DIABETES MELLITUS INTERAGENCY COORDINATING COMMITTEE MEMBER OVERVIEW OF DIABETES RELATED ACTIVITIES

Natcher Building, Conference Room C1/C2
National Institutes of Health Campus
Bethesda, Maryland
8:30 a.m. – 12:10 p.m.
September 20, 2007

SUMMARY MINUTES

WELCOME AND GOALS OF THE MEETING

Judith Fradkin, M.D., Director, Division of Diabetes, Endocrinology and Metabolic Diseases, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH)

Dr. Fradkin welcomed participants and spoke of the importance in having Diabetes Mellitus Interagency Coordinating Committee (DMICC) members share what their Institutes and Centers are implementing and planning for diabetes research. It has been a while since this type of meeting has occurred, and there is important research being conducted across NIH related to the growing problem of diabetes in the society. She reviewed the agenda and reiterated that the purpose of the meeting is to hear what research or programs are being conducted at NIH that relate to the Diabetes National Plan for Action (DNPA).

Griffin Rodgers, M.D., M.A.C.P., Director, NIDDK, NIH

Dr. Rodgers welcomed participants and expressed the commitment of NIDDK for implementing a full agenda for diabetes research in this time of shrinking budgets. He spoke of the importance of the DMICC in keeping a focus of NIH on diabetes research. He said that he is optimistic that funding will be continued for special diabetes programs in coming years.

DIABETES: A NATIONAL PLAN FOR ACTION

Dr. Fradkin

Dr. Fradkin provided background information on the DNPA, which was developed under the auspices of the U.S. Department of Health and Human Services. The goals of DNPA are to increase national awareness of diabetes and its impact and what can be done to prevent and manage the disease; reduce the prevalence of diabetes and its risk factors; promote improved detection, monitoring, and treatment; and coordinate public and private efforts and leverage existing resources. DNPA focused on both type 1 diabetes (T1D) and type 2 diabetes (T2D), was published in December 2004, and may be found on the Internet at the following URL:

http://aspe.hhs.gov/health/NDAP/NDAP04.pdf. Topics in the DNPA include strategies for addressing T1D and T2D for individuals and families, schools, health care providers, employers, communities, health insurance providers, media, researchers and educators, and governments. The DMICC is integral to the federal response to the DNPA. The key components of the DNPA are prevention, detection, and treatment.

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
Dr. Fradkin

Dr. Fradkin reviewed ongoing initiatives at NIDDK for diabetes, beginning with the major NIDDK prevention clinical trial, the Diabetes Prevention Program (DPP). The DPP showed that lifestyle changes (i.e., diet, exercise, and behavioral modification) could reduce the development of T2D in high-risk individuals; DPP also showed that pharmacological intervention (metformin) is effective in reducing the onset of T2D, but less than lifestyle changes. Taking advantage of the impressive results from DPP, the DPP Outcomes Study (DPPOS) currently is being conducted to investigate the long-term effects of DPP interventions on diabetes prevention. DPPOS participants include 86 percent of the DPP cohort, with 99.9 percent retention at 4.5 years of followup. The study also has large representations of minorities (45 percent), women (65 percent), and the elderly (20 percent older than age 65 years).

The DPPOS is investigating the impact of DPP interventions on microvascular and neuropathic complications, cardiovascular disease (CVD), atherosclerosis, and CVD risk factors. Results are expected in the next few years.

Dr. Fradkin presented results of the Finnish Diabetes Prevention Study that showed the persistent effect of lifestyle intervention in delaying the onset of diabetes. Risk reduction during the 7-year trial was 58 percent, which supports results reported by the DPP regarding the impact of lifestyle interventions on diabetes prevention.

The lessons from DPP are being translated to different populations around the country; these efforts focus on implementing the interventions in high-risk populations in various environments. For example, the Kaiser health system has a project using a telemedicine intervention for weight control in minority women. The YMCA and San Francisco public health department have implemented DPP interventions to reduce risk in individuals identified with prediabetes. Weight loss programs are being implemented in church-based programs for African American women, in primary care practice, and at worksites. The Reach-Out community-based, family-directed intervention in Chicago is using DPP interventions to reduce diabetes risk factors in children; the same interventions are being conducted in the Bienstar school-based program for Hispanics. DPP provided a wealth of useful information for research translation efforts.

