (2002).

Early pioneers of DM predicted that interest in DM would grow among providers, employers, and health plans, and would eventually catch the attention of Medicaid and Medicare programs. Medicaid programs in approximately two dozen states are pursuing one or more of an array of DM program options varying across capitated and fee-for-service environments relying on state or locally developed DM programs or upon specific DM vendors. Current Medicare initiatives explore a variety of DM approaches, including managed care and fee-for-service DM opportunities.

Disease management is closely intertwined with quality improvement initiatives, best practices guidelines, and improvement in patient's quality of care. DM's promise for reducing costs is based principally on the effective delivery of timely and appropriate interventions, care management, education and social support in the most appropriate settings so as to maintain an optimal level of health status for the patient. Although there is increased hope among policy-makers and health professionals alike that DM can constrain costs and enhance quality (optimal health) of populations, there are needs for research that demonstrates these impacts and for policies that support access for various populations to effective DM approaches.

HISTORICAL PERSPECTIVE: PRECURSORS TO DM

Formalized DM programs among health plans, health providers, and DM companies have become prominent within the last 10 years. Disease management may be viewed, however, as an important member of a family of population health management strategies (McAlearney, 2002). A focus on population health and "purchasing population health" is common to much of the discussion of DM. But few have given attention to the wide range of agents or organizations that are responsible for ensuring population health (Kindig, 1998). There are several elements within nursing and medical practice that share a population focus that are related to DM. We briefly examine precursors to DM that reflect major elements of DM today.

Case Management

Case management in health care dates back a century or more to visiting nurses managing their own caseloads and over 50 years to nurses managing rehabilitation care for Workmen's Compensation clients or expensive medical cases for insurance companies (Lyon, 1993). Case management has since extended to other areas such as mental health, care for the elderly and, more recently, to AIDS patients. Chen *et al*. (2002) offers a distinction between case management (individualized care, relying on case manager judgments, targeting a higher risk or frail population) and DM (addressing a specific condition and employing structured protocols and clinical guidelines).

In DM discussions, *case management* and *care coordination* are frequently referred to as forms of DM. Case management activities extend across patient assessment, education, monitoring, referral, service coordination, and support for DM administrative functions (Huston, 2002). The Centers for Medicare and Medicaid Services (CMS) has defined eligible case management services for Medicaid as including "(1) assessment of the eligible individual to determine service needs, (2) development of a specific care plan, (3) referral and related activities to help the individual obtain needed services, and (4) monitoring and follow-up" (CMS, 2001; CMS, 2002). This is in contrast to the CMS disease management pilot program, authorized in the Medicare Modernization Act (MMA) that focuses on management of *specific illnesses* such as congestive heart failure (CHF), diabetes, and chronic obstructive pulmonary disease (COPD) (Medicare

Prescription Drug, Improvement, and Modernization Act, 2003).

Patient Education

Patient education has a long history in the clinician–patient relationship (HSTAT, 2000) and remains an important element of services in prevention, primary care, and acute care (Eakin *et al.*, 2002). It is also an important component of DM. The effectiveness of patient education has been found to vary widely according to the setting and approach employed (Clark, 2003). Educational effort alone, however, may have little impact (CDC, 2003). At its best, patient education empowers patients to take control of basic but important steps to self-management (Fulton *et al.*, 2001; Barlow *et al*., 2002; Bodenheimer *et al.*, 2002; Rollins, 2002; Tattersall, 2002).

Nurse Call Centers, Telenurse

Nurse call centers, telenurse and similar programs have been used for patient education, referrals, "telephone reassurance," or "teletriage" in situations ranging from mild symptoms or prevention issues to emergency situations. In managed care, nursing call centers have been used to control utilization, as well. Ability of costly telenurse programs to work with customers across state boundaries remains a stumbling block in many states. Seventeen states have implemented participation in the nurse licensure compact that enables such RNs and LPN/VNs licensed in one state to practice in another consenting state, including practice via telenurse programs (NCSBN, 2004). In some integrated delivery systems, variations of this approach are used in DM care coordination for periodic contact with patients. One integrated delivery system has used similar telephone-based approaches to enable specially trained nonnurse paraprofessionals to work with patients on anticoagulant management (Schmelzer, 2003; Hillman, 2004). Similarly, Indiana's Medicaid chronic DM program employs similar telephone-based approaches manned by nonprofessionals, with regular backup by nurses, to monitor and support DM for Medicaid primary care case management (PCCM) enrollees (Bella, 2003; Indiana Chronic Disease Management Program, 2004).

Community Health Nursing

Community health nursing has a significant history among population health initiatives. Community health nurses focus on interventions associated with individuals, families, groups, schools, worksites, or communities and can include specialization in case management (Clemen-Stone *et al.*, 2002; Kingma, 2003). Closely related is *public health* nursing which is a practice that supports population health, assessing health needs, and influencing the direction of prevention and care (Public Health Nursing Section APHA, 2004).

Community Oriented Primary Care

Community oriented primary care (COPC) combines a population focus with elements of several of the above approaches. COPC, traceable to the work of two South African physicians in 1940, focuses on the health of a defined population. COPC combines population or epidemiologic study, social interventions, and clinical care of individual patients. The patient, community, or subpopulation are the subjects of diagnosis, treatment, and ongoing surveillance. In its earliest form, COPC combined the interests of public health and medical care, empowered patients and communities in the pursuit of health, and relied upon trained community health workers (Mullan and Epstein, 2002). COPC is widely endorsed in family medicine programs, but has remained a model rather than a widely implemented practice (IOM, 1984).

THE HEALTHCARE MARKET AND MAJOR GOVERNMENT HEALTHCARE PROGRAMS

Within integrated delivery systems, DM programs may be "owned" by the clinic, by the health plan, or by both (Zuniga *et al.*, 2003). While health plans have traditionally been the principal sources of DM, over the last 10 years, a new industry of DM programs has become a major player along side payer, provider, and patient. It is ironic that although DM is premised on gaining patient involvement, self-management, and compliance in his/her own treatment, few public or private policies have focused on providing incentives for a stronger patient role. Although there are precedents for self-insured employers, managed care plans, and life insurance companies rewarding employees or subscribers for not smoking (e.g., lower premiums), such behaviors are not commonplace in fostering patient involvement in their treatment for diabetes, CHF, or other chronic illnesses. One exception is PacifiCare Health Systems, which offers a premium reduction to enrollees who earn sufficient "health credits" by joining an online health club, complete a health risk assessment survey, or participate in a weight-loss program (Sipkoff, 2003).

Physicians have been slow to move toward chronic DM. Knowledge of critical educational and behavioral interventions for more effective chronic DM has been shared in the professional literature (Von Korff *et al.*, 1997) but infrequently adopted among professionals or provider organizations. A study of over 1000 group practices and Independent Practice Associations found two factors to contribute most strongly to physician adoption of organized care management processes—public recognition and better contracts for health care quality (Casalino *et al.*, 2003). Availability of various degrees of clinical information technology was another important factor in the use of these processes. Physicians tended to use less than a third of care management processes presented; and one-third reported no external incentives to use the processes and one-half reported no clinical IT capability.

In a related study of nine leading physician organizations, top executives, finance, and information officers pointed to several barriers to adoption of care management processes, especially to population DM and case management. "Frequently mentioned barriers were lack of financial and staff resources, inadequate clinical information systems, doctors' heavy workload, compensation not being related to quality of care, and doctors' resistance to change" (Rundall *et al.*, 2002). Among facilitators of such DM are "a group culture oriented to quality and supportive managerial and medical leadership" (Rundall *et al.*, 2002). Health plans were frequently cited, too, as an important facilitator, especially those paying more for high quality.

Health plans, even those in integrated delivery systems, have been slow to adopt DM. Today, however, most of the major national and regional health plans offer one or more DM programs. Medicare and, especially, Medicaid in many states have shown increased interest in DM. These public payers and many private payers have been particularly interested in "return on investment (ROI)." At a minimum, the expectation among payers is that within a year, DM programs will reduce claims equal to DM program costs (Foote, 2003). Although there is interest in evidence of improved outcomes associated with DM; the principal concern seems to be with reducing, or constraining the growth rate of, costs of care for populations identified with targeted diseases. In the case of Medicare, unlike private health plans or even Medicaid, there is a high likelihood that a patient will be enrolled until death, a situation which encourages a long-term look at the contribution of DM.

A key question to ask in both policy and practice is how major players in the health system shift from here (traditional care) to there (DM practice). Both the market and Federal and State policy have contributed to growing

interest in DM (Berenson and Horvath, 2003; Foote, 2003). The general movement toward DM in America, however, has not followed a clearly defined chronological development. Major DM developments in the medical care organization and funding arenas have overlapped, but have occurred roughly in the following order:

- Provider case management—service lines.
- Health plan DM roll-outs—internal and outsourced.
- Medicaid targeted populations case management—elderly, HIV, prenatal.
- Medicaid PCCM—addition of DM.
- Medicaid DM initiatives—pharmaceutical and DM companies.
- Medicare demonstration programs—early demonstrations and current broad experiments.
- DM for the poor and uninsured—FQHCs and community partnerships.

Hospital-Based Case Management

Hospital-based case management, dating back to Boston's New England Medical Center in the 1970s, coordinates multidisciplinary care activities and resources for patient populations according to type of illness or condition (Zander and Etheredge, 1989). Medicare's prospective payment system policy of 1983 and its diagnostic-related group (DRG) payment may have contributed to increased interest in this form of health management. Such case management attends to both cost and quality of care to produce desired outcomes for "predictable" patients and quickly identifies patients who do not follow a predictable path and require additional attention during their hospitalization (Daniels and Ramey, 2005). In some instances, hospital-based case management follows a particular patient after hospital discharge, as hospital-based nurses continue to coordinate patients' care in their homes or other settings (Griffith *et al.*, 2003). Some would argue that this extension should rightfully be referred to as community-based case management even if hospital-based personnel are the principal case managers.

In 2001, 71.2% of hospitals responding to the AHA annual hospital survey reported offering case management services. Case management of CHF, for example, is employed by some acute care facilities to avoid preventable admissions or readmissions that will result in significant costs beyond the DRG-based reimbursement (Griffith *et al.*, 2003). In some larger integrated delivery systems, in particular, case management activities may be closely associated with the development of clinical service lines such as cardiology, women's health, or mental health that are intended to improve care coordination, marketing, and/or efficiencies (Parker *et al.*, 2001). The role of rural hospitals in integrated pathways for managing chronic illnesses or specific treatments, e.g., total hip replacement, has been outlined in terms of biopsychosocial approaches to ensuring an appropriate match between the patient and medical and social services (Hicks and Bopp, 1996).

Apart from payment by Medicaid and some health plans for PCCM, payers have not traditionally reimbursed providers for their additional case management activities. There is some evidence today of a greater willingness of some payers to "pay for performance," an approach closely allied in some instances with chronic DM. Private payers in California and several other states are increasingly engaging "pay for performance" approaches wherein medical groups and other providers are paid at a higher level if they meet quality goals. California's Integrated Healthcare Association's participating insurers pay higher percentage add-ons to capitation to providers who demonstrate higher quality. Michigan's Blue Cross Blue Shield program pays higher performing hospitals a percentage increase to the DRG rate (Managed Care Week, 2004). The California Integrated Healthcare Association's measures include elements of prevention as well as chronic DM components associated with diabetes,

asthma, and coronary artery disease. These are weighted at 50% while patient satisfaction receives a 40% weight and IT investments a 10% weight (Integrated Healthcare Association, 2004).

Health Plan DM

Health plan DM rollouts began in the 1990s. Some health plans associated with integrated delivery systems date their significant work on DM to the early to mid-1990s. Some health plans outsourced DM services to DM specialty companies like Cor-Solutions that trace its history back to 1994. Pfizer, Bristol-Myers Squibb Co., GlaxoSmithKline, and McKesson are among the pharmaceutical companies with DM units that have contracted with state Medicaid and other health plans over the last 10 years.

Managed care plans' growing interest in DM as a means of controlling costs and coordinating care is occurring just as such plans pull back from primary care gate-keeping and preauthorization approaches in controlling utilization of care. These DM programs and voluntary case management programs, focused on high-risk patient populations, have attracted limited participation among patients but are expected to become more important in containing costs and improving care delivery (Felt-Lisk and Mays, 2002; Mays *et al*., 2003).

Medicaid Programs

Medicaid programs in two dozen states have been adopting various forms of DM over the last decade. Medicaid and/or other state agencies in some states have pursued targeted populations case management for high-risk groups such as elderly in community settings, HIV, and poor, high-risk pregnant women. Over 20 states have pursued or initiated steps toward adopting some form of DM for their enrollees. Medicaid programs have encouraged their capitated health plans to employ DM, and more recently a number of states are pursuing DM in conjunction with their Medicaid PCCM programs. Medicaid programs in some of these and other states are also risk-contracting with pharmaceutical and other DM companies for controlling costs and improving health outcomes.

Given that Medicaid accounts for about 20% of state budgets and that care for the chronically ill accounts for about 80% of Medicaid spending, the rapidly growing interest among State Medicaid programs in DM approaches is not surprising. As of February 2004, 21 state legislatures had considered legislation on DM; many of these legislatures between 2002 and 2003 authorized pilot DM programs, required health plans to offer DM programs, or otherwise moved their Medicaid programs toward establishing or expanding DM activities (NCSL, 2004).

A recent report based on an examination of over 300 DM programs and a more intensive analysis of about two dozen with the most credible evidence of reductions hospital use and costs recommended a number of elements for State Medicaid programs to consider in pursuing DM options (Brown and Chen, 2004). Among the observations were the availability of a comprehensive set of interventions, not just one or two; participation of bachelors and masters trained nurses as care coordinators and case managers; close working relationship between DM professionals and primary care providers; and a prevention emphasis on early detection and intervention.

The most common form of modern DM among state Medicaid programs is in the form of contracts with DM companies or pharmaceutical-based DM companies. The Florida Medicaid program signed another two-year agreement in 2003 with several pharmaceutical-based DM programs—Pfizer, Bristol-Myers, Squibb Co., GlaxoSmithKline PLC, and AstraZeneca PLC. The companies promise at least $64.7 million in savings to Florida's Medicaid program over two years. In return, the drug companies are able to keep their products in the state's formulary and

avoid price discounts such as those demanded of them by Medicaid programs in more than a dozen states (Meier, 2003). Because prescription drug claims are the most timely data available to DM organizations, access to such claims can both help to identify eligible DM participants (based upon knowledge of the illness for which a drug is prescribed) and to monitor aspects of appropriate care (MEDPAC, 2003). To demonstrate the volatility in Medicaid DM contracting, Florida recently announced its intention to drop its DM contracts with pharmaceutical-related companies at the completion of current contracts in 2005. Announcements cited dissatisfaction with resultant savings from the contracts (Associated Press, 2004).

In February, 2004, the Centers for Medicare and Medicaid Services offered to match state government costs in operating DM programs. The state is free to contract with DM organization or establish a PCCM program working with PCCM providers to offer enhanced care to those Medicaid patients with chronic conditions (CMS, 2004).

Medicare

Medicare is becoming more active in the consideration of DM programs for Medicare beneficiaries. In April, 2004, the RFP for the chronic care improvement pilot program pursuant to Section 721 of the Medicare Modernization Act (Medicare Prescription Drug, Improvement, and Modernization Act of 2003) was announced. The pilot program is a first step toward extending a voluntary chronic care improvement program to enrollees in the traditional Medicare fee-for-service. The program will fund 10 applicant organizations across regions of the nation to offer DM services to a total of several hundred thousand traditional fee-for-service Medicare enrollees. A wide range of DM providing organizations can apply—DM companies, insurance companies, integrated delivery systems, physician group practices, consortia, or others. Initial efforts will concentrate on CHF and/or diabetes with significant co-morbidities; one or two areas may focus on COPD. More information on this program will be discussed later.

The new program is not Medicare's first foray into DM. Evaluation results of fee-for-service Medicare Case Management Demonstration projects between 1993 and 1995 at three sites found little success because of lack of patient and physician interest in participating and little evidence of outcomes improvement or cost reduction (Schore *et al*., 1999). A capitated DM demonstration was initiated with proposals due in 2003. Also, the Medicare Coordinated Care Demonstration with 15 projects sites is nearing completion. An early 1990s study of "fee-for-service" in Medicare fee-for-service found it hard to gain participation in DM.

The three-year Medicare Disease Management Demonstration mandated under the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, BIPA, got underway in early 2004. It will evaluate how the addition of DM services combined with a prescription drug benefit improves the health outcomes of fee-for-service Medicare beneficiaries suffering from serious CHF, diabetes, or coronary heart disease. Like many state Medicaid programs, it relies upon contracts with DM companies to offer the services—to 30,000 people in parts of three states in this program (CMS, 2003).

The DM pilot for Medicare fee-for-service will attempt to test three innovative elements in what might become a broad new strategy: provision of evidence-based care support services for patients and providers, a new business model where DM providers are at risk for outcomes, and a new administrative model for Medicare in setting goals, working with new providers, and analyzing data performance and costs (Foote, 2003).

The focus on 10 regions may allow for demonstrating the effectiveness of different DM models in different settings and different Medicare populations (e.g., rural, minority, and poor). Although most discussion of the

pilot program point to CMS contract with large DM companies including pharmaceutical DM programs, other models are possible, as well, so long as each encompasses at least 30,000 enrollees. For example, MMA emphasizes that some DM projects must emphasize communication with local providers.

At the same time, the Medicare population with more co-morbidities and drug prescriptions than the typical health plan beneficiary served currently by DM programs, may prove more impervious to DM initiatives (Foote, 2003).

DM for the Poor, Uninsured, and Safety Net Providers

DM for the poor, uninsured, and safety net providers is a relatively new phenomenon as well. In 2002, the number of uninsured Americans was estimated to be 43.6 million, up from 41.2 million in 2001. A report from Families USA estimates the number of uninsured for one or more months during the 24-month period of 2002 and 2003 at 82 million (Families USA, 2004). Estimates of one-third or more of the population under the age of 65 being uninsured underscore the importance of DM among the uninsured. Moreover, health and health access conditions among the uninsured create a scenario for "the perfect storm" of costly, uncontrolled chronic disease: the uninsured are more likely to suffer from chronic diseases, are less likely to have a regular or usual health provider, have less timely access to health care, and are less likely to receive preventive services for chronic diseases (Gamm *et al*., 2003).

Several examples of community-based DM efforts that serve the uninsured or underinsured have achieved impressive results. Delta Community Partners in Care serve a 10 county Mississippi delta area. They employ a community-based case management model to improve the health status and risk factors in its target population of African American women under the age of 65. Social workers, nurses, and lay health workers work directly with patients who have a diagnosis of diabetes, hypertension, or both and have achieved major gains in patient health status (Keys, 2003). A Rural Minority Geriatric Care Management Model has been employed at FQHC sites in rural South Carolina to meet the need of poor primarily African American adults 55 and older. This broad-gauged program emphasizes eligibility finding, financial assistance, and other services as well as health screening and care management for diabetes, prostate cancer, and other illnesses. It has attained major successes on all counts (Forti, 2003). St. Elizabeth of Hungary clinic offers a DM program for the uninsured poor in Tucson, Arizona, described in Part 5 of this book, and is still another example of safety-net provider-based DM program.

An examination of chronic DM-related activities among California safety net providers found a few bright spots in five urban counties and a rural region, but noted that most chronically ill patients in these areas served by the safety net providers did not receive such additional care management. Major policy barriers were identified in addition to funding cutbacks in Medi-Cal and other health related programs. Among these are the unwillingness of health plans and other payers to pay for chronic care improvement programs or related services offered by non-PCP personnel, insufficient funds and expertise to acquire clinical information systems or advanced registries to support DM, and shortage of personnel to maintain antiquated registry systems or to offer DM support that does not require medical professional expertise (Bodenheimer, 2003).

Policy recommendations growing out of the analysis of DM among California's safety net providers include the following:

- Medicare, Medi-Cal and its managed care plans, and county indigent care programs

should "pay for programs" rather than creating new categories of service or caregivers for reimbursement, e.g., an annual bonus to a clinic that maintains a registry, a "monthly global fee" to a clinic for the care of each diabetic maybe with a bonus added for avoiding hospitalization or ER use, or a "global budget" for inpatient care in county health systems with additional payments to primary care DM programs making DM profitable and hospitalization a cost;

- Payers should assist safety net providers in developing and using registries and reminder systems and other tools supporting guideline based care;
- States and counties should support collaboration on information systems and registries between county providers and community clinics and health centers that often serve the same patients;
- Payers and safety net providers themselves should encourage clinics and other providers to develop simple reminder systems and train nonprofessional staff to undertake some nonclinical tasks supporting care management;
- Federal, state, and local governments (and foundations) should invest in clinical information systems for safety net providers and facilitate conversion of county primary care sites into FQHCs to gain additional reimbursement that could contribute to improved chronic care (Bodenheimer, 2003).

It is also possible for States to exert their influence in pressing for DM services among plans and providers serving state Medicaid and SCHIP programs and state employee and retiree insurance programs. Apart from those concerted efforts even municipalities collectively, or alone as in the case of Asheville, NC, can design care management programs for city employees and reap savings on several fronts. In the case of Ashville, the city paid pharmacists $40 per patient per month to provide counseling on diet, exercise, stress reduction, and medications to city employees with asthma, hypertension, asthma, or high cholesterol. Health care spending for these employees declined, as did negative clinical findings, and worker absenteeism (Connolly, 2002).

CONTINUING POLICY AND RESEARCH ISSUES IN DM

The preceding section offers a historical perspective and initial reflections on several relevant DM policies and related research. There remain, however, other policy-related issues that will require the attention of researchers and policy-makers alike. A few of these are presented here.

Return on Investment

Return on investment remains a key issue for chronic DM programs. One study identifies significant savings and quality gains associated with a diabetes DM program operated by a health plan in a multispecialty group practice (Sidorov *et al*., 2002). A recent analysis of ROI for diabetes DM in two managed care organizations suggests that there is only a weak business case to be made (Beaulieu *et al.*, 2003). More specifically, it suggests that because of initial costs of the program, the health plan's saving may not occur for 10 years after the member is in the plan. Because of patient turnover, the plan may not realize the kind of financial benefits it needs to convince investors and boards of the financial soundness of such programs. In contrast, Medicare and Medicaid may benefit eventually from the plans' programs because the member will maintain good health longer. Moreover, the employer may benefit from lower premiums, less disability outlay, reduced absenteeism, and increased productivity. The evaluators suggest that policies are needed to ensure that those organizations and programs that benefit contribute to the financing of DM programs.

A recent survey found that a majority of large businesses offer or are considering

offering DM programs, health screenings, flu vaccinations, prenatal care, well baby/child care, or nurse hotline (DM News, 2003). While some employers depend on their health plans to select DM eligible employees, other employers have found that their health plan's DM program miss a high percentage of employees whose conditions are most important among their younger workforce, e.g., high-risk pregnancies. As a result, some employers have purchased DM programs directly from vendors (Short *et al.*, 2003). A 2004 report from American Association of Health Plans/Health Insurance Association of America reports on successes in 10 health plans with 25 different DM programs. The report documented savings in health care costs across a number of programs along with reduced hospital admission and ER visits (Ghose, 2004).

Return on investment studies continue to be plagued by significant problems associated with measuring costs impacts and clinical outcomes associated with DM interventions (Johnson, 2003). Although there are both growing optimism and reports of cost savings and impacts on quality of care, the evidence to date is both limited and mixed (Short *et al.*, 2003). The Pacific Business Group on Health found a lack of comparable-population-based outcomes to enable evaluation of DM programs offered by health plans and calls for improved sets of outcomes measures (Pacific Business Group on Health, 2002).

State Incentive Programs

Some states have created incentives for physicians to provide DM services by paying an additional per member per month to Medicaid PCCM physicians who provide "enhanced services" associated with DM or care coordination (Sprague, 2001). The North Carolina Medicaid program links hundreds of thousands of PCCM patients to Community Care Networks of primary care providers, health departments, and social services departments. The networks work to coordinate services and ensure appropriate utilization and cost management for costly Medicaid patients. In conjunction with asthma and diabetes, the work of the networks has improved care, reduced costs, and reduced ER use and hospitalization in comparison with patients of PCCMs who are not participating in such networks (Simms, 2003).

Early research on Medicaid DM programs identifies quality gains and limited cost savings (Wheatley, 2002). Additional steps that could be taken by state Medicaid programs include automatic enrollment of Medicaid patients in DM programs (with an opt-out period) and addressing problems of low voluntary enrollments. Medicaid DM programs that could appoint DM care managers to work directly with hospitals or other providers to identify DM program eligibles can reduce the costs of locating hard to reach Medicaid enrollees. Hiring staff to locate DM eligibles may be preferable to paying the cost of emergency room visits or acute care hospitalization (Wheatley, 2002).

Co-morbidities

Co-morbidities remain a challenge for DM efforts. In particular, there is need for evidence of the ability to simultaneously manage multiple chronic conditions in the same patients. Foote (2003) contends that new generation DM programs are addressing a broader array of illnesses and are cross-training DM personnel to address overall self-care for patients rather than a specific disease (Foote, 2003). Nonetheless, a number of payers still rely on a number of separate DM programs to serve disease specific populations, but patients eligible for multiple services are generally assigned to only one (Foote, 2003).

The importance of DM providers being able to address multiple co-morbidities is underscored by evidence that 88% of Medicare spending is directed to beneficiaries with three or more chronic conditions with another 77% to those with two chronic conditions (Crippen,

2002). This concern is reflected in part by testimony from the American Academy of Family Physicians who testified that a primary care physician should be the primary point of contact for DM and that federal support of DM organizations will further fragment care, be more costly, and nonbeneficial to the chronically ill elderly patient (American Academy of Family Physicians, 2003).

In Florida, the PCCM Medicaid recipient with multiple illnesses is assigned to the DM vendor that has responsibility for the most serious illness. Performance audits of the Florida program have been critical of this approach doubting the ability of the specialized DM vendor who focuses professionally on one illness to adequately manage the co-morbid conditions; the DM organizations counter that their nurse care coordinators have sufficient experience to deal with the additional conditions as they arise (Silberman *et al.*, 2003). In any case, there is no evidence that the DM organizations coordinate around particular types of patients or share "best-practices" with one another regarding the various co-morbidities.

Because patients with concurrent chronic conditions are more likely to generate higher expenditures than a patient with one condition, one wonders whether evaluations of DM program performance considers costs and cost savings for each condition. Behavioral health conditions, for example, combined with other chronic conditions illustrate research and policy challenges. Psychosis and depression alone and together score the greatest yearly costs among Medicaid patients, and often combine with other conditions like diabetes, asthma, or peptic acid disease to produce high costs (Garis *et al.*, 2002). Diabetic adults are more likely than nondiabetics to have a major depressive disorder, but diabetics, with worsening health status, are nearly six times more likely to develop a major depressive disorder. Diabetics with depression report poor physical and mental health, use more outpatient care, and fill more prescriptions. Those with this combination of illnesses tally 4.5 times greater total health care expenditures than for individuals without depression (Egede and Zneng, 2003).

To Buy or Build a DM Program

To *"buy" or "build"* is a choice that Medicaid programs and health plans must make. Building a DM program from scratch, assembling "off-the-shelf" components, partnering with a DM vendor in a "turn-key" arrangement, and buying from a DM vendor are among an array of options. Although it appears that the "buy" option is becoming more popular, the "build" or "assemble" choice may offer greater payoff for state Medicaid programs and other payors. In particular, it may offer the opportunity to address more conditions, more providers, and more populations through DM programs. Moreover, it may be possible to attain savings and synergies among Medicaid and many other health and human services programs in the state. It may also optimize DM program lengths between Medicaid and those responsible for health care for state employees and retirees.

Alternatively, negative aspects of the build approach can include greater upfront costs and time to hire expert personnel and expert consultant to construct the DM program from scratch or combine components from other sources; and lack of knowledge of likely effectiveness until the product has been operating for a year or more (NGA, 2003). Also, where one works with local providers and others to construct DM programs, DM accomplishments might be constrained by continuing provider resistance to adopt clinical protocols and related care management opportunities.

There are some key advantages for buying, i.e., contracting for, DM that may be appealing to Medicaid agencies, especially in times of financial stress. DM vendors may be relied upon to provide the necessary research development, information systems, and to put personnel in place immediately. Also, DM

vendors may put their fees at risk; vendors may forgo up to 100% of their fees if agreed up cost-saving targets are not met. Negative elements of "buy" approaches include: DM companies may not manage all of the services desired; relationships between the companies and providers may be distant; placing DM vendors at risk can create adversarial stance between the vendor and the State; and negotiating and monitoring such contracts requires expertise on the part of the responsible state officials. Pharmaceutical companies may present a special form of contracting, but may in some instances be principally limited to management of pharmaceuticals in conducting DM. Some address multiple aspects of care and multiple conditions.

The Indiana Medicaid program emphasizes an "assemble" approach in contrast to build or buy approaches. That is, they have assembled a number of existing components into a custom built DM program for their Medicaid fee-for-service patients. They are now proposing to open its services to other providers as well (Indiana Chronic Disease Management Program, 2004).

For any DM option that relies on on-site DM providers, there is a need for a sufficient population base to cover the cost of a DM provider, something which may be problematic for rural or frontier areas. It is possible that higher payments or other resources could be offered for provision of DM in such geographic areas either directly by Medicaid or through an external DM company (possibly making up some of these revenue losses in DM provision in more populated regions). It appears to be the case that in states relying on external DM vendors, telephonic DM approaches are more regularly used in rural areas (Silberman *et al.*, 2003).

