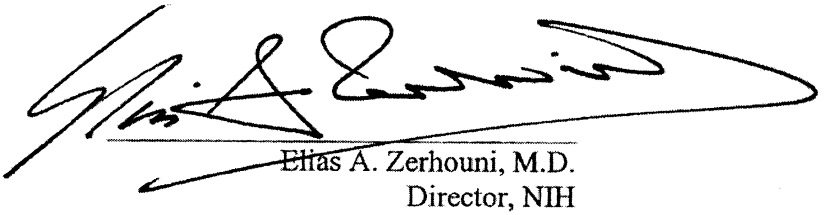
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases

REPORT ON CLOSING THE DISPARITY BETWEEN HEMOGLOBIN A1C TREATMENT GUIDELINES AND PRACTICE



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In the House report No. 109-143, the Committee on Appropriations requested that the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) prepare and submit a report examining the disparity between available guidelines for type 2 diabetes management and actual treatment; and on actions the government can take to close that disparity (p. 66). The following is submitted in response to the request.

Type 2 diabetes is a chronic, debilitating disease that exacts a heavy human and financial toll on a large and growing segment of the U.S. population. The disease most commonly afflicts the elderly, but is seen with increasing frequency in younger adults and even children. Type 2 diabetes afflicts all races and socioeconomic groups, but is particularly widespread in minority populations and among the poor. Diabetes leads to a wide variety of serious complications, including but not limited to heart disease, kidney disease, blindness and peripheral nerve damage, all of which can greatly diminish quality of life, and be extremely expensive to treat. However, several major studies have provided hope by showing that people with diabetes can prevent or significantly delay onset of these complications through effective control of their blood sugar. These studies led to the development of the guidelines for diabetes management referred to in the House report.

To examine the disparity between guidelines and treatment, this report examines adherence to blood sugar control recommendations for the population as a whole, and within various demographic groups. Unfortunately, a variety of studies show that blood sugar control has not improved, overall, among people with diabetes in the U.S. Although some sub-populations—most notably white Americans and those with health insurance—have seen modest gains, others, especially poor and minority populations, have not. Further, in no group does more than 50 percent of the population achieve guidelines for blood sugar control. This report goes on to explore the medical and, socioeconomic factors contributing to the disparity.

The Diabetes Mellitus Interagency Coordinating Committee (DMICC) has representatives from all of the federal agencies with a direct role in diabetes research, surveillance or care. The issue of what actions government can take to help close the disparity was referred to the DMICC for input, which was incorporated in the final section of this report. Such actions may include support for developing better ways to treat diabetes, diabetes education, disease surveillance and medical care. Each of these can be tailored to subpopulations that are at particular risk.

Introduction

In its report on the Fiscal Year 2006 budget for the Department of Health and Human Services, the House Committee on Appropriations stated:

> "*Type-2 diabetes.*—Type-2 diabetes exacts an enormous human and economic toll on Americans. Diabetes costs the healthcare system more than $92 billion a year. Medical research has shown that achieving and maintaining a blood glucose level below 7 percent significantly lowers the risk of blindness, amputation, and other serious complications of diabetes. The Committee is concerned that, despite these advances, only about 2 in 5 diabetics report having a blood glucose level of less than 7 percent. The Committee recognizes that treatment guidelines for diabetes exist that include recommendations for achieving and maintaining appropriate glucose levels, and the Committee encourages NIDDK to promote greater use of treatment guidelines in clinical practice. The Committee requests that NIDDK examine the disparity in available guidelines and actual treatment and report to Congress within six months of enactment on actions the government can take that will rapidly close the disparity between treatment guidelines and the care diabetics receive within the first year of being diagnosed." (House report No. 109-143, page 66)

The following report has been prepared by the NIDDK, National Institutes of Health of the Department of Health and Human Services in response to this request.

Background

*The Burden of Diabetes***:** Diabetes is a debilitating disease that affects an estimated 20.8 million people in the U.S.—over 7 percent of the total population—and is the sixth leading cause of death[1]. Diabetes lowers average life expectancy by up to 15 years[2], increases cardiovascular disease risk two-to-four-fold[1], and is the leading cause of kidney failure, lower limb amputations, and adult onset blindness[1]. Effective therapy can prevent or delay these complications, but approximately one third of Americans with diabetes do not

[1] NIDDK. National Diabetes Statistics fact sheet: general information and national estimates on diabetes in the United States, 2005. Bethesda, MD: U.S. Department of Health and Human Services, National Institute of Health, 2005.
[2] *Diabetes in America* Chapter 10, pp. 221-232 (1995), National Diabetes Data Group, NIH.

know they have the disease. In addition to these human costs, the estimated total financial cost for diabetes in the U.S. in 2002 was $132 billion[3].