The HEALTHY middle school program for diabetes prevention is a randomized intervention trial being conducted in 42 middle schools with the goal of reducing the risk factors for T2D. Interventions include environmental changes to school food service and physical education class activities, behavior change activities, and communications and promotional campaigns. Of the

6,000 accrued participants (2006), approximately 80 percent are minority students. HEALTHY will be completed in spring 2009.

The detection of diabetes is becoming increasingly possible with the advent of new technologies and methodologies. One standard method of detection, the non-fasting glucose challenge, is being supplemented with new proteomic methods and genomic tests, including the identification of variants of HbA1c. Future research on detection will focus on the search for new biomarkers with higher sensitivity and specificity to identify prediabetes, and to identify individuals earlier in the progression to overt disease.

Translational projects for treatment are focused on physicians, nurse/pharmacist case management, community-based programs, and behavioral interventions. Programs to improve physician adherence to treatment guidelines are being conducted in rural Alabama by an Internet intervention program, with health maintenance organization (HMO) systems to improve diabetes care, and through office system changes in primary care settings. Examples of nurse/pharmacist case management are telemedicine projects in rural Montana and South Carolina, general nurse case management in primary care clinics, and in pharmacist-delivered medication adherence programs at Kaiser and the Veterans Administration. Community-based programs for the translation of diabetes treatment include a group intervention to improve self-management in urban African Americans, and a telephone intervention program in New York City for those with identified high HbA1c levels. Research translation projects of treatments using behavioral interventions are being conducted in clinics serving low income Hispanics, lifestyle case management in a health plan, and programs for spousal partners and family support. Many of the translation programs are conducted using R18 grants.

Dr. Fradkin provided updates on two treatment translation trials being supported by NIDDK: Action for Health in Diabetes (Look AHEAD), and Treatment Options for type 2 Diabetes in Adolescents and Youth (TODAY). Look AHEAD, which is co-sponsored by NIDDK, National Heart, Lung, and Blood Institute (NHLBI), National Institute of Nursing Research (NINR), the Office of Research on Women´s Health (ORWH), the National Center for Minority Health and Health Disparities (NCMHD), and the Centers for Disease Control and Prevention (CDC), is investigating the long-term benefits of weight loss among overweight persons with T2D. Outcomes include the incidence rate of the first post-randomization occurrence of a composite outcome, including cardiovascular death (fatal myocardial infarction and stroke), non-fatal myocardial infarction, and non-fatal stroke. The trial began in 2001 and will be completed in 2012; more than 5,000 participants are being studied in 16 centers. Look AHEAD will compare lifestyle intervention to diabetes support and education.

TODAY is a randomized, treatment trial comparing metformin alone, metformin plus intensive lifestyle intervention, and metformin plus rosiglitazone. Primary outcomes include time to "treatment failure" and HbA1c levels equal to or greater than 8.0 percent for six months. Average TODAY participants at baseline were 14.2 years of age, had body mass indexes (BMIs) of 35.5, were 77 percent minority, and had diagnosed diabetes for 5 months. Recruitment will end in November 2008, with completion of the study in November 2010, which allows for a minimum 2-year followup for each participant.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
Peter J. Savage, M.D., Director, Division of Epidemiology and Clinical Applications, NHLBI, NIH

Dr. Savage presented information on completed and ongoing cardiovascular (CV) clinical trials at the NHLBI that include diabetes outcomes or assessments, including those that may be used for retrospective analyses. Cardiovascular complications related to diabetes are well known, and there is ample evidence from longitudinal epidemiological studies to support assessing diabetes as a co-morbid condition related to CV. NHLBI and NIDDK have increased co-sponsorship of clinical trials, and will continue to do so in the future. He highlighted studies that have reported data on CV and diabetes risk and complications.

The Coronary Artery Risk Development in Young Adults (CARDIA) is a population-based observational study of 5,115 participants aged 18-30 years recruited in 1985-1986. Of particular interest for diabetes, CARDIA showed that average weight gain at 20 years followup was approximately 30 pounds. There was a 16-fold increase in T2D among CARDIA participants who were overweight at baseline and gained weight during the trial. Data from the Framingham study also showed that obesity increased the risk of diabetes and renal disease. Results of the Cardiovascular Health Study (CHS) regarding diabetes indicate an increased risk of CVD morbidity and mortality with new-onset diabetes, as well as an increasing cost of CVD care with co-morbid diabetes.

Dr. Savage presented information and data on seven NHLBI-supported trials focusing on reducing CV complications related to diabetes. For example, the Action to Control Cardiovascular Risk in Diabetes (ACCORD) study is a randomized controlled trial that collects outcomes data on the management of patients, including combination drug therapy for tight blood pressure and glycemic control among patients with T2D. Ancillary studies in ACCORD will be investigating, among other diabetic complications, eye and renal outcomes. Another ongoing study is the Stop Atherosclerosis in Native Diabetics Study (SANDS), a 3-year randomized (open-label) trial to investigate the effects of aggressive lipid and blood pressure reduction versus standard goals. SANDS is being conducted in American Indian men and women with T2D to assess the presence and progression of atherosclerosis; primary outcomes include change in carotid artery intimal medial thickness and fatal/nonfatal CV events. The cumulative results of the ongoing trials, expected over the next few years, will improve our understanding of the interaction of diabetes and CVD complications, including mortality. The wide breath of these trials is significant for addressing the many questions raised in previous clinical trials.

Dr. Fradkin commented that translating clinical trial results to standard practice remains a challenge. Dr. Savage indicated that NHLBI will be conducting a study with HMOs to target people in a real-world clinical situation. This should help address the need for translation. Dr. Fradkin also asked how many patients with diabetes have been, or are being, included in NHLBI trials. Dr. Savage responded that in most trials, such as Framingham, there are few people with diabetes and to obtain statistically-sound data, the trials must be pooled. This has always been a

problem with ancillary studies to analyze diabetes information from clinical trials not designed specifically for inclusion of those with diabetes.
Drs. Fradkin and Garfield asked about the possibility of analyzing samples from past trials for genetic studies. Dr. Savage indicated that it is difficult to complete retrospective genetic studies because there may not be a clear enough phenotype collected from individuals to allow the genetic study to produce valid associations within the data. The use of DNA sample collection in studies being planned is valuable, as long as they are planned beforehand so that a well-defined phenotype can be described.

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT
Gilman D. Grave, M.D., Chief, Endocrinology, Nutrition and Growth Branch, Center for Research for Mothers and Children, National Institute of Child Health and Human Development (NICHD), NIH

Dr. Grave presented information on diabetes initiatives at the NICHD. Results of the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) Study were presented. HAPO is a 7-year international study of approximately 25,000 pregnant women in nine countries. The goal of HAPO was to determine the level of glucose intolerance during pregnancy, short of diabetes, that is associated with the risk of adverse outcomes. Results, reported in 2007, indicate that as glucose levels increase in the mother during pregnancy, there is an increased risk of having a large baby, a first-time Cesarean delivery, low blood glucose levels in the newborn requiring treatment, and high blood insulin levels in the baby that may indicate future problems. The effects were continuous over the entire range of glucose levels in the mother, even at levels considered in the normal range for pregnancy.

Dr. Grave also described the NICHD Maternal-Fetal Medicine Units (MFMU) Network comprised of 14 clinical centers and a data center. The goals of the MFMU are to reduce the rates of preterm birth, fetal growth abnormalities, neurologic sequelae of the newborn, and maternal complications of pregnancy, as well as to evaluate maternal and fetal interventions for efficacy, safety, and cost-effectiveness. The network conducts randomized trials and includes a translational research component, as well as studies in genetics and the evaluation of new technologies. One study being conducted by the MFMU Network is investigating whether early identification and dietary treatment of mild gestational diabetes mellitus (GDM) reduces composite fetal outcomes.

Other clinical studies at NICHD include the Trial to Reduce IDDM in the Genetically at Risk (TRIGR), which is investigating whether weaning a neonate to a highly hydrolyzed casein-based formula in infancy reduces the incidence of T1D in children with increased risk of developing the disease during the first 10 years of life. Accrual for TRIGR has been completed and the treatment arms have been balanced for baseline characteristics. Retention and followup will be conducted according to protocol, and the trial should be completed by 2016.

The Diabetes Research in Children Network (DirecNet) is co-funded by NICHD and NIDDK and is comprised of five clinical centers and a data coordinating center. DirecNet is studying the use of continuous glucose monitoring systems in children with T1D. Monitors being

investigated include the GlucoWatch Biographer, the Medtronic Minimed, and the Abbott Diabetes Care FreeStyle Navigator®. The goal of the study is to provide children and their parents with tool to improve diabetes self management. Of particular interest is to alleviate many of the glycemic-control problems seen in children during overnight hours as well as during exercise.

Dr. Fradkin asked what types of samples were collected in the HAPO study. Dr. Grave indicated that cord blood was collected and that these samples should be available from the repository. Ms. Joanne Gallivan asked at what age neonates were weaned in the TRIGR study. Dr. Grave said that most of the neonates were breast fed for 1-to-2 months, with at least 2 months of exposure to one of the two formulas. However, a small percentage of mothers continued to breastfeed until six months. Infants of these mothers were started on one of the two formulas at six months and continued on formula until eight months.

CENTER FOR MEDICARE AND MEDICAID SERVICES

Sheila H. Roman, M.D., M.P.H., Senior Medical Officer, Center for Medicare Management and John Pilotte, Senior Research Analyst, Office of Research, Development and Information, Centers for Medicare & Medicaid Services (CMS)

Dr. Roman and Mr. Pilotte presented information on the Centers for Medicare & Medicaid Services (CMS) physician-focused care improvement initiatives. The focus of the initiatives is to improve quality and efficiency within the Medicare system. Incentive programs that reward performance are being developed and tested. The U.S. Congress and Administration is encouraging the initiatives' concepts by funding demonstration projects on health care quality, care management for high-cost beneficiaries, physician group practice, and Medicare care management performance. Patients with diabetes are a focus in all of these demonstration projects. Challenges for Medicare include the diverse and unique needs of seniors, issues of fragmented care, and the overwhelming number of beneficiaries (approximately 44 million) and physicians (approximately 700,000) who participate in the program.

Dr. Roman and Mr. Pilotte provided details of one demonstration project, the Physician Group Practice (PGP) demonstration, which is a 3-year project that began in 2005. The PGP is comprised of 10 physician groups representing 5,000 physicians and 224,000 assigned Medicare fee-for-service patients. In the PGP demonstration project, the patient population is retrospectively assigned based on whether patients receive a plurality of office or other outpatient services at each group. Each of the 10 participating physician groups is assigned between 46 and 76 percent of patients with visits at the group, and are accountable for their total Part A and Part B Medicare costs. This encourages groups to redesign care processes based on the medical evidence and standardize care processes across all patients and payers. Physician groups are measured on how well they control the growth in spending and improve and deliver high quality care for their assigned populations. Physician groups may share in savings if their assigned beneficiary total Medicare spending growth rate is more than two percent below the local market growth rate. PGP participants share up to 80 percent of these savings, and receive performance payments for cost efficiency and quality; the annual performance payment is capped at 5 percent of the Medicare Part A and Part B target.

PGP participants are evaluated based, in part, on their management of care for diabetes, congestive heart failure, coronary artery disease, and hypertension and cancer screening. Dr. Roman and Mr. Pilotte reviewed expectations for each disease category and strategies assessed to evaluate performance. For example, for diabetes care, assessment areas include Hb1Ac management and control; blood pressure and lipid management; urine protein testing; eye and foot exams; and influenza and pneumonia vaccinations. Results after the first year of the demonstration project indicated that all PGP groups improved the clinical management of diabetes patients.

A redesign of the diabetes care of the demonstration participants is underway at several of the physician groups. An emphasis on team-based care is encouraged, with enhanced attention to patient registries. Provider feedback is being provided to assist in gaining actionable information to improve care. Areas that have been identified for improvement include the need to bring nurses and other members of the care team more actively into the process of diabetes care, and to make patient visits more productive. In addition, transition management for post discharge follow-up and emergency room visits is a focus at several groups and will be evaluated under the demonstration.

In summary, first year results from the PGP demonstration project are encouraging. All physician groups improved their clinical management of diabetes and two groups shared in total savings of $9.5 million to the Medicare Trust Funds. Care management and process redesign initiatives are focusing on targeting patients with chronic illness, transitioning care, multiple admissions for co-morbidities, and near end of life issues. Goals are to reduce avoidable admissions and to improve quality of care for Medicare patients. Quality and cost efficiency are improving, possibly due to physician acceptance and commitment to improving care. CMS is working to determine if there are models for improving the quality, access and efficiency of healthcare for broad implementation. . Second year results from the PGP initiative will be available during the summer of 2008.

CENTERS FOR DISEASE CONTROL AND PREVENTION
Edward Gregg, Ph.D., Epidemiologist, Division of Diabetes Translation, CDC

Dr. Gregg presented materials on diabetes initiatives at the CDC. The Division of Diabetes Translation (DDT) is comprised of a program development branch and an epidemiology and statistics branch. The three primary thrusts of the DDT is to provide for a diabetes surveillance system that supports epidemiological and effectiveness research; these in turn provide strategies for public health programs. The CDC supports diabetes prevention and control programs (DPCPs) in each of the 50 states. DPCPs support diabetes surveillance, assessment and strategic planning, partnership and workforce development, quality care assessment, and technical assistance.

Current national diabetes objectives are to increase the number of people with diabetes who receive the following preventive care services: two HbA1C tests per year, annual foot and dilated eye exams, annual flu vaccinations, and a pneumococcal vaccination once in a lifetime.

The CDC's National Diabetes Education Program, jointly sponsored by NIDDK, is structured to support partnerships, community programs, health systems, and special populations with prevention and treatment information on diabetes and its complications, all in support of the national diabetes objectives.

The DDT is primarily focused on translation research. The surveillance program assesses the present and future burden of disease, diabetes complications, delivery of services, diabetes risk factors, economic costs, diabetes in youth, and the international burden of diabetes. The Division has been on the leading edge of characterizing and tracking the emerging diabetes epidemic. In addition, DDT is evaluating the public response to the increasing burden of diabetes worldwide.

DDT also supports diabetes clinical trial research in conjunction with NIDDK and other NIH institutes. For example, the current Translating Research into Action for Diabetes (TRIAD) study, co-sponsored with NIDDK, is a multi-center study to determine how managed care systems influence the processes and outcomes of diabetes care. Ten health care plans and 66 provider groups are participating in TRIAD, which has a goal of improving the quality of care and quality of life for people with diabetes.

Cost-effectiveness research, education, and communications campaigns are an integral part of DDT's mission and goals. For example, education and communications are disseminated via the World Wide Web, media outlets, publications in peer-reviewed journals, and literature distributed at scientific conferences and through health promotion clearinghouses. These extensive efforts directed towards diabetes are supplemented with comprehensive initiatives for vision health and chronic kidney disease.

Dr. Grave commented that he had read reports that T1D was increasing by 3 percent a year in Finland and wondered how that compares to the United States. Dr. Gregg responded that there is no U.S.-wide incidence data available so it is not possible to make the comparison. A recent article in *The Journal of the American Medical Association* addressed the issue of the need for better incidence data on diabetes (refer to: SEARCH Writing Group. Incidence of diabetes in youth in the United States. *JAMA* 2007;297:2716-2724. Editorial 2760-2761).

THE MEDICARE DIABETES SCREENING PROJECT

Jerry Franz, American Diabetes Association/Novo Nordisk, Inc

Mr. Franz discussed the Medicare Diabetes Screening Project (MDSP), a public-private partnership designed to: (1) encourage seniors age 65 and older to be tested for diabetes, using new Medicare diabetes screening benefits that became available in 2005; and (2) increase awareness of these benefits among primary care providers and encourage them to "think diabetes" and screen appropriately. The goals of the MDSP are to: increase usage of the diabetes screening benefits authorized by Congress in 2005 (in the long term), as measured by CMS data; go "upstream" in disease management and reach seniors with pre-diabetes and undiagnosed diabetes, and their providers, with messages about diabetes detection, prevention, and treatment; and gain an understanding of provider-patient interactions regarding diabetes detection and any counseling based on results of testing.

Data on seniors indicate that 61 percent (21 million) have diabetes or pre-diabetes, and this number is increasing each year. Estimates suggest that at least 2 million Medicare recipients have undiagnosed diabetes, as are almost all 14 million who have pre-diabetes. MDSP is committed to correcting this situation. The 2005 legislation guarantees that Medicare recipients may have a free, annual test for anyone age 65 and over with one diabetes risk factor (e.g., hypertension, obesity or overweight, or a family history of diabetes), and two screenings per year for those with pre-diabetes. Tests authorized under the legislation may include a fasting plasma glucose (PPG) or oral glucose tolerance test (OGTT).

MDSP pilot programs are being conducted in Columbus, Georgia, and in New Hampshire. To illustrate strategies for the pilot, in Columbus, MDSP is providing radio and print advertising support for the launch of the program; religious community outreach; civic and community group involvement (e.g., Veterans of Foreign Wars and American Legion); outreach to providers; and collaboration with the local area agency on aging.

Research on seniors indicates that they are getting tested, although this is questionable. They recognize that diabetes is serious, yet about one-half feel no personal vulnerability; they indicate that they will ask questions of their doctors but will ignore the advice, possibly for fear of challenging their doctors. Next steps for research are to develop programs among health care providers, with an emphasis on primary care physicians.

A participant asked why seniors are unaware that they have diabetes. Mr. Franz said he was not sure if the patients are being asked about diabetes, or if they are asking but not receiving interventions. Dr. Gregg commented that patients have numerous ways to be diagnosed with diabetes or pre-diabetes. Another participant asked if AARP is involved in these efforts.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

David Atkins, M.D., M.P.H., Chief Medical Officer, Center for Outcomes and Evidence, Agency for Healthcare Research and Quality (AHRQ)

Dr. Atkins described initiatives at the Agency for Healthcare Research and Quality (AHRQ) on diabetes research. The mission of AHRQ is to improve the quality, safety, efficiency, and effectiveness of health care for all Americans. Improving diabetes chronic care is an important part of this mission. AHRQ is generating new knowledge about diabetes care and synthesizing knowledge through its initiatives to develop evidence-based treatment guidelines, as well as efforts to disseminate and translate this knowledge. The agency is studying ways to promote change to improve diabetes care at the level of the healthcare system, practice, and patient. AHRQ has developed a diabetes care website (http//ahrq.gov/browse/diabetes.htm) that has links to tools and resources for improving diabetes care.

Dr. Atkins provided information on selected AHRQ diabetes projects. These include the following:

- For practice-based research, a patient-centered registry has been established in Colorado, and a California project is bridging language and literacy with telephone management versus group visits.
- In the area of health information technology, AHRQ is developing a county-wide diabetes registry in Santa Cruz, California, as well as an electronic decision support system, the Web Patient Empowerment project, in Cleveland, Ohio.
- To focus on healthcare disparities, AHRQ has established a project using telemedicine for diabetic foot care and rural barriers to eye care project in Louisiana, as well as a project focused on disparities in elder Native Americans in Colorado.

AHRQ activities in the area of new knowledge include: the collection of data on costs, utilization, and hospitalizations related to diabetes care; Developing Evidence to Inform Decisions about Effectiveness (DEcIDE) centers research for the study of the safety and effectiveness of exenatide; research on improving the quality of diabetes care; Health Plan Disparities Collaboratives; practice-based research networks; and Accelerating Change and Transformation in Organizations and Networks (ACTION), an integrated delivery system network.

For synthesizing knowledge, AHRQ has comparative effectiveness reviews on the safety of oral medications in T2D (2007) and the safety of pre-mixed insulin analogues in T2D (in progress). Evidence-based Practice Center Reports are being developed on *Diabetes Education and Medical Nutrition Therapy Education for Families with Children with Type 1 DM, Management of Gestational DM, Bariatric Surgery in Women of Reproductive Age.*

AHRQ has an active program of dissemination and translation. It annually produces the National Healthcare Quality Report and National Healthcare Disparities Report, which contains 12 measures for diabetes. The AHRQ National Guideline Clearinghouse and National Quality Measures Clearinghouse, as well as the Innovations Clearinghouse disseminate research translation products to professionals and the public. The Medicaid Care Management Knowledge Translation program is a learning network of 15 states, with the majority targeting diabetes as well as other chronic diseases. There also is a translation effort on diabetes in Hispanic women. Dr. