

December 12, 2005—DMICC meeting summary-DRAFT

**National Institute of Diabetes and Digestive and Kidney Diseases  
Diabetes Mellitus Interagency Coordinating Committee**

**HbA1c, Diabetes, and Public Health**

**Natcher Conference Center, Conference Rooms E1/E2  
National Institutes of Health  
Bethesda, Maryland**

**December 12, 2005  
Summary Minutes—DRAFT**

**WELCOME AND OPENING REMARKS**

*Allen Spiegel, M.D.; Director, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH), Bethesda, Maryland*

Dr. Spiegel, Director of NIDDK and Chair of the Diabetes Mellitus Interagency Coordinating Committee (DMICC), welcomed members of the DMICC, guest speakers, and guest attendees. He provided background on the Congressional mandate for the DMICC initiative on glycemic control and hemoglobinA1c (HbA1c). He noted the mission of NIDDK is primarily to support research to increase knowledge on the prevention and treatment of disease to improve public health. Other member agencies of the DMICC have a mission of improving quality of care, delivering healthcare, and providing funding for care. Dr. Spiegel reviewed the agenda and stated that information to be presented in this meeting will form the basis of a mandated report from NIDDK to the U.S. Congress summarizing what the DMICC member agencies can do to address the important goal of improving glycemic control in the U.S.

Dr. Spiegel commented that chronic diseases, such as diabetes, impose a tremendous burden on the U.S. healthcare system in the public and private sectors. The challenge for the current initiative on glycemic control is that while scientifically sound evidence supports current guidelines for HbA1c in type 1 and type 2 diabetes, national data suggests that a majority of

Americans with diabetes are not meeting these guidelines. Improved glycemic control will benefit individuals significantly and help reduce the public health burden of diabetes. Dr. Spiegel asked the meeting participants to think about the issues underlying widespread suboptimal diabetes control and to offer suggestions for research and public health efforts to mitigate this problem. In particular he urged partnerships among member organizations of the DMICC to address the common goal of improved glycemic control.

## **UPDATE ON DMICC INITIATIVES**

*Judith E. Fradkin, M.D.; Director, Division of Diabetes, Endocrinology, and Metabolic Diseases, NIDDK, NIH, Bethesda, Maryland*

Before moving on to the major topic of the meeting, Dr. Fradkin reviewed the progress of selected ongoing DMICC initiatives (slides 1-2).

### **Requirement for the FY 2005 DMICC Annual Report to Include Material Addressing the Pancreatic Islet Cell Transplantation Act of 2004**

Dr. Fradkin reviewed the Pancreatic Islet Cell Transplantation Act of 2004 (P.L. 108-362), which mandates that the DMICC Annual Report include an assessment of the Federal activities and programs related to pancreatic islet cell transplantation (slides 3-4). DMICC members will be asked to submit their agency or organization's report in this area by January 5, 2006. NIDDK staff will draft a narrative based on information that DMICC members submit in their report. This request is in addition to the submission of the DMICC Annual Report previously requested.

### **Type 1 Diabetes Strategic Plan**

Dr. Fradkin summarized progress on the Strategic Plan for Type 1 Diabetes Research being developed under the auspices of the DMICC and acknowledged the effort and leadership of Dr. Mary Hanlon at NIDDK in developing the strategic plan. The Executive Committee for the Type 1 Diabetes Strategic Plan met on September 28, 2005, to discuss the draft of the

first five goals of the plan (slides 5-6). The plan was subsequently revised in accord with recommendations from that meeting and with development of additional sections including: introductory material on the public health impact of type 1 diabetes, patient-oriented materials to explain each of the report's chapters, and a chapter on Goal VI: Attract New Talent and Apply New Technologies. The revised and augmented plan was distributed to the Executive Committee for further review.

After January 1, 2006, the strategic plan will be placed on the NIDDK website to solicit input from DMICC members, Working Group members, and the public (slide 7). Revisions to the document will occur during spring 2006, with an anticipated printing of the final report in summer 2006.

### **Efforts to Address the Disparity Between HbA1c Guidelines and Practice**

Dr. Fradkin then turned to the subject of today's meeting-- addressing the disparity between HbA1c guidelines and practice (slide 8). She noted that the National Institutes of Health's major mission is to conduct research that underlies prevention and treatment of disease; there is, however, a strong interest on research to practice translational research. Moreover, NIDDK, in partnership with the Centers for Disease Control and Prevention (CDC) supports research dissemination and educational outreach efforts through the National Diabetes Education Program (NDEP) and surveillance efforts (slides 13-14). Although NIDDK is not directly involved in funding or providing patient care, other members of the DMICC are integrally involved in these areas. Goals of this DMICC meeting are to pool expertise and identify barriers and solutions to affect changes in the disparity between Hb1Ac guidelines and practice.

Dr. Fradkin reviewed data from the Diabetes Control and Complications Trial (DCCT) and the follow-on Epidemiology of Diabetes Interventions and Complications (EDIC) study on the importance of glycemic control in preventing microvascular complications of diabetes (slide 9). She noted that recently presented data indicated that glycemic control reduced macrovascular complications as well (slides 10-11). These new results should stimulate the

diabetes community to redouble their efforts to ensure that patients receive the benefits of glycemic control. However, diabetes control is difficult and we don't yet have optimal tools to achieve it. It is important to focus on initiatives that will provide the maximum benefit for public health regarding glycemic control. There is a need not only to enhance application of tools available now for glycemic control, but also to develop improved approaches to glycemic control that are less burdensome and costly.