Diabetes is characterized by the body's inability to produce and/or respond appropriately to insulin, a hormone which is necessary for the body to absorb and use glucose (sugar) as a cellular fuel. These defects result in persistent elevation of blood glucose levels and other metabolic abnormalities, which in turn lead to the development of disease complications. The most common form of diabetes is type 2 diabetes, which accounts for up to 95 percent of diabetes cases in the U.S. In patients with type 2 diabetes, muscle, fat, and liver tissue do not respond adequately to insulin, a condition known as insulin resistance. Gradually, the pancreas secretes progressively less insulin, and the timing of insulin secretion becomes abnormal. To control blood glucose levels, treatment approaches include diet, exercise, and medications; some patients also need to take insulin by injection. Risk factors for type 2 diabetes include older age, overweight and obesity, and a family history of diabetes. Type 2 diabetes occurs more frequently among minority groups, including African Americans, Hispanic Americans, American Indians, and Native Hawaiians.

Type 2 diabetes was previously called "adult-onset" diabetes because it was predominantly diagnosed in older individuals. However, this form of diabetes is increasingly being diagnosed in children and adolescents, and it disproportionately affects minority youth. Believed to be related to increasing rates of pediatric obesity, this is an alarming trend for many reasons. First, the onset and severity of disease complications correlate with the duration of diabetes; thus, those with early disease onset are at greater risk with respect to health complications. Second, maternal diabetes during pregnancy—either onset of type 2 diabetes before pregnancy or the development of gestational diabetes during pregnancy—confers an increased risk of diabetes in offspring. Thus, the rising rates of diabetes and pre-diabetes in young women could lead to ever-growing rates of diabetes. Third, diabetes often becomes more difficult to control over time. With longer duration of disease, health care providers may find it increasingly difficult to strictly control a patient's blood sugar and thus prevent or delay the development of complications. Therefore, the advent of type 2 diabetes in youth has the potential to drastically worsen the enormous health burden that diabetes already places on the U.S.

[3] NIDDK. National Diabetes Statistics fact sheet: general information and national estimates on diabetes in the United States, 2005. Bethesda, MD: U.S. Department of Health and Human Services, National Institute of Health, 2005.

HbA1c as a Measure of Glycemic Control: Most of the serious complications associated with diabetes are the result of chronic hyperglycemia (high blood sugar). The level of sugar in a person's blood can be directly measured at any point in time, but because it is constantly changing as a result of diet, exercise, time of day, and medication, a single test performed in a doctor's office or even a large number of tests performed over several days would not provide a precise measure of how well a patient's diabetes is controlled over the long term.

Variants of the protein hemoglobin A, which carries oxygen in the blood, can be created by the addition of sugar molecules—a process that happens more easily when blood sugar is high. One of the forms of hemoglobin with additional sugars attached is designated HbA1c. In cases of chronic high blood sugar, the percentage of hemoglobin A in the HbA1c form slowly rises. Thus, the amount of HbA1c present at any given time has been proved to be an excellent indirect measure of how well a person's blood sugar has been controlled over the preceding two to three months. In healthy non-diabetic people with normal blood sugar levels, HbA1c represents between about five-to-six percent of hemoglobin A; in people whose diabetes is not controlled by appropriate treatment, HbA1c can exceed 15 percent.

Origin of Current Recommendations: Two large, landmark randomized controlled clinical trials have provided extremely persuasive evidence that careful blood sugar control greatly reduces the risk of diabetes' most terrible complications. The NIDDK-supported Diabetes Control and Complications Trial (DCCT) demonstrated that, in patients with type 1 diabetes, intensive glucose control can prevent or delay damage to the small blood vessels in the eyes, kidneys, and nerves (microvascular complications). The follow-on study, the Epidemiology of Diabetes Interventions and Complications (EDIC), continues to demonstrate long-term benefits of intensive therapy in preventing disease complications. Exciting results announced in December 2005, have shown that intensive therapy also had dramatic long-term benefits in preventing large blood vessel damage that can lead to heart attacks and strokes (macrovascular complications), which is the leading cause of death in people with diabetes.

The findings of the DCCT paved the way to studies that replicated these impressive results in type 2 diabetes patients. Another landmark trial, the United Kingdom Prospective Diabetes Study (UKPDS), demonstrated that careful control of blood sugar was also an effective means of preventing disease complications in people with type 2 diabetes. The dramatic and positive results of these clinical trials demonstrate the importance of intensive glucose control in preventing the complications of diabetes. Notably also, the DCCT/EDIC and UKPDS

effectively validated the use of HbA1c as a measure of overall glycemic (blood sugar) control. This test subsequently became an important outcome measure for future clinical trials of both type 1 and type 2 diabetes, and was accepted by the Food and Drug Administration as a basis for approval of diabetes medications.

These studies led to estimates that in general, every percentage point drop in A1c blood test results (e.g., from eight percent to seven percent) reduces the risk of microvascular complications (eye, kidney, and nerve diseases) by about 40 percent. Based primarily on the findings from these major studies, most organizations of clinical professionals and government experts suggest maintaining a level of HbA1c lower than seven percent.

While the American Diabetes Association's Standards of Medical Care in Diabetes recommend an HbA1c goal lower than seven percent for patients in general, the goal *for the individual patient* is a level of HbA1c as close to normal (less than 6 percent) as possible without significant hypoglycemia. Some people newly diagnosed with diabetes retain substantial function of insulin-producing cells, and thus, with careful management, may be able to maintain HbA1c close to normal without risk of hypoglycemia. However, often diabetes is first detected at a more advanced stage, in people who have had the disease for years prior to diagnosis. There are currently no evidence-based guidelines for glycemic control specific to those who have received a diagnosis of diabetes within the last year, and it is unclear whether the disease should be managed differently in the newly diagnosed.

The Diabetes Mellitus Interagency Coordinating Committee (DMICC): This statutory Committee, chaired by the NIDDK, includes representatives from 23 federal departments and agencies whose programs are relevant to diabetes and its complications. A DMICC meeting was convened by the NIDDK on December 12, 2005, to examine the disparity between HbA1c treatment guidelines and practice, and to discuss steps that the government can take to close the disparity. Input from the meeting is included in this report.

Examination of the Disparity in Available Guidelines and Actual Treatment

Adherence Rates by Demographic Group: The National Health and Nutrition Examination Surveys (NHANES), conducted by the National Center for Health Statistics of the Centers for Disease Control and Prevention (NCHS/CDC) with co-support from the NIH, are designed to assess the health and nutritional status of adults and children in the U.S. through interviews and direct physical examinations. NHANES III data, collected from 1988-1994, show that only 44

percent of adults with previously diagnosed diabetes had good control (defined as an HbA1c level less than seven percent). Furthermore, there was no significant change in average HbA1c levels between NHANES III and more recently published NHANES 1999-2002 data presented at the December 12, 2005 DMICC meeting.

NHANES data also show that diabetes is less well controlled in some demographic groups than in others. For example, about 49 percent of non-Hispanic white Americans with diabetes have HbA1c less than seven percent, compared to just 37 percent for non-Hispanic African Americans, and 35 percent for Mexican Americans. These data are particularly noteworthy because type 2 diabetes is more common in minority populations: non-Hispanic African Americans are about 1.8 times as likely to have diabetes, and Hispanic Americans are about 1.7 times more likely to have diabetes, than non-Hispanic white Americans of the same age.
(http://www.cdc.gov/diabetes/pubs/estimates05.htm#prev3)

In another important trend, younger people with diabetes are less likely to maintain healthier levels of HbA1c than older people with the disease. Just 37 percent of people between the ages of 20 and 44 years have HbA1c less than seven percent, compared to 44 percent for people between 45 and 64 years of age, and 47 percent for people 65 years of age and older. This is significant because, as discussed above, rates of diabetes are rising rapidly in young people and they are at particular risk for complications because of the longer duration of exposure to high blood glucose.

Also striking, good glucose control is significantly less likely in people with diabetes who have no health insurance than in those who have coverage (39 percent compared to 45 percent). In contrast, diabetes patients participating in certain organized systems of care have been improving. The joint CDC-NIDDK sponsored Translating Research into Action for Diabetes (TRIAD) study of people with diabetes and health insurance found a significant improvement in patients' HbA1c levels during an 18 to 24 month period between 2001 and 2003 among all groups of patients. In another study of diabetes patients treated in 125 Veterans Health Administration (VHA) facilities nationwide, there was a mean decrease in HbA1c levels over a two-year period between 1998 and 2000. In both studies, however, there was a substantial variability in the level of HbA1c improvement within different facilities. Given that UKPDS data show that HbA1c tends to worsen over the course of the disease, system–wide improvements such as those observed in TRIAD and the VHA system are

particularly exciting. These findings underscore the beneficial effect of health insurance or access to health care for people with diabetes.

Although rates of diabetes in American Indians are among the highest in the world, a positive trend has been noted in average HbA1c levels. The Indian Health Service (IHS) Diabetes Care and Outcomes Audit (a diabetes care surveillance system carried out in Indian health facilities) found that average HbA1c levels decreased about 1.4 percentage points over the period from 1994 to 2004 in American Indians treated at facilities participating in the Audit. These data further highlight the importance of access to healthcare. Congress established the Special Diabetes Program for Indians to provide prevention and treatment services. The program has resulted in over 300 new prevention and treatment services throughout the country, and may be contributing to this improvement.

Notable Barriers to Achieving HbA1c Less Than Seven Percent: Control of diabetes is highly burdensome both in terms of its economic costs and the human effort required to achieve recommended levels of glycemic control. Moreover, glycemic control, the subject of this report, is only one of the aspects of diabetes care proven to reduce complications. Patients and care providers must also strive to achieve recommended levels of blood pressure and cholesterol control. Managing blood sugar, blood lipids and blood pressure may each require use of multiple medications. Because individuals with diabetes may therefore require 10 or more medications taken multiple times daily, adherence to prescribed medications can be costly and challenging.

Some of the most important barriers to achieving recommended HbA1c levels are essentially financial rather than medical. As noted above required medications are costly, as are supplies for testing blood glucose levels at home, a key component of glycemic management for many patients. The demographic data in the preceding section indicate that lack of health insurance and/or lack of access to health care are critical barriers to good diabetes management. The problem is particularly serious because type 2 diabetes is increasingly a disease of the poor, and because previously diagnosed diabetes may make it harder for a person to obtain health insurance. Even among people with health insurance, reimbursement practices do not always favor aggressive management of blood sugar levels. Patient education on diabetes self-management and nutrition has been a key component of the clinical trials which demonstrated that improved glycemic control reduced complications of diabetes. Diabetes education requires substantial provider time that may exceed what can be accommodated or reimbursed in typical health care settings. It has been reported that

reimbursement is more often provided, and more likely to cover actual provider time spent in patient care, for expensive procedures like dialysis and limb amputations required after complications have developed than for relatively inexpensive preventative care, such as visits to nutritionists.

A major barrier to the practice of intensive glucose control with medical therapies, such as insulin, is the potential for acute episodes of hypoglycemia (low blood sugar). Fear of hypoglycemia may discourage patients from aggressively managing their diabetes with these methods, and may discourage some physicians from prescribing them. Using these medications properly requires careful regulation of nutrition and physical activity, along with frequent self-testing of blood sugar, typically by pricking a finger, which can be both burdensome and painful. Insulin and some other diabetes drugs are taken via injection, which may cause discomfort and serve as a barrier to control. Further medical barriers include accompanying medical conditions such as mental health problems or alcohol or drug dependency that may increase the risks of medication use and affect adherence to therapy. Other side effects of diabetes therapies such as weight gain associated with insulin and some oral medicines, also limit the acceptability of these therapies.

An additional compounding problem is that of "clinical inertia," defined as the inadequate intensification of treatment in response to worsening symptoms. While there is evidence that providers are improving at meeting guidelines for measurement of HbA1c in patients with diabetes, they may not appropriately intensify care when this measure is above the threshold for taking action. For example, one study found that doctors delayed prescribing insulin for as long as possible (*Diabetes Care* **28**:2673-2679). Another found that African American patients with diabetes were less likely to receive aggressive therapy to lower their HbA1c in a standard primary care practice than they were in a specialty diabetes clinic, even though the average HbA1c of the patients in the general practice clinic was significantly higher than that in the diabetes clinic (*Diabetes Care* **31**:564-571). Another study showed that although by several criteria the disparity between care obtained by white Americans compared to African Americans is narrowing, it continues to widen in the area of diabetes management (*N Engl J Med* **353**:692-700).

The growing national problem with obesity and overweight represents another major barrier to improving diabetes outcomes in the U.S. Obesity/overweight is the single most important risk factor for developing type 2 diabetes, and reducing weight and keeping it off can help patients with diabetes lower their blood sugar. It has been suggested that were it not for new therapies for diabetes and

intensified management, HbA1c values would have risen rather than remained constant over the past decades as overweight has increased. Unfortunately, losing weight and maintaining a healthier weight are challenging. While clinical trials such as the Diabetes Prevention Program have demonstrated that lifestyle change could yield sustained weight loss and prevent or delay development of diabetes, reimbursement for the quantity of education and behavior change therapy provided in the trial is not generally available.

Importantly, an estimated 6.2 million Americans with diabetes do not know they have the disease. In its early stages, diabetes may have few symptoms, yet silent damage to the blood vessels is ongoing. Many patients with type 2 diabetes already have serious and costly diabetes-related complications at the time of diagnosis. The DCCT/EDIC study found that intensive glycemic control early in the course of the disease continues to yield benefits decades later. Early diagnosis is essential for achieving the recommended level of HbA1c control early in the course of the disease when it may be most effective in preventing long term complications.

Actions the Government Can Take To Close Disparity

Develop Better Ways To Treat Diabetes: A major mission of the NIDDK is to support and conduct research leading to the development of better means of treating diabetes. This research seeks to produce better tools for diabetes monitoring and treatment; better medications that are more effective, have a lower risk of side-effects, and/or are easier to take; and better methods for helping patients achieve lifestyle changes that improve their blood sugar control. The NIDDK, other NIH institutes, and Federal agencies represented on the DMICC maintain vigorous and active research programs to move this mission forward.

Of particular importance is "translational" diabetes research. One type of translational research—bench to bedside translation—seeks to leverage the findings of basic scientific research to develop new interventions with potential to help health care providers and patients manage diabetes. A second type of translational research—research to practice—seeks to help move valuable clinical discoveries into widespread use. An NIDDK-led initiative on "Translational Research for the Prevention and Control of Diabetes" supports research demonstration and dissemination projects, which develop, test, and evaluate health services and develop cost effective approaches to foster the application of knowledge derived from clinical trials into clinical practice to control disease. The Institute also supports an initiative to support "planning grants," which are

awards that allow researchers to collect sufficient preliminary data to apply for the larger award.

Several researchers funded through these initiatives are pursuing research to improve blood sugar control in people with type 2 diabetes by directly helping patients manage their disease. For example, one award, "*Improving Control with Activity and Nutrition*," is to conduct research aimed specifically at improving glycemic control through teaching improved diet and exercise habits. "*Family-Based Prevention of Diabetes and Its Complications*" will test at-home visits to families of patients with diabetes as a means of helping the patient manage his or her disease, as well as for preventing the development of the disease in other family members. "*Prevention and Control of Diabetes in Families*" tests a similar intervention in married couples where one of the partners has the disease. "*Diabetes Management for Low-Income Hispanic Patients*" will test a culturally- and literacy-tailored behavioral intervention in a Hispanic community. "*Effective Care Management of Depressed Diabetes Patients*" will test a telephone-based intervention as a means of helping a particularly large and vulnerable group of diabetes patients—those who are simultaneously depressed—better care for themselves.

Several projects will examine the use of the internet to improve diabetes care. For example, "*Internet Intervention for Improving Rural Diabetes Care*" will assess the usefulness of an internet-based intervention in a rural Alabama setting for improving disease management. Similarly, "*Bridging Barriers to Diabetes Care with Telemedicine*" will test video-conferencing as a means of delivering care to rural and other underserved community health settings. "*Internet Diabetes Self Management Evaluation*" will compare standard care with standard care plus a special diabetes self-management course and with standard care plus the course plus the use of an email discussion group.

Other studies are designed to help improve medical care for patients with diabetes. For example, "*Using Teams for Reflective Adaptation for Diabetes*" seeks to overcome clinical inertia by influencing the response of health care providers to patients with poorly controlled diabetes. "*Use of Midlevel Providers in Diabetes Management*" tests the utility of employing nurse practitioners to help patients manage their disease in both urban and rural settings. "*Impact of Nurse Case Management on Diabetes Co-morbidity*" will assess a low-cost alternative to the traditional physician-based care model as a means of helping patients at high-risk of complications manage their illness.

In addition to research supported under the initiative described above, the NIH vigorously supports investigator-initiated translational research efforts. For example, an NIDDK-supported researcher is developing and evaluating the Vermont Diabetes Information System (VDIS), which is a registry-based decision support and reminder system targeted to primary care physicians and their patients with diabetes. If proven beneficial, VDIS could be widely disseminated to practices across America and the world with a substantial impact on the outcomes and costs of diabetes. Some of the materials that have been developed for VDIS have been shared with New York City health officials, who are creating a database with patients' HbA1c test results in order to follow how well diabetes is being managed. The Department plans to periodically send reports on adequacy of glycemic control to individuals with diabetes and their physicians. Another research example being translated into practice is a National Institute of Nursing Research (NINR)-supported randomized clinical trial that has compared intensive diabetes management (IDM) *versus* IDM plus coping skills training (CST). Results have shown that use of CST among younger type 1 diabetes patients led to improved levels of HbA1c. The results of the study have been introduced into over 100 practices across the country. A follow up study is currently being conducted with children at risk for Type 2 diabetes.

The CDC's state-based diabetes prevention and control programs (DPCPs) operate in all 50 states and the District of Columbia. Many of the DPCPs are making considerable progress in improving preventive care practices—and specifically, in closing the disparity between HbA1c treatment guidelines and practice. The DPCPs are working with diverse partners in their states to implement public health interventions, which represent thoughtful, cooperative and sustained efforts to translate existing science into health system or community-based actions to improve diabetes preventive care. For example, in New York, regional community coalitions and academic Centers of Excellence united to improve the quality of diabetes preventive care and access to care. The result: rates of annual HbA1c testing more than quadrupled, increasing from 15 to 77 percent over a five year period.

The government's research funding arms, including the NIDDK, also convene meetings and conferences intended to bring together experts in the field of diabetes research to share and discuss recent scientific findings, as well as to identify future research directions that can accelerate research progress. For example, "From Clinical Trials to Community: The Science of Translating Diabetes and Obesity Research" was co-sponsored by the NIDDK, the NIH Office of Behavioral and Social Sciences Research, and the CDC, in January 2004. The meeting focused on the challenges of determining how to translate

findings from the comparatively optimal setting of clinical studies to the more complex situations facing providers caring for diverse communities with limited resources.

In December 2005, the NIDDK convened a meeting of experts in scientific areas such as hypoglycemia and glucose sensors, to discuss "Obstacles and Opportunities on the Road to an Artificial Pancreas: Closing the Loop." If the scientific obstacles can be overcome, an artificial pancreas would continuously monitor a person's blood sugar, infuse insulin as necessary when blood sugar gets too high, and warn the patient of dangerously low blood sugar. Such an instrument could be a tremendous boon both to patients with type 1 and type 2 diabetes. While significant obstacles remain to achieving a closed loop instrument, there has been substantial progress toward a continuous glucose monitor. Access to such new technologies can help patients improve their glucose control and help close the disparity between treatment guidelines and practice.

As noted above, nearly one third of patients with type 2 diabetes are undiagnosed. Diabetes therapy is generally initiated when glucose levels are above thresholds recommended based on preventing the heart, eye, nerve and kidney complications of diabetes. New public health efforts are leading to diagnosis of type 2 diabetes earlier in the course of the disease. However, rigorous clinical trials have not addressed key questions about optimal management of diabetes detected earlier, when glucose levels are lower. In the past 25 years, many new types of oral drugs for type 2 diabetes have become available, yet most patients eventually go on to require insulin injections. Determining whether earlier and more aggressive use of available therapies would slow the loss of an individual's own insulin production, and thus improve glucose control and/or reduce the need for insulin later in the course of the disease, has major implications for both the human and economic costs of type 2 diabetes.

Promote Education on Diabetes Management: A key component to the government's efforts to promote greater use of diabetes treatment guidelines in clinical practice, is to enhance awareness of the public and health care providers. Indeed, diabetes education has been shown to be effective in reducing HbA1c, with contact time being the best predictor of effect: approximately 24 hours of contact time translated to a 1% absolute decrease in A1c (*Diabetes Care* **25**:1159-1171.) Therefore, the NIDDK and CDC created the National Diabetes Education Program (NDEP). One campaign that the NDEP has created to disseminate the message of the importance of intensive glucose control is "Control your Diabetes. For Life." In addition, the "Be Smart About Your Heart: Control the ABCs of

Diabetes" educational campaign focuses on the ABCs of diabetes care which are: (Hb)**A**1c; **b**lood pressure; and **c**holesterol. The campaign educates people with diabetes about the link between diabetes and cardiovascular disease (CVD) and teaches them how to manage their CVD risk factors to help prevent heart attacks, strokes, and premature death. The campaign encourages patients to maintain HbA1c levels less than seven percent and to have their levels checked at least two times per year.

The NDEP has also developed an online tool, called Betterdiabetescare.nih.gov, which is a comprehensive resource to assist with designing and implementing effective systems for diabetes care. The website was developed to help improve clinical management of blood glucose, lipids, and blood pressure in persons with diabetes. The NDEP has recently expanded the website to offer continuing education for healthcare providers.

The NDEP is actively taking steps to evaluate progress and enhance educational campaigns. For example, the NDEP is planning to survey adults who already have type 2 diabetes, as well as those at-risk for the disease. The survey will assess peoples' attitudes and awareness about treatment and management of the disease, including regulating their blood glucose levels. Results of the survey will be used, for example, to identify barriers to and gaps in patients' awareness about the importance of regulating their blood glucose levels, and the factors that contribute to them not achieving good glucose control. Furthermore, the "evaluation workgroup" of the NDEP collects data relevant to NDEP campaigns to assess progress. The NDEP plans to continue to use these and other indicators to evaluate progress and further tailor their campaigns to enhance adherence to treatment guidelines, and to disseminate the important message of controlling blood glucose levels to reduce the risk of diabetes complications.

Overcoming Financial Barriers to Diabetes Care: As noted above, recent data from NHANES indicate a significant disease management disparity between insured and uninsured people with diabetes. Programs that either directly or indirectly increase the insurance rate among people with diabetes can thus be expected to improve blood sugar control within the population. Further, programs which help to fund or to lower the cost of diabetes medicines and supplies for people with diabetes would be expected to make it easier for those with and without insurance to lower their blood sugar, effectively reducing the human and financial burdens of later complications. Because Medicare benefits are often used as a model by other insurers, diabetes coverage by Centers for Medicare and Medicaid services (CMS) can have an effect which extends even beyond those

eligible for CMS-funded programs. Of note in this regard is coverage for testing for diabetes and for nutrition and diabetes self-management education.

Enhance Systems of Care: Governmental agencies that are involved in treating and caring for patients with type 2 diabetes are actively enhancing their systems of care to make real improvements in patients' health and quality of life. The VHA, for example, is implementing enhancements to treat the nearly 1 million veterans who have diabetes. Almost all VHA facilities have locally developed clinical reminders linked to the completion and level of HbA1c testing. The VHA has also launched the "My Health*e*_Vet Pilot," which is a prototype project developed to demonstrate that veterans could be provided with a safe, secure, and private electronic copy of their own health information through an Internet web environment. This tool will track personal health indicators, such as blood sugar, blood pressure, weight, heart rate, and cholesterol. VHA is also developing Home Care Coordination Strategies for individuals with chronic diseases, including diabetes, that may serve as a model to support care coordination at the patient, caregiver, clinician and health care organization levels. The VHA actively monitors facility level performance with comprehensive diabetes measures, including HbA1c, using the National Quality Forum endorsed National Diabetes Quality Improvement Alliance public reporting and quality improvement measures.

VHA has also developed a weight management program for veterans, called *MOVE!* (Managing Overweight/obesity for Veterans Everywhere).Based on NHLBI/NIH guidelines for identification, treatment, and management of obesity, *MOVE!* is a comprehensive, multi-disciplinary, patient-centered weight management program. *MOVE!* is designed to be implemented into primary care and addresses nutrition, physical activity, and behavior change through self-management support and group sessions and/or referral to specialty care, as indicated. As this program is fully implemented in all VHA facilities, it will provide an important resource for weight management for patients with or at risk for diabetes.

In addition, VHA has recently launched a new initiative for obesity and diabetes prevention, in collaboration with the Department of Health and Human Services. Called "HealthierUS Veterans," the initiative promotes healthy eating and increased physical activity to veterans and their family members and others in their communities. "HealthierUS Veterans" includes promotion of web-based components of the *MOVE!* program to veterans and others who receive care outside VHA facilities, creation of a "Fit for Life" Corps of volunteers to partner

with community physical fitness activities, and a "Prescription for Health," a prescription for a pedometer and to encourage walking.

The IHS Indian Health Best Practices Workgroup identified a diabetes systems-of-care approach as fundamental to providing quality diabetes and chronic disease care, prevention, and treatment. The Diabetes Systems of Care and seventeen other model approaches to clinical and community based topics of diabetes care, prevention and treatment disseminate best practice guidance to health care providers in the IHS system. Similarly, as part of the DHHS strategy towards eliminating health disparities, Health Resources and Services Administration (HRSA)-supported health centers participating in collaboratives that address senior leadership, implement a care model by using improvement and learning models to change practice, support an infrastructure to support and sustain improvement, and develop partnerships at the local and national level.

Support and Enhance Diabetes Surveillance: Surveillance data are needed to track population trends, to establish baseline and trend lines, show change, analyze progress, and determine outcomes. Without surveillance data, it would be impossible to determine if glycemic control was improving, worsening, or staying the same over time. Therefore, the government vigorously supports diabetes surveillance in order to monitor the health of diabetes patients.

As described previously, the NCIS/CDC, with NIH co-funding, supports the National Health and Nutrition Examination Surveys (NHANES) to assess the health and nutritional status of adults and children in the U.S. NHANES data are used, for example, to inform and evaluate educational campaigns developed by the National Diabetes Education Program. In addition, the "SEARCH for Diabetes in Youth" study, led by the CDC in partnership with the NIDDK, will not only define the prevalence and incidence of diabetes in children and youth less than 20 years of age in six geographically dispersed populations that encompass the ethnic diversity of the U.S, but also provide important data on glycemic control and development of complications.

The VHA is developing a national diabetes registry to facilitate identification and treatment of individuals with or at risk for diabetes using linked administrative codes, pharmacy and laboratory data. This registry is intended to assist clinical managers in identifying populations of individuals in whom care coordination strategies may be of benefit.

Studies have suggested that reporting of clinically valid measures of healthcare quality by physicians may lead to improved healthcare outcomes. Therefore, in

an effort to improve patient care, the CMS have instituted the Physician Voluntary Reporting Program (PVRP). The PVRP asks doctors to report on 36 measures of quality of care, which include whether or not the physician addressed the issue of HbA1c control in diabetes patients between the ages of 18 and 75.

Target Programs to Important Subpopulations: Subpopulations differ in their response to therapy and these differences must therefore be considered in efforts to develop better ways to treat diabetes to ensure that results are valid for subgroups. However, subgroup participation in efforts focused population-wide is not sufficient. Research must also focus on developing approaches to improve glycemic control specifically targeted to vulnerable subgroups, such as minority populations, older age groups, and children, as is being done in the diabetes prevention and control projects described above. Because minority populations are disproportionately affected by diabetes, and to address the gap in achieving recommended levels of control in some minority populations, special attention much be given to minority subpopulations in research, outreach and education, surveillance, and health care delivery.

The government supports numerous programs to address the disparity between guidelines and actual diabetes care within minority populations and for youth. The Agency for Healthcare Research and Quality (AHRQ) participates in a "National Health Plan Collaborative to Reduce Disparities and Improve Quality in Diabetes Care." This Collaborative brings together 9 of the nation's largest health insurance plans to improve the capacity to collect and analyze data on race and ethnicities; link data to quality measures; develop quality improvement interventions to close gaps in care; and produce results that can be replicated by plans serving commercial, Medicare, and Medicaid populations nationally.

The HRSA has been implementing a series of Health Disparities Collaboratives (HDCs) in Federally Qualified Health Centers with the goal of reducing health disparities and overall improved functional clinical status of health center patients. Currently, the 645 health centers participating in the HDCs are calculated to be able to reach 9.24 million patients, since they represent 2/3 of all the health centers in the country. This model of care for diabetes has evidence of effectively implementing the guidelines and achieving desired results among patients. HRSA is currently tracking 235,635 health center patients with diabetes in the Diabetes Collaborative alone. From 2000 to 2005, the average HbA1c levels decreased for health center patients with diabetes from 8.55 for 21,126 patients to 7.86 for 235,635 patients.

To further promote improving the quality of diabetes care delivered to American Indian and Alaska Native people, a new software application, called GPRA+ (Clinical Reporting System, Office of Information Technology, IHS, Albuquerque, New Mexico), was deployed throughout the IHS to support passive electronic retrieval of clinical data. Ongoing dedication to effective resource allocation, program accountability, and partnership among tribes, tribal leaders, and federal programs will be required in the implementation, adoption and dissemination of HbA1c guidelines. The IHS also established the Chronic Care Working Group (CCWG) in 2004 that includes health professionals from the IHS, the Urban Indian Health Institute at the Seattle Indian Health Board, the McColl Institute of Group Health Cooperative, the Department of Veterans Affairs, and the Institute for Healthcare Improvement. The goal of the CCWG is to develop a strategic plan for the Indian health system to approach chronic disease in a coordinated manner. The Chronic Care Workgroup is developing a Collaborative in FY 2006 to support pilot projects that will facilitate system-wide implementation of the Chronic Care Model. The Collaborative will also support other innovative efforts within the Indian health system, such as the implementation, adoption, and dissemination of HbA1c guidelines.

The Pima Indians of Arizona have the highest reported prevalence and incidence rate of type 2 diabetes of any population in the world—about half of the adult population have the disease. The NIDDK's Phoenix Epidemiology and Clinical Research Branch is studying the natural history of type 2 diabetes in this unique American Indian population to improve treatment and prevention of diabetes and its complications through research. The Diabetes-Based Science Education in Tribal Schools (DETS) program is developing a national, science-based diabetes prevention education curriculum for American Indian students in grades K-12. The goals of the program are to enhance awareness and understanding of diabetes among students, families, community members, and teachers in order to improve disease management; and also to increase the numbers of American Indians entering the health research professions. The program is sponsored by the NIDDK in close collaboration with American Indian tribal colleges, the IHS, the CDC, and the NIH Office of Science Education.

Children of all ethnicities represent a key population for federal programs, because complications of diabetes tend to get worse as a function of duration of the illness and because the disease is expanding in youth. However, because type 2 diabetes was previously rare in children, little information exists about how best to treat the disease in young people. The NIDDK has therefore initiated Treatment Options for Type 2 Diabetes in Youth (TODAY) to compare treatment approaches for children aged 10 to 17 at medical centers across the country.

Just as research must focus on vulnerable populations, outreach and educational materials to translate research into practice must be developed that are targeted at specific high risk subpopulations. For example the NDEP's "Be Smart about your Heart" campaign, discussed above, has developed specific, focus group tested materials for African Americans, Hispanic Americans and American Indians. The NIDDK has developed "tip sheets" for children with the newly emerging problem of type 2 diabetes in youth. Similarly the NDEP's "Control your Diabetes for Life" campaign provides materials targeted at the Medicare eligible older population.

Conclusion

A substantial body of research exists to highlight the importance for people with type 2 diabetes of adhering closely to established guidelines for good glycemic control. Data on diabetes management clearly indicate, however, that the majority of Americans with diabetes do not meet those guidelines, a fact with grave implications for the future health and health-care costs of tens of millions of Americans. This report describes many of the reasons why achieving good glycemic control can be challenging for people with diabetes, and suggests some approaches that government can take to help overcome these challenges.