DM as a Benefit or Administrative Service

The issue of treatment of *DM as a benefit or administrative service* is likely to become a more important issue as DM benefits or services are made available to additional target populations. Both public and private markets have treated DM services as administrative services rather than defined benefits. This allows for more experimentation and easier dropping and adding of services by health plans or other payers (Foote, 2003). At the same time, however, as the DM services become more widely accepted, it will become obvious that additional services (benefits) are being offered to some populations (and not to others) even though the revenues contributed by or on behalf of each "enrollee" are the same. The fact that some patients view DM as a benefit is reflected in the efforts of enrollees to "buy" DM services after their group had been dropped by a health plan that had offered the DM services (Bolin *et al*., 2003). And, of course, physician providers may see an additional DM "benefit" or "service" provided by a new "provider," the DM company, as bleeding off revenues that should be coming to traditional medical care providers (American Academy of Family Physicians, 2003).

DM Programs' Dependence Upon Information Systems

DM programs' dependence upon information systems has brought renewed attention to the need for more widespread clinical information systems and/or registries. In some instances, attention is focused on systems that combine clinical guidelines with patient data from claims, self-reports, or other sources (Foote, 2003). Disease management registries within FQHC administered chronic disease "collaboratives" reflect similar integration. Less common, but occasionally found in integrated delivery systems, is the integration of information in the form DM personnel of the health plan being able to review and write to the clinic's electronic medical record and, thus, communicate directly with the physician regarding care coordination for the patient (Bolin *et al.*, 2003). Via the MMA of 2003 and other Federal initiatives, additional incentives are being offered to enable providers to develop clinical information systems that can

support DM and other quality related activities.

DM and Clinical Quality

DM and clinical quality are closely related topics. Much of the content of DM programs is parallel to clinical guidelines prescribing certain tests and treatments for chronic illnesses. In many respects the contributions of physicians, hospitals, and health plans to DM efforts is dependent upon their day-to-day support of quality-related guidelines. Moreover, DM may contribute or detract from ability of health care providers to conduct their work. Although DM programs may help the Medicare patient overcome fragmented care offered by up to six physicians and up to 20 prescriptions in a given year (Anderson, 2002), it may add to clinical complexity for providers. That is, multiple DM companies may contact the same physician about his/her patients. Moreover, DM in such a fragmented situation may offer little in the way of support for quality improvement or reengineering of clinical practices in the direction of better overall chronic DM (Foote, 2003).

Training Needs of DM Paraprofessionals

Training needs of DM paraprofessionals should be addressed on a state or national level. Paraprofessionals play an important role in DM efforts. If DM grows as rapidly as anticipated in Medicaid and Medicare, the capacity of current DM companies and even that within integrated delivery systems may be quickly exceeded (Wadhwa *et al*., 2004). This capacity limitation is linked in large part to the short supply of nurses. Nurses are the principal disease managers, care coordinators, or case managers in most DM programs. Some telehealth programs, community-based DM initiatives, and other DM-related programs make some use of social workers, community health workers, or other paraprofessionals to handle nonmedical aspects of DM. For example, the Indiana Medicaid plan offers telephone-based DM to fee-for-service/PCCM Medicaid patients, relying on paraprofessionals (backed up by nurses); making this service available to other patients as well. This trend is in keeping with treating DM as an administrative service. If DM were treated as a benefit, it might point toward consideration of new classes of health workers for reimbursement, something which is frequently the subject of intense debate.

Predictive Modeling Technologies

Predictive modeling technologies are important components of DM. The technologies can identify those patients at various risk-levels calling for DM interventions are also criticized as potentially being used to weed out chronically ill patients from insurance coverage. Large insurers are investing in predictive modeling technology that can be used to estimate total spending for a group of members, forecast individuals most likely to be hospitalized, and to perform analyses that support such functions as targeting preventive care or DM or pricing contracts with employers and providers. Using data such as age, gender, zip code, medical and pharmacy claims, and laboratory results, predictive models are increasingly accurate in predicting costs for groups and individuals (Benko, 2004).

A series of recent lawsuits against a few health insurance companies for canceling policies or increasing premiums of sicker patients (Benko, 2004) suggest that policies will be needed to ward off unethical use of such technologies. (Does the denial of the right to sue HMOs in state courts apply to HMO decision to deny coverage?) Misuse of these technologies may dissuade some patients from seeking tests or screenings if they think the results could be used to exclude them from insurance coverage. Such predictive modeling, however, offers significant promise for better targeting of DM efforts and for "severity adjusting" in assessing the quality and effectiveness of both medical care and DM programs. The same technologies, it should

be noted, can be used by state governments or possibly by self-insured employers to better assess the risk-levels present among those for whom they provide benefits; they can use such information in negotiating contract with health plans.

CONCLUDING COMMENTS

Disease management offers the promise of reducing a portion of the high cost of care for the chronically ill by enlisting the full participation of the patient and informal support system and ensuring timely and appropriate high quality medical care to ensure optimal health. Even as studies are still underway to establish DM's impact on quality and cost in health plans and Medicaid PCCM based programs, DM is about to be tested in what has been considered the most formidable market, i.e., Medicare fee-for-service.

As DM continues to evolve and to penetrate additional markets, it affects nearly every policy area in health services. Its definition as an administrative service or insurance benefit, the form of payment for DM services, DM's reliance on paraprofessionals or its reliance on nurses in new roles, the outsourcing of DM or the building DM into existing health plans or newly created community care networks, the acceptance of DM practices into ongoing definitions of quality care and criteria for pay for performance suggest just a few of the policy areas affected by DM. More broadly, DM may be part of new "delivery system" for Medicare fee-for-service. In the same vein, whether Medicaid chooses to outsource DM to external companies or includes it as a component in a community-based and state integrated system may set a new course for Medicaid programs. Finally, a number of policy decisions will help to determine whether DM becomes just another service for the insured, or whether it becomes a central element in the prevention and management of chronic diseases across the larger population.

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23

Legal and Regulatory Considerations of Diabetes Disease Management

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INTRODUCTION

Laws and regulations pertaining to health care have increased dramatically in the past 20 years and have assumed heightened, some would say overstated, significance in the operation of health plans and patient care services. Many health care organizations are not fortunate enough to have an attorney available for frequent consultation. Therefore, acquiring a basic understanding of the laws affecting the delivery of health care is a valuable investment of time and money.

In this chapter, we provide an overview review of laws and regulations and discuss certification and accreditation options that pertain to diabetes disease management (DM). Our discussion includes recently enacted Medicare and Medicaid DM provisions, HIPAA, as well as a discussion of accreditation programs such as the Joint Commission for Accreditation for Hospital Organizations (JCAHO), National Commission for Quality Assurance (NCQA), Utilization Review and Accreditation Committee (URAC), and the American Diabetes Association (ADA).

PROLIFERATION OF DM REGULATIONS AND GUIDELINES

Observers of health care delivery in the United States have recognized the trend toward greater regulation and standardization in the delivery of health care services. The realities of tightened fiscal constraints, and recognition that adherence to DM guidelines improves overall quality of care, have motivated the development of new approaches to caring for chronic disease and contributed to the proliferation of guidelines. Indeed, over 67 guidelines exist on diabetes mellitus alone (National Guideline Clearing House, 2004). Professional standards and review organizations (SROs and PROs) have sprung up both in the private and public health care sector. Federal and State public health programs have launched several new initiatives. In 2003, Medicare initiated the chronic care improvement program (CCIP) for fee-for-service programs (MMA, 2003) and began testing pay-for-performance (P4P) reimbursement incentives and directives intended to encourage the use of DM guidelines (*NCQA*, 2004;

CMS, 2004). The focus of these programs is on encouraging health providers to adopt standards and guidelines relating to care of patients with chronic diseases, addressing, for example, diabetes, asthma, congestive heart failure (CHF), and chronic obstructive pulmonary disease (COPD).

Compliance with the numerous laws, regulations, guidelines, and standards can be overwhelming and confusing. Yet, much of the work required for compliance with federal regulations and guidelines can be accomplished through accreditation or certification with organizations specializing in quality of care and outcomes evaluation, such as JCAHO or NCQA. Accreditation and certification are evidence of compliance with evidenced-based guidelines, and in many cases are recognized by Medicare and Medicaid programs that a program meets appropriate standards and guidelines. Adherence to evidence-based guidelines also demonstrates that a DM provider is capable of implementing guidelines that improve patient outcomes and improve overall quality of care. Much of an organization's success in marketing and expanding DM programs will be based on an ability to demonstrate improved health, reduced acute health events, and cost-savings while carrying out population-based management of chronically ill patients. However, implementation of guidelines, regulations, and DM processes takes time and effort, and can be challenging for DM programs. Accreditation and certification requirements also may vary state-by-state and therefore the information discussed in this chapter is offered solely to provide an overview and is not intended to be offered as specific legal advice. Decisions relating to legal considerations for individual programs should be made after consulting with those familiar with applicable state laws as well as health law generally.

Federal Laws and Regulations in Disease Management

Numerous federal laws and regulations apply to health providers and health care facilities, as well as the operation of health plans generally, but not all apply specifically to DM. It is beyond the scope of this chapter to discuss all of the tangentially relevant federal health care laws. Instead, our focus is on those laws and regulations that pertain most to the provision of DM services, and demonstration of compliance with regulations and guidelines. For example, the recently passed Medicare Prescription Drug, Improvement, and Modernization Act (MMA, 2003) contains specific requirements and inducements for providers to initiate and implement chronic disease care, including CCIPs and other pilot projects. Numerous other federal laws relate in some measure to DM and include the Healthcare Quality Improvement Act (HCQIA); Benefits Improvement and Protection Act (BIPA); the Health Insurance Portability and Accountability Act (HIPAA) and discrimination laws

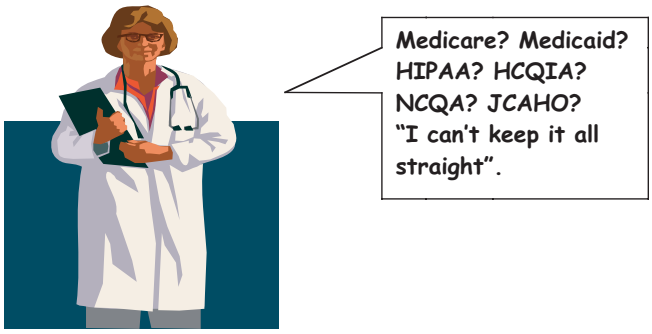

TABLE 23.1. Laws and Regulations to Consider

Regulation or agency	Who is covered?	What is covered?
Medicare [MMA]	All participating health care providers	Initially CCIP will be tested in pilot programs and later launched in all FFS and managed care programs.
Medicaid (state-by-state)	Diabetes and other chronic diseases	See state summary in Table 23.2
HCQIA (Health Care Quality Improvement Act)	Hospitals	Requires peer review and credentialing of physicians.
	Health plans (if accredited by NCQA)	Legal responsibilities include a defined process for the appointment of "medical staff", creation and approval of medical staff by-laws.
BIPA ["Benefits Improvement and Protection Act of 2000"]	Applies to DM plans participating in the BIPA demonstration projects	Patients with advanced CHF, diabetes or CHF. Program reimburses for patient visit plus cost of prescription drugs.
HIPAA ["Health Insurance Portability and Accountability Act"]	All health plans. All health care providers who have access to PHI including electronic transmittal of PHI.	All PHI generated in any format, including electronic, paper, and oral information.
Consolidated Health Informatics Initiative	About 20 federal departments or agencies, including HHS, DoD, SSA, GSA, and VA.	Federal agencies, which share health data, are required to adopt the same clinical vocabularies and integrated methods of transmitting that information. Establishes a portfolio of existing clinical vocabularies and messaging standards enabling federal agencies to build interoperable federal health data systems.
Discrimination Laws (Title VII, ADA, ADEA, and state discrimination laws)	All health care providers, and health care employers	It is unlawful to discriminate on the basis of one's race, ethnicity, gender, religion, disability, or age.

such as the Civil Rights Act of 1964 (Title VII), Americans with Disabilities Act (ADA), and Age Discrimination in Employment Act (ADEA).

Table 23.1 provides an overview and summary of the laws, which are discussed in more detail subsequently:

Medicare Prescription Drug, Improvement, and Modernization Act of 2003

The MMA (2003) contains numerous provisions relating directly or indirectly to the provision of chronic care or DM services. MMA requires the Secretary of the U.S. Department of Health and Human Services (DHHS) to develop a plan to reduce the cost of care for chronically ill Medicare beneficiaries providing for a phased-in development, evaluation, and implementation of the Chronic Care Improvement program. The Act includes provisions establishing testing sites for the CCIP. The CCIP is intended for Medicare beneficiaries enrolled in the traditional fee-for-service program to ensure access to chronic DM programs for conditions such as congestive health failure, diabetes, and COPD. The implementation of chronic DM programs for Medicare enrollees requires that the beneficiary participate in the care program on a voluntary basis

and be able to terminate participation at any time.

Under MMA–CCIP, chronic care can be provided either directly by the provider or through contracts with DM organizations, health plans, and consortiums. Programs that can demonstrate improvement in quality of care, beneficiary satisfaction, and achieve targeted cost-savings, will be able to expand chronic care programs in the future. Although this new legislation introduces new protocols and regulations for care management plans, the opportunities for DM activities seem to outweigh the restrictions.

Most legislated care management elements in the MMA–CCIP are consistent with widely used DM care plans as published by the JCAHO, NCQA, and DM Association of America (DMAA). These elements include:

- designated point of contact,
- self-care education for beneficiary,
- education for physicians and other providers,
- use of monitoring technology,
- the provision of information to patients about hospice and end-of-life care,
- demonstration projects to evaluate methods to improve the quality of care provided to beneficiaries with chronic conditions, and
- diabetes laboratory screening tests covered for individuals at high risk for diabetes.

With its numerous other provisions and amendments, the law brings about the most sweeping changes to Medicare law in over 40 years. One can expect more changes as data from the CCIP demonstration projects becomes available.

Medicaid and State Regulation

As of 2004, 24 states had passed specific laws pertaining to state-level or Medicaid DM programs, with 15 states mandating or requiring diabetes DM. States with *any* DM specific laws are: Alabama, Arkansas, Colorado, Delaware, Florida, Georgia, Illinois, Indiana, Iowa, Maryland, Maine, Minnesota, Missouri, Mississippi, North Carolina, New Jersey, New Mexico, Oregon, South Carolina, Tennessee, Texas, Utah, Washington, and West Virginia (NCSL, 2004). According to the National Conference of State Legislatures (NCSL), DM for patients enrolled in their Medicaid programs (NCSL, 2003). Some states have contracted with commercial vendors to provide diabetes DM to their Medicaid patients, while other states require Medicaid managed care companies contracting with the state to provide diabetes DM. Table 23.2 provides a listing of states that have passed legislation pertaining to Diabetes DM.

Federal Health Care Quality Improvement Act

The HCQIA was passed in 1986. In passing this law, Congress made five specific findings:

> (1) The increasing occurrence of medical malpractice and the need to improve the quality of medical care have become nationwide problems that warrant greater efforts than those that can be undertaken by any individual State.
>
> (2) There is a national need to restrict the ability of incompetent physicians to move from State to State without disclosure or discovery of the physician's previous damaging or incompetent performance.
>
> (3) This nationwide problem can be remedied through effective professional peer review.
>
> (4) The threat of private money damage liability under Federal laws, including treble damage liability under Federal antitrust law, unreasonably discourages physicians from participating in effective professional peer review.
>
> (5) There is an overriding national need to provide incentive and protection for physicians engaging in effective professional peer review. (See 42 U.S.C. §11101).

While the HCQIA does not specifically target DM, the HCQIA does include a requirement that health care providers who seek

TABLE 23.2. Summary of State Mandated Diabetes DM Programs

State	Type of program	Medicaid related?	Other diseases
Colorado	Pilot program funded through private donations	No	Asthma
Florida	DM provided by DM organizations under contract to state	Yes	Asthma, CHF
Illinois	Voluntary diabetes DM phased in.	Yes	Asthma
Indiana	Currently testing pilot program evaluating possibility of future DM programs	No	Asthma, hypertension, CHF
Maryland	Diabetes DM provided through six MCOs under contract to the state.	Yes	Asthma and high risk pregnancy
Maine	Diabetes DM required by Medicaid laws	Yes	
Minnesota	Diabetes DM required by Medicaid laws	Yes	
Missouri	Diabetes DM required by Medicaid laws	Yes	
Mississippi	Diabetes DM required by Medicaid laws	Yes	Asthma
North Carolina	Diabetes DM required by the Carolina ACCESS program.	Yes	Asthma and CHF
New Jersey	HMOs with DM services in place are available to enrolled Medicaid beneficiaries	Yes	Asthma and CHF
Oregon	State contracts with commercial DM vendors	No	Asthma and CHF
South Carolina	State contracts with Medicaid MCOs for adult diabetes DM	Yes	Asthma
Washington	Contracts with outside vendors of FFS Medicaid patients to provide diabetes DM	Yes	Asthma and CHF
West Virginia	Contracts with MCOs to provide Medicaid DM to high risk	Yes	Other high risk conditions

Source: National Conference of State Legislatures, August 2004.

privileges and credentialing through health maintenance organizations (HMOs) or managed care organizations (MCOs) will adhere to the standards of their peers and established clinical guidelines for disease prevention and management. The majority of MCOs and HMOs now use evidence-based guidelines to decrease deviations in health care services and outcomes (Gosfield, 1996). Both the NCQA and the Joint Commission require the use of evidence-based guidelines to become accredited or certified, and can require providers to adhere to such guidelines in order to maintain privileges and credentialing.

Benefits Improvement and Protection Act

Benefits Improvement and Protection Act legislation was designed to determine whether providing DM services to Medicare beneficiaries with advanced CHF, diabetes or coronary heart disease results in improved outcomes without increasing program costs. Those covered under BIPA received funding for the cost of prescription drugs required for beneficiaries enrolled in the program, in addition to their usual patient fees (HHS.gov, 2003). BIPA also enhanced reimbursement for services delivered via telehealth and modified

requirements of reimbursement eligibility of delivery and receiving sites. Eligible services include psychiatric services, professional consultations, and office visits (Mueller, 2001; AAFP, 2004).

Federal Health Insurance Portability and Accountability Act

Virtually everyone involved in health care and health research has been affected by *HIPAA*. This wide-sweeping privacy law was originally intended to lead to "administrative simplification" of health care transactions as well as protect patients' privacy and right to leave one employer for another without interruption in health insurance. Most health plans have found *HIPAA* to be anything but simple or simplifying. This discussion will focus exclusively on the sharing of private health information (PHI).

HIPAA and Business Associate Agreements. The Department of Health and Human Services issued the final *HIPAA* privacy regulations in December 2000 and these regulations have slowly been phased in throughout the health industry. Under most circumstances, health care providers are mandated to protect the privacy of patients' PHI. Ordinarily, patients also must consent to the release of any PHI and other health care providers, such as DM companies should be asked to sign a "Business Associate Agreement." A model "Business Associate Agreement" can be accessed through the Office of Civil Rights at http://www.hhs.gov/ocr/hipaa/contractprov.html#1. The DHHS Office of Civil Rights and Office of Continuing Review also have issued advisory standards clarifying that health care providers may share PHI for purposes of treatment, payment or health care operations (TPO), and that such information falls under the exceptions to "marketing." Certain common health care communications undertaken for "case management or care coordination for the individual or to direct alternative treatments, therapies, health care providers, or setting of care to the individual" are not "marketing" and may be shared subject to a business associate agreement and provided the PHI is used only for communication activities (OCR, HIPAA Privacy Guidance, 2003). The DHHS advisory opinion states:

> A communication is *not* "marketing" if it is made for case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual . . . . For example, under this exception, it is not "marketing" when: (1) an endocrinologist (such as when dealing with a diabetic patient) shares a patient's medical record with several behavior management programs to determine which program best suits the ongoing needs of the individual patient (OCR, 2003).

HIPAA and Contacts by the Media. Health care providers may be asked by media representatives for private health information on private or public record patients involved in a public event such as a police investigation. While police and fire personnel are not bound by HIPAA, health care entities are required to honor a patient's right to privacy. Members of the press may go to great lengths to get a story, including waiting in hospital hallways, calling patients' rooms, waiting outside facilities for patients or family as they are coming and going, and contacting friends at home or at work. Nevertheless, any health care provider with access to patient information may not share that information with anyone not involved in *treatment, payment or health care operations* (TPO) involving the patient. Most health care entities have adopted policies and standards for employees and medical staff to follow when contacted by members of the media.

Other HIPAA considerations:

- Privacy rule and cell phone use
- Communication regarding minors
- When case managers call and are unable to talk directly to a patient

These areas are murky and if not covered by state laws may have to be handled on an institutional basis through the establishment of policies. Some legal advisors do not feel health matters should be communicated

by a health provider by cell phone, while others argue that digital technology has advanced to the point where detection of messages and conversations is not possible. Communication directly with minors also should be a matter of policy consideration. Many organizations request authorization or consent to treat and communicate with minors as medically necessary.

Consolidated Health Informatics Initiative

This initiative was launched by the federal government in 2001 with a mandate to adopt integrated systems of exchanging existing health information between all federal agencies with health-related missions who are required to exchange their health information with other public or private entities. Federal officials believe that adopting systems that "speak the same language" will reduce error rates, improve patient safety and lower administrative costs. Thus, any agency that exchanges health-related information is required to adopt common messaging standards and acquire ability to transmit that information in a way that maintains its meaning. The Consolidated Health Informatics standards will affect health plans and DM programs by requiring the adoption of vocabulary and messaging adopted by the "Government-wide Health IT Governance Council." To date standards have been adopted in the following domains:

- Laboratory result names
- Messaging standards: includes scheduling, medical record/image management, patient administration, observation reporting, financial management, patient care
- Messaging standards: includes retail pharmacy transactions
- Messaging standards: connectivity
- Messaging standards: includes image information to workstations.

Discrimination Laws

Under Title VII of the Civil Rights Act, ADEA and the ADA, and most state laws, it is illegal for a health plan or DM program to discriminate against a health plan member or participant on the basis of gender, race, ethnicity, religion, age, or disability. In addition, several states prohibit discrimination on the basis of sexual orientation. These rights apply to all aspects of patient care, including DM. Many health care entities, as well as private and public programs require all new employees to receive training concerning patient rights and documented training of all employees at least annually. One example given by the Department of Justice illustrates the resolve of the U.S. Government to prosecute discriminatory behavior:

> "An HMO that enrolls Medicaid patients tells a Mexican American woman with cerebral palsy to come back another day for an appointment while it provides immediate assistance to others.
>
> This example may be a violation of federal laws that prohibit discrimination because of disability as well as laws that prohibit discrimination because of national origin. If you believe you have been discriminated against because you have a disability you may contact the Disability Rights Section at (800) 514-0301 (voice) or 800-514-0383 (TTY). You may also write to: Disability Rights Section, P.O. Box 66738, Washington, D.C. 20035-6738" (U.S. Department of Justice, 2004).

Role of Accreditation and Certification in Diabetes DM

Accreditation and Certification are two methods through which DM programs and individual providers demonstrate professional competence and attainment of excellence in meeting DM standards and improving quality of care. Several organizations provide accreditation, and Table 23.3 lists prominent accrediting/certification programs.

The National Committee for Quality Assurance (NCQA) began offering accreditation and certification for diabetes DM in 1991. According to the NCQA web site, a total of 21 organizations have been accredited by NCQA, and three are certified in disease specific areas. Nearly all health care organizations providing

TABLE 23.3. Accrediting Organizations

NCQA	National Committee for Quality Assurance
JCAHO	Joint Commission for Accreditation of Hospital Organizations
AAHC/URAC	American Accreditation Health Care Commission/Utilization Review and Accreditation Commission
ABQAURP	American Board of Quality Assurance and Utilization Review Physicians
ADA	American Diabetes Association
AADE	Association of Diabetic Educators

direct patient care are eligible, including: (1) DM organizations; (2) HMOs, MCOs, physician/provider organizations (PPOs), and behavioral health organizations; (3) Physician organizations and physician groups, (4) Hospitals, (5) Pharmaceutical or Drug companies; (6) Pharmacy benefit companies; and (7) Case Management or population management organizations (NCQA, 2004—brochure).

The NCQA requires health plans and health providers to evaluate and measure performance against at least two evidence-based clinical practice guidelines and demonstrate consistency with practice guidelines in utilization (Gosfield, 1996, p. 196). The *NCQA's DM Accreditation and Certification Program* principles and "best practices" in chronic care management are available online at: http://www.ncqa.org. The NCQA makes three accreditation options available for organizations depending upon the nature of the health organization and their operation. These three options are:

> (a) *Patient and practitioner oriented accreditation*. For those organizations that work with both patients and individual practitioners.
>
> (b) *Patient oriented accreditation*. For those organizations that work directly with patients but have no contact with practitioners.
>
> (c) *Practitioner oriented accreditation*. For those organizations that work only with practitioners and not patients. (NCQA's Disease Management Accreditation and Certification Programs, 2004: Accessed 4/20/04).

According to the NCQA, "[a]ccreditation is a rigorous and comprehensive evaluation process through which NCQA assesses the quality of the key systems and processes that define a health plan. Accreditation also includes an assessment of the care and service plans delivered in important areas . . . " (NCQA, 2004). Being accredited signifies that a health plan meets "best practice" guidelines, is in compliance with standards and protocol for disease specific care, and has proven, through data, that it meets the benchmarks.

The Joint Commission for the Accreditation of Health Organizations is primarily known for its accreditation of health care organizations that are in compliance with its standards. More recently, the JCAHO developed Disease Specific Care Certification Programs for health plans, DM service companies, hospitals, and other organizations providing health care. To achieve JCAHO certification, a DM program must show compliance with consensus-based national standards, use of those guidelines, and an organized approach to self-evaluation and permanence measurement. The JCAHO initial certification process requires an off-site and on-site evaluation. Thereafter, to remain certified, organizations must demonstrate that they are utilizing updated guidelines and complying with applicable standards (JCAHO, accessed 4/20/04).

The Utilization Review and Accreditation Committee is a nonprofit independent organization that provides accreditation and certification programs found in various health care settings. URAC provides 16 accreditation programs, including DM and case management. The organization also provides certification to vendors of DM services or claims management organizations—but who are not DM organizations. One of URAC's strengths is its recognized expertise in HIPAA privacy and security rules and implementation of Compliance Plans by an organization. The accreditation process

TABLE 23.4. Accreditation and Certification Organizations

Disease management accreditation program	Who is affected?	Additional comments
JCAHO accreditation	All health care organizations that demonstrate compliance with	JCAHO accreditation is institution specific—applying primarily to hospitals and in-patient care facilities.
JCAHO certification	Health plans, DM service companies, hospitals, and other health delivery organizations	Disease-specific certification diabetes certification requires implementation of the Wagner chronic care model
NCQA accreditation	Organizations, health plans, pharmaceutical companies.	Applies to health plans and organizations offering disease management. Disease specific
NCQA certification	Hospitals health plans (if accredited by NCQA)	Requires peer review and credentialing of physicians
URAC accreditation	All health plans. All health care providers who have access to PHI including electronic transmittal of PHI.	Institutions apply for accreditation
URAC certification	Vendors of DM support services	Applicable to vendors of electronic applications and hardware.
ADA (diabetes self-management certification program)	Individual health providers, health organizations, regardless of corporate status or all health care providers and health care employers	A certified diabetes educator certificate is awarded recognizing health care professionals with expertise in diabetes education, who has met eligibility requirements and successfully completed a certification exam.

begins with a self-evaluation proceeding to review, on-site visit, and final review by an Accreditation Committee. A listing of the URAC accreditation programs can be found at http://www.urac.org/prog.

The American Board of Quality Assurance and Utilization Review Physicians (ABQA-URP) is an organization of interdisciplinary health care professionals dedicated to providing health care education and certification for physicians, nurses, and other health care professionals. It provides accredited health education services and is sponsored by the American Medical Association (AMA), the American Hospital Association (AHA), and the Federation of State Medical Boards.

The American Diabetes Association and the American Association of Diabetes Educators (AADE) provide certification in Diabetes Self-Management Education (DSME). Both the ADA and the AADE support team management as an essential component of diabetes care. The ADA is a nonprofit health organization that provides diabetes research, information, and advocacy and whose mission is to prevent and cure diabetes and to improve the lives of all people affected by diabetes. The AADE is a multidisciplinary organization whose core objective is to advance the practice of diabetes self-management training as a fundamental component of health care for patients with diabetes.

Table 23.4 provides a summary of DM accreditation and certification organizations.

CONCLUSION

For a diabetes DM program to operate effectively, leaders and administrators must take the time to acquaint themselves with all laws and regulations as well as accreditation and certification requirements that may be

applicable. Failure to become familiar and follow applicable laws and regulations may not only impact payment for services, but also could subject your staff and organization to needless investigations and/or sanctions. This chapter has provided only an overview of the many laws that may be applicable to a given program. Those who operate DM programs would be well advised to invest the time and money in a full consultation with legal advisors who can advise more specifically about both state laws and changes in federal laws that may impact your organization.

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Economics

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The annual cost of diabetes (direct and indirect) rose from $98 billion in 1997 to $132 billion in 2002, according to a study published by the American Diabetes Association (ADA). The direct medical care more than doubled in that time, from $44 billion in 1997 to $98.1 billion in 2002. "Diabetes continues to be a huge financial burden on patients, their families and society, a burden that continues to grow in parallel with the obesity and diabetes epidemics in this country. We must all work to fight this disease that touches so many of our daily lives" (Overbay, 2004).