### **GLYCEMIC CONTROL AS INDICATED BY Hb1Ac LEVELS IN ADULTS WITH DIABETES IN THE UNITED STATES**

*Sharon Saydah, Ph.D., Epidemiologist, National Center for Health Statistics, U.S. Centers for Disease Control and Prevention, Hyattsville, MD*

Dr. Saydah provided data from the third National Health and Nutrition Examination Survey (NHANES III) and NHANES 1999-2002 on glycemic control and HbA1c levels in the U.S. population. To provide some perspective to the data, Dr. Saydah noted the following were reported by DCCT investigators:

- Intensive glycemic control reduces microvascular disease by 70 percent;
- A 1 percent reduction in HbA1c levels corresponds to a 40 percent reduced risk of developing microvascular disease; and
- Treatment regimens that reduced the average HbA1c levels to approximately 7 percent (i.e., approximately 1 percent above the upper limits of normal) were associated with fewer microvascular complications and reduced cardiovascular disease (CVD) in clinical trials.

The American Diabetes Association (ADA) Standards of Care for diabetes recognizes that glycemic control is fundamental to the control of diabetes, and that glycemic control should be determined by measuring HbA1c levels. Furthermore, the ADA defines glycemic control as HbA1c levels less than 7 percent among non-pregnant adults with diagnosed diabetes.

Dr. Saydah reviewed NHANES protocols used to collect data on the approximately 2,000 participants who had self-reported diabetes in the two NHANES surveys presented. The distribution of HbA1c levels in NHANES III was 7.7 percent (mean) and 7.4 percent (median); for NHANES 1999-2002, the distribution was 7.6 percent (mean) and 7.1 percent (median). This represents little change between the surveys, though there does appear to be an increase in the highest levels of HbA1c in the later survey. Overall, only 40 percent of U.S. adults with previously diagnosed diabetes had HbA1c levels less than 7 percent, which indicates recommended glyceemic control. Results from the surveys indicated that demographic and socioeconomic disparities may indicate the level of glyceemic control. Specific variables analyzed showed the following:

- Those 65 years and older have better glyceemic control than those in other age groups.
- Non-Hispanic whites have better glyceemic control than those from other race groups.
- The lower the educational level of the participants, the less glyceemic control occurs.
- Participants at the lowest economic level, as determined by the poverty index ratio, have lower levels of glyceemic control.
- There is no statistical difference when participants are compared by body mass index (BMI).
- Less glyceemic control occurs among those with abdominal obesity than among those with no abdominal obesity.
- Among those reporting their health to be “excellent or very good,” glyceemic control was lower than among those who reported their health to be “fair to poor.”
- Participants who had their blood pressure checked within the last 6 months had significantly better glyceemic control than those who had not had their blood pressure checked in the previous year.
- Those with health insurance had significantly better glyceemic control than those without health insurance.

## **Discussion**

Dr. Leonard Pogach, National Program Director for Diabetes, Veterans Health Administration, East Orange, New Jersey, asked Dr. Saydah to address duration of type 1 and type 2 diabetes in the surveys. Dr. Saydah responded that type 1 diabetes diagnosis was determined by insulin use and age less than 30 years, but this only represented 70 of the approximately 2,000 study participants, and removing them from the data analyses did not significantly change the results. Duration also was not significant. Dr. Joe Selby, Director of the Division of Research, Kaiser Permanente of Northern California, Oakland, asked if duration changed between the two surveys. Dr. Saydah said that the mean age of diagnosis decreased in NHANES 1999-2002, and mean duration increased in the later survey.

Dr. Fradkin asked to what extent the increased detection of diabetes explains the shift in the median seen in the data. She commented that as the number of people with undiagnosed diabetes decreases, the median would shift. Dr. Saydah commented that she had not looked at this but this was an interesting idea.

Dr. Sanford Garfield, Executive Secretary of the DMICC and Senior Advisor in Biometrics and Behavioral Science, NIDDK, NIH, Bethesda, Maryland, noted that over the period of years described by the NHANES data, the ADA definitions had changed. He wondered if this was considered in analyzing the data. Dr. Saydah said this wasn't taken into consideration because the data is based on self-report of diagnosed diabetes.

Dr. Michael Engelgau, Chief, Epidemiology and Statistics Branch, CDC, DHHS, Atlanta Georgia, commented that he was interested in the increase in the higher levels of HbA1c. He asked Dr. Saydah to comment on this situation, and if there will be an impact on public health if this continues. Dr. Saydah responded that her slides do not show the increase well, but the data does indicate some increase, although the impact is not known from the data. Dr. Fradkin noted that if the data were not adjusted for race and ethnicity, the increase may reflect the higher rates in minority populations, as well as the effect of higher rates of type 2 diabetes in younger age groups. Dr. Siegel added that there may be an enrichment of the data for the type 1 diabetes group, which is intrinsically harder to control, and for a type 2 group

that is heavily minority. In addition, lack of health insurance is a significant factor in controlling diabetes.