Diabetes is a costly disease. The economic impact includes the quantifiable direct costs of medical care, along with the more elusive indirect costs of lost productivity and the intangible social costs of pain and suffering. Studies in India estimate that, for a low-income family with an adult with diabetes, as much as 25% of family income may be devoted to that individual's care. For families in the Unites States with a child who has diabetes, the corresponding figure is 10%. The total health care costs of a person with diabetes in the United States are between twice and three times those for people without the condition (World Health Organization [WHO], 2002).

An estimated 30 million people throughout the world had diabetes in 1985 but by 1995, this number reached 135 million. Estimates indicate that the number will be closer to 300 million by the year 2025. The number of deaths related to the disease are on the rise and often related to cardiovascular issues. An estimated 9% of the total global population will die from the disease and complications; many are thought to be premature deaths when people are still in the work force (WHO, 2002).

It has been estimated that diabetes affects more than16 million Americans. Although those diagnosed account for only 3.8% of the United States population, the disease is responsible for 5.8% of all personal health care expenditures (ADA, 2002). Type 2 diabetes is a preventable disease and some practitioners now apply the modalities of eating disorder treatment to their patients. With the rising costs of health care, primary and secondary diabetes prevention become more significant.

LITERATURE REVIEW

Several studies on the costs of diabetes appeared in the late 1970s and increased during the 1980s. Comparison among the economic estimations is fairly consistent, but the methodologies and baseline years differ. Additional studies followed in the 1990s paralleling the reduced reimbursement for health care providers as the country moved away from indemnity fee-for-service health care plans to the managed care organizations. *Diabetes Care*, published by the ADA, is the leading journal of clinical research that includes a peer review process.

Currently published materials match disease management models and outcomes. A 2002 report by Jaan Sidorov, *Does diabetes disease management save money and improve outcomes*, presents a study comparing health care costs for patients who fulfilled health employer data and information set (HEDIS) criteria for diabetes and were in a health maintenance organization (HMO) Geisinger Health Plan (GHP) sponsored disease-management program with those not in disease management (Sidorov, 2002).

During a two-year period, 6,700 patients fulfilling HEDIS criteria for the diagnosis of diabetes for GHP, 3,118 (45.9%) who were enrolled in the disease management program were compared to 3,681 who were not enrolled. The following data were revealed:

- Program patients incurred $394.62 per member per month in mean total claims compared to $502.48 for those not in disease management.
- The mean number of emergency room visits was 0.49 per patient for program participants compared to 0.56 among the comparison group.
- Program patients experienced a higher mean number of primary care office visits: 8.4 per patient per year compared to 7.8 for nonprogram patients.
- Program participants experienced favorable HEDIS scores: HbAlc, lipid, eye, and kidney screening were 96.6, 91.1, 79.1, and 68.5%, respectively, compared to 83.8, 77.6, 64.9, and 39.3% for the other group.

These differences amounted to $104.86 per member per month or $1,294.32 per year. For the continuously enrolled patients in this study, a savings of $4,035,689.70 per year in fewer claims were paid compared to the nonprogram participants.

The Economic Costs of Diabetes in the U.S. in 2002 estimates the medical expenditures for the U.S. population with and without diabetes by sex, age, race/ethnicity, types of medical condition, and health care setting (Hogan *et al*., 2003). Health care use and total health care expenditure attributable to diabetes were estimated using etiological fractions and calculated based on national health care survey data.

This study found that the prevalence of diabetes increases with age and is higher among certain racial and ethnic minority populations. If diabetes prevalence rates remain constant over time, based on U.S. Census Bureau population projections, the number of people with diabetes could increase to 14.5 million by 2010 and to 17.4 million by 2020. The projected increases suggest that the annual cost in 2002 dollars of diabetes could rise to an estimated $156 billion by 2010 and to $192 billion by 2020. The actual costs could be even higher if the cost of health care rises faster than the cost of living or if the complications increase prevalence rates.

Among patients with diabetes examined in a study from the Agency for Healthcare Research Quality, 30% had two or more hospital stays that contributed to more than 50% of total hospitalizations and total hospital costs (the hospital cost per patient was nearly three times as high for patients who had multiple admissions). The researchers used 1999 Healthcare Cost and Utilization Project (HCUP) discharge data for five states to identify 648,748 individuals who had one or more hospitalizations listing diabetes. The likelihood of having multiple hospitalizations was higher for elderly Hispanics (37%) and blacks (34%) compared with whites (31%), as well as for patients covered by Medicare or Medicaid and

those living in low-income areas. The authors conclude that clinical and policy interventions should be developed to target vulnerable populations (Hogan *et al*., 2003).

DIRECT COSTS OF DIABETES

Direct costs are divided into direct medical costs and direct nonmedical costs. Direct medical costs are those resulting from the delivery of clinical services such as office visits, hospitalizations, medications, and health programs. Direct nonmedical costs derive from activities such as transportation and the value of time used for care.

From an economic perspective, the cost of a service is different from the price of that service. Price is a function of what the marketplace will bear (in comparison to the charges of other providers of the same or like service). Cost is a function of the multiple inputs required to produce the good or service-labor, materials, etc. Estimated costs are less, often times much less, than the common price. For example, the current cost of an HbAlc in rural Arizona is $7.80 but the price is $14.00. This difference often skews the comparison data available unless the distinction is declared.

Direct medical costs and indirect expenditures attributable to diabetes in the year 2002 were estimated at $132 billion by the ADA (Hogan *et al*., 2003). In a Position Statement, *Economic Costs of Diabetes in the U.S. in 2002*, direct medical expenditures totaled $91.8 billion including $23.2 billion for diabetes care, $24.6 billion for chronic complications attributable to diabetes, and $44.1 billion for excess prevalence of general medical conditions.

This tabulated breakout of the dollar total costs included institutional care cost of $54+ billion; hospital in-patient care of $40+ billion; nursing home care of $14 billion; and outpatient care cost of $20+ billion. It also included $10 billion spent in physician offices; $2 billion for emergency care; $146 million on ambulance services; $3+ billion on hospital outpatient care; $4 billion on home health care; half-a-billion on hospice care; $17.5 billion for outpatient medication and supplies; and $40 billion to indirect costs due to lost productivity. Senator Scoop Jackson's famous quip on the floors of Congress comes to mind, "A billion here, a billion there, soon we're talking about real money." For diabetes costs, the real money two years ago was $132, 000,000, and projections for the near and distant future suggest it will rise at an increasing rate.

INDIRECT COSTS

Indirect costs are largely related to a disability from the complications of diabetes rather than from the disease itself. For example, macrovascular diabetes such as retinopathy, nephropathy, and neuropathy are the leading cause of blindness, end stage renal diseases, and nontraumatic amputation (National Institutes of Health, 1995).

Indirect costs also include the value of changes in the work force or the worth of lost work time. Indirect costs are often discussed in terms of productivity. Working age individuals with serious illness will cost their employer more in terms of absenteeism and medical costs than those without serious morbidities. A 2002 study found that, in 1998, the employer's mean annual per capita costs were higher for all diabetes beneficiaries than for control subjects without the disease ($7,778 $\pm$ $16,176 versus $3,367 $\pm$ $8,783; $p < 0.0001$), yielding an incremental cost of $4,410 $\pm$ $18,407 associated with diabetes (Ramsey *et al*., 2002).

Another study examining the economic impact of obesity discovered that the cost of type 2 diabetes (attributable to poor weight management) was $12.7 billion in 1990 (Wolf and Colditz, 1994). This figure included some, but not all the costs of the associated lost productivity resulting from excess mortality, because many are difficult to quantify.

More recent studies have examined the costs to the individual and society of initial treatment, follow-up, and late treatment for type 1 diabetes. The costs of this disease peak at diagnosis and again with the development of complications. A consensus in the literature is that cost control is considerably more difficult for type 1, but that intensive patient education, shortened hospital stays, maintenance of good metabolic control, and mental health can reduce and contain costs (Simell *et al*., 1996).

SOCIAL COSTS

Intangible costs are the economic value of grief, pain, suffering, and other difficult to value costs for the patient and their families. Many people have no signs or symptoms until the disease process is well underway. Symptoms also can be so mild that they might not be noticed. More than 5 million people in the United States have type 2 diabetes and do not know it (National Diabetes Information Clearinghouse, 2004).

This study of 3,234 people at high risk for diabetes showed that a 5–7% weight loss can delay and possibly prevent diabetes. The low-cost intervention of diet and exercise for people with increased thirst, increased hunger, fatigue, increased urination, weight loss, blurred vision, and sores that do not heal can have a significant impact on intangible health care costs.

Advances, the Robert Wood Johnson Foundation (RWJF) Quarterly Newsletter, outlines 10 rules for health care reform—four of which seek to make the patient not the object of care but a care collaborator (RWJF, 2004). The concept of patient activation in relationship to the control of chronic illness is one of the keys to controlling the costs of health care.

RWJF's $6.3 million, two-program national Diabetes Initiative places patient activation in the forefront of the campaign to combat the disease. The social control of setting goals, acquiring the skills to meet those goals and trouble shooting as problems arise require the patient to actively collaborate at every stage (RWJF, 2004).

THE COSTS OF PREVENTING DIABETES

The Diabetes Prevention Program (DPP) has demonstrated that type 2 diabetes can be prevented (Diabetes Prevention Research Group, 2002). The cost analysis performed in the DPP revealed that the annual direct costs of the metformin and lifestyle interventions averaged $1,000–$1,400 more than the placebo group the first year and about $700 each year thereafter. The cost of identifying patients with impaired glucose tolerance and the intervention was less than half the direct medical costs for the three-year period of the study. The study also attempted to quantify the direct nonmedical costs. Costs were assigned to the value of physical activity per hour and another dollar value of leisure time.

According to a recent study, *Diabetes: Disabling, Deadly and on the Rise*, released in 2004, the many complications of diabetes can be prevented (Gerberding, 2004):

- *Eye disease and blindness.* Regular eye exams and timely treatment could prevent up to 90% of diabetes-related blindness; only 64.2% of people with diabetes received annual dilated eye exams in 2002.
- *Kidney disease.* About 42,813 people with diabetes develop kidney failure each year and over 100,000 are treated. Better control of blood pressure and blood glucose levels could reduce diabetes-related kidney failure by about 50%.
- *Amputations.* About 82,000 people have diabetes related leg, foot, or toe amputations each year. Foot care programs that include regular examinations and patient education could prevent up to 85% of these amputations.
- *Cardiovascular disease.* Heart disease and stroke cause about 65% of deaths among people with diabetes. The deaths could be reduced by 30% with improved care to control blood pressure, blood glucose, and blood cholesterol levels.

- *Pregnancy complications.* About 18,000 women with preexisting diabetes and about 135,000 women with gestational diabetes give birth each year. Risks can be reduced with screenings and diabetes care before, during, and after pregnancy.
- *Flu and pneumonia-related deaths.* Each year, 10,000–30,000 people with diabetes die of complications from the flu or pneumonia. They are roughly three times more likely to die of these complications than people without diabetes.

HOW TO COMPUTE THE DIRECT AND INDIRECT COSTS OF TREATMENT

The computation of either direct or indirect costs of the treatment of diabetes in a standardized form is difficult because the severity of the disease determines the treatment, medications, and services required. Differences also exist in categories such as the price of testing equipment (i.e., glucometers) and the supplies (test strips).

Prior to the 1970s, the United States health care system functioned primarily under an indemnity insurance payment mechanism, with separation of health care delivery and financing. Premiums were collected and providers were paid on a fee-for-service basis. This structure resulted in a lack of incentives for providers and consumers to use the health care system efficiently. The passage of the HMO Act in 1973 revolutionized health care delivery with the development of health maintenance organizations as a means of reducing costs. Managed care organizations have proliferated, capturing a large portion of the market share formerly held by indemnity plans. More than 43% of the population is insured by some type of managed care plan (Tobin and Godley, 1997). The Balanced Budget Act of 1997 provides Medicare coverage for diabetes and patient education.

According to some assessments, with the development of well-organized Diabetes Disease Management Programs, there is potential for providers to turn the programs from an expense center to a revenue center (Hall, 2002). An expense center is a business unit created to accumulate outflows of cash or other using up of assets or incurrence of liabilities during a period from delivering or producing goods, rendering services or other activities that constitute the entity's ongoing major or central operations. A revenue center is a business unit created to accumulate inflows of cash or other enhancements of assets or settlements of its liabilities during a period from delivering or producing goods, rendering services or other activities that constitute the entity's ongoing major or central operations.

This may be an optimistic view but we do know that optimal diabetes control is best achieved by a patient through a multidisciplinary approach from a team of providers and skilled workers (i.e., certified diabetes educators and behavioral health counselors). Cost savings are realized when the program outcomes are targeted and realized. Estimations indicate that such costs can be reduced at 4, 10, 20, and 30% for each 1% reduction in HbA1c from 7% to 10%, respectively (Gilmer *et al*., 1997). The standardized cost differences for 1% change in HbA1c for 3,017 adults with diabetes over a three-year period are illustrated by the following (Diabetes Care, 1997, pp. 1847–1853).

> Reduction in HbA1c levels, corresponded to a savings measured in standardized costs. For example, in patients with diabetes, only, a change from 10% to 9% HbA1c yielded a $1,200 savings. From 9% to 8%, the savings was $900; from 8% to 7% it was $600; and from 7% to 6% the savings was $400. The rates of savings are proportionally larger for patients with diabetes with hypertension, and more for patients with diabetes and heart disease. For patients with diabetes with hypertension and heart disease, a reduction from 10% to 9% yielded a $4,000 savings; 9% to 8% saved $3000; 8% to 7% saved $2,200; and 7% to 6% saved $1,500.

HbA1c level measurements are an excellent index of diabetes management in the patient, and an excellent feedback mechanism for the conscientious patient who manages

his or her diabetes by frequent blood glucose measurement. Cost reduction does not stop with glycemic control. Managed care organizations have discovered that enrollees with diabetes have higher rates of cardiovascular, eye, lower-extremity, and renal disease compared to other enrollees. Prevention and early treatment for these issues may translate into further savings.

The $132 billion-cost estimate is conservative and understates the true burden of diabetes. Diabetes prevention, early detection, intensive treatment, and control can contribute a significant cost saving to the overall health care system, to the patients, and to their families.

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25

Funding

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INTRODUCTION

Establishing a diabetes disease management program involves careful planning. Not only must the program be shaped from a thorough-needs assessment and program-design process, but it must also include a strategic plan for funding and sustainability. This chapter will provide information on funding strategies and sources that can be considered wherever an organization may be along this continuum of disease management.

FUNDING STRATEGIES

Funding strategies for a diabetes disease management program is considered a part of the program design, expandability, and sustainability. Therefore, the following key financial-related program issues must be considered when developing a financial plan.

1. Who is the target population(s) to be served? And what are their needs?
2. What are the local, state, and national trend analyses for reimbursement issues that will help position the program for short- and long-term potential?
3. What are the sociodemographic, economic, and cultural barriers of the target population?

After careful consideration of these aspects, a program design and funding strategy is developed. So often, programs are designed and implemented because they are given funding for a project. This can be shortsided if the "real" issue of needs, barriers, and long-term sustainability are not addressed. Too often, these programs are closed and the results can be a negative public image of the program and its affiliated organization. Therefore, a funding plan depends on several key elements:

- the target population to be served,
- the organization's incentives to provide a full or partial disease management program,
- potential partners with this program,
- the continuum of care that the program will encompass, and
- short- and long-term expectations, including sustainability.

The following steps will incorporate these key elements into a funding plan.

Identify the Target Population and Diabetes Care Needs

It is critical to identify the target population for the diabetes disease management program in order to begin defining funding strategies. The targeting process will provide direction for reimbursement and funding needs in both short- and long-term perspectives. It will also guide the health care provider systems of the disease management program in policy reform to address long-term financial sustainability.

If the target population has health insurance: then the following questions will be helpful

- What elements of diabetes care does the health insurance cover: provider visits, group visits, 1:1 or group education visits by nursing and dietitians, medication, supplies, and equipment?
- Does the plan require that educators be a Certified Diabetes Educator (CDE) and that their education program is ADA certified?
- Does the individual have a co-payment with each of these elements? If so, how much is the co-pay and could this be a barrier for the individual?

For example, one organization may only want to provide a specific service to an already-identified target population because of a reimbursement initiative. This may be a local hospital that has been approached by a health plan to provide a diabetes education class to the plan's enrollees. In this case, a cost analysis of the service would drive the charges and lead to appropriate contract and funding arrangements. In other words, what is cost of staff, materials and space . . . and then, how much does the hospital need to charge the plan?

An important issue of this case is if the plan decides to pass on some of the costs to the patient. If the plan requires that health educators are CDEs and that the program is certified by the American Diabetes Association (ADA), then the cost of the program will be much higher in order to maintain these standards. In some cases, the health plan may pass this higher cost onto the patient by requiring larger co-payments for the educational series. Then the question is whether most patients can afford—or feel that it is important enough to pay the co-payments. In some way, this could be a disincentive for the patient and the program may not be able to maintain a certain volume to offset their costs. Therefore, it is critical to work out these details upfront and include a clause regarding any type of reimbursement or co-payment changes.

In another example, a primary care clinic is offered a "pay for performance" incentive program by their local health plan. In this case, the clinic would receive a bonus for improved HbA1cs over time. Like the other organization, a cost analysis process would serve as the premise for implementing the type or types of proven outcome practice models such as the "Planned Visit" or "Group Visit" models discussed in the case studies and "Chapter 6." Again, detailed discussions must be addressed with the health plan prior to entering into any arrangements, since appropriate staffing issues could be a financial burden rather than a benefit.

If the target population is uninsured, then a different set of questions must be asked.

- What is the uninsured target population's diabetes needs? Is it for primary care, education, medications, supplies, and equipment?
- Are there specific cultural barriers that will need to be addressed in the funding strategies, such as bilingual providers, educators, and materials?
- Will the uninsured individual be able to pay some type of co-payment? If so, what will they be able to afford?

An uninsured population requires a more community-based focus where a provider organization or a provider coalition would take a proactive approach to influence the health of a community or target population. In this scenario, a population-driven model would include a funding plan that lays a foundation to progressively build a full service diabetes chronic care management system that addresses health promotion, disease

management, and acute care components. The outcomes could then be capable of influencing health policy changes as a result of demonstrated cost benefit analyses and clinical outcomes.

Define the Diabetes Disease Management System and Process

The first aspect to consider in funding a disease management system and process is what type of program and services will be implemented initially. It is important to determine the infrastructure that will be needed to support the program, i.e., manpower, publicity, information system software and manpower support, regular reports, etc. The following checklist provides general guidance in developing a budget and identifying funding support.

Program/Services

- What is the scope of diabetes program or services that the organization has decided to do?
- Can the program be broken down into separate components, i.e., manpower, equipment, supplies, etc.?
- Who is the target population?
- How will the revenue be generated?
- Does there need to be a research component? If so, does it require an Internal Review Board process?
- What kind of development effort is needed?
- Will the program/services need to go through a legal review (i.e., consent forms, HIPAA, etc.)?
- Are there other agency/community partnerships that should be considered?

Infrastructure Support

- What type of manpower is needed in the direct program/service delivery (nursing, dietitian community health worker) and indirect (i.e., Medical Director, clerical support)?
- What type of information must be collected?
- Who will manage the information (i.e., collect, enter, and manage the data)?
- Is outside/consulting needed?
- Is there a billing function involved? Who will do this?

For example, if the decision is to do diabetes education classes, then what are the data that need to be collected and does the organization have the software to support it. In most cases, a simple excel program will sufficiently track data, but will the data entry require an additional part-time or full-time position.

On the other hand, if the organization decides to take a more extensive approach and establish a full diabetes disease management system, then your organization may want to set up a registry with a more intensive effort at clinical data. What data are important to collect—clinical, financial? How will this data be transferred from the visit to the registry? Who will manage the registry? What type of reports will be generated, i.e., patient lists, aggregate data, etc.? All of these components must be factored into the funding program.

Equipment and Supplies

- Does the program/services require additional equipment (i.e., DCA machine) or supplies?
- How will patients receive their equipment and supplies?

Medications

- Does the program/services need to cover medications?
- Does the organization need to establish a Pharmacy Assistance Program? If so, who will manage the program?

These are just a few questions, but critical to consider when building a full diabetes disease management system and identifying potential funding sources.

Identify Funding Sources for Your Program and Services

Matching the funding source(s) with the program and services requires a knowledge of

		Partnerships		Grants			
Service	**SEHC**	**YWCA**	**CHN**	**Grant 1**	**Grant 2**	**Grant 3**	**Primary Care Funding**
				$25,000	**$25,000**	**$5000**	
1. Find and Assess	**X**			**X**			
- ICD9 Analysis	**X**	**X**					
- TriFit Diabetes Health Risk Assessment (SEHC Registration and YWCA Outreach)							
- Mobile Podiatry							
2. Stratify							
- Known	**X**						
- Unknown	**X**						
3. Treat							
a. Quarterly Clinic Visits per Protocols	**X**						**X**
HbA1c	**X**				**X**		
Glucometers	**X**						**X**
Glucometer Strips	**X**				**X**		**X**
Insulin						**X**	
b. Program Manager	**X**			**X**			
c. Clinical Educators							
Clinic Nurse				**X**	**X**		
Dietitian				**X**	**X**		
e. Community Ed							
Carondelet Community Classes			**X**				
f. Education Material	**X**		**X**	**X**	**X**		
g. Newsletter			**X**				
4. Train	**X**						
Staff	**X**						
Community Health Advisors (Promotoras)		**X**					
5. Track							
Registry	**X**						
Outreach	**X**	**X**	**X**				
Evaluation	**X**		**X**				

FIGURE 25.1. St. Elizabeth's diabetes disease management funding grid: Year 1.

"*who are the potential funders"* and *"what are they willing to fund."* It is helpful to develop a Funding Grid that breaks down the program. It can be drafted for a program that addresses manpower, supplies, publicity, etc. or it can be for a system illustrated in Figure 25.1.

The Funding Grid is a tool to help sort out what pieces of the program are being cover/reimbursed and what elements need funding. In some cases, one-time purchases such as equipment can be easily funded by local business or service groups such as the Rotary or Kiwanas Club. Other funding might include grants, private donations, special taxes, or fundraising events.

Here are a few options in funding. One key rule to remember: it is vital that the program goals match with the funder's goals. It is

a waste of time to submit to a funding agency who only wants to fund programs in a certain geographic location.

FUND SOURCES

Government Agencies

Government agencies grants can be broken into three major categories: local, state, and federal government grants.

Local: County and City Block Grants

These are provided by the city and county governmental entities, such as City Block Grants and health department grants. These grants may be for new services, equipment, building opportunities, or infrastructure. They have very specific guidelines requirements and may mandate attendance to a workshop prior to grant submission.

State Grants

State grants are available through the state's Governor's Office, State Health Department, or other State agencies. Again, these grants have very specific guidelines and reporting requirements.

Federal Grants

Federal grants offer a broad range of opportunities to support research, service, and program development. A resource list is provided at the end of the chapter to identify key government granting agencies. It is always helpful to have the support of your local state senator or representative to facilitate grant support. Contact their office and meet with them or their health assistant to build knowledge and support of your needs and efforts.

University (Co-sponsors)

University partnerships are important. Not only does the university offer a wealth of knowledge, but it also brings opportunities for student learning experiences that will translate into volunteer manpower to an organization. This has also been an avenue to obtain evaluation services and other research opportunities that can demonstrate the outcomes of your program and lead to quality improvement.

Another positive aspect in working with a university is the Student Work Study Program. This program pays students for their work experience and places students in identified organizations that they have an arrangement with. In return, the organization pays a small percentage of the student's salary.

Foundations

Foundations are another resource for funding programs and services. Many of the professional foundations, such as the National Kidney Foundation will offer grants for research. Foundations can be found at a local, state, or national level and are an important source of support for healthcare organizations. Here are a few tips to increase chances of funding from a foundation:

- Be sure to match your objectives with the foundations objectives. If the foundation is only funding programs in a certain geographic region, and your organization is outside of that region, do not waste your time.
- Establish a rapport early with the funding contact.
- Attend any meetings or conference calls that are offered by the foundation to discuss the grant requirements.
- Follow the guidelines closely and answer the questions that are asked.
- Use charts, graphs, photos, or other attention-getting features in your proposal.

Faith-Based Grants

Faith-based grants may be available through government and foundation sources.

Pharmaceutical

Most pharmaceutical companies offer a number of financial support. Many companies have an indigent medication program, which provides medications for free as long as a patient qualifies financially. Another funding opportunity with pharmaceutical companies is their grant program. Contact the pharmaceutical company directly or work with the local representative to learn more about their funding programs.

Diversify your Revenue Streams: "Don't Put All Your Eggs in One Basket."

When establishing your revenue sources, develop a variety of funding avenues. In other words, do not put all your eggs in one basket. It is imperative to create a reimbursement mechanism through patient fees and/or contracts with payers. If the program is dependent solely on one or two grants, what happens when those grants are finished?

Include Fundraising As Part of Your Program

Do not overlook the opportunity for fundraising to help support your activities. This can become a teambuilding experience for the staff and patients.

FUNDRAISING ACTIVITIES

Fundraising also should be considered. An organization can decide to hold their own fundraising activities or become the recipient of another agency's fundraising activities. For example, one organization has received an annual donation from a local professional women's sorority. This sorority holds an annual dinner-dance and auction. Their proceeds go to the indigent clinic for cancer care. Some examples could include the local medical auxiliary, the dental association, or the Student Nurses Association. Explore the community.

In closing, funding sources are available, but a strategic plan is critical to the long-term viability of the program. It is difficult to keep asking agencies to continue to fund the same services—most funders will not get involved if there is not a solid plan for sustainability. Therefore, the new program or service must be well thought out with their financial viability before seeking funding.

RESOURCES

Kenner, C., and Walden, M. (2001). *Grant Writing Tips for Nurses*. Washington, DC: American Nurses Association.

Web Resources

General:

Grants and Related Resources: www.lib.mus.edu/harris23/grants/federal.htm.
Grants Resources on the Internet: A Detailed Guide: www.library.wisc.edu/libraries/Memor.
Grants Web: www.infoserv.rttonet.psu.edu/gweb.htm.
Welcome to GrantsNet: www.grantsnet.org.

Government Grants:

HRSA Grants and Contracts: www.hrsa.dhhs.gov/grants.htm.
National Institute for Health (NIH) Guide Index: www.med.nyu.edu/hih-guide.htm.
NIH: www.grants.nih.gov/grants/.
Centers for Disease Control and Prevention (CDC): www.cdc.gov/od/pgo/forminfo.htm.

Foundations:

The Foundation Center: www.fdncenter.org.
Bill and Melinda Gates Foundation: www.gatesfoundation.org.
National Foundation Funding Sources for Rural Health: www.nal.usda.gov/ric/richs/foundat.htm.

Faith-Based Grants

http://www.whitehouse.gov/government/fbci/grants-catalog-index.html.

26

Tools for Getting Your Message Out about Diabetes

Marketing/Public Relations, Social Marketing, and Media Advocacy

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INTRODUCTION

Communication is an important element of change, whether at an interpersonal level (patient–doctor) or at a community wide level. Many prevention activities and public health interventions utilize marketing, communications, and public relations techniques to accomplish their objectives.

It is important to distinguish the basic differences among the models of communication used by health professionals. There are five general strategies of communication that are related to treatment and health promotion programs:

- Public relations and marketing.
- Social marketing.
- Media Literacy.
- Speaking Engagements.
- Media advocacy.

Although these strategies may look similar in the ways they are executed, they vary immensely in their approach, target audience, and effect.

Public Relations and Marketing

This strategy is perhaps the most familiar. The main objective of this level of communication is to *inform*.

The initial goal is to get the message to a specific or general audience that a program (or product) exists. The ultimate goal might be to recruit participants for a study, to inform patients of new services, to publicize an accomplishment, or to get name recognition.

For example, a health care provider of a diabetes complications prevention program might utilize public relations strategies to inform the community about the program. They may contact a local reporter and tell them about the program. The reporter then might interview key people and write a story; the story runs in the newspaper or is broadcast

on TV; and finally the provider's phone rings with calls from people interested in participating in the program. This example is public relations (sometimes known as media relations) at its best.

Using the same example, the health provider may decide that the program has a small advertising budget, so they contact the marketing departments of their local media representatives to find out how much an ad would cost. An ad is designed and placed and, in turn, phone calls result from people interested in participating in the program. This example illustrates the differences between public relations (or media relations) and marketing activities.

Generally, in public relations, the placement of a message is free (the time spent with the reporter is the only real expense). However, one cannot control how the reporter will write the story, how long the story will be, what quotes he or she will use, the angle of the story, or in what section or page the story will be placed.

The same is true of broadcast journalism. One cannot control where in the news report the story will run. It could be aired as a "top of the news" story or it could wind up being a "sound bite" or end of the news show "kicker." A person might even agree to do an interview for an evening news report and, because of another "late-breaking" news story, the story might air in the morning news show, which typically has fewer viewers, or none at all.

In most cases, you can get a general feel for the story during the interview with the reporter. But it also is okay to ask upfront what the angle is on the story. You also may influence the angle of the story if you contact the reporter initially and "pitch" an angle. Later on in this chapter, we will provide some tips on how to handle media interviews that will enhance the chances of your message being placed prominently in the news.

In marketing, you have greater control over the message and its placement; however, the cost of placing an ad can be high for newspapers and magazines, and in some instances, prohibitive for television. To maximize your investment, you will want to decide ahead of time who your target audience is and whether you want to use print or broadcast advertising. Another difference from public relations activities is that you would be calling the marketing/advertising department and speaking to an account executive instead of a reporter.

Creating brochures, special publications, and web sites also fall in the province of marketing activities. The costs involved in the production and distribution of these tools of marketing vary on size, colors used, quantity, dissemination method, etc. Again, deciding who your audience is and the best way to reach them will help determine how much investment is needed.

Public relations and marketing efforts can target internal or external audiences. Many large organizations (and even some smaller ones) create newsletters or other modes of communication to inform their employees about company news that affect them personally. This audience would be considered an internal audience. An organization may want to communicate items to an internal audience, but not want to publicize this information to an external audience (i.e., the general public). Examples of internal marketing items would be brochures, special publications, and internal web sites that are written to provide information specifically to employees.

Later in this chapter, we will discuss in detail the different tools of communication and marketing and show examples of press releases and public service announcements (PSAs). We also will discuss different marketing tools, such as brochures and web sites and considerations to take into account when using these.

Social Marketing

Social marketing is a term that borrows from marketing theories used in business and commercial settings. When used in

the prevention or health care setting, its major aim is to *change individual health behaviors*.

Communications at this level typically attempt not only to increase the awareness of a target population about a certain health issue, but also aim to motivate this audience to change. A social marketing intervention will sometimes utilize the four "P's" of marketing (product, price, placement, and promotion).

For example, the product might be encouraging people to start doing a 30-minute walk in the mornings or to quit smoking. The respective price of each product would be the target audience's time commitment of 30 minutes or of dealing with the symptoms of nicotine withdrawal. Placement of a walking or tobacco cessation program might consider the habits of people with sedentary lifestyles or who smoke and their exposure to media outlets. It may also include nontraditional placement venues like church bulletins, billboards, grocery store bulletin boards, etc. Promotion of either program will attempt to package the program in its most sellable form. In health promotion activities, it focuses on increasing the perceived benefits of the activity. The target audience then "gets" how important it is for their health, quality of life, and longevity to engage in a morning walk or to quit smoking.

Unlike commercial marketing, which is driven by the profit margins of an organization, social marketing is driven by the benefits obtained by a target group or "society" in general. Common examples of social marketing ads include antitobacco and antidrug TV ad campaigns geared toward teenagers, which attempt to steer them away from smoking or using drugs. Another common example is ads on how wearing car seat belts can save lives during an automobile accident.

Media Literacy

There are two main, distinct aspects of media literacy. The *first* looks at the capacity of individuals and communities to read and interpret media messages. Media literacy professionals that focus their work on this aspect develop interventions that train target audiences to interpret the messages they receive via the different modes of communication (i.e., newspapers, television, movies, etc.).

Interventions presented by this aspect of media literacy range from the development of basic skills to identify the frames in which messages are presented to the development of all-out conspiracy theories related to large media conglomerates aiming to allegedly brainwash consumers to a particular political view or product purchase.

For example, these interventions show how photographs are cropped by print and broadcast media to change actual events (e.g., a political rally that was attended by only 10 people will show a small group of people cropped tightly with the podium in front of them to give the illusion that the rally was well attended) or they discuss how large corporations mass distribute specialty items with their company logo and tag line. Others will discuss how sex and sex appeal are weaved into visual and text messages to sell a product.

Some of the more moderate interventions can be helpful for many target audiences. Interventions that educate younger audiences on how the media sometimes glamorizes, for example, smoking or alcohol consumption, may help this audience decide not to take up these habits to emulate media icons.

The *second* aspect of media literacy is a more practical one for health providers and health promotion professionals. It is based on the theory that effective health communications take into account the target audience's culture, age, gender, ethnicity, socioeconomic status, regional differences, and so on. The aim of health professionals that focus on this aspect of media literacy is to create communications that speak directly to the audience they are trying to reach.

Activities under this aspect include translations and back-translations (to ensure these items are translated without changing

their meaning) and conducting focus groups to evaluate the success of the messaging or framing of the message in relation to the specific characteristics of the target audience (gender, ethnicity, etc.).

Speaking Engagements

The participation of health professionals in speaker's bureaus, seminars, grand rounds, and conferences cannot be underestimated as an effective communications strategy. Often these speaking engagements offer an opportunity to raise awareness about a particular health or public health subject and to offer tips on better health management and disease prevention.

These engagements also offer an opportunity for networking or getting a person's name out as an expert in a particular subject. No group is too smal or too large to not be considered as an opportunity to get a message out there. Groups like the Kiwanis Club, the Knights of Columbus or other membership organizations are constantly seeking a speaker for their regular meetings.

To get the word out to these groups, some health organizations offer a directory of speakers and topic areas to community groups. Some organizations even have dedicated staff who take calls from community members seeking speakers for their groups and who match an organization's experts to these requests.

Media Advocacy

More and more, health professionals are moving toward media advocacy to effect change. Media advocacy is about applying pressure on policy makers and community leaders so that changes can occur at the policy or environmental level. The philosophy behind these efforts is that individual behavior changes need to be supported by the environment in which individuals coexist.

Media advocacy uses the same modes of communication as public relations, marketing, and social marketing, but the biggest difference is in its target audience: policy makers and community leaders. When gaining a placement (via advertising, news story, or editorial), media advocacy succeeds when *a new policy or a change in policy is suggested*.

Used effectively, media advocacy can reframe public debates; it can help shape new laws that protect the health of individuals (such as no-smoking policies in restaurants or in the workplace); and it can help push legislators, for example, to fund neighborhood renewal projects that include walking/cycling paths.

Media advocacy will play an ever increasing role in the fight against obesity in the United States and the related high incidence of type 2 diabetes. Some visionaries argue that media advocacy might ultimately help shape the environment we live in to make it *inconvenient* for people to engage in an unhealthy lifestyle.

However, it will probably take concerted communication strategies at all levels to effect necessary lifestyle changes in the fight against obesity and the higher incidence of chronic conditions in this country.

The reduction in the prevalence in smoking serves as a good example of how the different strategies of communication have been used effectively:

- At the public relations/marketing level are the news stories providing information about tobacco cessation programs, along with ads related to a smoker's helpline or cessation program.
- At the social marketing level, are the news stories and features about a smoker dying of emphysema or the TV ad campaigns targeting youth. Both of these levels aim at the individual's personal ability to change behavior, but in the first the aim is to inform and in the second, the aim is to encourage smokers to quit or youth to avoid starting the habit.
- At the media literacy level, are the many studies that showed, for example, how tobacco companies were specifically targeting women or youth and the consequent interventions that raised the public's awareness of these tactics. Another example that fits the media literacy level, are the

tobacco cessation ads directed at particularly "vulnerable" groups, like ethnic minorities and youth.

- At the "speaking engagements" level, are the countless of forums and public presentations about the questionable tactics of large tobacco corporations as well as those presentations elucidating the detriments to health caused by tobacco products.
- At the media advocacy level are the editorials on smoking and news features that discuss the importance of changing or implementing a policy (such as creating a smoke-free workplace or banning smoking in restaurants). Editorials and news features help influence legislators and other policy makers to sponsor bills or vote on a bill related to smoking.

By looking at the success of the efforts against tobacco use and the methods utilized, one can develop a similar communication strategy for any health intervention, including those focusing on prevention or management of diabetes or any chronic condition.

DEVELOPING KEY MESSAGES

One of the most important steps in developing effective communication strategies is figuring out exactly what you are trying to say. The identification of a few clear, key messages and repeating them as often as necessary is the best way to build an image campaign and is a rationale behind large companies developing "tag lines" such as "Think Outside of the Bun" (Taco Bell®) or "Can You Hear Me Now?" (Verizon®).

Without the selection of a few key messages (preferably one to three), you will confuse the audience you are trying to reach. You also may confuse the people who work with you. Often organizations or programs fail to inform their constituents of their goals in a clear, succinct manner. Key messages can serve as compass points for the direction of an agency or program and the efforts of the people who participate and work in these programs.

Key messages can be found in a mission statement or prime directive. Once key messages are developed, it is important to disseminate these to both your internal and external audiences.

Let us say that you decide that your key messages are:

1. We want to reduce the incidence of diabetes in the Hispanic/Latino population.
2. We are the only program in northwestern Atlantis doing this.

If a reporter were to call anyone on your staff, they should all be able to include these two messages as part of their responses.

Communication tools used by this program should contain this information somewhere. In press releases or brochures, for example, you can add a "tag paragraph" at the end that says "Program XXX is the only program in northwestern Atlantis aimed at preventing diabetes among the Hispanic/Latino population."

DRAWING ATTENTION TO YOUR MESSAGE

Once you have established what you want to say, the next step is to determine the target audience and the best way to reach them.

Who do you want to hear your message? Are you trying to reach a particular cultural group, such as Hispanics or African Americans? There are several sources of information that provide this information. A quick search on the internet or in the references section of a library usually results in a plethora of information that can help determine how to reach a specific audience.

Arbitron®, for example, is a company that specializes in compiling demographic trends for U.S. radio listeners. Available free online, you can download and print a report that will illustrate how many radio stations there are countrywide (more than 13,800 in 2004) and the listening patterns of Americans. The reports provide information that ranges from the general, such as

the time of day Americans listen to the radio most (during the morning commute time on weekdays) and least (while most people sleep, 12–5 a.m.), and the gender and age of listeners. Arbitron's 2004 "Radio Today: How America Listens to Radio" illustrates many details of the American listening patterns, such as people's favorite formats (teens prefer music that is "current" while "oldies is the format of choice for older baby boomers in the 45–54 age group, followed closely by Adult Contemporary/Smooth Jazz").

The report also can tell you items and details you would not normally expect to see, such as the fact that nearly "one-third of the people living in households planning to buy a new SUV are Adult Contemporary listeners." According to this report, 35% of this group also has gone in-line skating in the past 12 months and about 29.1% have eaten at a fast-food restaurant five times or more in the past 30 days.

Arbitron also offers reports that describe a specific demographic, such as Hispanics or African Americans. In the 2004 Edition of "Hispanic Radio Today: How America Listens to Radio," Arbitron notes that of the more than 13,800 radio stations in the United States, about 650 offer Hispanic formats. This report provides station trends, age of listeners, hour-by-hour data, overnight listening habits, listening locations, formats by region, favorite formats and more.

Another corporation that is dedicated to tracking audience habits is Nielsen Media Research, which is best known for its Nielsen Ratings. This company not only measures trends in television (network, cable, and satellite) and radio audiences in the United States and worldwide, but also measures Internet usage. Available on their web site are reports and CDs on viewing trends (which include anything from average daily viewing to VCR penetration in U.S. households), local market reports (ranging in cost from $60 to $1,300), and maps illustrating designated market areas (ranging in cost from $35 to $550).

For theme-specific reports that analyze the consequences of marketing practices and how these affect certain demographics, the Federal Trade Commission offers reports on violence in TV and films, national marketing practices, cigarette sales, advertising and promotion, weight-loss advertising practices, false claims on spam and more.

Similar demographic data exist for print readers. Most magazines and newspapers can provide, on request, a synopsis of their demographics. Local TV and radio stations can do the same. Tracking this information is a useful tool for media outlets when they sell advertising space.

After determining the audience you want to reach and how, the other question you need to ask is why do you want to reach this particular audience? Is there a call to action in your message? Do you, for example, want them to participate in a study or contribute money to a cause? Or is your program part of a social marketing strategy that aims to change the behavior of a target audience? For example, you develop a marketing campaign that encourages teenagers to steer away from using tobacco or to talk to their parents about safe sex. The answer to this question is a primordial component of a key message.

At this point, you should determine whether or not to disseminate this message using marketing or public relations techniques (or both). If you decide the former, then you need to get the attention of your target audience by designing a publication, web site, ad, etc., that will effectively speak to that audience (culturally, age-appropriate, literacy level, and so on). If you decide the latter, then you need to know how to get the attention of media representatives.

Marketing Your Message

If you decide to use a marketing strategy, the size of your budget will play a key role in how you get the attention of your target audience.

The resources you have on-hand (budget, creative staff, dissemination methods) need to match your objectives. For example, you cannot aim to change the lifestyle habits of all community members in the United States, when your program's budget supports a slight reduction in smoking in two neighborhoods of Southside Atlantis.

There are several marketing models you can use to ensure that you are spending your budget in the most effective way. Focus groups can help hone your messages and learn whether or not these messages are being heard the way you want them to be heard. Pretest and posttest evaluations also are useful or you may choose to hire a consultant or agency that specializes in evaluating the effects of program strategies.

In any program, it is important to have an evaluation component early in its design and implementation whether or not you decide to use marketing or public relations strategies. Measuring outcomes is key when you are seeking to re-fund a program, to evaluate its effectiveness, or to report back to the community.

Later on in this chapter, you will see a description of the different tools used in marketing (from print and broadcast ads to brochures and specialty items).

Getting Your Message into the News

If you decide to follow a public relations strategy, then your strategy shifts from selling the story directly to the target audience to selling your story to a reporter or news editor. In the news business, the reporters and editors are essentially the gatekeepers of information.

The following characteristics make a story sellable to a reporter/editor:

- The story needs to be *interesting.* Think of the old adage "dog bites man, no news, but man bites dog is news." The story does not have to be a cure for cancer, but it needs a new angle to it, like the "first" or "latest" in something. Often, finding an interesting statistic helps sell the story. For example, "one of every two Pima Indians over the age of 35 has type 2 diabetes" is a remarkable statistic that should prompt media coverage. It is also valid to say "the first XX in the northernmost region of Atlantis that specializes in nasal warts."
- The story needs to be *timely*, particularly if you are writing a letter to the editor or a guest editorial. For example, when former U.S. President Ronald Reagan passed away, headline news stories related to Alzheimer's disease permeated both print and broadcast media for a week. Angles on the story varied from the controversy and promise of stem cell research to how to recognize and test for Alzheimer's and available resources for people affected by Alzheimer's.
- Along with timeliness comes being *responsive* and *available*. Sometimes a reporter will call your organization to speak to an "expert" on a story they are working on. If your organization is large enough to have a public relations officer, reporters may call them directly. The public relations officer will call the experts at hand to see if they are available and willing to talk to the reporters. This benefits the "experts" because they are not receiving a call directly from a reporter without at least a few minutes to prepare for the interview. This also protects expert's time if they are not available to speak to the reporter. Public relations officers benefit the reporters because they will know who in the organization can best answer the questions.

Press Releases

The most common tool used for distributing information and garnering "free" attention about an entity's activities and accomplishments is the writing and distribution of press releases. Press releases often can result in a media story that carries an important public health message to a wide audience.

When writing a release, remember to be factual. Do not exaggerate the points of your story and do not use all caps or exclamation marks. Many smaller media outlets will sometimes print your release verbatim, so try to write it as if it were a news article. Read

newspapers to get a feel for what this writing looks like.

Keep press releases as short as possible. Editors and reporters do not have the time to read through lengthy releases. One 8.5 × 11 inch page is standard. Use a font that is at least 10 points in size. Use a letterhead for your release that has your organization name and logo, address and main phone number.

There are several types of press releases depending on the type of event/program you want to publicize. (See sample releases in "Appendix").

- A *calendar release* announces a specific event that will happen in the community, such as a health fair, a lecture, or a seminar series. At a minimum, this release should include:
  - Event Name (e.g., "Unhealthy Eaters Anonymous," "Diabetes Health Fair," "Cancer 5K Fun Walk/Run").
  - Time (when the event is held).
  - Location (where the event will be).
  - Fee or cost (if none, write "Free").
  - Contact information (name and phone number of where to RSVP or who to contact for more information about the event.) *Double check phone numbers before sending the calendar release out.*
- A *media advisory* is typically used to announce a press conference or an event that is closed to the public, but open for media coverage. Its format is similar to that of a calendar release and contains the same minimum information listed above. Print and broadcast media receive thousands of press releases a day. Placing the words "Calendar Release" or "Media Advisory" at the beginning of the release will quickly tell the recipient whether the release needs to go to the calendar editor or whether it is a story that needs to be assigned to a reporter.
- A *general press release* is the most commonly used format used. It generally has six parts:
  - A *headline* that summarizes what the story is about.
  - A *date* (date of when the press was written/released to the media *and, if applicable*, a date of when an event that is the subject of the release happened or will happen) or a *dateline*, usually in the format of "date (City, Abbreviation of State)", e.g., Feb. 9, 2004 (Paris, TX).
  - *Contact information* of the person reporters can call for more information about the subject of the release. Sometimes releases will have two contact numbers, one for the public relations representative who wrote the release and another for the person to contact who knows more about the subject of the release. For example, a release about a new cancer clinical trial seeking participants will list the number of the person to contact if reporters would like to interview the principal investigator on the study and another number for the general public to call if they wish to participate in the study. *In all cases, double-check phone numbers and e-mail addresses, before sending the release out.*
  - A *lead paragraph* (the first paragraph) that summarizes the story. Headlines are typically written from the lead paragraph. If possible, summarize the "what, when, where, who, why, and how" in the lead paragraph. If possible use a "hook" in the lead paragraph, such as "study reveals for the first time, the benefits of cinnamon in the control of diabetes."
  - The *body* of the release elaborates on the "what, when, where, who, why, and how" and provides additional background information. Unlike fiction or essay writing, where the writing builds up to the most important information and draws the reader in slowly, a press release is written with the most important information first. This is known as an upside down pyramid structure of writing. The reason releases (as well as the news stories that journalist write) are written this way is because in trying to fit the story on a page, an editor will cut the last paragraphs first. *Repeat contact information at the end of the release.*
  - *Tag paragraphs* are an optional part of releases and are included as part of a general image campaign for your organization or program. These are usually one to three sentences that summarize the goals of your program or organization and serve as a background to the reporter about your entity. Typically, the font is italicized on the tag paragraph to distinguish it from the rest of the release.

Center the characters "—MORE—" on the bottom of the page if the release continues. On the bottom of the last page, center the characters "—30—" or "###" to indicate the end of the release. These symbols are an industry standard and are expected by most reporters and editors.

After sending a press release out, it is a good idea to follow up with a phone call to ensure they have received the release. During this call, simply state who you are and that you are calling to make sure they have received the release. Use a "soft-sale" approach when you do this. Usually what will happen is that they will search through the pile on their desk to see if they can find the release. If they cannot find it, offer to fax or e-mail it to them again. If they do find it, just say something to the effect of "Great! Just wanted to make sure you got it."

You may want to add an encouraging line, such as "I personally was impressed with the results of this study and I just wanted to make sure you knew about them." But try to steer away from a hard sale approach or ask them if they will cover it. Whether a story gets covered or not is usually discussed in early staff meetings. Stories that are "fast-breaking" get top priority, followed by interesting stories. Often, those "interesting stories" do not pan out and reporters scramble to fill the news with quick, easy stories. Often, this is where your press release will come in. Forcing an answer early from an assignment editor might preclude your story from being placed. Your phone call, however, succeeded in bringing attention to your release and it also tells them you have an "expert" in place if they should need one.

Phone Calls or E-Mails

Writing a press release and sending it out to several media outlets may result in one or two of these outlets picking up the story (sometimes running it verbatim) or, more often, a reporter calling you to develop a more in-depth story. Mass mailings of press releases are appropriate if you would like coverage about a specific event or about a noteworthy achievement by one of your program members (i.e., an award or some other special recognition).

However, if you want to encourage a larger feature or human interest story, you may decide to target specific newspapers, TV stations, or reporters and contact them personally. Sometimes, providing them with an "exclusive" on your story increases your chances for getting a bigger placement of your story.

Making phone calls or sending a personal e-mail to a specific reporter also may result in a more in-depth human interest story, because by talking to the reporter one-on-one you might be able to better illustrate the importance of your story or show the reporter the "passion" behind a story that cannot be conveyed on a release.

E-mails do not garner the immediate attention that a phone call will, but they are less intrusive on a reporter's time and often are the preferred method of contact. If you decide to call or e-mail a reporter, be sure to find out which method they prefer.

Make sure you know about the topics that are covered by the reporter you call or e-mail. If your story has a business angle, you should call or e-mail a business reporter. If it is about health, talk to a health reporter. Nothing frustrates a reporter more than to get story ideas that are outside of their coverage area. If the media outlet focuses on reaching a specific audience (Hispanics, Catholics, teenagers, sports enthusiasts, etc.), make sure that your story will interest their readers.

It also helps if you have read any recent articles written by the reporter or watched/listened to any of their recent broadcasts. You can even pitch your story as a follow-up to one of these stories. Showing reporters that you are familiar with their work not only is flattering to them, but also makes them more willing to listen to what you have to say.

Use phone calls and e-mails sparingly. Overwhelming a reporter with frequent phone

calls and e-mails can be a turnoff to them and can place your credibility in jeopardy.

Press Conferences

Press conferences should be used at a minimum and only when a story has elicited enough media interest that all parties involved benefit from a news conference.

Sometimes the number of media calls received drives the need for a press conference because it would be difficult to arrange for separate interviews. For example, a patient who has received the latest state-of-the-art artificial heart transplant or a celebrity patient may get a lot of requests for interviews from the media. Arranging a press conference, during which time many press members can interview the patient at the same time not only facilitates the interview process, but might be less cumbersome for the patient and physicians.

Press conferences also are typically used during a crisis, particularly when it is important to get the same information out to a large group of media representatives and it is fast-breaking news. Examples of these could be a large-scale disaster, a kidnapped child, corporate wrongdoing, or announcing study results that show sizeable implications for the health of a certain population (e.g., the use of hormone replacement therapy and its potential negative side effects on women).

Crisis Communication Plan

Every organization should have a crisis communication plan that outlines what to do in the event of a disaster or crisis. When crises strike, swift and precise communications—often in the midst of chaos—are demanded by the media (who are acting on behalf of the public). One of the most important components of a communication plan includes identifying a key spokesperson *and* a backup spokesperson in case this person is not available.

To develop a crisis communication plan, you may need to bring together key people of your organization to "dream up" worse case scenarios and response plans. There is no way to anticipate all crises that may befall your organization. It could be a major accident, a medical error, a disgruntled employee threatening to harm or harming other employees, an accounting fiasco or other corporate wrongdoing, an infectious disease and more. Depending on the organization, simply practicing for the worst-case scenario may be enough or you may have to develop a manual containing a specific crisis communication strategy.

TYPES OF MASS COMMUNICATION/MEDIA

Each media type is driven by different basic principles. The following section will describe the different types of media by medium (i.e., broadcast, print, and Internet) and include tools used for both marketing and communications.

Broadcast Media

At its most elementary level, broadcast media, which includes television and radio, is about filling time slots with news and advertising. The biggest limitation to this medium is time; hence, communications are short and to the point. Radio news stories usually are 15–30 seconds long; TV news stories are usually between 1 and 3 minutes long. News stories on public broadcast stations typically run longer and are more in-depth, but have a smaller audience.

TV and Radio News

TV and radio reporters are always on the hunt for that important "sound-bite" that is going to make their story. Reporters need "experts" in the fields of research, particularly in the area of health, to add credibility to their stories.

Reporters value experts who make themselves available on short notice for an interview. They will go to these experts first when working on the next story. As noted earlier, one of the most important things to remember when working with reporters it to make yourself available.

Like print news, topics for broadcast news stories can include human interest features and commentaries. Some stories are a complete "package" that include reporter introductions and segues, sound bites from experts, and "b-roll," which are action shots used to illustrate a story (people walking down a hallway or street, walking into a lab, running, etc.). Because of the nature of the medium, TV news stories demand that interview topics be visual. TV reporters and producers are constantly seeking innovative settings for interviews (office interviews with a bookcase in the background are simply overused). And they like any kind of props or graphics you can provide to illustrate the story.

Unlike the print media, which is open to printing guest editorials, broadcast media rarely offers an opportunity for commentary from people who are not staff members. Instead they offer a sundry of formats for round-table discussions or on-set interviews/talk shows.

Public Service Announcements

Many radio and TV stations assign a certain percentage of their air time, usually not during prime time, to designated charities and public events. Each radio and TV station decides how to allot this differently. Some take requests from area agencies year round and others decide what fund-raising events or causes they will sponsor for a year.

Typically this sponsorship includes the production of a PSA. A writer, a narrator and voice "talent" are required for radio PSAs. A writer, cameraman, "talent" (i.e., actor), and a narrator are required for a TV PSA. Sometimes the stations will donate all of these roles and other times, they will expect the agency to provide them.

Both radio and TV PSAs are usually kept under a minute in length, with radio PSAs sometimes being as short as 15 seconds.

Larger fund-raising organizations, such as the American Diabetes Association or the American Heart Association, will produce PSAs and distribute them to television and radio stations nationwide. Whether or not they get aired depends a lot on whether or not the associations buy air time. Although not common, some stations will air the "canned" PSAs to fill time slots that were not successfully sold to a business for advertising.

Before investing the time and expense of producing a PSA on your own, you should meet with target broadcast station account executives to discuss the availability of air time and their willingness to sponsor these. Before you meet with them, however, determine your target audience, because a station might agree to sponsor your PSAs, but run these at 3 a.m., when most of your target audience is asleep.

Video News Releases

Video news releases (VNRs) differ from PSAs in that they are preproduced news stories that are packaged and distributed by agencies to television stations nationwide. VNRs are the video version of a wire story and are usually about "nonbreaking" news, such as a health topic or business tip.

Agencies that produce VNRs will cover the cost of producing and distributing these stories in exchange for interviewing the "experts" of your organization. If a local TV station airs a VNR, they pay a fee to the agency. For the agency, it is a way of making money. For the TV station, it is a way to fill air time, and for you, it is a way to get free publicity potentially on a national level.

The only consideration about using VNRs is that your story has to be something that affects a national audience. A story about a new vaccine against the common cold would

interest them, but a story about a local health fair, would not.

Radio News Releases

More affordable to produce and distribute are radio news releases. These are tape cassettes or compact discs with two to three radio news reports and include narration, interviews, sound bites, and scripts. Radio stations that are short on reporters (or have none) use these to fill air space. These can be sent to local, statewide, or national radio stations.

Considerations to take into account when producing radio news releases is having access to recording and sound editing equipment or a radio booth as well as cassette and CD reproduction equipment. As with VNRs, it is difficult to track the placement of these stories.

Television and Radio Advertising

Radio and television advertising can be very expensive, especially on national networks. Running a television ad during the Super Bowl, for example, can cost you millions for a few minutes. However, purchasing air time on local radio, television stations, and cable networks can be more affordable.

Most organizations that purchase television and radio ads work through an advertising agency. Using an advertising agency may seem to add to the costs, but in the long run, using good agencies will save you money and your ads will have a larger effect on the audience you are trying to reach.

Advantages to using advertising agencies include they:

- Typically have a creative department that can come up with an ad concept and produce these in-house.
- Know where to find the talent for these ads.
- Have established relationships with local broadcast stations.
- Know what media outlets to use when trying to reach a certain demographic group.
- Know when to schedule the ads and how often.

Print Media

At its most elementary level, print media is about filling space with news and advertising. The biggest limitation to this medium is space; stories have to fit within the columns of an assigned page.

Newspaper and Magazine Articles

Most articles in print are considered straight news stories (i.e., articles that report the news) or features (i.e., articles that have a human interest angle and are written more in-depth about the subject). Straight news stories contain factual information and cover the "what, when, where, who, why, and how" questions that reporters are trained to ask. Human feature stories have a more intimate dimension but still try to remain objective. Straight news stories are also considered "fast-breaking," meaning that they are happening at the moment or in recent time; whereas human feature stories typically have a timeframe, but are not necessarily timely.

Opinion Editorials/Letters to the Editor

Opinion editorials and letters to the editor are excellent tools for disseminating an important message to a newspaper's or magazine's readership. Placement is not guaranteed, but one does control the message, although not to the extent of paid advertising because editorials are still edited by the newspaper or magazine.

Both opinion editorials and letters to the editor should address timely issues. Direct reference to a recent event or article

greatly enhances the chances of being published. Word counts should be kept to up a maximum of 250 for letters to the editor and 500 for opinion editorials.

Also remember to keep scientific and technical jargon out of submissions to newspapers. In other words, write the editorial or letter in layperson's terms.

Most newspapers also will publish their own editorials that represent their official point of view. Not many people know this, but a group or an individual can arrange a meeting with the editorial board and "pitch" a particular point of view. The editorial board will then discuss the topic and collaborate on an editorial that agrees or disagrees with the group's or the individual's point of view; or they may decide to not write one on the topic altogether.

Newsletters

Newsletters are typically used for an "internal" audience. The mailing list usually includes people who have been identified as being part of a certain group. Examples include alumni, resellers, program participants, consumers, company employees, financial donors, sports enthusiasts, hikers, travelers, seniors, Catholics, and many more.

The cost of producing newsletters varies depending on the number of pages and if color is used. Many organizations will save costs by producing a one-page, double sided newsletter that is photocopied on $8^1/_2 \times 11$ inch paper. A larger version can be photocopied onto 17×11 inch paper and folded, effectively creating a four-page newsletter.

A larger budget will allow more colors, ranging from a "spot" color to four-color newsletters.

If you decide to go with a commercial printer, the number of pages in a newsletter is often determined by how the offset presses cut, collate, and fold these. Typically, the number of pages grows in sets of four (i.e., 4-page, 8-page, 12-page, 16-page, and so on). Talk with prospective printers about the best format to use.

Print Ads

Subscriptions account for only a small percentage of the revenue made by newspaper and magazines. Profits are made by selling advertising space. This also is true for broadcast media, however, the space a newspaper or magazine has is more flexible. You cannot create more time, but you can create more pages. Because of this, the number of pages and space available for news stories is often determined by advertising.

Fees for ads are determined by its size and calculated by columnar inch. Some print media will provide fees for 1/8-, $^1/_4$-, $^1/_2$- or full-page ads. Most newspapers and magazines offer a discount to nonprofit organizations, requiring only that these organizations show them a copy of their 501(3) (c) status.

Most print ads need to be provided as "camera-ready art," meaning that they are in the appropriate dimensions and are clean enough to be photographed for printing.

Some newspapers and magazines will have in-house creative departments that can create ads according to your needs. If you have the budget for a larger print ad campaign, you may want to work with an advertising agency. They can be invaluable in helping come up with an ad concept, design and production, as well as having an effective distribution system in place.

Other Print Media and Communication Tools

There is a wide range of print media options for disseminating your message, including brochures, postcards, business reply cards, flyers, and posters.

At some point in the design of a publication you will need to consider the specifications in Table 26.1:

TABLE 26.1. Print Specifications

Specification	Choices	Comments
Paper grades (listed choices are the most commonly used)	Bond	Bond paper is commonly used in photocopy machines and for 8.5 × 11 business letters.
	Coated	This paper literally has a coating on in that improves ink absorption on the page. Choices include a dull or glossy coating or coating on one or both sides of the paper.
	Text	This paper offers many choices of different colors and textures and is commonly used for flyers, brochures, and pamphlets.
	Book	Typically used for textbooks and books. This paper is cheaper than text and offers a wider variety in weight and bulk.
	Cover	Coated and text paper are made in heavier weights in matching colors and are used as a cover sheet for brochures, pamphlets, reports, etc.
	Newsprint	Used mostly for printing newspapers.
	Lightweight (e.g., onion)	Specialty grades used for bridal announcements, etc. Because of their weight, these papers can save on postage.
Colors	Black or one color	One color printing should cost the same, whether it is black or another color.
	One color (usually black), plus spot color	Spot color means that a different color is used in specific elements on a page (e.g., the headings, borders, boxes, lines, or other graphic elements). The color on these elements will be different from the text. Two plates (one for each color) are needed for spot-color printing.
	Four-color (cyan, yellow, magenta, black)	Four-color printing, which is the most expensive, involves the use of four industry hues: cyan (reflects blue and green light, absorbs red light), yellow (reflects red and green light, absorbs blue light), magenta (reflects blue and red, absorbs green light), and black. *Note*: In addition to charging a fee for each plate (one for each color), some commercial printers will charge a nominal fee (known as a "press wash" fee) for when they clean the printing equipment between ink colors.
	Screens	Screens are an area on a page (usually a box shape or a silhouette) that uses a color that is scaled back to allow text to be printed on top. A 10% screen reflects black text well; a 50% or higher color screen reflects reverse-text (i.e., white text) well.
	Half-tones and Duo-tones	In addition to four-color printing, photographs can be printed as a black and white half-tone or by using a color and black, known as a duo-tone. Printing a half-tone or a duo-tone is more cost effective than printing a four-color photograph.
Paper size	Standard and custom	Printers offer a variety of sizes for publications, ranging from standard sizes to custom sizes. Standard sizes are typically more inexpensive than custom sizes.
Folds	Standard and custom	Folds are used most commonly in trifold and accordion type brochures. If you use a heavy stock, such as a cover paper, the paper might need to be scored before it is folded automatically. Some printers will charge an extra fee for scoring.
Binding	Saddle stitch	A saddle stitch is a staple along the center fold of a publication. The back of the staple is on the outside cover. The pages and a cover are folded and placed on a saddle. It is then stapled two to three times on its center fold, making a booklet.

	Side-stitch	When a publication is too bulky for a saddle-stitch, a side-stitch can be used. A side-stitch is basically two to three staples along the left edge of the pages, binding them together. Sometimes a tape adhesive is used to hide the staples.
	Spiral	There are two types of spiral binding. In one, a spiral wire is woven through several holes down the side of a publication. In another, a binding machine makes many rectangular holes in a line along the left side of a publication. Then a plastic spiral is opened with the same machine and its "teeth" are fed through the holes.
	Adhesive	A glue is used to bind all the papers along the left-hand edge. To reinforce the edge, a cloth tape is usually added.
Pockets and inserts	Custom, including business card size	A feature in some publications, including folders, is pockets in which inserts can be placed. Generally, the pockets will require trimming, scoring, and folding. Inserts for the pockets can be printed at the same time or as needed. A popular design is the use of step or staggered inserts, these are different sizes of paper that follow the same design as the brochure or folder and whose headings are staggered. The biggest advantage of using step inserts is that it increases the shelf life of the publication. If an update is needed, you simply update the relevant inserts, pull the old ones, and replace them with the new ones. A considerable disadvantage to these is that as years go by and some items are printed more than once, you wind up having an uneven number of different inserts. Having a need for eight inserts of different sizes and quantities may cost you more in the long run than simply updating and printing an entire eight-page brochure. Another common specification is cutting corner lines to insert a business card. These cuts are fairly inexpensive and the advantage is that anyone can place their business card in these precut slots.
Perforations	Custom	Many publications will have a card with a call to action on it. Commonly you will see a dotted line with scissors telling a person where to cut the card, so they may fill out a form and return. Some people argue that asking a person to find a pair of scissors may deter them from sending in the card. Commercial printers can add perforations along the edge of the card, so that all they would need to do is tear along the edge. It also helps if you add a business reply card on the back with a postage permit. See more on business reply cards below.

Brochures

A general brochure outlining the mission, history, programs, and contact information can be used for providing orientation and information about your organization to prospective customers, program participants, students, benefactors, or the general public. Brochures can be designed in all shapes and sizes. The most common brochures are trifolds, named that way because they have three panels (front and back). Technically, however, they only have two parallel folds in them.

Brochures can be simple black and white copies, black and a spot color or full-fledged four-color glossies, depending on the size of your budget and the quantity you need. You may decide to use photographs, graphics, or tables to better convey your message in a succinct manner.

Large print runs (500+) will sometimes give you a better price break than if you print a short run (<150). Get at least three estimates from different printers to get the most cost-effective rate. You will be surprised to see how much these estimates vary on type of paper, colors and coatings, number of folds, binding, and custom specifications (such as inserts, ragged edges, perforated cards, etc.).

Make sure the date of when you produced the brochure is printed on it somewhere inconspicuously (in month/year format). Also include an address and phone number of where readers can get more information about your organization.

Flyers and Posters

Flyers and posters are typically one-sided announcements. Flyers can be useful to hand out at different locations and can be used to announce programs or special events. Posters and flyers can be placed on walls or bulletin boards in establishments that allow it.

Keep the text on flyers and posters as simple as possible and with the most important information written in a succinct manner. Make sure you have a phone number and address on the flyer or poster where someone can get more information or respond. *Double check phone numbers on flyers before distributing these.*

Special Publications

You may decide to create a publication that serves only an immediate need, such as an invitation card with an RSVP card for a special event or a direct-mail advertising piece. The design and distribution of these will vary on what you are trying to accomplish (subscription renewal, meeting reminder, gauge interest in a program, etc.). The cost will vary depending on the design and the quantity.

Business Reply Cards

Some brochures, flyers, newsletters, etc., may contain a business reply card insert. These cards usually have a form on one side and the address of your organization preprinted on the other side, along with a postage permit number and bar code, allowing the recipient to fill out the form and send it back to you without costing them postage.

Most direct-mail campaigns and business reply cards strategies expect no more than a four to six percent return. Phone call follow-ups will often generate more responses, but are labor intensive.

Public Advertising

Billboards and ads on park benches and buses can be a cost-effective form of advertising. Locations of billboards and park benches will affect the cost as well, with busier streets having the highest fees. Some billboard companies will donate the space of a billboard (usually the locations with the least traffic) but will request the nonprofit event or agency to pay production costs.

Specialty Items

Sometimes just getting the logo, phone number, and tag line of your company or program out there is the most cost-effective marketing. Some of the most popular specialty items include pens, water bottles, sticky pads, key chains, and note pads. Price breaks are offered as quantities go up. There are numerous corporations that offer specialty items and who are willing to send customers catalogues where one can pick out a favorite specialty item.

Internet and E-Mails

A whole new world of public relations and marketing opportunities has opened up with the advent of Internet and electronic messaging technologies. In the last few decades:

- Newspapers and magazines have created online versions of their publications, most still

maintaining the production and distribution of the paper versions as well.

- Television and radio news, along with wire news (such as Associated Press and United Press International) have created online news web sites.
- Many organizations have created e-news and e-magazines that are electronically distributed via an electronic mailing list of subscribers.
- Organizations have created their own web site, many of them replacing newsletters and brochures and thereby saving them money while still disseminating necessary information.

Internet

The advantages of using web sites are many, including

- More flexibility in using color, photographs, and graphics. It really does not matter how many colors you use on a web site, it will cost you the same. However, do keep web sites as simple as possible. If your web site is memory-intensive, some users, especially those who access the Internet via dial-up modems, will have trouble loading the pages of your web site onto their computers.
- The possibility of updating information in a matter of minutes.
- Unlimited number of subsites/web pages. Unlike a publication, which is limited in size by budget constraints, a web site can have an unlimited number of subsites and options. The only real limitation is the memory capacity of the server on which the web site resides.

Disadvantages to web sites include:

- Vulnerability to outside computer hackers. Be sure to include strong firewalls and update virus detection software frequently to protect the server and other computers.
- Many organizations underestimate the labor and skill involved in creating and maintaining web sites. It often is necessary to dedicate personnel to maintain and continuously update the information on a web site.
- Despite its popularity, Internet access is still limited. If your target audience falls in a group marginalized by the latest information technology, it would not make sense for you to build a web site.

E-News

There are at least two options for "e-news." One is to send out memo-like announcements on an as-needed basis to a listserv. The second is to compile and format announcements into an e-newsletter that is sent to a listserv on a monthly or other regular basis.

Advantages to the first are that it is more timely and specific to an issue. A disadvantage is that recipients may tire of receiving many e-mails they feel they have no time to read.

Advantages to the second option include a concise way of communicating news in a semi-timely fashion (not as timely as individual e-mail announcements). Disadvantages include that it requires more time to format and has a high risk of repeating already disseminated information (i.e., high risk for duplication of effort and e-mails). To avoid duplication, a "gatekeeper" role would have to be created to ensure that individual messages that should be part of the e-newsletter are not sent out separately. In addition, a mechanism for collecting newsworthy items needs to be established.

E-newsletters should contain no more than 10 items with hypertext links to relevant web sites. To shorten the length of an e-news, some organizations provide a headline with a short paragraph of the story, with a hyperlink text that jumps to more details about the story on a web site. Other organizations summarize as much as possible in their e-news and include hyperlink texts only as-needed or for those readers who want more than the basic information. More and more e-mail users can read HTML, so incorporate graphics into e-news. For photographs be sure to use JPEGs or GIFs, because these are smaller files (than BMPs, TIFFS, PNGs, etc.) and run less of a chance of bogging down the user's e-mail system.

Monitoring and Tracking Placements

One way to track effective communication strategies is to ask people how they heard

about a specific program or organization when they call or visit.

Another way is to monitor the number of news stories in print or broadcast media. It is difficult to track the placement of radio news stories, because it is difficult to monitor all radio stations and there are few organizations that monitor these. Local television news stories are easier to monitor, because there are fewer of them. In addition, many medium to large cities have television news monitoring organizations. For a subscription fee, they will fax every morning the topics covered on local TV news programs. They also can provide national news broadcasts lists as well, although many national broadcast media (including national public radio stations) offer scripts online for free or for a fee (if they are in the archives).

Newspapers are much easier to track. Clipping services hire people to read through stacks of newspapers and clip articles containing key words. The advent of the Internet has also made clips easier to track. You can program some Internet search engines to notify you via email if key words come up in news articles published on the web (which many times will have a paper edition as well). Most of the search engines on the Internet are free; however, accessing some articles may cost a subscription or per-article fee.

In addition, many newspapers offer archives of their prior editions online. Typically reading a current issue is free, but reading archived issues will cost you a fee or subscription. Most of the archived issues offer a search engine.

IDENTIFYING AND TRAINING SPOKESPERSONS

Although ideally everyone in an organization can serve as a spokesperson, it sometimes is best to identify and train a pool of spokespersons.

For crisis communications, it is best to identify and train a person in a leadership position. But for regular communications, it is best to identify and train spokespeople by their area of expertise.

Having a cadre of trained spokespersons who feel comfortable speaking with the media and who know the techniques of getting their message across effectively can be crucial in an image campaign and during a crisis.

If, for example, the media is writing a story about the possibility of fraud by one of the accountants in your organization, then having a chief financial officer prepared to answer these questions can make a difference. A well-trained, savvy spokesperson also can turn the prospect of endless dogging by the paparazzi and front-page headlines into a two-inch, ho-hum story buried in the business section. Providing information to a reporter is *always* better than a "no comment."

If, in another example, a reporter is writing a story about an unusually high incidence of nose warts in southern Chile and you happen to have an expert on nose warts on hand, then you have effectively garnered some free publicity for your organization. You can capitalize even more on this media opportunity, by having the nose wart expert weave your organization's key messages into his or her answers.

If your program is conducting a study on nose warts and you do not have the resources to contact news outlets yourself, but your organization is big enough to have a public relations officer, inform these officers of your expertise. Then when a story come ups in the media related to your area of research or expertise, they will know to contact you.

As you have probably surmised by reading this chapter, there are different ways and levels of selling a story. You can either do it yourself directly, or you can ask a PR/media relations person or a reporter to do it for you. The answer will reside in the resources you have at hand. If you doubt your writing abilities or if you feel unsure about contacting reporters directly, seek out the resources you

might have in the community or in your organization to accomplish your objectives.

Listed below are tips to follow before, during and after an interview.

Media Tips

Preparing for an Interview

- When a reporter calls you, always find out what kind of deadline he or she is facing. If they leave a voice message, call back right away.
- Ask for the reporter's name and the media organization for which he or she is reporting. However, it is best not to play favorites when deciding whether or not to grant an interview to a specific reporter. It may seem like a good idea in the short run, but in the long run it will damage your relationship with reporters and may come back to haunt you. Even if the reporter has disappointed you in the past, be as cooperative as possible.
- Think of two to three main points you would like to make about your subject. Gather facts, figures, and anecdotes to support your points. Try to anticipate questions the reporter might ask and have responses ready. The tougher your anticipated questions, the more comfortable you will be during the interview.
- Have printed materials to support your information whenever possible to help the reporter minimize errors. If time allows, offer to fax or mail the reporter printed information in advance of the interview.
- If a reporter calls asking your response to the results of a recently published story, it is okay to ask the reporter to see a copy of the study. If the reporter is working on a very tight deadline, ask the reporter to summarize the main points of the study over the phone.
- Be aware that reporters' schedules are determined by the "breaking" news of the day. Do not be offended if an interview gets canceled or rescheduled because a more urgent story arises.

During the Interview

- Avoid academic or technical jargon; explain special terms if you must use them. A few examples:

Technical Jargon	**Substitute**
Amblyopia	Lazy eye
Surgical intervention	Operation
Physician	Doctor
Meds	Medicines
Oncology	Cancer
HbA1c	Average blood sugar level

- Be brief! We live in the age of the sound bite. Television and radio stories may use only a 10–30 second cut. Even print reporters look for short, snappy quotes.
- Be colorful—tell stories and anecdotes that illustrate your point; give examples. Be friendly and positive.
- Do not ramble, state message and restate it whenever opportunity arises.
- Remember you can direct the spin of the story. You can say "that is the wrong question. What you should be asking is . . . ." Or "I think the key point to this story might be . . . ."
- Speak in complete thoughts. The reporter's question may be edited out and your response should stand on its own.
- Do not overestimate a reporter's knowledge of your subject. When a reporter bases a question on information you believe is incorrect, do not hesitate to set the record straight (in a friendly manner). Offer background information where necessary.
- If you do not understand a question, ask for clarification rather than talking around it. If you do not have the answer, say so. Tell the reporter where to find the information, if possible. Or say that you will find the answer and get back to them (remember to follow through).
- Never say, "No comment." Instead, if you cannot or do not choose to answer, explain briefly. For example, "It is our policy not to discuss lawsuits currently in litigation" or "I can't answer that because I haven't seen the research paper you are referring to." If the latter is true, ask the reporter if they have time for you to quickly review the research paper; after which you can provide them with a better answer.
- Avoid saying things "off the record." Reporters may or may not honor this, and it annoys them. If you do not want to hear it on the evening news, you had better not say it.

- Be honest. Do not try to conceal negative information; rather, let your interviewer know what you are doing to solve a problem.
- If appropriate, give the "call-to-action" phone number or other contact information (this is particularly helpful if you are trying to recruit participants for a study).

Tips on Broadcast Media

- For television interviews, wear solid-color clothing (blue is best). Stripes, plaids, or other designs can cause problems with color TV pictures. Avoid large, dangling, or reflective jewelry. Avoid red or white.
- Sit on back of jacket/blazer, button up if possible. Make sure jacket/blazer does not bunch up, sit erect, leaning slightly forward. Avoid tight clothing or, if wearing a skirt, short hemlines.
- Place feet flat on the floor.
- Look in a mirror, if possible, just before going on camera. The reporter may not tell you that your collar is folded over or your hair is out of place.
- Choose a location where you can screen out extraneous noises. Hold your calls and turn off your computer, if possible. Avoid rooms with loud background hums from refrigerators or air conditioning or heating units.
- Find out in advance whether the interview is edited or "live." If you agree to a live interview, be sure you are comfortable thinking on your feet and responding off the cuff.
- In edited interviews, do not answer questions too quickly; pause briefly before answering. This helps the reporter get a "clean" sound bite and also has the added benefit of allowing you time to think out your answer.
- In edited interviews, it is OK to stop and start over again if you do not like the way you worded your answer.
- In a TV interview, look at the reporter and not the camera. The only exception is in a satellite interview, when the reporter or anchor may not be on location. If you are uncertain where to look, ask.
- Stay stationary in front of radio or TV microphones and avoid sitting in a chair that rocks or spins. Wandering around or rocking in your chair can cause the recorded volume to rise and fall.
- Be aware of and avoid nervous habits such as pen tapping that can interfere with the interview. Do not cross arms.
- Do not expect the reporter to announce when the camera is on, just assume that it is always rolling.

After the Interview

- In most instances you will not have the opportunity to check over the reporter's story before it appears. However, you can ask questions at the end of an interview to test for comprehension. For example, you might inquire, "What do you think is the main story angle here?"
- You may want to ask when a story will appear. The reporter may not have an answer, but if he does he will be happy to tell you.
- Give the reporter your business card to make sure your name and title are spelled correctly.
- If you feel after reflecting on an interview that you misspoke or gave incorrect information, call the reporter as soon as possible and let him or her know. Similarly, you can call with additional information if you forgot to make an important point.
- Give positive feedback to reporters, if merited, after a story appears. Like the rest of us, they usually hear only complaints and rarely get a call or note to say they have done a good job.

SPECIAL CONSIDERATIONS FOR HEALTH ORGANIZATIONS

IRB and Study Participants

If a program or study involves human subjects, investigators may be required to obtain approval of their study design from the organization's institutional review board (IRB) or human subjects committee. This approval, however, does not mean that investigators have a blanket approval on the press releases and ads they use to recruit study participants.

If you are working on such a study, be sure to obtain approval on any collateral you use for recruitment, including releases, ads, brochures, flyers, etc.

HIPAA Regulations

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 (which

went into effect April 14, 2003) contains specific regulations on how health care professionals can share information about a patient's health, including guidelines on how a health-care organization releases information about a patient's health to the media. Many hospitals have public information officers or public relations officers whose jobs are to answer calls from media representatives on topics ranging from the names and conditions of auto accident victims to the conditions of patients who have received an unusual procedure or who were diagnosed with an uncommon disease.

Most hospitals carry a continually updated list of patient's names, their room numbers and their conditions. If the patient has not requested that this information be restricted or that their name be excluded from the list, the hospital may release the general condition of a patient. But the reporter must provide the patient's complete name. If the reporter cannot provide a name, the hospital cannot release any information that will identify the patient.

HIPAA also requires the hospital obtain written authorization from the patient or patient's family before the media can approach them for an interview.

FURTHER READING

Ailes, R. *Dealing Effectively with the Media.*

Bennett, P., and Calman, K. (eds.). *Risk Communication and Public Health.*

Bensley, R.J., and Brookins-Fisher, J. (eds.). *Community Health Education Methods: A Practical Guide.*

Brown, L. *Your Public Best.*

Nelson, D.E., Brownson, R.C., Remington, P.L., and Parvanta, C. (eds.). *Communicating Public Health Information Effectively: A Guide for Practitioners.*

APPENDIX

Sample Releases

MEDIA ADVISORY

EVENT: *Groundbreaking Event for Major University*, seminar presented by John Doe Hall of Biomedical Research
DATE/TIME: Friday, November 7, 4 to 5:30 PM

PLACE: Intersection of Big City America Avenue and Small City Street

RSVP: Although the event is open to the public, we ask individuals planning to attend the ceremony to please RSVP by Oct. 31 by calling (333) 999-2222.

Editors Please Note: Reporters are encouraged to attend/cover this event. A riser will be available for videographers and photographers, and officials and scientists will be available for interviews. Press kits also will be available.

From: Vicki Gaubeca, (333) 999-1212 Oct. 14, 2004

A new era in scientific discovery, collaborative research and health education is set to begin at the University of America when a major facility breaks ground Friday, November 7, 4 PM., at the intersection of Big City America Avenue and Small City Street.

In addition to addressing the University's severe shortage of research space, the John Doe Hall of Biomedical Research will ensure it serves an even greater role in the "biomedical revolution" and should spur significant economic development in our region. The project also will provide new facilities to educate much-needed professionals in public health, pharmacy, and nursing.

The event is scheduled to feature brief remarks by University President Jane Doe, recognition of several donors and dignitaries. Project-related posters and displays will be exhibited and festivities will include entertainment, food, and refreshments.

At a time when funding from the National Institutes of Health (NIH) has doubled, a recent space-needs assessment by Hallelujah & Associates found that the university currently has a deficit of 266,254 square feet of research laboratory space.

Last session, the State Legislature passed House Bill 3456, which gives the state universities bonding authorization for $30 million for research facilities, allowing the University to proceed with construction. The money will be well spent: each dollar invested in biomedical research is estimated to have a six-fold multiplier effect.

Estimated completion date for John Doe Hall of Biomedical Research will be June 2005.

# # #

Calendar Release

EVENT: *Community-Based Chronic Disease Prevention: Why Promotoras are Successful.* A public health seminar presented by Juana Lopez, Promotora, Duncan, Ariz., Mary Hawkins, Rustic College of Public Health.

WHEN: Tuesday, September 30; NOON to 1 PM

WHERE: Kasper Auditorium, Arizona Center 3440 N. Vista Ave.

FEE: Free and open to the public.

Editors Please Note: Media are welcome to cover this event. For more information, call Vicki B. Gaubeca, (333) 999-1212 or Jena Franks, (333) 222-4444, ext. 2233.

From: Vicki B. Gaubeca, (333) 999-1212 Aug. 15, 2004

The Rustic College of Public Health invites the public to attend *Community-Based Chronic Disease Prevention: Why Promotoras are Successful.*

This public health seminar will be presented by Juana Lopez, promotora, and Mary Hawkins, MPH, MA, director, Data Collection and Recruitment for Community Based Programs, both are with the Center for Community Health Promotion at the Rustic College of Public Health. Ms. Lopez, who lives and works in Duncan, Ariz., dedicates her efforts in prevention programs for chronic diseases, such as diabetes.

The seminar is part of the *Engaging Our Communities Public Health Seminar Series* that brings together experts from around Arizona and the nation to discuss the most salient public health issues. Presentations focus on local, state, national or global public health topics, including those from other disciplines that may affect public health. The free seminars are set for every first, third, and fifth (if applicable) Tuesday of the month in Kasper Auditorium in the Arizona Center, 3440 N. Vista, noon to 1 PM.

Continuing Education credits are offered. The seminar series is open to the public. For more information, please call Jena Franks, professional development coordinator (333) 222-4444, ext. 2233.

# # #

Rustic College of Public Health Receives Grant to Study Effects of Teas on Lung Cancer and Oxidative Stress

From: Vicki B. Gaubeca, (333) 999-1212 June 4, 2004

Researchers at the Rustic College of Public Health have been awarded a grant totaling $4.6 million over four years to study the effects of tea on preventing disease. The study will look at preventing lung cancer among former heavy smokers and minimizing oxidative stress, a naturally occurring reaction in the human body that, when enhanced, may contribute to lung cancer, cardiovascular diseases, diabetes, and other chronic diseases.

The study, funded by the U.S. Department of Alternative Medicine, is looking at the effects of green and black tea on minimizing oxidative stress in smokers and former smokers. Smoking enhances oxidative stress and may lead to tissue damage even after people cease smoking. Participants in this study should have some form of chronic obstructive pulmonary disease (COPD).

"The overall goal is to reduce the incidence of tobacco-related diseases by establishing an efficient and feasible intervention approach for patients with COPD," explains Stuart Venezuela, MD, MPH, director of the Division of Health Promotion Sciences at the Rustic College of Public Health and principal investigator on the study. "These individuals are at a particularly high risk for lung cancer."

Although tea studies have not conclusively shown that tea will prevent cancers, preliminary results indicate potential benefits. "Tea compounds can inhibit the transformation process at many checkpoints and both green tea or its extracts may be equally effective in preventing cancer in humans," explains Dr. Venezuela.

Participants interested in volunteering for the study should call, Norma Monique, at the Tea Studies' office, Rustic College of Public Health, 333-8787, ext. 1244.

- - -

Established by the Rustic Board of Regents in February 1919, the Rustic College of Public Health is the first public health college in Mid-Atlantis. The Rustic College of Public Health's mission is to promote the health of individuals and communities with a special emphasis on diverse populations.

# # #

Case Study 1

Diabetes Disease Management Program

Donna Zazworsky[1,2] and James Dumbauld[1]

[1]*St. Elizabeth of Hungary Clinic, Tucson, Arizona;*
[2]*Case Manager Solutions, LLC, Tucson, Arizona; Carondelet Health Network, Tucson, Arizona*

St. Elizabeth of Hungary Clinic (SEHC) established a proactive diabetes disease management program in 2000 to respond to the alarming numbers of patients with diabetes being treated at the clinic. The clinic's program offers a bilingual continuing care approach to population-based management (see Figure 1) by integrating health promotion, disease management, and acute episodic care through culturally sensitive activities.

A PROACTIVE DIABETES DISEASE MANAGEMENT PROGRAM

In order to address the special needs of diabetes prevention, early detection and managing diabetes of the clinic's population and the community it serves, the clinic adapted a disease management framework to guide their efforts. A Proactive Disease Management System incorporates the following components (Eichert and Patterson, 1998):

- Early identification system (risk assessment and stratification)
- Practice guidelines and protocols
- Behavior education (staff and patient—1:1 and group)
- Tracking system (data management systems).

SEHC adapted the FAST Approach to Disease Management (Lamb and Zazworsky, 2000) as their operational methodology for addressing diabetes care within the clinic. This model includes the above components in a comprehensive and systematic approach identified below:

- *Find.* Identify the patients at the time of enrollment (proactive) or through database querying (retroactive);
- *Assess.* All patients are assessed through a standardized risk assessment;
- *Stratify.* Patients are stratified into low-, moderate-, and high-risk categories in order to receive appropriate interventions; and
- *Treat, train, and track.* All patients receive medical treatment and self-care education based on their level of risk and treatment

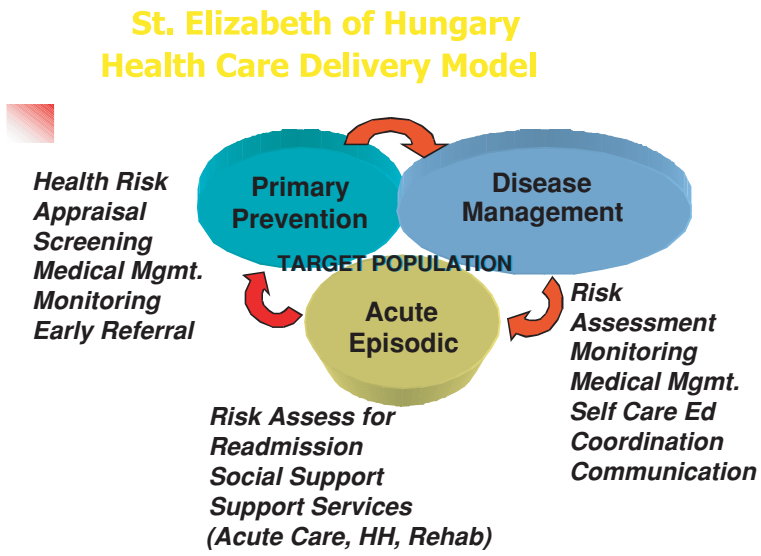

FIGURE 1. St. Elizabeth of Hungary Clinic's Healthcare Delivery Model.

guidelines. In addition, these patients are tracked in a database to monitor adherence to the disease management protocols.

ACTION PLAN

Find

1. Identify all new patients at the time of enrollment to the clinic and administer the Diabetes TriFit© Health Risk Appraisal.
2. Identify active SEHC patients diagnosed with diabetes.

Assess

1. Perform assessments during eligibility/enrollment.
2. Audit charts with diabetes risk grid for HbA1c, blood pressure, ldl, microalbumin, foot score, and retinopathy.

Stratify

1. Place patients into low-, moderate-, and high-risk interventions.
2. Develop treatment guidelines and protocols for providers (Figure 2).
3. Develop self-care education guidelines and programs for patients according to risk categories (Figure 3).

Treat

1. Develop and implement treatment guidelines and protocols. Train staff on guidelines and protocols.
2. Train providers and staff on guidelines and protocols.

Train

1. Develop and implement education guidelines and programs for patients.
2. Train staff on guidelines and material.

Track

1. Track the following information:

   a. Patient outcomes (service visits, adherence to treatment, and HbA1C results);
   b. Cost outcomes (hospitalizations, complications, and service utilization);
   c. Patient and provider satisfaction;
   d. Patient referrals and feedback.

St. Elizabeth of Hungary Clinic
140 W. Speedway Blvd
Tucson, AZ 85705-7698
(520) 628-7871

St. Elizabeth of Hungary Clinic

Diabetes Quality Indicators: Clinical

Patient: _____ DOB: _____

MR# _____ Provider: _____

		Frequency	Baseline	3 mo	6 mo	9 mo	1 year
Date/Initials							
Assessment	FS Blood Glucose R or F	qvisit					
	HbA1c	quarterly					
	Blood Pressure ≤130/80	qvisit					
	Urine Protein Dip	Annual					
	Height	Annual					
	Weight	qvisit					
	Body Mass Index (BMI)	qvisit					
Lab	Chol/TG <200/200	Annual					
	HDL/LDL >45/<100	Annual					
	Micro Protein (If protein dip negative)	Annual					
	Bun/Creatinine	Annual					
Interventions	Oral Agents Y or N	qvisit					
	Insulin Y or N	qvisit					
	ACE Inhibitor if hypertensive Y or N	qvisit					
	ACE Inhibitor if proteinuric Y or N	qvisit					
	Statin Y or N	qvisit					
	ASA Y or N	qvisit					
	Vaccines Specify (ie. flu, pneumonia, etc)	Annual					
PE	Full Physical Exam Y or N	Annual					
	Eye Exam Re or C	Annual					
	Foot Exam Re or C	qvisit					
Self Care	SMBG and records S or SME	qvisit					
	Meal Plan S or SME	qvisit					
	Physical Activity S or SME	qvisit					
	Medication Instruction S or SME	qvisit					
	Tobacco Cessation S or SME	qvisit					

S= Satisfactory SME= Self-Management Education Referral R= Random F=Fasting Re=Referred C=Completed

This flow sheet indicates recommended services to be provided in the continuing care of persons with diabetes. The frequency of each service is a recommendation from the American Diabetes Association. Document values where indicated. Any discussions with patients or significant others should be documented in the "notes" section in date order.

Signature	initials	Signature	initials

INITIAL WORK

The initial work focused on a chart audit to identify clinic system and process needs. An alarming gap was noted in the ADA standard and what patients were able to afford and perform. There were a number of barriers in cost and clinic processes. Therefore, initial

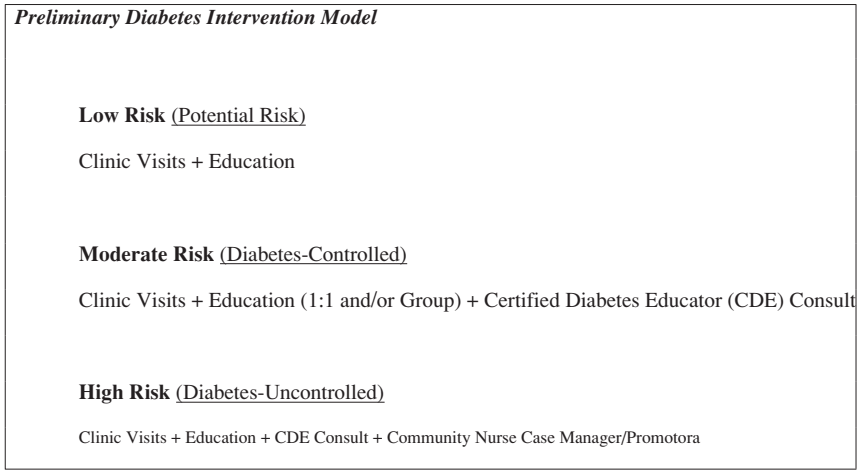

FIGURE 3. Patients with Diabetes Intervention Grid.

efforts were to obtain the necessary equipment and funding and simultaneously developing clinic protocols for providers and staff.

FINDINGS

The following descriptions provide a brief overview of the programs and systems that have been developed. As a result of these programs and services, the clinic has demonstrated an increase in patients achieving quarterly and annual requirements as well as an improvement in health status indicators. From June 2001 through June 2004, the clinic has seen a reduction of patients who have HbA1cs greater than 9%. This went from 32.9% down to 18.3%. Another promising improvement is in those patients who have HbA1cs less than 7%. That number increased from 22.6% to 35.3% in those 3 years. This was based on a total of 371 patients who had two or more HbA1cs with a first and last HbA1c.

ST. ELIZABETH OF HUNGARY CLINIC CONTINUUM

Health Promotion

Outreach efforts are proactive and provide early identification and prevention activities through a number of programs and partnerships.

- *Diabetes health-risk appraisals to the community*. SEHC partners with the YWCA promotoras to offer a proactive approach to early detection. The promotoras administer the TriFit© computerized diabetes health risk appraisal to the general public at health fairs, community events, church gatherings, and other community activities. Individuals are mailed their results in approximately 1 week with an accompanying letter explaining their need for certain follow-up depending on their results. People who are identified as high-risk for diabetes or as diabetic receive a phone call from the promotora. If people do not have health insurance, the promotora works to connect them with a community provider who provides care for the uninsured.
- *Diabetes health-risk appraisals to SEHC new registrants*. The Diabetes TriFit© Health Risk Appraisal is administered to new patients registering for clinic services. The computerized results are then posted in their chart for the provider to review at their first visit. The provider may decide to do a plasma insulin test to identify early prediabetes through insulin resistance. If the individual is diagnosed with this prediabetes condition, the provider will provide education on diet and exercise, make a nutrition and/or nursing referral and may even start a medication regime. A nurse tracks all "high-risk for diabetes" and "self-identified diabetics" and sends letters to those who have not made their first appointment.

- *Mobile podiatry*. SEHC's Mobile Podiatry Unit travels to 10 senior sites monthly to provide podiatry outreach to the low-income elderly. More than 100 people receive this basic podiatry service. Many of these individuals have diabetes and desperately need this preventive service, since basic podiatry is no longer a covered benefit under Medicare. Individuals are referred to podiatrists in the community if further needs are identified. This year, SEHC received funds to help those with special diabetes footwear needs.

Disease Management

The clinic offers the following diabetes disease management efforts based on an initial risk assessment that helps to guide the provider and determine an intervention scheme:

- *Quarterly provider diabetes visits*. All patients diagnosed with diabetes are automatically placed on the evidence-based guideline, called the Diabetes Clinical Flow Sheet (see Figure 3). This flow sheet follows the recommendations established by the American Diabetes Association. Referrals are made accordingly.
- *Prediabetes program.* Patients who have been identified as high-risk potential for diabetes through their health-risk appraisal are referred to the provider for further testing. If appropriate, a serum insulin test may be performed. If the patient is identified to have the prediabetes, the provider initiates the Prediabetes Clinical Flow Sheet (see Chapter 13). Patients can be referred to 1:1 or group education classes.
- *Nutrition counseling*. A dietitian, who is also a Certified Diabetes Educator (CDE), provides 1:1 diet instruction based on their learning needs and level of readiness. The CDE dietitian utilizes a number of different educational tools that may include a personalized laminated food pyramid, food models, brochures, and many other individual handouts.
- *Nursing education*. Specially trained diabetes nurses offer 1:1 education and counseling on lifestyle, self-management, and glucometer use. All newly diagnosed individuals must be seen by the nurse in order to obtain a glucometer. The nurses utilize the Patient Diabetes MAP (see Chapter 12) as their teaching tool and documentation form.
- *Medication and glucometer supplies support*. The clinic offers special programs to help patients maintain medication compliance. Patients can become involved in the clinics Pharmaceutical Advocacy Program and receive many of their medications free through pharmaceutical programs coordinated by clinic. Also, a special Insulin Program offers free insulin to bridge patients while they wait to get on the Pharmacy Advocacy Program.
- *Glucometer strips program*. Glucometer strips are now available through a low cost, incentive program. The patients sign an agreement (see Figure 4) to participate in a self-management program that includes regular testing and exercising. The patient is given a monthly log, passport, and Patient Diabetes MAP.
- *Open access*. This is an informal clinic process where the diabetes nurses encourage patients with diabetes to call or stop by if they have a problem. The nurse will work them into the doctor/NP if necessary.
- *Diabetes day group visit*. This is a once a month clinic where a group of 8–10 patients are scheduled. They are selected based on risk, individual need, and their ability to learn better in a group format. The provider and nurse discuss who would be best to attend. The group visit lasts approximately three hours and includes: a retinopathy exam by the ophthalmologist, foot evaluation by the podiatrist, group education by the nurse and nutritionist, and primary care visit with the PCP. This is all documented on a Group Visit Form (Refer to Case Study 5 for complete description of this program on other examples).
- *Community Nurse Case Management and YWCA promotora home visits*. This service is available to individuals who are having difficulty managing their diabetes and are unable to come to the clinic regularly. The Community Nurse Case Manager and YWCA promotora provide an initial home visit to complete a needs assessment and develop a mutually agreed upon plan of action. The individual and YWCA promotora establish regular a time for regular visits to monitor the person's progress and report back to the diabetes team.
- *Diabetes patient registry*. The SEHC Diabetes Registry has been specifically designed to track patient data related to demographics, visit types, patient data, medications, supplies, and risk level.

Glucometer Strip Program

Participant Agreement

I, _____, agree to participate in the SEHC Glucometer Strip Discount Program. I understand that I will only pay $5/bottle of 50 strips.

I will make a commitment to take care of myself by:

- ❑ Checking my blood sugar at least 3X/week and record the results on the calendar.
- ❑ Exercising 3X/week as recommended by my provider and record on the calendar.
- ❑ Handing in my calendar monthly to the nurse
- ❑ Seeing my provider every 3 months
- ❑ Participating in any classes or special visits recommended by my doctor/nurse
- ❑ Following my Diabetes MAP.

I will contact my doctor/nurse if I am having any problems with any of the items in this agreement.

_____

Name Date

_____

Nurse **Date**

FIGURE 4. St. Elizabeth of Hungary Clinic.

- *Diabetes health care team conferences*. Once a month, the diabetes team meets to present cases and discuss a multidisciplinary plan of action for each case. This is also the time that the team will review and Continuous Quality Improvement items based on the PDCA (Plan–Do–Check–Act) process.
- *Carondelet diabetes education classes*. Offered by Carondelet Health Network's Parish Nurse Program, this free seven-week education series covers nutrition, exercise, stress management, blood sugar control, and a supermarket tour.
- *Diabetes update newsletter*. This bilingual quarterly newsletter promotes healthy lifestyle tips, calendar of events, and success stories for patients with diabetes and their families.

Acute Episodic Care

The clinic offers a triage service for patients who have immediate medical needs. The clinic also promotes an "Open Access"

philosophy with the diabetes nurses to promote early identification of problems.

BARRIER REDUCTION STRATEGIES

St. Elizabeth continuously works to reduce patient barriers that may interfere with successful diabetes self-management. The following strategies have been or will be implemented:

1. *On-site HbA1c finger-stick tests that are performed at the time of the PCP visit*. This strategy has dramatically improved the management of diabetes by reducing time and cost barriers for the patient. The patient can receive their HbA1c results within 6 minutes and have their medications adjusted at the same visit.

2. *Open access visits with the nurse*. This strategy empowers patients to openly and proactively pursue self-management success by knowing that the nurse will be able to respond to telephone or face-to-face questions and concerns when they arise. This process has also expedited immediate medical intervention when needed to reduce further complications.

3. *Telemedicine*. St. Elizabeth of Hungary Clinic has been involved in the Arizona Telemedicine Program since 2000 through the teleradiology program. We will begin a teleophthalmology with an ophthalmologist who provides this service. This will enable our patients with diabetes to have their annual retinopathy exam during their PCP visit through a "Store and Forward" capacity.

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Case Study 2

Carle's Diabetes Management Program

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Diabetes mellitus (DM) is a chronic disease increasing in epidemic proportions. It is estimated that approximately 16 million Americans have DM and 200,000 each year die from its complications (Boyle *et al*., 2001). Diagnosed cases of DM are expected to increase dramatically in coming years, primarily related to our eating behavior (obesity) and sedentary lifestyle (lack of physical activity; Flegal *et al*., 2002). Diabetes mellitus has its greatest effects on the elderly; one in five adults, 65 and older, has diabetes (Modkad *et al*., 2001) and approximately 66% of diabetes-related expenditures are for the care of the elderly (Basile, 2000).

Over the past 30 years, DM care has been at the forefront of the changes in disease management (Griffin, 2001). The majority of patients with DM are inadequately treated despite the proliferation of medical guidelines specifying optimal management of the disease and there are wide variations in care (Saaddine *et al*., 2002). The most pressing problem in DM care is the poor translation of this accumulated knowledge into routine clinical practice (Berger and Muhlhauser, 1999). These pressing reasons provided strong motivation and incentive for the Carle health care system to make patients with DM a priority focus for the organization. The purpose of this chapter is to present an overview of the Carle diabetes management program and our achievements to date.

THE CARLE HEALTH CARE SYSTEM

The Carle organizations (Carle Clinic Association, Carle Foundation, Health Alliance Medical Plans), located in Urbana, Illinois, are a vertically integrated health care system that serve as the regional medical

center for over eight million individuals living in urban and mostly rural areas of east central Illinois and western Indiana. The Carle Clinic Association is a multispecialty, physician group practice, with over 280 physicians representing 50 medical and surgical specialties and subspecialties, including 120 primary care physicians (PCPs), and a substantial ambulatory nursing component. Carle's delivery system provides primary care through a network of nine branch clinics. The branch clinics provide access to health services using networks of local practitioners and community service providers to create smaller "hubs" of service within a 30-mile radius of the branch. The main campus, located in Urbana, is the primary referral and specialty care center. The Carle Foundation owns the 295-bed Carle Foundation Hospital and other related health care services and is affiliated with the University of Illinois College of Medicine. Health Alliance Medical Plans (HAMP) is a managed care organization (MCO) owned by Carle Clinic Association and is the largest MCO in downstate Illinois.

CARLE'S DIABETES MANAGEMENT PROGRAM

The overall purpose of the program is to educate and update PCPs and RNs on evidence-based clinical guidelines to improve management of patients with diabetes within Carle's primary care network. The program is designed to help clinicians focus on individual patients as well as facilitate a population-based approach that provides specific feedback on their entire panel of patients with diabetes. Although most of the individual program components existed within the Carle system for a long time, it was decided to formalize the program on a system wide basis in 1999 as a major quality improvement initiative. The program's overriding theme is "if you're not measuring it you're not doing it." The only way to do this was to give individual physicians and their staff specific information that was accurate, patient specific and "actionable."

Carle's diabetes management program consists of the following components:

(1) *Patient registry*. The diabetes registry, which contains approximately 10,000 active patients, is updated on a monthly basis and includes all individuals who have been treated at Carle with at least two contacts related to their diabetes care (i.e., physician visits, hospitalizations, eye or foot exams, and laboratory tests) during the past 18 months. The registry contains the following patient information: name, date of birth, age, gender, insurance status, PCP name, medical specialty and practice location, date the patient was diagnosed with DM, termination date, and reason from the registry.

(2) *Evidenced-based clinical guidelines*. Guidelines from the American Diabetes Association (ADA) facilitate patient management and care (American Diabetes Association, 2003). The guidelines are reviewed and updated on a yearly basis (American Diabetes Association, 2004) and are available online to all physicians and staff through Carle's intranet system. Signed standing orders are in place to facilitate laboratory testing. When a patient is scheduled for a PCP visit, they are also scheduled for laboratory testing so the PCP will have the latest results.

(3) *Diabetes self-management education program*. Both group and individual classes are offered at four of Carle's branch clinics and focus on nutrition, exercise, medication, and self-testing. All classes are taught by certified RNs, dietitians, and endocrinologists. Over 1,200 individuals a year participate in this program.

(4) *Inpatient self-management program*. Carle's inpatient education program has a twofold purpose. The first is to keep Carle Foundation Hospital staff, especially RNs and Family Practice physician residents, updated on policy and procedures and diabetic treatment protocols. The second is to educate and refer newly diagnosed hospitalized patients or patients hospitalized with complications to the self-management education program or to the endocrinologist. Over 300 patients a year are seen in the inpatient setting.

(5) *Referral*. Patients who have glycemic levels that are severely uncontrolled are referred to endocrinologists for specialized care.

(6) *Program outcomes and reporting*. Specific outcomes, at both the individual patient and physician level, are based on the guidelines for monitoring and glycemic (HbA1c) and lipid control (low-density lipoprotein [LDL]) levels. HbA1c values should be monitored at least twice a year and LDL values at least once a year. Therapeutic HbA1c control should be below 7% and LDL control below 100% (Carle has taken a conservative approach to calculating outcomes and a missing laboratory value is considered not in control). Blood pressure control and yearly eye examinations also were considered for disease management outcomes but they could not be easily accessed electronically so were not included.

(7) Reports are distributed to individual physicians and clinic administration on a quarterly basis (April, July, October, and January). Individual physician reports contain the following information:

- Physician name, medical specialty, and practice location;
- Total number of active patients with diabetes;
- Calculated HbA1c status: number and percent of patients who in the past 6 months have no laboratory value, number and percent who have severely uncontrolled values (>9.5); number and percent who are uncontrolled, and number and percent who are controlled.
- Calculated LDL control status: number and percent of patients who in the past 13 months have no laboratory value, number and percent who are uncontrolled, and number and percent who are controlled.
- HbA1c and LDL statistics are provided comparing an individual physician with their peers within their medical division (Adult Medicine or Family Practice), by their medical specialty and practice location, and the organization overall.
- Patient information includes a new patient icon, patient name, age, HbA1c and LDL testing dates and results.

See Figure 1 for a sample report.

Program rollout took approximately 2 years to finalize. There were primarily two reasons for this. First, it was decided that all program training had to be done at the site level and it took a lot of time and effort to schedule and complete multiple training sessions at Carle's nine different clinics. It was a challenge to complete the training with as little disruption as possible to extremely busy clinical practices. Second, in order to provide feedback that was specific to individual physicians, it had to be accurate. Considerable time was spent on developing and cleaning up the patient registry. In the Carle system, only MCO members have to designate a PCP, so physicians and their staff had to review and verify their patient panels and indicate which patients were deceased or otherwise not theirs. Most physicians cooperated in this task but not all were timely returning the information. At the end of the second year, we felt this process resulted in data that were more than 90% accurate.

Implementation occurred in several stages over the two-year period. First, a kick-off meeting was held with all PCPs to introduce and inform them about the program, the guidelines being used for care management, and outcomes that were going to be measured. Second, initial training was conducted for physicians, office staff, and RNs with emphasis placed on regular ordering of laboratory tests according to the guidelines and attaining HbA1c control. This training took approximately 1 year to complete.

At the same time, individual physician reports, described above, were being developed, modified, and refined. By the second year, the reports were distributed to all PCPs on a quarterly basis. When these reports were first rolled out, training and one-on-one support was given to physicians and RNs to assist them in identifying their patients who were not being tested according to the guidelines (noncompliant) and to identify those patients who were severely uncontrolled. The training sequence was the same, first in the larger urban clinics and then in the smaller rural branches.

Physician Diabetes Patient List

Physician Name
Organization
Physician Location – Medical Specialty

Reporting Period (A1c 07/01/2003-12/31/2003 and LDL 12/01/2002-12/31/2003)

Patient 162

A1c Control Status	No. of Patients	Doctor	Medspc Site	Medspc Division	Carle
(1) No A1c	18	11.1%	22.0%	28.7%	26.5%
(2) Severely Uncontrolled A1c	1	0.6%	1.8%	3.4%	3.8%
(3) Uncontrolled A1c	38	23.5%	25.3%	26.4%	27.0%
(4) Controlled A1c	104	64.2%	50.5%	40.5%	41.0%
(5) Uses Outside Lab	1	0.6%	0.3%	0.9%	1.7%

LDL Control Status	No. of Patients	Doctor	Medspc Site	Medspc Division	Carle
(1) No LDL	18	11.1%	17.7%	25.4%	26.3%
(2) Uncontrolled	41	25.3%	39.8%	37.6%	35.2%
(3) Controlled	98	60.5%	40.2%	33.2%	32.0%
(4) Not Calculable	5	3.1%	2.0%	2.8%	2.8%

(1) No A1c

(No A1c completed at Carle Lab during last 6 months of reporting period)

Clinic #	Patient	Age	PCP In Cadence	HAMP MCCD	A1c Date	A1c Result	LDL Date	LDL Result	LDL Status
		45	C						(1) No LDL
		54	C				1/13/2003	86	(3) Controlled

(2) Severely Uncontrolled A1c

(A1c Value for all age groups is 9.6 and greater)

Clinic #	Patient	Age	PCP In Cadence	HAMP MCCD	A1c Date	A1c Result	LDL Date	LDL Result	LDL Status
		82	C	HAMP	8/15/2003	9.7			(1) No LDL

(3) Uncontrolled A1c

(A1c Value at 0-2 yrs 9.0 - 9.5; 3-4 yrs 8.5 - 9.5; 5-11 yrs 7.5 - 9.5; 12-17 yrs 7.2 - 9.5 ; >17 yrs 7.0 - 9.5)

Clinic #	Patient	Age	PCP In Cadence	HAMP MCCD	A1c Date	A1c Result	LDL Date	LDL Result	LDL Status
		52	C	HAMP	11/10/2003	9.5	1/2/2003	92	(3) Controlled
		81	C		10/28/2003	7.2	7/16/2003	103	* (2) Uncontrolled

(4) Controlled A1c

(A1c Value at 0-2 yrs 8.9 & less; 3-4 yrs 8.4 & less; 5-11 yrs 7.4 & less; 12-17 yrs 7.1 & less; >17 yrs 6.9 & less)

Clinic #	Patient	Age	PCP In Cadence	HAMP MCCD	A1c Date	A1c Result	LDL Date	LDL Result	LDL Status
		54	C		9/29/2003	5.9	3/28/2003	90	(3) Controlled
		59	C	HAMP	7/31/2003	6.2	7/31/2003	106	* (2) Uncontrolled

(5) Uses Outside Lab

(Uses outside lab, not able to determine status)

Clinic #	Patient	Age	PCP In Cadence	HAMP MCCD	A1c Date	A1c Result	LDL Date	LDL Result	LDL Status
		63	C						(1) No LDL

FIGURE 1. Individual physician report.

PROGRAM OUTCOMES

In January 2001, with comfort that the patient registry information was 90% accurate, Carle established a baseline of patient demographics and program outcomes. The typical patient in the registry is 62 years old, 53% are 65 years or older, 52% are female, and 30% have health insurance through Carle's MCO. The average Carle PCP has approximately 111 patients with diabetes on his/her panel, although there is wide variation per physician, especially for those who have practiced at Carle for over 15 years. Throughout the Carle system, 28% of patients were in glycemic control, 34% had not had their HbA1ctested according to the guidelines, 20% were in lipid control, and 48% had not had their LDL tested according to the guidelines. After three years, glycemic control increased by 13% to 41%, lipid control increased by 12–32%, and lack of HbA1c and LDL testing decreased by 7% and 22%, respectively, to 27%.

The positive movement of these outcomes is encouraging, especially when viewed from a system-wide basis. While there remains room for continued improvement, glycemic and lipid control has increased while noncompliance had decreased; these results are similar to other published interventions that have attempted to improve the management of diabetes in primary care settings (Renders *et al*., 2001). Glycemic and lipid control outcomes are now key performance indicators for both Adult Medicine and Family Practice, and achievable yearly benchmarks for both medical divisions and individual physicians are being tracked. Carle will soon add nephropathy monitoring to our program outcomes.

CONCLUSION

Improving health outcomes for individuals with diabetes is a challenging process. Diabetes is a chronic illness that is generally considered harder to treat than other conditions by PCPs because of patient nonadherence to treatment regimens, a conscious decision based on patient age and comorbid illness, lack of trained staff, and lack of consultative assistance and follow-up (Larme and Pugh, 2002). This is compounded because self-management plays such a central role in care (Schechter and Walker, 2002) and until there is a cure for diabetes these behaviors must be done for a lifetime.

Carle's diabetes management program was founded on the theme "if you're not measuring it you're not doing it." Carle has a system in place that provides regular feedback to PCPs on the glycemic and lipid control of their patients with diabetes. The system is not perfect and not all physicians are convinced that the outcomes being measured and reported are the best way to change or improve care. However, the results the system has attained are worth the continued efforts to improve the primary care delivered to our patients with diabetes.

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Case Study 3

The Scott and White Experience—Chronic Disease Management on a Shoe String

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THE BEGINNINGS

It was a good year—1999. One of our Scott and White Medical Directors had been sent elsewhere to learn about Chronic Disease Management (CDM) and implement a pilot CDM program at Scott and White through the Scott and White Health Plan (SWHP).

Scott and White is an integrated health care system composed of a 450-bed hospital, a 500-physician multispecialty clinic, and a 186,000-member HMO, with 15 regional clinics. The appointed leader, one of SWHP's medical directors, was young, energetic, and authoritative. Without much ado, four RNs were hired, and a physician champion was appointed at each clinic where the nurses would be assigned. Each nurse was given a laptop computer and BOOM—we were in business. Patients were identified by SWHP data or by physicians. The nurses were expected to assess the patients' status and implement a plan of proactive care.

PROBLEMS, PROGRESS, AND LESSONS LEARNED

First, three of the RNs hired were selected because they were in-house employees from other departments that had just downsized. We were in a nursing shortage, and it seemed to be the best decision, at the time. None of these three nurses is still with the program. However, one nurse was hired from within the clinic where she would work as the CDM nurse. There was already a strong working relationship and a good deal of trust between that nurse and the physician staff. This ideal situation has blossomed beautifully. The nurse has earned her CDE credentials and the highest esteem of the physicians with whom she works.

Lessons learned. A preexisting, good working relationship between the doctors and the nurse rendered the best working situation. If time constraints were not an issue, we might have done better to select nurses based on background, experience, and communication skill level.

Next, none of the nurses had computer skills, and at the best, had minimal key boarding skills. This reflects the picture of most of our organization at that time. Computer skills had never been a prerequisite for hiring nurses and very few nurses had computer access. We began with a simple Excel spreadsheet to collect data. It was traumatic for the nurses when we moved into an Access database because they had to learn new skills. The first Access database was very limited. Within 6 months, we moved into a much more complex Access database that was networked so that all CDM patients' data would be in the same database—another traumatic experience to the nurses. Today, the computer changes are a little more easily integrated, and our nursing staff has developed good computer user skills. In a related issue, at the beginning, a clerical support person was to be assigned to each nurse to assist with data entry. Those positions were eliminated before they were ever filled. However, for 6 months, we were able to hire one clerical support person to assist all four nurses. She rotated daily, and besides doing data entry, did other tasks such as assemble patient education materials.

Lessons learned. Many nurses have not had the opportunity or need to develop computer skills. Data entry is a huge issue. Our organization did not support the idea that nursing time should not be spent on data entry. Until organizations have a perfect electronic medical record that automatically aggregates data on specified patients, this should be an early consideration in program planning.

Next, there was differing practice among the clinics. Some doctors trusted their nurses a great deal, and the nurse developed substantial skills. Others had a hard time establishing that level of trust. Some physicians wanted to maintain total control, and did not rely on the nurse at all. Our nurses offered care to patients with diabetes and patients with congestive heart failure. We had no idea how many patients a nurse could handle, or how much time it would take to educate a patient. Some physicians wanted to try group visits. Nurses developed their own protocols, and the physicians in their own areas signed them. All of those protocols varied. Our philosophy was to operate on a shoestring and do whatever was necessary to get the job done. This was not necessarily a bad thing; because we knew from the beginning, we would learn by doing.

Lessons learned. Physicians must trust a nurse's judgment before they will be willing to sign a protocol. Even when a protocol is available, they appreciate close oversight of the nurse's work. A standardized protocol is nice. An education session of two hours is how we routinely schedule a patient with newly diagnosed diabetes now. Patients newly diagnosed, those with recent hospitalizations, ER visits, or major changes in medications or co-morbidities require the most time and intervention. We still do not have absolute numbers but we believe one nurse can handle between 400 and 800 patients, depending on intensity. This is where patient stratification becomes important.

PROGRESS AND SUCCESS

Our goals were to improve the quality of care and to decrease cost of care. Our evaluation measures for the care rendered to patients with diabetes related to HbA1c improvements and cost of care. Evaluation measures for the care rendered to patients with congestive heart failure were hospital days and cost of care. In measuring improvement in HbA1c, we examined the number of HbA1c tests for a year. Then we examined values for the first and last test during the time period. At that time, we considered a value of $\geq$9.5 "out of control." Measures for patients in our database included: number and percentage of patients with one HbA1c; number and percentage of patients with two or more HbA1c who were either improved or in control versus number and percentage of patients out of control or unmeasured; hospitalizations and hospital days; and ER visits. In regard to our HbA1c measures, our Information Systems department was able to identify a control group of patients

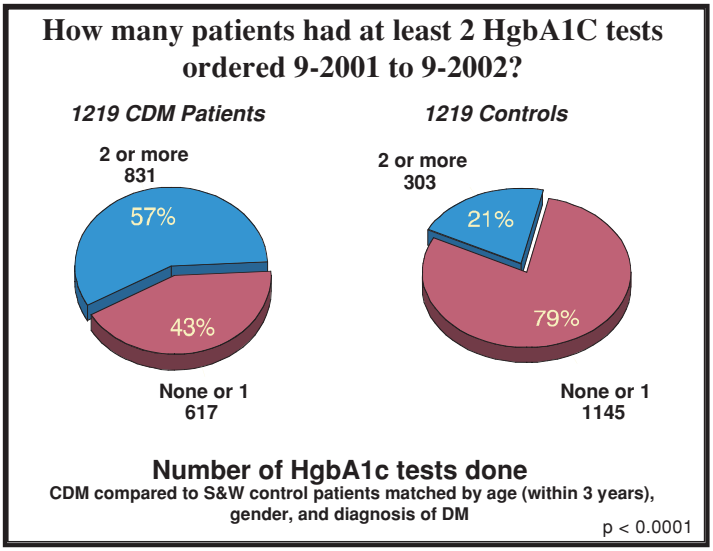

FIGURE 1. SWHP patients with diabetes with 2 or more HbA1c tests in one year.

with diabetes based on matching age within 3 years, sex, and diagnosis of diabetes—but no access to CDM. We have repeated the measures at least annually and we show wonderful results (see Figures 1–4 that demonstrate care delivered September 2001–September 2002).

Lessons learned. Early results demonstrated success, but the organization did not necessarily receive the results as believable. However, later results of cost effectiveness and return-on-investment analysis prepared by an objective person not associated with CDM in any way (a SWHP actuary) were considered valid.

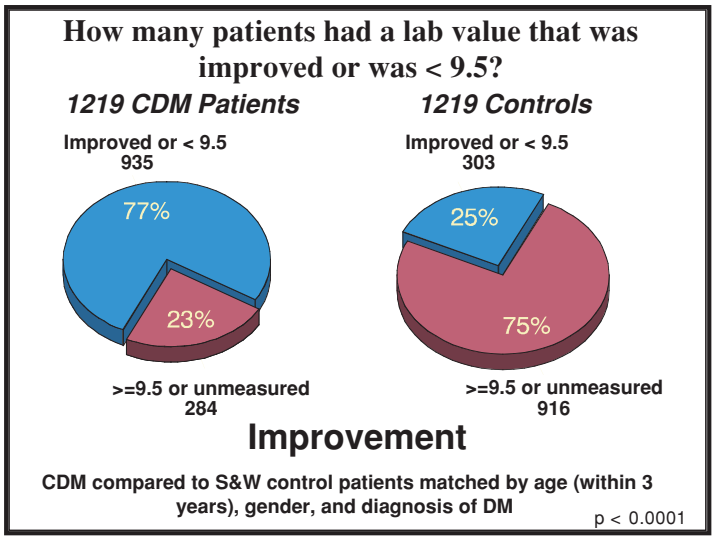

FIGURE 2. SWHP patients with diabetes with improvement between September, 2001 and September, 2002.

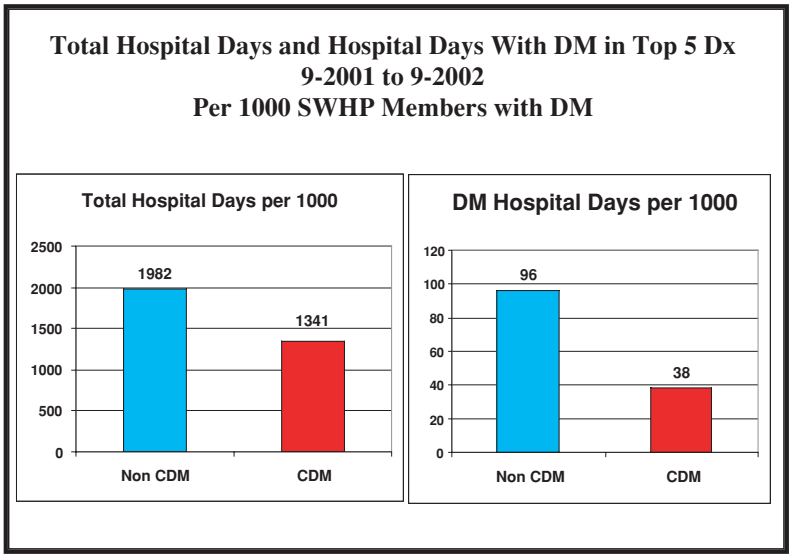

FIGURE 3. Hospitalization rates for SWHP members with diabetes September, 2001 to September, 2002.

NEXT STEPS

Ours is a work-in-progress. SWHP's CDM program was initiated as a quality improvement process in pilot format. The investment cost was the salary and benefits of 4 RNs and computers for them. Four nurses have been used to care for SWHP members in five clinics, and the results demonstrate success. Since the program has been deemed successful, SWHP will roll the program out to all SWHP members. Careful consideration is

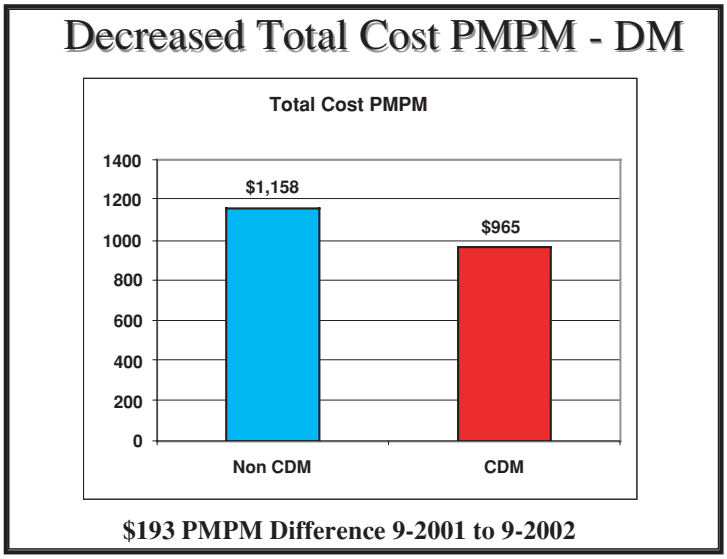

FIGURE 4. Difference PMPM cost of care based on charges for CMD and non-CDM SWHP member with diabetes.

currently being given to the most cost effective way to implement CDM across the entire 186,000 membership. Along with computations of requirements to continue and expand the program internally, commercial programs are being evaluated. Of particular interest, though our program was not standardized, we still demonstrated significant patient improvements and decreased the cost of care substantially.

Case Study 4

Nutrition Survival Skills for Diabetes—A Personal Experience

Annette I. Peery

Department of Adult Health Nursing, School of Nursing, East Carolina University, Greenville, North Carolina

Practice guidelines for diabetes recommend that patients be referred to a dietitian for medical nutrition therapy (MNT) within the first month after diagnosis. However, more often than not, reality prevents this from occurring—the reality of not having enough dietitians or dietitian appointments, and the reality that patients do not always keep their appointments. These realities also hold true for having patients in to see a diabetes educator.

In practice, physicians and physician extenders are limited in the amount of time they have for patient education, including nutrition. Therefore, they may often tell the patient "nutrition is important in controlling your diabetes. Do not eat any sweets and we will make an appointment for you to see a dietitian who will tell you about your diet." The patient leaves with no nutrition education or guidance, an appointment with a dietitian for 2 months later, and a follow-up appointment with the physician in 4 weeks. The patient is not seen or heard from again for 9 months, when they come to the clinic as a walk-in for an acute problem, and see a provider they have never seen before. Sounds familiar? We saw this scenario repeated time and time again in our family practice group.

The Family Practice Center is located in a rural county in the southeastern United States. The clinic serves as a training site for 36 family practice residents and provides care to a traditionally underserved, mostly minority, population. As the aforementioned problem was prevalent in our practice, we felt we needed to intervene. The diabetes educator and team of two dietitians and one nutritionist worked together to develop a patient education handout entitled "Nutrition Survival Skills for Diabetes" (Figure 1).

The handout was developed to serve three main purposes: (1) provide a one-sided, one-page, low reading level handout for our patients; (2) give providers a guideline, or outline, to follow, to provide patients with

Nutrition Survival Skills For Diabetes

Important!!! Please Read!!!

Having diabetes does **not** mean that you can no longer enjoy good food, or that everything you eat "tastes bad." It does **not** mean that you cannot have foods that are sweet.

What it **does** mean, is that you will need to be more aware of what you do eat and how much you eat. Your doctor or dietitian can help you to develop a plan that is right for you and fits into your life style, but until that time, the following are some "survival skills" that may help you to gain better control of your diabetes and blood sugars.

Survival Skills

- ✓ Foods to eat – low fat, high fiber foods and artificially sweetened beverages (not sweetened with sugar)
- ✓ Drink all you want of diet sodas, tea, coffee or Kool-Aid either unsweetened or sweetened with an artificial sweetener such as Sweet 'N Low, Equal, saccharin or Splenda
- ✓ Do **not** drink sugar sweetened beverages such as regular sodas, Gatorade, sugar sweetened tea, coffee or Kool-Aid, Hi-C, Hawaiian Punch
- ✓ Limit your fruit juice (orange, grapefruit, apple, grape, cranberry) to ½ cup every day with a meal until you receive more specific instructions from your doctor or dietitian
- ✓ Do **not** eat concentrated sweets. These include candy, cookies, cakes and pies. Your doctor or dietitian may help you add occasional small amounts of these back into your diet at a later time
- ✓ Eat at least 3 different times throughout the day and about the same amount at each time. That is, do no skip a meal and then eat twice as much at the next meal. This will make it hard to control your diabetes and it may make you feel bad.
- ✓ Cut back on your serving sizes. A serving size is ½ cup fruit, vegetables, pasta or rice; 3 to 4 ounces of meat (about the size of a deck of cards); ½ cup fruit juice; 1 cup of milk; 1 slice of regular white bread; a medium apple or orange; 15 to 20 seedless grapes; ½ of a medium banana.
- ✓ Try to avoid alcohol until you discuss it with your doctor or dietitian.
- ✓ **Remember!!!** Just because a food says it is "dietetic," "sugar free," "fat free" or "low fat" does not mean that it is low calorie or that it will not cause your blood sugar to go up. Do **not** rush out to buy these often more expensive foods – talk to your doctor or dietitian!

Eastern Carolina Family Practice Center
Annette Peery, MSN, RN, CDE

FIGURE 1. Nutrition survival skills for diabetes.

important nutrition education in a concise manner; and (3) implement the handout as an educational tool for family practice residents. The handout focuses on key nutrition education points that have a major impact on glycemic control. Whenever possible, we stated items in the positive rather than the negative (i.e. "do not . . . "). The handout also

focuses on problems we consistently encountered in our patient population—portion sizes and beverages.

As an illustration, we worked with one patient who could not figure out why her blood sugars were always elevated. Upon further assessment and questioning, we found that she believed fruit juice to be a "healthy" beverage and was drinking one gallon per day. Another patient came in one morning for education and had an elevated blood sugar. He seemed shocked about this, especially since he had not yet had breakfast. When questioned about whether or not he had a snack the evening before, he stated that he had a bag of fries. Well, in our minds, that meant an order of fries from a fast food restaurant. When questioned about whether this was a regular or large order, he responded "neither." The patient had eaten a family sized bag of frozen fries.

In our practice, this handout is used by all providers to assist them in remembering what to tell the patient about nutrition and diabetes, and is given to patients to take home. Patients are encouraged to post the handout on their refrigerator as a reminder of these "survival skills" that may have a tremendous impact on their well-being.

Personal experience and using this handout helped this diabetes educator to develop a series of questions to ask to assess the patient's routines and dietary habits. These questions include:

- What time do you get up in the morning? Do you eat breakfast? If yes, what time do you eat? What do you usually eat for breakfast? What do you usually drink for breakfast? If you drink coffee, what do you put in it?
- What do you usually eat for lunch? What time do you eat lunch? What do you usually drink with lunch?
- Do you usually eat or drink anything between breakfast and lunch? If so, what?
- What time do you eat dinner? What do you usually eat? What do you usually drink with dinner?
- Do you usually eat or drink anything between lunch and dinner? If so, what?
- Do you usually eat or drink anything between supper and bedtime? If so, what?
- When you are thirsty, what do you drink?
- Do you ever drink sodas? What kind? How often?
- Tell me about your daily activity. What do you do everyday for physical activity?

These, and other, questions assist in learning about the patient's typical dietary habits and their daily routine. While this is only a small portion of assessment, it is extremely important. After learning more about the patient, you will quickly find many ways that they might improve their nutrition and their glycemic control, but keep in mind, the patient will become overwhelmed if you try to make too many changes. Try involving your patient by saying, "from everything you've told me, I think there are some things that you might consider doing that would help to improve your blood sugars. Some of these things are .... Of all the things I listed, which two do you think you could do between now and when I see you next?" This approach empowers the patient and puts them in control, as opposed to the paternalistic approach of telling patients "this is what you have to do."

Above all, remember that diabetes is a chronic condition and therefore requires chronic education.

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Case Study 5

Diabetes Continuing Care Clinic Group Visits for the Uninsured—A Case Study of Three Community Health Centers

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INTRODUCTION

The Continuing Care Clinic (CCC) model is a relatively new approach to chronic disease management. Also known as the group visit model, the CCC was originally established by the Group Health Cooperative of Puget Sound (Wagner, 1998), demonstrating a positive methodology that leveraged the planned visit protocol format with group education and support. Ultimately the outcomes are improved disease management and enhanced self-care abilities.

In 2003, three community health centers in Arizona participated in the Arizona Department of Health Services pilot project to apply the CCC model to patients who were uninsured and served by the three clinics. The CCC model discussed in this case study exemplifies how the initially defined format can be applied and modified to appropriately fit the practice and patient needs of different populations served.

A detailed Continuing Care Clinic Group Visit Manual can be downloaded from the Improving Chronic Care Website (www.improvingchroniccare.org) under the Critical Tools section. This section includes detailed timelines and formats with sample patient letters and job descriptions of team members. It is notes that the key elements of a CCC Group Visit include:

1. Contact with the primary care team
2. Patient education and coaching
3. Medication management
4. Self-management support
5. Routine clinical/preventive care

6. Periodic health assessments (i.e., annual foot exam, retinopathy exam, nutrition counseling, psychosocial counseling, laboratory work) (Group Health Cooperative, 2001).

PLAN-DO-STUDY-ACT

Each clinic adapted the continuous quality improvement process of Plan, Do, Study, Act or otherwise referred to as PDSA. Every month, each clinic team performed PDSA cycles to improve processes. Included in each clinic description is a sample of their PDSA cycle activities. For more information on the PDSA process refer to Chapter 3.

ARIZONA DEPARTMENT OF HEALTH SERVICES PILOT PROJECT

The Arizona Department of Health Services received a grant from the ASPE to implement the CCC model within two federally qualified community health centers. ADHS funded a third community health center that had more than a year experience in delivering group visits within the uninsured framework. Clinica Adelante, Mountain Park and St. Elizabeth of Hungary Clinic participated in the project. The following summaries describe the different CCC models adapted by each clinic.

CONCLUSION

The pilot program was successful in improving patient diabetes status as measured by the HbA1c (Results can be obtained through the Primary Care Services of the Arizona Department of Health Services). In addition, all three clinics demonstrated improvement in documentation of self-management goals and completion of annual requirements. As a result of the pilot project work, a workshop was given to other community health centers to share the experiences and lessons learned.

Table 1 compares the programs and discusses their preliminary results after providing the CCC for one year.

CASE STUDIES

St. Elizabeth of Hungary Clinic

St. Elizabeth has designed their group visits with the primary purpose to increase accessibility to annual exams and to provide diabetes education to more patients through a "one-stop shopping" format. The clinic had a low rate of patients completing their annual exams for retinopathy and foot. Therefore, the medical director designed a monthly Diabetes Day.

The special day became known as the Diabetes Day Group Visit (DDGV) and was scheduled for the third Friday of every month. Patients were referred from clinic providers and nurses based on any of the following three criterion:

- the patient had an HbA1c greater than 8%;
- the individual had difficulty completing their annual exams; or
- the patient was newly diagnosed with diabetes.

Patients were usually asked to attend the DDGV at the time of their quarterly planned visit with their provider. Their name was placed on a list with others. Usually 15–20 people would be referred and approximately 10–15 would actually attend. An administrative fee of $20 is charged for the entire 3-hour program, which included an ophthalmologist and podiatrist visits. It is coded as a Group Visit.

The program process is as follows:

1. When patients check in they receive a clipboard with the various visit forms and are instructed to the waiting area where they will receive a visual acuity exam and then have eye drops instilled for dilation later in the morning. Annual influenza vaccines are given at this time during the

TABLE 1. Comparison of ADHS Continuing Care Clinic Pilot Programs

	St. Elizabeth of Hungary Clinic Diabetes Day Group Visit	Mountain Park Health Center	Clinica Adelante
Program description	A different group attends the monthly Diabetes Day Group Visit. Group size = 10–12. Takes 3 hours and documented on Group Visit Form.	Groups are identified and the same groups meet once every 3 months. Group size = 25	Groups are identified and the same group meets every 3 months. Group size =7–12
Patients	Tobacco tax eligible (uninsured) adults with type 2 diabetes HbA1c >8, newly diagnosed, difficulty obtaining annual exams. New group every month.	Uninsured patients with diabetes chosen from existing PECS registry	Uninsured (TT) and Insured (very few)
Cost	$20 admin fee for 3-hour group visit	$25 fee	$20.00 for provider visit
Setting	Clinic conference room for education classes and dedicated area for 1:1 exams and checkout	Clinic	Clinic
Comments on setting	Patients move from room to room. Need to keep patients together and utilize staff to facilitate flow, so not to lose them	Patient stays in exam room and providers rotate	Setting is very small, need a larger class room.
Goals	Complete annual exams improve	Complete annual exams Improve HbA1c, LDL, and BP	Complete quarterly exam.
	HbA1c, LDL, and BP		Focus is on the HbA1c
	Complete specialist and class referrals		Improve national collaborative indicators
	Complete self-management goals and follow-up plan with promotoras		Review self-management goals and revise as necessary.
	Motivate patient to attend group classes		
Intervention staffing	Diabetes nurse educators and CDE Dietitian for classes (English and Spanish)	Provider	Nurse practitioner
	PCP	Pharmacist	Endocrinologist
	Pharmacist	Diabetes Case Manager	RN
	Ophthalmologist	Dietitian	Dietitian
	Podiatrist	Dentist	MA
	Promotoras	Behavioral health	Senior leader
	2 Support staff	Senior leader	Support staff
	Senior leader		

(*Cont.*)

TABLE 1. (*Continued*)

	St. Elizabeth of Hungary Clinic Diabetes Day Group Visit	Mountain Park Health Center	Clinica Adelante
Interventions topics	The Basics of Diabetes and Nutrition	Nutrition video	Diet, exercise, and stress management
	Self-management goals	1:1 visits with provider, dietitian, nurse case manager, behavioral health	Vitals and BMI
	Group snacks	Group lunch and socialization	Medication review
	General eye exam Retinopathy exam Foot exam Medication review Referrals to specialists and 7-week classes Flu shots Lab when necessary		Foot exam Laboratory work Group lunch
Results	98–100% receive annual exams	Improved HbA1cs and lipids	Not available at this time.
	100% complete self-management goals	100% complete self-management goals	Total # participating (POF-167)
	78% agree to referral to classes	50 patients have participated in all 3 visits	
	30% no show rate More than 100 patients have participated in DDGV in past 11 months.		
Citation	Lamb, G., and Zazworsky, D. (2002). Disease Management. In Cesta: *The Case Manager's Survival Guide: Winning Strategies for Clinical Practice*, 2nd ed., St. Louis, Mosby. Zazworsky, D. (2002). Disease Management in Managed Care. In Cesta: *The Nurse's Guide to Managed Care*. St. Louis, Mosby.		National Collaborative Literature (list serve literature)
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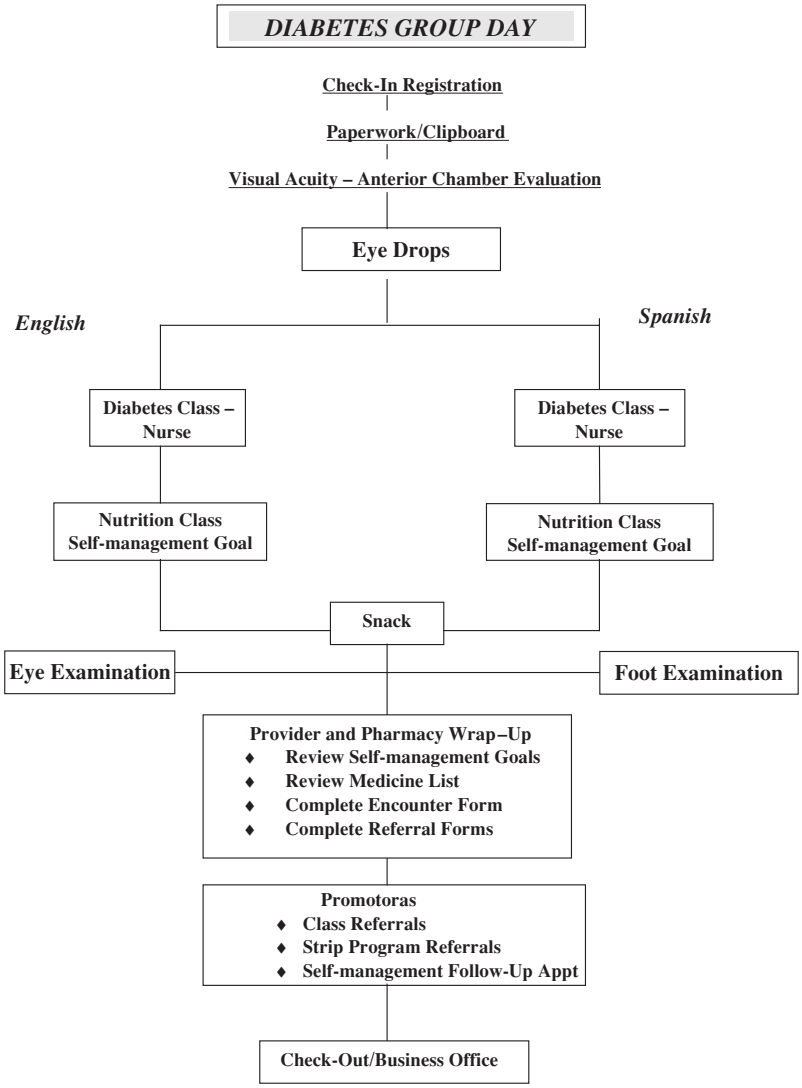
Additional Comments	Difficult tracking results in one-time group visits due to patients not returning to clinic for 3 or 6 month follow-up visits		Patients who have not participated in the classes tend to be the patients who do not follow-up on a consistent basis.

TABLE 2. St. Elizabeth of Hungary Clinic Diabetes Group Visit Flow Chart



appropriate time of the year. Table 2 describes the flow of the group visit.

2. Then patients are directed to the education room. They are divided into two groups: English or Spanish speaking.

3. Each group receives educational sessions on the basics of diabetes and nutrition by the Diabetes Nurse Educators and Dietitian. At the end of the sessions, each patient is given a self-management goal form and asked to complete it. The form is in a checklist format (see Tables 4 and 5) to simplify the process. There is room to write other self-management goals.

4. Individuals are given a healthy snack, then directed to the exam rooms to receive their individual annual exams.

5. Each person receives an individual exam from the ophthalmologist and podiatrist on the DDGV Form. Clinic staff serve as translators when needed (see Table 6).

6. Each person then has an exit interview with the Primary Care Provider who reviews the

TABLE 3. St. Elizabeth of Hungary Clinic Diabetes Day Group Visit Job Responsibilities

PCP	RN project lead	Clinic diabetes nurse (English)	Clinic diabetes nurse (Spanish)	Dietitian	QA RN
Refer patients	Contact podiatrist	Send reminder to staff	Refer patients	Teach class complete self-management goals	Satisfaction evaluation
Contact eye doctor	Data oversight	Coordinate case conference	Teach class (Spanish)	Diabetes day menu/snacks	Education evaluation
Formulate, communicate plan of care for patients	CQI oversight	Teach class (English)	Implement care plan	Refer patients	Assist with QI, PDSA and Promotoras
Scheduler	**Flow master 1**	**Flow master 2**	**Flow master 3 (Volunteer)**	**Pharmacist**	**Promotora**
Call/remind patients	Direct patients	Direct patients	Assist patient flow	Review meds with PCP and patient	Patient checkout
Keep attendance list	Administer eye drops	Assist podiatrist		Make recommendations	Follow-up 'no-shows'
Give patients clipboard with Flow Chart	Assist eye doctor				Follow-up SMG

results and self-management goals, and completes referral forms as needed. The PCP signs off on the self-management goals or makes adjustments with the patients based on the patient's medical needs. The referrals may include further follow-up with an ophthalmologist, podiatrist, dietitian, and/or nurse.

7. Finally, the person is directed to the Promotora table. Here the Promotora and the patient complete any other paperwork, agree on a time when the Promortora can call to see how their self-management goals are progressing, and to enroll the patient and family into the group classes.

Each person has specific responsibilities before, during, and after the DDGV. Table 3 defines these activities.

The providers and staff document on the DDGV form (Table 4) and this becomes part of the patient's record.

Outcomes

The DDGV evaluation process focuses on three areas: clinical, quality, and financial.

The clinical parameters looked at the issue of how many people were receiving annual exams for retinopathy and foot exams and identifying self-management goals. Approximately 98% of the patients who attend the DDGV completed their annual exams. Hundred percentage of the patients completed self-management goals. It also should be noted that 78% of the patients who attended DDGV agreed to attend the 7-week educational series and 50% of those patients actually completed the classes (see Tables 5 and 6).

The quality measures looked at patient satisfaction. Table 7 illustrates patient satisfaction outcomes for DDGV.

TABLE 4. St. Elizabeth of Hungary Clinic Diabetes Quality Indicators

St. Elizabeth of Hungary Clinic
DIABETES DAY

Spanish_____

English_____

Patient's Name _____ Date _____

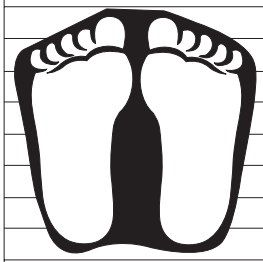
Address_____ D.O.B. _____

Age _____ Sex _____ Chart No._____

Home Phone _____

Date of Last Exam _____

Foot Neuropathy Screening Exam



General Diabetes Class

Diabetes Nutrition Class

Retinopathy Screening Exam

	V_A	V_A
Ophthalmoscopy Dilated	c̄	
Disc		
Vessels		
Macula		
Retina		

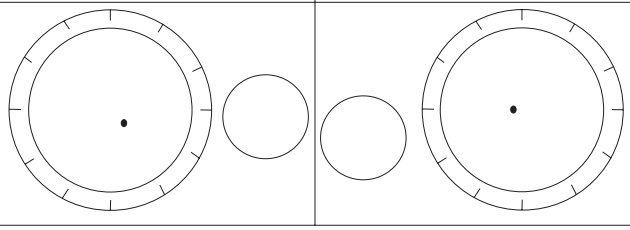


TABLE 5. Self-Management Tool

ST. ELIZABETH OF HUNGARY
SELF-MANAGEMENT SUPPORT TOOL
HEALTHY CHANGES PLAN

Patient Name:_____ MR #_____

Telephone Number:_____ Date:_____

Please initial and place an ✔ in the box next to *one* self-management goal that you agree to follow. This goal will be evaluated on your next monthly visit to the clinic.

✔ Initial

❑ ___ I will lose about 1–2 pounds this month.

❑ ___ I will eat foods containing carbohydrate in moderation at regular times every day.

❑ ___ I will eat 3 or more servings of vegetables each day.

❑ ___ I will limit my servings of fat to 2 or 3 each day.

❑ ___ I will not skip meals.

❑ ___ I will do some type of exercise (physical activity) for a total of 15–30 minutes,

3–5 times per week (includes walking, stair climbing, running, and swimming).

I agree to have St. Elizabeth contact me by telephone calls or mail. Yes □ No □
Patient Signature indicates agreement to do the selected goal. It also grants permission for follow-up telephone calls or to send mail).

Patient Signature:_____ Date:_____

Reviewer Signature:_____ Date:_____

Restrictions: Yes G No G Comment _____

Care Provider Signature:_____ Date:_____

Weekly Telephone Contact:

Date: _____ Time: _____ Provider Name: _____

Weekly Telephone Contact:

Date: _____ Time: _____ Provider Name: _____

Weekly Telephone Contact:

Date: _____ Time: _____ Provider Name: _____

Three Month Follow-up Appointment:

Date:_____ Time:_____

The financial outcomes were examined from a cost burden perspective. In other words, what did it cost to run a DDGV and how many patients are needed to attend to make it worthwhile for the clinic. There is not a true breakeven point here, because we are talking about the uninsured with no real reimbursement incentive. Therefore, the incentive is to improve access to care and enhance patient adherence and motivation to pursue further self-management activities.

TABLE 6. Self-Management Tool in Spanish

ST. ELIZABETH OF HUNGARY CLINIC
INSTRUMENTO DE APOYO PARA EL AUTOCUIDADO
PLAN DE CAMBIOS SANOS

Nombre del Paciente:_____ MR #_____

Numero Telefónico:_____ Fecha:_____

Ponga sus iniciales ✔ en la caja junto a una de las metas que usted se compromete a seguir. Esta meta será evaluada en su próxima cita.

✔ Inicial

❑ ___ Voy a perder de 1 a 2 libras este mes.

❑ ___ Voy a comer comidas que contienen carbohidratos en moderación y a horas regulares del día.

❑ ___ Voy a comer 3 o mas porciones de vegetales al día.

❑ ___ Voy a limitarme a de 2 o 3 grasas al día.

❑ ___ NO me saltare comidas en el día

❑ ___ Haré algún tipo de ejercicio (actividad física) por lo menos de 15 a 30 minutos, 3–5 días por semana (incluye caminar, subir y bajar escalera, nadar, o correr).

Otorgo mi permiso para que la Clínica Sta. Elizabeth me hable por teléfono o me mande una carta por correo. Si.❑No.❑
(Al firmar este documento, usted se compromete a seguir una de las metas. También le da permiso a la clínica de llamarle por teléfono o contactarlo/a por correo.)

Firma del paciente:_____ Fecha:_____

Firma del Evaluador:_____ Fecha:_____

Firma del Proveedor:_____ Fecha:_____

Llamada semanal:

Fecha: _____ Hora: _____ Nombre del proveedor: _____

Llamada semanal:

Fecha: _____ Hora: _____ Nombre del proveedor: _____

Llamada semanal:
Fecha: _____ Hora: _____ Nombre del proveedor: _____

Próxima Cita durante tres meses:

Fecha:_____ Hora:_____

Cost Breakdown

The clinic estimates that an average cost for the clinic is approximately $600–$1000 for 3 hours every month. This would include the costs related to staffing the clinic, preparation, and follow-up time. The average revenue of $20/patient for an administrative fee barely offsets any of the costs. Since there is an uninsured population, there is no reimbursement and the "one-stop shopping" philosophy is an advantage for both patients and providers. The outcomes related to completed annual exams and increased likelihood of participation in

TABLE 7. St. E's Diabetes Day Group Visit Patient Satisfaction Survey Results

Question	Response score
Information presented clearly	2.8
Learned new information	2.9
Going to change eating habits	2.9
Enjoyed DDGV	3.0

group education classes are important. Therefore, it is imperative that the focus on attendance be addressed to keep the cost per patient between $50 and $70.

In an insurance reimbursement or pay-for-performance framework, the group visit is a very positive approach to achieve clinical, quality, and financial outcomes.

PDSA Cycles

A major effort of the clinic PDSA process improvement focused on attendance (Table 8). The DDGV consistently experienced a 50% "no show" rate. Although this was alarming, the promotora phone follow-up of the "no shows" regularly reported family crisis or they did not think it was necessary right now (Table 9). Some patients reported transportation or financial issues as a barrier, so we established a scholarship program. Now, when the promotoras do the reminder calls prior to the group visit, they explore potential problems and have the option to offer scholarship vouchers. The end result has taught the team they need to schedule 20–25 people in order to have 10–12 attend.

Lessons Learned

As a result of the DDGV, the following lessons were learned:

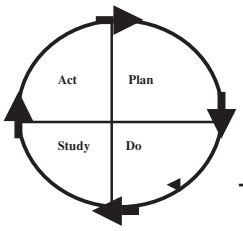
- Even when patients are administered eye drops to dilate their pupils, they will still be active participants in the group education process.
- Clinic staff members were comfortable in one-to-one teaching scenarios, but must develop new skill sets to manage the larger group visit format.
- Be prepared for New Patient Shows—people read the quarterly newsletter and just showed up.
- DDGV serves as a motivator into group education classes.

Mountain Park Health Center

Mountain Park Health Center (MPHC) is a nonprofit community health center that has been providing comprehensive primary care services to the greater Phoenix metropolitan area since 1980. Mountain Park Health Center has health center sites in four locations: South Phoenix, Maryvale, Tolleson, and East Phoenix. Services offered include primary medical care, dental care, pharmacy services, nutrition counseling, behavioral health services and community-based tobacco prevention, and cessation services. In 2003, the MPHC provided primary health care services to more than 38,000 individuals, comprising more than 120,000 patient visits. To date, more than 1,500 individuals with diabetes have been enrolled in the health center's diabetes program. Efforts to improve the health care and health status for patients with diabetes have included the development of the CCC, successful use of the tele-ophthalmology retinal screening program, and the development of a diabetes case management program. Classes also are offered for patients with diabetes in English and Spanish.

Mountain Park Health Center adapted the group visit model that is defined in the Group Visit manual. Under the leadership of the Quality Director, MPHC organized a CCC Care Team that included: a pharmacist, nutritionist, behavioral health specialist, physician, RN, and MA to do the retinal screening. The team also established checklists, assessment tools, and documentation forms. The

TABLE 8. Process Improvement Form: PDSA



St. Elizabeth of Hungry
PDSA Form

Team: Donna, Chris, Linda, Paula, Mary, Catherine, Belen, Yvonne

CHRONIC CARE MODEL COMPONENT: **Self-Management Support**

Community Linkages Organization of the Healthcare Delivery System

Problem: Poor Self-Management Goal Documentation

Objectives of the Test
Plan: 1) Develop a self-management tool for the patient provider to document self-management goals on Diabetes Day Group Visit (DDGV).
DO: 1) Create a tool with the multidisciplinary team 2) Train the promotoras and providers on the use of the tool 3) Administer the tool at the DDGV scheduled for September 12, 2003 4) Analyze the results
Study: 1) 100% of DDVG patients completed a mutually set (patient and provider) SMG
Act: 1) Implement the tool at every DDGV 2) Create a PSDA on SMG follow-up

team also hired a part-time Diabetes Case Manager to provide one-on-one education and self-management coaching at the time of the group visit as well as follow-up on patients after the clinic.

The CCC Care Team held numerous planning meetings to organize the flow of the group visit, develop forms and determine the educational format. The Team Leader also contacted local sales representatives from

TABLE 9. St Elizabeth of HungaryDiabetes Telephone Visit Log for Promotoras (Visit Code 99371)

Patient Name	**MR #**	**Date**	**Caller Initials**	Logged in database **(Y or N)**	**Hospitalized Since Last Clinic Visit/Call? (Y or N)** Yes requires a comment in pts chart	Reason for Follow-Up Inquiry SMG – Self-management goal L – Reminder to complete logs AR-Appointment reminder O- Other (please specify)	Comments M-Patient Moved TD-Telephone disconnected NA-No answer (p 3 tries) D-Deceased DNC-Do not contact/pt request H-Currently hospitalized O- Other (please specify)

Callers Signature:_____ Callers Signature:_____
Callers Signature:_____ Callers Signature:_____

pharmaceutical companies to provide lunch on the CCC Day.

To begin, eligible patients were identified from their patient registry. Each patient was notified about the new CCC opportunity. If they agreed to participate, the patient was scheduled for the CCC. Prior to the day, a data entry staff member keeps track of patients that are in clinic and organizes the schedule. She pulls the charts and runs the super-bills the day before clinic.

On the day of the CCC, the Medical Assistant triages patients and, if needed, does a HbAlc and checks cholesterol before putting patient in the room. They are then placed in a room and each provider floats through the exam room on 15-minute intervals. The lead RN tracks the patients through the process, making sure that each provider has seen the patient. One advantage of this process is that it is the provider who rotates rooms, not the patient. After all patients have been seen through the provider rotations, they are given lunch and participate in a group session that includes a video on the PACE Nutrition Program with time for group discussion.

The following three forms are examples adapted for the Mountain Park Health Center Continuing Care Clinic.

Patient Behavioral Health Questionnaire

In the past 2 weeks have you:	(Circle patient answer)	
1. Had little interest or pleasure in doing things.	Yes	No
2. Felt depressed or hopeless.	Yes	No
3. Had trouble falling/staying asleep, or slept too much	Yes	No
4. Felt tired or had little energy?	Yes	No
5. Experienced a noticeable change in appetite	Yes	No
6. Had trouble concentrating on things?	Yes	No
7. Had thoughts of harming yourself?	Yes	No

Over the past 6 months, have you experienced excessive worry and anxiety? **YES NO**

If yes, please ask about the following and circle those that apply.

Does your anxiety or worry include: **restlessness, fatigue, difficulty concentrating, irritability, or muscle tension?**

1. Have had nightmares about it or thought about it when you did not want to?
YES NO

2. Tried hard not to think about it or went out of your way to avoid situations that reminded you of it? **YES NO**

3. Were constantly on guard, watchful, or easily startled? **YES NO**

4. Felt numb or detached from others, activities, or your surroundings? **YES NO**

Do you currently, or have you ever had problems with alcohol or drug use? **YES NO**

If available at Mountain Park Health Center, would you pursue specialty assistance for these difficulties? YES NO

DIABETES CONTINUING CARE CLINIC
PROVIDER CHECK SHEET

PROVIDER_____

PHARMACIST_____

DIABETES CASE MANAGER_____

DIETICIAN_____

DENTIST_____

BEHAVIORAL HEALTH_____

RN_____

PROGRESS NOTES FOR CONTINUING CARE CLINIC
MOUNTAIN PARK HEALTH CENTER

DATE: MEDICAL RECORD:
PATIENT NAME: D.O.B.:

DIABETIC EDUCATOR:

Provider Signature:
PHARMACY:

Provider Signature:
BEHAVIORAL HEALTH:

Provider Signature:
NUTRITION

Provider Signature:

DENTAL:

(SEE DENTAL SCREENING FORM)

Clinica Adelante, Inc.

Clinica Adelante, Inc (CAI) is a community and migrant health center dedicated to providing primary care services to all residents of western Maricopa County and its rural communities. Primary and specialty health care services are provided at Clinica Adelante's community health centers in Surprise, Buckeye, Gila Bend, Mesa, Sun City West, and Wickenburg.

Clinica's Diabetes Continuing Care Clinic (CCC) was offered to patients with diabetes who were identified by providers as high-risk individuals who would most likely benefit from a group visit. The clinic consisted of three components over a 3-hour timeframe:

1. *Medical*: A planned diabetes visit was performed by the endocrinologist
2. *Social*: Peer support was experienced as part of the educational and group support process.
3. *Educational*: Participating patients received group and individual education on nutrition, self-management, and physical needs.

The following staff members were part of the CCC Team:

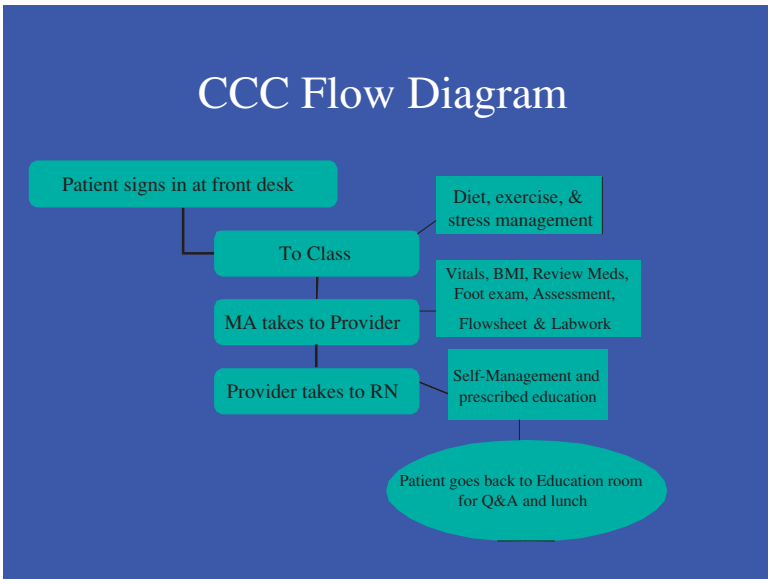
- Medical Records,
- Front Desk,
- Nutritionist/CDE,
- Medical Assistant,
- Provider,
- RN,
- Administrative Assistant, and
- Senior Leader.

Below is a Flow Chart of Clinica Adelante's Continuing Clinic.

PDSA Cycles

Over the year, the CCC Team performed the PDSA cycles on a number of different process improvement aspects.

- *Business cards*. The team tested using business cards to provide continuity of communication between patients and staff. This worked well and was implemented throughout the clinic.
- *Ophthalmology vouchers*. Each patient who participated in the Group Visits received a voucher to go to an ophthalmologist for their annual retinopathy exam. CAI subsidized the cost of the visit to increase the compliance rate of annual retinal exams. Unfortunately the cost was prohibitive and did not reduce the no-show rate. Other options are being tested.
- *Medication lists*. A medication list was developed to encourage that a medication review was completed with each visit. The medical



assistants initiate the review and providers check for accuracy and sign off on the form.

- *Patient reminders*. The administrative assistant, through use of the data registry, provides staff with reports that indicate those patients who are due or overdue for a visit. Team members use the list to call patients to remind them of the need for follow-up.
- *Voice mail box/E-mail notifications*. This PDSA was initiated to provide feedback from specialists about patients who "no-showed". The process worked, however, we have not continued to use it due to time and cost factors.
- *Flow sheets*. This was a multicyle PDSA. The end result was a flow sheet that incorporated one year of quarterly visits, correlated with data entry flow, provided an area for the patient to sign off acknowledging receipt of a patient education folder, and reminded the provider to check for other chronic disease flow sheets.

Lessons Learned

1. *Large team structure*. Initially the team was too large, consensus was difficult to obtain. In the future, we will start with a smaller cross-functional team.
2. *Communication*. Members of the team came from different beliefs and interests on how the CCC should be created and managed. Change came about slowly.
3. *Cultural diversity*.
   - *Patient perspective*: Patient comments reflect that they preferred a class that is facilitated in their native language. We noticed improved participation and outcomes when classes were separated into Spanish and English.
   - *Clinical perspective*: We learned that cultural diversity plays an important role in providing care and education.
4. *Loss of provider staff for clinical day*. We learned that we needed to change the day of the CCC to a day when walk-ins were less heavy. Initially, we held the classes on a Monday morning. This created a heavy work load for providers not involved with the CCC.

To paraphrase the National Collaborative's motto under the Bureau of Primary Health care (Health and Human Services), changing practices does change lives for everyone involved. It is evident by our improved functional and clinical outcomes that the concept of the CCC is a valuable framework from which both patients and staff benefit.

ACKNOWLEDGEMENTS. We would like to acknowledge the Arizona Department of Health Services, Patricia Tarango, Director, ADHS Primary Care Services and Gordon Jensen, AHDS Primary Care Services for leadership, funding, and encouragement to explore new models of care for the uninsured.

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Case Study 6

A Hospital Case Study in Diabetes Management—Carondelet Health Network

Rose Marie Manchon

Diabetes Care Centers, Carondelet Health Network, Tucson, Arizona

HISTORY

Carondelet Health Network (CHN), a member of Ascension Health, is the oldest and largest not-for-profit health care provider in Southern Arizona. Carondelet serves the community with multiple inpatient and outpatient facilities. Presently, the Carondelet Health Network is made up of St. Mary's Hospital on the west side of Tucson, St. Joseph's Hospital on the east side, Holy Cross Hospital in the border town of Nogales, AZ, and the outpatient Medical Mall of Green Valley, AZ.

Carondelet St. Mary's Hospital began in the 1880s when the Sisters of St. Joseph of Carondelet came to the area to provide education and health care to a then remote area. The Sisters built the hospital to continue their philosophy of caring for all persons and fulfilling the mission of the Roman Catholic Church through St. Mary's Hospital, St. Joseph's Hospital, Holy Cross Hospital, and Green Valley Medical Mall.

Today, the Carondelet Health Network serves a diversity of clients—Anglo, Latino, Native American, and Black Americans, reflecting the population of Southern Arizona. As is noted in the literature on diabetes, the highest prevalence is in the Latino, Native American, and Black communities. This diversity in Pima County presents unique challenges for health care providers. Diabetes is the 4th leading cause of death among Native Americans; the 5th leading cause of death among Latinos; and 4th leading cause of death among Black Americans (Arizona Department of Health Services [ADHS], 2003). The Anglo community is certainly contributing to the growth and widespread concerns about diabetes; however, the ratio of developing the disease is almost twice as high among non-Anglos (ADHS, 2003).

The CHN sits in the pocket of an area with a high prevalence of diabetes and diabetes related diseases. Over the last few years, Pima County has estimated 44,235 people with diabetes: the largest age group

being the 45–64 group with 18,133 (ADHS, 2003).

This case study will describe the inpatient and outpatient programs at St. Mary's and St. Joseph's Hospitals specifically. Refer to Appendix 1 for a profile of the clients and annual program outcomes.

In the late 1980s, Carondelet followed through with their commitment by beginning a Diabetes Care Center (DCC) at St. Joseph's Hospital that served inpatients and outpatients. This Center was devoted to the education and improvement of lifestyles of those with diabetes. The DCC also focused on education for the staff of the hospitals and other outpatient facilities. Early on, CHN recognized the need to help the people in Southern Arizona learn about and live with diabetes and to respond to working toward prevention of the disease.

OUTPATIENT AND INPATIENT ISSUES

The Diabetes Care Center at St. Joseph's Hospital started outpatient classes; the DCC nurses studied for certification exams, and implemented statistical measures to apply for the American Diabetes Association Recognition Program. As the nurses received their Certified Diabetes Educator (CDE) credentials, the program moved forward with an increased numbers of clients. Soon after, the center applied for and received the American Diabetes Association (ADA) Recognition Award. St. Mary's Hospital followed in the early 1990s with a separate DCC to accommodate those on the west side of town and was granted the Recognition Award in the early 1990s.

Originally, in both DCCs, educators handled inpatients diagnosed with diabetes or with diabetes as co-morbidity on a referral basis and by daily assessment of the admissions list of newly admitted patients These were loosely organized inpatient programs that worked only when DCC personnel was not stretched to the limit. On the other hand, the outpatient programs provided a structured series of classes for clients referred by their physician and was more effectively managed.

Both inpatient programs were not formalized in the early years and were sporadic at best. The outpatient programs, with the advantage of ADA Recognition Award were blossoming. Endocrinologists, Internists, and Family Practitioners began referring at a regular pace. The Obstetricians began sending their gestational diabetes patients to the program in their early pregnancy, and Pediatricians recognized the unique knowledge and skills of the CDEs with children.

Strong relationships built through good communications were the underlying factor to the success of the outpatient programs. The physicians trusted the veracity of the educational assessment and recommendations of the CDEs and were willing to work collaboratively. The nurses and dietitians considered each client as a unique individual with different lifestyles and different coping skills. This individualization remains today as a cornerstone and most respected aspect of the Carondelet Diabetes Care Centers.

Because of the magnitude of the inpatient referrals with new or out-of-control diabetes, the limited staff of the DCCs was overwhelmed and could no longer accommodate inpatients with appropriate education during their stay. St. Mary's Hospital instituted a Nurse Resource Program to address this problem. The Nurse Resource Program included a seminar 2–3 times a year to update and reeducate nurses and health care providers on the newest and most current information on the care of the person with diabetes. Each unit or department sent representatives to the seminars to learn about diabetes and serve as a resource person to that unit. The response to the classes was always amazing—nurses, dietitians, and other health care workers were vitally interested in learning about diabetes. The Nurse Resource Program was creative and effective for a period of time. Gaps in service occurred when the resource person moved on to other jobs. The hospital units were slow to recognize that the special resource nurse was

no longer available. Over time, very few units retained the resource nurse, leaving the hospital wide diabetes education program as an episodic event.

INPATIENT CASE MANAGEMENT

Many discussions and consequent experiments occurred at both St. Mary's and St. Joseph's Hospitals. At St. Joseph's Hospital, the DCC educators and staff supported the Diabetes Case Manager (DCM) model as the appropriate way to handle inpatients with diabetes. Ideally, the DCM is a combination case manager and diabetes educator. Duties include: (a) client risk assessment, (b) coordination of comprehensive care, (c) meeting immediate diabetes education needs, (d) assisting clients in identifying necessary lifestyle changes, (e) problem solving with clients, (f) linking clients with providers, and (g) enrolling clients in an outpatient program (Hospital Case Management, 2000).

The DCM, a full time, dedicated educator (preferably a CDE), uses the DCCs as an education resource and for backup coverage. Because educators are available, this model works well in providing survival skills to the newly diagnosed and refreshers to the patient with diabetes who is out of control.

The outpatient DCCs accumulated a plethora of booklets, instructional tapes, handouts, diets, general, and specific information on diabetes that the inpatient DCM has available. Ideally, the DCM would be part of the Diabetes Center as a regular Full Time Equivalent (FTE); however, it works well if the educator is under the Nursing Department with collaborative ties to the Diabetes Centers.

While St. Joseph's Hospital pilots the DCM position, St. Mary's will reinstitute the Nurse Resource Program for another trial, correcting problems that were identified in the last seminars. The Nurse Resource Program will reach for a wider audience—including all team members of the diabetes management group.

Outpatient programs have been the largest and most successful programs addressing diabetes care that Carondelet offers. It is a recognized fact that outpatient education with CDEs as instructors is the best way to affect the lives and behaviors of those with diabetes.

STAFFING

The DCC staff at both hospitals is staffed with CDEs, qualified registered nurses and registered dietitians, administrative support personnel, and an office coordinator. Currently, the DCC's Program Coordinator position is filled by a full time CDE, an academically prepared and experienced educator (ADA, 2004), replacing the former manager who was a Clinical Nurse Specialist with graduate credits in management. The Program Manager is responsible for the efficacy and coordination of the education program. The diabetes team is led and advised by a mandatory advisory committee headed by the Program Manager. An endocrinologist, with specialization in diabetes management, as well as all members of the advisory committee, is available to the staff for questions and advice on an as-needed basis.

STRUCTURE AND CONTENT

The DCCs, as recognized education programs, follows the curriculum recommended by the ADA. The curriculum and content must address: (a) diabetes disease process, (b) nutrition, (c) physical activity, (d) medications, (e) monitoring/using results, (f) acute and chronic complications, (g) goal setting and problem solving, (h) psychosocial adjustment, and (i) preconception care, pregnancy, and gestational diabetes mellitus—GDM (ADA, 2004).

In addition to the regular classes that follow the ADA content and curriculum requirements, St. Mary's Hospital conducts a weekly general overview diabetes class—in English and in Spanish—to the public, free of charge. The bilingual classes are headed by

a registered nurse who has met the necessary continuing education units (CEUs) to be eligible to teach in the Recognized Centers. The class attracts people with diabetes and/or interested family members from the community.

The outpatient class structure has changed over the years to accommodate the numbers of referrals, the changes in insurance reimbursement or co-payment, and to take full advantage of the team teaching talents of the staff. Four years ago, the class structure was six, one and a half hour classes divided by content, and one follow-up visit as part of the series. The maximum number in those classes was 6–8 clients with one instructor. Today the DCCs offer 4-hour-long classes with a maximum number of 10–12 clients and two instructors. The content is more integrated and addresses burning questions on the first visit. A registered nurse and dietitian, both CDEs, teach each class. The classes are formatted to accommodate the lengthy time span by adding regular breaks, group interaction, chair exercises, and even light dancing.

All materials used at the centers are ADA-approved, the power point and slide presentations are offered by the American Association of Diabetes Educators (AADE). Pharmaceutical companies that produce drugs to control diabetes are generous with their educational material.

Anyone can make referrals to the program—patient, family member, or concerned health care provider. However, a physician order is needed to enroll the client and begin instruction. Referral forms are sent to area physicians, nurse educators, case managers, and office referral nurses for their use.

Most insurance programs do cover diabetes education. However, in the last few years, insurance companies have offered menus to the employers and it is the employer's choice as to whether or not diabetes education will be covered. Medicare covers diabetes education with a physician order. The physician's referral nurse is often asked to check on coverage, or the client is asked to call and inquire, especially about the expected co-payments as they progress through the program. Of course, the staff often calls for the client.

BUDGET ISSUES

Each year when the budget was set, the focus was on FTEs needed to carry out the program. Obviously, diabetes education is a labor-intensive effort. Supplies included in the budget increased as the number of enrolled clients increased. In fiscal year 2002–2003, both St. Mary's and St Joseph's Diabetes Care Centers accommodated 6,051 class attendees. This was a jump from 4,641 attendees in 2001–2002. At one time, an HbA1c was done on each client to compare the "before" and "after"; however, as our numbers grew and time span of class shortened, it became too difficult to continue. Now, the department depends on the physician's office to give the HbA1c results both prior to and after the series.

The most expensive supplies were the testing strips and cartridges needed for the occasional HbA1c measurement. General office supplies and laboratory services were included as was money to support the attendance of the staff at conferences and specific CEU offerings that were needed in order to retain the ADA Recognition.

RECOGNIZED PROGRAM

Recognition by the ADA was a very important step for the Carondelet Diabetes Care Centers for many reasons. As a result of being ADA recognized, the program setup was a systematic process in delivering education and monitoring for each person enrolled. The National Standards for Diabetes Self Management Education (ADA, 2004) outlines the content and curriculum, staffing and qualifications necessary to deliver a top quality program. As the standards are put into place, the program takes form as an organized, salient program. Information on the ADA Recognition status can be retrieved from the ADA Web site www.diabetes.org.

Recognition is a necessary designation for Medicare reimbursement on diabetes education.

CARONDELET FOUNDATION GRANT

In October 2001, the Carondelet Foundation's Parish Nurse Program received a $600,000 federal appropriations grant that was designated for diabetes education for an underserved community in the St. Mary's Hospital catchment area. The overall aim of the grant was to give those with diabetes the knowledge and skills to control the disease and avoid long-term complications (Carondelet Foundation Community Diabetes Program, 2004). Because the Carondelet Parish Nurse Program and the DCCs shared the same manager, staff members from both programs were involved in the grant. The grant eventually was approved for 3 years, enabling the grant workers to become deeply involved in the community.

The grant was modeled after the Promotoras Model used by the Mel and Enid Zuckerman College of Public Health in several border health grants. Promotoras are Community Health Workers (CHW) chosen from the local, ethnic community, who have met education requirements and are supported by the American Public Health Association. The CHW's conduct outreach, participate in the education classes and do individual and group follow-up of enrolled clients (Carondelet Foundation Community Diabetes Program, 2004)

The planning and development of the program took 4–6 months, laying out the direction that the staff would take and began to lay the groundwork for partnering with the community, for developing needed policies, curriculum, and forms.

The staff worked hard at creating partners in the community to help with implementing prevention strategies and supporting lifestyle changes for the community. The cooperation and willingness to help was impressive. Community partners included: Carondelet Community Trust, El Pueblo Health Center, St. Elizabeth's of Hungary Community Health Center, Mel and Enid Zuckerman College of Public Health, Canyon Ranch, University of Arizona College of Nursing, El Pueblo Fitness Center, and the local Young Women's Christian Association (YWCA).

The staff developed a series of classes that addressed the basic content of the ADA recognized classes. They offered behavioral strategies that would build capacity in the participant. Grocery store tours, walking programs, passes for the graduates to the local fitness center, a diabetes empowerment card, and support groups were among the activities tied in to the program.

The total number served was 350. About 75% of those graduated by attending at least 4 out of 5 pertinent classes. A third of the participants took part in a 6-month follow-up questionnaire (Carondelet Foundation Community Diabetes Program, 2004). Program results demonstrate the classes immediately impacted the health of the participants. The measures used to evaluate were: HbA1c, blood pressure, random blood sugar, and weight. At the end of the program, the results were reported as follows:

- Average random blood sugar decreased 26 points—187 to 161.
- Average random blood sugar decreased 49 points among those with HbA1c >6.9.
- Average weight decreased by 3.3 lbs.
- Among those with elevated blood pressure, the systolic decreased by 5.2 and the diastolic by 18.8.
- After 6 months, the HbA1c dropped 1.2% from 8.8 to 7.6 among the high-risk population (Carondelet Foundation Report, 2004).

SUMMARY

The Carondelet Diabetes Care Centers continue to adapt to the needs of their clients and the institution. As a member of Ascension Health, Carondelet has committed to the goal of providing health care access to

all. The Diabetes Program is an example of the outreach to all levels of clients—high or low risk, insured or noninsured, educated or noneducated. The challenge and the goal of the Sisters of St. Joseph of Carondelet continue through these outreach efforts.

APPENDIX 1

Profile of Clients Served—January 1, 2003—to December 22, 2003

	St. Joseph's		St. Mary's	
Age group				
18 years or younger	0	0%	1	0%
19–44	203	29%	212	24%
45–64	306	43%	417	47%
65 years and over	177	25%	220	25%
Unspecified	12	0%	30	0%
Total	698		880	
Gender				
Females	418	59%	576	65%
Males	247	35%	295	33%
Total	698		880	
Ethnicity				
American Indian	0	0%	8	0%
Asian	15	2%	11	1%
African-American	28	4%	27	3%
Hispanic	140	20%	451	51%
White/Caucasian	499	71%	349	39%
Unspecified	16	2%	34	3%
Total	698		880	
Diabetes type				
Gestational	99	14%	101	11%
Type 1	3	0%	7	0%
Type 2—insulin	10	1%	88	10%
Type 2—noninsulin	585	83%	677	76%
Other	1	0%	1	0%
Unknown	0	0%	6	0%
Total	698		880	
Treatment type				
Combination	524	75%	422	56%
Diet only	75	11%	238	31%
Insulin	12	2%	35	5%
Oral	2	0%	41	5%
Unspecified	85	12%	121	16%
Total	698		759	
Hemoglobin A1c	92 patients had 2 A1c levels recorded		70 patients had 2 A1c levels recorded	
Average time 1	7.76		7.89	
Average time 2	6.45		6.55	
Percentage of change	16.88% decrease		17.03% decrease	
Body mass index	269 patients had 5 weights recorded		288 patients had 5 weights recorded	
Average BMI time 1	32.70		32.60	
Average BMI time 5	32.14		32.09	
Percentage of change	1.71% decrease		1.57% decrease	
	345 Patients had 4 weights recorded		425 Patients had 4 weights recorded	
Average BMI time 1	32.88		32.78	
Average BMI time 5	32.46		32.37	
Percentage of change	1.27% decrease		1.25% decrease	

Source: Carondelet Diabetes Care Centers Annual Statistics Report (2004).

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