Dr. Selby offered the observation from his experience that older Americans are being treated more aggressively for milder disease than younger people with diabetes. Dr. Roman added that he agrees with Dr. Selby that the data may be reflecting milder disease, but there also is a survivor effect for younger onset of type 2 and type 1 diabetes; older patients also have Medicare coverage and the time to see physicians for more regular care.

### **HbA1c, THE TRIAD STUDY, AND KAISER PERMANENTE**

*Joe Selby, M.D., M.P.H., Director, Division of Research, Kaiser Permanente of Northern California, Oakland*

Dr. Selby presented background information and data from the Translating Research Into Action for Diabetes (TRIAD) Study and recent trends in HbA1c control from the TRIAD cohort Kaiser Permanente diabetes disease registry in Northern California. The TRIAD Study is a multicenter cohort study of diabetes in six managed care settings funded by NIDDK and the CDC. For analyzing Hb1Ac comparisons, two surveys were used (June 2000 to October 2001 and July 2002 to July 2003), and there were 4,610 participants with HbA1c values for both surveys.

Dr. Selby compared cohort to cross-sectional studies, and the differences in results that may be confusing what we believe about diabetes control. Issues included the following:

- In cohort studies, time trends show the effects of patient aging and the increasing duration of diabetes.
- The United Kingdom Prospective Diabetes Study (UKPDS) suggested that the “natural” trend is for diabetes to worsen (e.g., HbA1c to rise) over time in both the control and intervention groups.

- Serial cross-sectional analyses are subject to changes in who is labeled as diabetic and included in the sample, especially when only diagnosed cases are considered.
- Increased screening and increasing obesity could each enrich later cross-sectional samples with more, and less severe, cases of diabetes.

Dr. Selby presented data from the TRIAD Survey that showed a mean reduction of HbA1c levels by 0.2 percent, which was statistically significant. Differences in HbA1c levels among minority populations persisted over the two surveys, although they also were reduced in minority populations. Data from the ten TRIAD centers showed there were reductions in each of the centers, although differences of approximately 1 percent were seen among the centers. Results from the TRIAD Study include the following:

- There was a clinically significant within-patient decrease in HbA1c levels over the 18- to 24-month period from 2000-01 to 2002-03;
- Decreases in HbA1c levels were similar for men and women; slightly greater decreases were seen for African-Americans than for other groups in this sample;
- The three non-white groups now have comparable HbA1c values, but disparity remains when compared to whites; and
- Improvements varied substantially among the 10 health plans participating in TRIAD, suggesting that greater improvements can be achieved.

Dr. Selby presented data from the Kaiser Permanente Northern California Diabetes Registry (KPNCDR) showing cohort and cross-sectional trends data for HbA1c. Data were collected from 9,000 to 11,000 HbA1c measures per month over a 10-year period. Results from the serial cross-sectional analyses indicated a reduction in HbA1c levels over the period of time. Analyses of cohort data indicated some decline; in newly diagnosed patients the decline was greater. Results from the KPNCDR include the following:

- Among patients with diabetes (cohort analyses), HbA1c levels are staying the same or declining slightly over the past 10 years;

- The diabetes registry (and other cross-sectional samples) are enriched with milder patients in later years, creating dramatic lowering of HbA1c levels in serial cross-sectional samples; and
- The proportion of patients with HbA1c levels greater than 10 percent has declined dramatically, with only 10 percent of TRIAD patients with levels this high in 2002-03 and only 7 percent of KPNC patients with levels this high in 2005.

Dr. Selby presented information on the impact on cost-sharing or drug co-payments on HbA1c levels. In comparing Kaiser Medicare patients who have a \$1,000 cap on drug benefits to Kaiser patients with full benefits, generally through an employer, Dr. Selby said that the patients with the benefit cap had poorer adherence to medications, used less medications by approximately 25 percent, had substantially higher HbA1c levels, had more emergency department visits and hospitalizations, and higher mortality. This provides a lesson about the impact of financial barriers to the control of chronic diseases.

## **Discussion**

Dr. Pogach commented that he has a cohort study being published on 142,000 Veteran's Administration (VA) patients from 125 centers that will show there are organizational characteristics among VA facilities that lead to disparities in control rates with VA centers. Dr. Engelgau asked if patients at higher income levels are less sensitive to insurance caps than are patients at lower income levels, and whether this could explain some of the disparities. Dr. Selby responded that he is analyzing and collecting data that will look at economic variables and disparities. Troubles with access to health care also can be associated with higher HbA1c levels; therefore, all variables need to be assessed to understand why some patients are able to attain lower HbA1c levels. Dr. Sheila Roman, Senior Medical Officer, Quality Measurement and Health Assessment Group, Centers for Medicare and Medicaid Services, Baltimore, Maryland, commented that a similar situation is occurring in managed Medicare; those with employer-based health care are in the higher socioeconomic stratum than those without employer coverage.

Dr. Fradkin asked if the Kaiser study assessed physician behavior. Dr. Selby responded that a manuscript is being published in the next few months that will review physician behavior for various chronic diseases. Results in this study indicated that physicians are more likely to intensify blood pressure and low-density lipoprotein (LDL) treatment in non-whites than in whites; it was reversed for HbA1c treatment. More significantly, most physicians did not intensify blood pressure or lipid control in patients with diabetes, which should be of concern to diabetes policymakers. Dr. Peter Savage, Director, Division of Epidemiology and Clinical Applications, National Heart, Lung and Blood Institute, NIH, Bethesda, Maryland, commented that there seemed to be some encouraging news as the Kaiser data appears to show more intensification of treatment to bring down glycosylated hemoglobin.

Dr. Rosaly Correa-de-Araujo, Senior Advisor on Women's Health, Agency for Healthcare Research and Quality (AHRQ), Rockville, Maryland, added that AHRQ is collecting data to study provider activities to determine why disparities exist in health care. A second project involves 21 health care plans to review diabetes and health services across race and ethnic groups. It is hoped that this report will be completed by next year.

### **GLYCEMIC CONTROL/HbA1c AND THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)**

*Sheila H. Roman, M.D., M.P.H., Senior Medical Officer, Quality Measurement and Health Assessment Group, Centers for Medicare & Medicaid Services, Baltimore, Maryland*

Dr. Roman provided information on CMS and its function as the federal agency responsible for paying for Medicare and Medicaid services provided by the health care system (slides 1-2). CMS is not a research institution, but supports demonstration projects on quality of care and models of healthcare delivery for diabetes and other chronic diseases. She presented a graphic showing how CMS approaches improvement in quality of care, which is multipronged with an emphasis on performance-measure based assessment. (slide 3).

Medicare costs for diabetes are grossly underestimated by looking only at Part A (Inpatient) and Part B (Physician Bills) directly attributable to diabetes (slide 4). An estimation of Medicare costs using modeling techniques to include diabetes-related complications (including end-stage renal disease) for FY 2004 was estimated at \$26.5 billion; the estimated marginal cost of being diabetic to Medicare independent of diabetes complications for FY 2004 was estimated at \$10 billion (slide 5). CMS has set goals under the Government Performance and Results Act (GPRA) to assess provision of HbA1c tests, biennial eye exams, and biennial lipid profiles for Medicare recipients (slide 6). In fiscal year 2004, performance measures showed that 83.6 percent of Medicare recipients had HbA1c tests, 69.1 percent had a biennial eye exam, and 86 percent had a biennial lipid profile. For fiscal year 2005, CMS will use National Quality Forum-endorsed Diabetes Alliance performance measures to determine GPRA rates and the goals will focus on HbA1c and lipid profiles.

Dr. Roman described the CMS Physician Focused Quality Initiatives, all of which include diabetes as one of the target conditions, and also build upon ongoing CMS strategies and programs in order to: (1) assess the quality of care for key illnesses and clinical conditions that affect many people with Medicare, (2) support clinicians in providing appropriate treatment of the conditions identified, (3) prevent health problems that are avoidable, and (4) investigate the concept of payment for performance.

The Physician Focused Quality Initiatives include the Doctor's Office Quality (DOQ) Project, the Doctor's Office Quality Information Technology (DOQ-IT) Project, and several Demonstration Projects and Evaluation Reports.

The Doctor's Office Quality (DOQ) Project, a CMS demonstration project designed to develop and test a comprehensive, integrated approach to measuring the quality of care for chronic disease and preventive services in the doctor's offices includes a clinical performance measurement set, Physician Practice Connections tool and a patient experience of care survey. The baseline results for the diabetes clinical performance measurement set of a convenience sample of 3,132 primary care practitioners in California, Iowa, and New York showed that 95 percent of patients had an annual HbA1c test, with 88 percent having an HbA1c less than 9 percent; 62 percent had blood pressure less than 140/90 mmHg; 85 percent had an annual lipid measurement, with 66 percent having an LDL less than 130

mg/dL; 39 percent had a urine protein test; 39 percent had an eye exam; and 34 percent had a foot exam. Of importance only 7 percent of patients had abstractable data for all measures . (slides 7-8). CMS recognizes the potential for information technology to improve the quality, safety and efficiency of health care services provided to all Americans. Through the Doctor's Office Quality - Information Technology (DOQ-IT) project CMS is working to support the adoption and effective use of information technology by physicians' office to improve quality and safety for Medicare beneficiaries and all Americans. DOQ-IT seeks to accomplish this by promoting greater availability of high quality affordable health information technology, and by providing assistance to physician offices in adopting and using such technology.

CMS Demonstration projects with diabetes populations include the following (slides 9-12):

- The Physician Group Practice Demonstration, which uses Diabetes Alliance measures with payments linked to financial and quality performance measures, in a shared savings model.
- The Care Management for High Cost Beneficiaries Demonstration which focuses on provider-directed models and includes a fee risk for savings threshold of 5 percent.
- The Medicare Care Management Performance Demonstration, which uses the Diabetes Alliance measures with payment for measure thresholds.
- The Medicare Disease Management Demonstration, which uses disease management services, including most drugs, with payments not tied to quality performance.
- The Informatics for Diabetes Education and Telemedicine Demonstration, which focuses on improvements in HbA1c, blood pressure, and lipids.

Other important CMS programs that include patients with diabetes include the Physician Voluntary Reporting Program (PVRP) which will launch in January 2006. The PVRP will better analyze the quality of care provided to Medicare beneficiaries by using a set of quality G-codes established by Medicare which include several that focus on care of diabetes including HbA1c, LDL, and high blood pressure control. In addition, Section 721 of the Medicare Modernization Act of 2003 (MMA) authorized development and testing of a voluntary chronic care improvement program, now called Medicare Health Support, to

improve the quality of care and life for people living with multiple chronic illnesses, including diabetes. The Medicare Health Support Program is currently being phased in in regions across the country and also has HbA1c, LDL, and high blood pressure control measures (slide 13).

CMS also maintains a number of important collaborations to further its quality agenda in all care settings. Most relevant to diabetes at the current time are the Hospital Quality Alliance (HQA) and the Ambulatory Care Quality Alliance (AQA). The HQA has plans to introduce the Surgical Complications Improvement Project measures for public reporting, which incorporate the control of peri-operative serum glucose (slide 14). The AQA incorporates the Diabetes Alliance performance measures which represent a longstanding collaboration between the relevant medical specialty societies and organizations as well as CMS, NCQA, and AMA.

Dr. Roman presented challenges for diabetes care across the various components of the health care system where CMS can play a large role (slide 15). They included:

- Transforming the health care system to patient-centered care.
- Improvements in systemness and adoption of health information technologies.
- Harmonizing and maintenance of guidelines and performance measures.
- Physician performance feedback to address overestimates in rating their own performance.
- Patient factors, such as adherence to home-glucose testing and medication management.

To meet these challenges, Dr. Roman said that care needs to be appropriate for each patient, that diabetes care needs to be coordinated across the continuum of care, and health information technologies should be incorporated in treatment and prevention programs (slide 16). In addition, reimbursements should align with quality performance, performance measures should be standardized to decrease the babel in performance measurement;

performance measures can be better utilized to promote and support effective healthcare; and better decision support for both physicians and patients can be implemented.

## **Discussion**

Dr. Fradkin asked Dr. Roman to address what is known about the manner in which performance measures act as incentives for physicians. Her concern was that if the incentive is set at a certain level, such as to reduce HbA1c levels to 9 percent the physician may not feel a need to continue to focus on the goal when it is met. Dr. Roman answered that CMS had little experience at the physician level at this time, but that CMS has an increasing experience with incentives for both reporting and performance at the hospital level. She said that measures do appear to act as incentives to improve care in the hospital setting but that vigilance was necessary to be sure the incentives and quality of care remain aligned. Suzanne Feetham, Senior Advisor, Acting Director Division of Clinical Quality, Bureau of Primary Health Care, Health Resources and Services Administration (HRSA), Bethesda, Maryland, commented that HRSA has found that system improvement is important if it is centered around data that provides incentives for the system.

Dr. Aaron Kowalski, Scientific Program Manager, Juvenile Diabetes Research Foundation (JDRF), New York, New York, commented that, in the patient-centered approach, there may be a case where a motivated patient has a motivated physician, but still is not able to reduce HbA1c. Dr. Roman responded that this is where health information technology and understanding patient factors allow the physician to do a better job. Performance measures and their benchmarks also should be constructed with taking these scenarios into account. Dr. Siegel invited participants to attend the December 19 NIDDK meeting on the artificial pancreas, which is co-sponsored by JDRF and will address new technologies.

## **ADOLESCENT INTERVENTION AND IMPROVEMENT IN GLYCEMIC CONTROL**

*Martha L. Hare, Ph.D., R.N., Program Director, National Institute of Nursing Research, NIH, Bethesda, Maryland*

Dr. Hare described a program developed by Dr. Margaret Grey, Yale University, on Coping Skills Training (CST) for diabetes management and control in teenagers (slides 1-2). The CST was created based on findings from the DCCT, and the knowledge that teenagers need to participate in their own management (slide 3). Dr. Hare presented the design and methods of a randomized clinical trial using CST (slide 4). A control group received 3 or more daily insulin injections or continuous subcutaneous insulin infusion, self monitoring of glucose at least 4 times daily, and behavioral recommendations from the DCCT. The experimental group received the same care as the control group with the addition of CST. In this study, CST included a behavioral component, skills building, cognitive-behavioral modification, conflict resolution, and social problem solving. Both groups were followed for 1 year for assessment of metabolic control and quality of life.

This study showed that CST training made a significant difference in maintaining metabolic control (slide 5). If this improvement could be maintained over time, a potential 40 percent reduction in the risk of microvascular complications could be attained. In addition, results from this study indicated that after 1 year, the experimental group reduced HbA1c levels lower than the control group; in addition, quality-of-life measures were better in the experimental group.

CST training is being implemented beyond the initial funded efficacy study in more than 100 clinical sites and comprehensive behavioral care is being incorporated in clinical guidelines (slide 6). Currently, the CST protocol has been used to train participants in 20 of the 100 sites. The trainers range from Registered Nurses or nutritionists with bachelor's degrees, to practitioners with Ph.D.s in psychology. Aside from having a knowledge base to use the CST manual effectively, it is important that the trainer know how to manage groups of

teenagers. So far, CST is being used mainly in university or academic health center-based diabetes specialty clinics where there are large groups of teenagers with diabetes.

## **Discussion**

Dr. Garfield asked if HbA1c was included in the studies on CST. Dr. Hare responded that HbA1c, height, weight, and adverse effects were measured weekly for the first 6 weeks, and then approximately every 6 weeks until the end of the first year of followup. The behavioral measures were checked at baseline, 3 months, 6 months, and 12 months. Interestingly, there was more weight gain and hypoglycemic events among boys than girls. That needs to be investigated to determine the cause of this finding. Dr. Engelgau asked if there are data on CST from other types of clinics, and whether the intensity of the intervention affects the results. Dr. Hare said CST is fairly intensive and can be implemented by nurse practitioners or certified diabetes educators.

## **THE VETERANS HEALTH ADMINISTRATION, GLYCEMIC CONTROL, AND REDUCTION IN HbA1c**

*Leonard M. Pogach, M.D., M.B.A., National Program Director for Diabetes, Veterans Health Administration, East Orange Veterans Affairs Medical Center, New Jersey*

Dr. Pogach provided background material on the Veterans Health Administration's (VHA) system of care, and current and future initiatives to support glycemic control and the reduction in HbA1c levels (slides 1-2). The goal of the VHA is to reduce variability and to proceed from evidence into practice. Identified barriers include the availability of real-time knowledge that can be applied at the time of a clinician-patient encounter. A national evidence-based practice program for chronic disease, including diabetes, is one goal of the VHA, but it must be useable at the individual level in a risk-stratification strategy that allows care to be offered that will provide the "right care at the right time" for the individual patients to reduce their risk of adverse outcomes.. Although progress is being made in this area, much remains to be done.

Dr. Pogach reviewed VHA policies and infrastructure related to data collected about patients and available for use in diagnosis and developing care plans (slide 3). This system is used for all chronic diseases and includes VHA-DOD Guidelines for Management of Diabetes in Primary Care. For HbA1c, the goal is to reduce levels to less than 7 percent for individuals without co-morbid conditions that would decrease benefit or increase risk of intensive control, consistent with ADA and other guidelines. The ADA notes that benefits of reducing HbA1c levels below 7 percent are well established in younger patients, but less well understood in those older than 65 years (slides 4-5), and may not be appropriate for patients with co-morbid illnesses..

In the VHA, approximately 19 percent of clinical users have diabetes, which is higher than in the U.S. general population, but this is largely because the VHA serves an older, predominately male, and poorer population (slide 6). In addition, more VHA users have diagnosed mental health, substance abuse problems, and medical co-morbidities than the general US population. Dr. Pogach presented data to show high levels of comorbid conditions present in the users with diabetes (slide 7). He also presented data showing VHA performance measures for diabetes for 2004, which showed that 96 percent of those with diabetes in the VHA had HbA1c tests conducted with 41 percent below 7 percent (slide 8).

The VHA in-house health services research program—Quality Enhancement Research Initiative (QUERI)—is a translation feedback and evaluation system that informs the research agenda at VHA (slide 9). A publication from the Translating Research Into Action for Diabetes (Kerr et al, *Annals Int Med* 2004) compared VHA processes and outcomes of diabetes specific care with those of Commercial Health Care Plans (CMCs). Compared to CMCs, VHA had significantly increased of screening for HbA1c (98% vs 86%), lipids (78% vs 64%), and proteinuria (90% vs 77%), as well as superior control of HbA1c (for <8.5%, 83% vs 65%), and LDL -C (for LDL-C <130 mg/dl 86% vs 72%) (slides 10-11); however, blood pressure control was comparable (53% vs 52% for 140/90 mm/Hg). However, multiple recent randomized trials of quality improvement interventions and/or case management from the private sector (academic centers and regional HMOs) and the VHA

have not been successful in improving A1c, hypertension, and other intermediate outcomes. This demonstrates the challenges in guideline implementation.

Dr. Pogach presented slides showing the VHA reminder system that tracks individual dates for appointments or other clinical milestones (slides 12-16). Because there are now more than 100 reminders in the VHA system, some clinicians are beginning to feel overwhelmed by the number of reminders they receive; A1c may not be the most important priority for an individual patient with more urgent medical needs.. The reminder database has a wealth of information on the critical elements of diabetes care, which can help the provider develop an individualized care plan. Dr. Pogach also described the use of new technologies, such as telemedicine and remote home monitors, that allow care managers to triage patients and allow for more frequent contact with patients who are most in need (slides 17-19).

Dr. Pogach summarized his presentation with the following points (slide 20):

- VHA has instituted a multifaceted, multidisciplinary approach to glycemic control based on evidence explicit from guidelines that inform individualized patient centric care.
- The locus of care is in primary care settings.
- Informatics support includes electronic medical record, timely and ongoing performance measurement, and feedback.
- Care coordination is expanding to tele-health networks.
- Population informatics support and Individual Clinical Decision Making Support is under development.
- VHA performance is comparable to, or exceeds, private sector providers despite a greater illness burden among its population.
- Barriers to intensive glycemic control for many veterans include the high prevalence of serious co-existing medical and mental conditions, as well as a high prevalence of adverse socioeconomic conditions.

## **Discussion**

Dr. Fradkin asked if Dr. Pogach's statement about the added benefit of reducing HbA1c at the highest levels (i.e., 12 to 9 percent) was based on epidemiological data, because clinical trial results are based on reductions from 9 to 7 percent. Dr. Pogach responded that VHA guidelines indicate that HbA1c levels should be negotiated with the patient, taking into account individual health factors and preferences. For example, coexisting conditions may dictate that higher or lower levels (pregnancy) are the appropriate goal. He added that life expectancy is also a factor in setting goals. Dr. Fradkin commented that it is important to set individual goals, but she wanted to know if there was evidence that greater benefit accrues in lowering HbA1c levels for, for instance, 11 to 9 percent than 9 to 7 percent. Dr. Pogach explained that while relative risk reduction resulting from reduction in A1c levels is linear across the continuum, there is a log-linear relationship in absolute risk reduction. In other words, that there are greater risks of incurring complications at higher A1c levels than at lower levels, as demonstrated in cohort analyses of the DCCT and UKPDS studies.

### **HbA1c: THE INDIAN HEALTH SERVICE EXPERIENCE**

*Kelly Acton, M.D., M.P.H., Director, National Diabetes Program, Indian Health Service, Albuquerque, New Mexico*

Dr. Acton discussed diabetes in American Indians and Alaska Natives (AI/AN), described the Indian Health Service (IHS) Annual Diabetes Care and Outcomes Audit, and presented data on HbA1c results from the 12 IHS Areas 35 states (slides 1-3). In comparing diabetes prevalence rates by race (white, black, Hispanic and AI/AN) and age, for every age group AI/AN have the highest diabetes prevalence in the U.S. A comparison of diabetes prevalence rates in AI/AN by state between 1991 and 2001 indicates that prevalence rates have significantly increased across the country (slides 4-6). The greatest increase in prevalence rates among AI/AN populations are occurring between ages 20 and 29, while in the general U.S. population, the largest increases in prevalence rates occurs between ages 30 and 39 (slide 7).

Dr. Acton presented data showing that greater increases in diabetes are occurring in some AI/AN tribes than in others, although all tribes appear to be affected. And the *rate of increase* in prevalence appears to be highest in those areas with the lowest prevalence of diabetes (slides 8-9). Among AI/AN children and adolescents, data from 1990 to 2002 indicate that there has been a 50 percent increase in prevalence of type 2 diabetes amongst those less than 15 years old, a 106 percent increase in those 15 to 19 years old, and a 132 percent increase in those 25 to 34 years of age. This trend of diagnosing more type 2 diabetes in children and adolescents is of great concern to the IHS (slide 10).

Dr. Acton described the IHS Annual Diabetes Care and Outcomes Audit, which has been conducted at Indian health facilities since 1986 as a quality improvement tool (slide 11). The audit is based on the IHS Standards of Care for Diabetes and includes 87 process and outcome measures (slides 12-13). The latest audit, from 2004, consisted of a national sample of data from 172 care centers with more than 30,000 medical charts (slide 14). Results from the 2004 audit indicated that for duration of diabetes, 39 percent of participants had had diabetes for less than 5 years, 31 percent had had diabetes between 5 and 10 years, and 30 percent had had diabetes for more than 10 years (slides 15-17).

Audit results for HbA1c from 1994 to 2004 showed the following (slides 18-25):

- The overall mean level of HbA1c in the AI/AN population with diabetes has decreased from approximately 9.3 percent in 1994 to 7.89 percent in 2004.
- HbA1c levels are lower in older members of the population than younger members.
- Women have lower mean HbA1c levels than men, though mean HbA1c has decreased in both genders over time.
- The mean HbA1c levels are decreasing in all IHS Areas, but more in some Areas than in others.

Dr. Acton commented on the \$150 million per year Special Diabetes Program for Indians grant program mandated by the U.S. Congress since 1997 to improve the prevention and treatment of diabetes in AI/AN. Many tribes are using these funds to focus on prevention of

diabetes in youth, including nutrition and physical activity programs provided through the schools and communities.

## **GENERAL DISCUSSION AND MEMBER REPORTS**

*Dr. Fradkin*

Dr. Fradkin began the discussion period by commenting that national cross-sectional data are stagnant regarding the reduction in HbA1c levels, but longitudinal data from various groups (e.g., Kaiser, IHS, VHA) show substantial improvement. She asked if the participants would comment on this conundrum. Dr. Saydah responded that cross-sectional data capture different patients each time a survey is conducted; longitudinal data survey the same people. This accounts for some of the differences in results and suggests that for the entire population there may not be much change overall. Dr. Selby interjected that he was puzzled by the NHANES data, and that cross-sectional data may be misleading, but data from TRIAD and the VHA show there may be modest improvement in patients with diabetes. Dr. Engelgau agreed that the direction of change is the direction we want to see it. Dr. Savage agreed with previous comments but observed that the tools being used for glucose control are suboptimal for reducing HbA1c below 7.0 percent. He said it would be harder to attain HbA1c levels below 7.0 percent because of the underlying physiopathology. The VHA and IHS appear to do better than many health care organizations because they approach the problem from a systematic viewpoint. This also speaks to the need to improve prevention programs so that fasting glucose does not go up naturally during the aging process.

Dr. Mark Eberhardt, Epidemiologist, National Center for Health Statistics, CDC, commented that NHANES data has been collected by the same laboratory using the same laboratory methods, and this should make the data more reliable. Dr. Fradkin noted that the NHANES data are normalized. Dr. Saydah said the NHANES data are weighted to the U.S. population to reflect demographics.

Dr. Jag Khalsa, Chief, Medical Consequences Branch, Division of Pharmacotherapies and Other Medical Consequences of Drug Abuse, National Institute on Drug Abuse, NIH,

Bethesda, Maryland, asked if the Kaiser group could correlate changes in the levels of HbA1c with decreased renal and ocular complications. Dr. Selby responded that theoretically, the number of complications should be decreasing, although there could be more patients with milder diabetes included in the data over time, which would make it difficult to separate the cause and effect of decreased complications.

Dr. Fradkin asked participants to address the barriers to achieving guideline levels of HbA1c control in those patients for whom the achieving good control is likely to be particularly important for reducing risk of complications, such as younger patients or minorities at increased risk of complications. Dr. Engelgau suggested that it is difficult to get patients to reduce HbA1c levels once some control has been achieved. Patient preference—what the patient is willing to do to achieve lower HbA1c levels—is an important factor or barrier in these cases. Dr. Fradkin asked if patient preference is really physician preference; physicians might not want to add insulin or recommend stricter treatments. Dr. Pogach recounted that a review of recent studies on HbA1c show that the average HbA1c levels achieved was approximately 7.6 percent. This included volunteers, older individuals, and individuals with significant amounts of hypoglycemia. Results from these studies do not point to one cause for failure to meet lower HbA1c levels. It is possible that it is a combination of patient and physician preferences, biologic or genetic factors, or systems of care. Even in randomized trials with extensive resources getting lower HbA1c is not easy to do. Dr. Roman added that even in the DCCT, intensive glucose control was not the true intervention; intervention was intensive glucose control associated with nurse management, nutritional management, and followup. This points to the importance of having systems of care, which is not the case for most patients in the United States. Dr. Fradkin agreed that the issue of systems intervention is key to achieving better adherence to treatment and reducing HbA1c levels.

Dr. Fradkin noted that the Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial had an even more ambitious HbA1c goal of 6.0 for the intensive group. She asked Dr. Savage to comment on what had been learned about how this could be achieved. Dr. Savage said he could not reveal much of the results because they were still not complete. He noted that goals were also not met for cardiovascular risk factors other than HbA1c.

Dr. Pogach said that future health care will include home glucose testing and monitoring that will use technology to pass this information to nurses or physicians who can adjust care depending on feedback from the monitors.

Dr. Fradkin listed the barriers discussed during the meeting. They included:

- Lack of knowledge
- Lack of time for care, both by physicians and patients
- Tools
- Co-existing diseases
- Financial issues
- Patient acceptability issues
- Toxicity of current therapies

Dr. Fradkin asked if there were other barriers. Dr. Roman commented that physicians need to be more engaged in treatment regarding guidelines. She said it is difficult for physicians to know if they are treating successfully if they do not have the data to see how they are doing. Dr. Spiegel agreed that there is a need for better data, similar to what is collected for the U.S. Renal Data System on ESRD in collaboration with CMS. There is a need for concrete followup to see if it is feasible for NIDDK and CMS to create similar common data on HbA1c. Dr. Feetham added that it also is important to determine how to use the data.

Dr. Spiegel asked whether it is feasible to include industry collaboration in the area of HbA1c initiatives, similar to what is done for blood pressure and lipid control. Dr. Roman said that CMS has collaborated with industry at the hospital level, but collaboration at the ambulatory level is evolving. Dr. Spiegel clarified that industry does include hospital or other health care providers, but consideration also should be given to including pharmaceutical companies.

Dr. Fradkin noted that the data suggest that there is worse control of HbA1c levels in the 25 to 45 year age group. She asked if this should be a target population for initiatives and

research. Dr. Acton agreed and added that her studies have shown that younger patients can do well if they have programs directed toward them. Dr. Pogach asked if it might be possible to raise awareness that an emerging consensus that diabetes is an epidemic and needs new thinking on ways to get control of this situation. Dr. Engelgau added that diabetes is a disease that goes beyond glycemic control and HbA1c, and it would be beneficial to address diabetes in a holistic manner.

Dr. Fradkin asked for input on which areas of research or initiatives should be the highest priority or held the greatest potential for addressing the problem of glycemic control. Dr. Savage suggested simplifying guidelines for chronic diseases because physicians have trouble sifting through the numerous recommendations. Is there a simple message that can apply to cardiovascular disease and diabetes? Dr. Khalsa suggested targeting physicians. Dr. Hare added that focusing on the team of health care providers will be beneficial because not everyone visits physicians. Dr. Audrey Penn, Deputy Director, National Institute of Neurological Disorders and Stroke, NIH, Bethesda, Maryland, commented that from the point of view of stroke, prevention makes a difference. Focusing on HbA1c, blood pressure, and lipid control is important to prevent strokes. Dr. Fradkin asked about the possibility of NIDDK collaborating with CMS in demonstration projects in Medicare recipients that focused on studying approaches to manage diabetes and associated chronic diseases. Dr. Roman said there may be an opportunity to develop such a collaboration.

## **ADJOURNMENT**

Dr. Fradkin thanked participants for attending and taking part in this important meeting. The meeting was adjourned at 4:15 p.m.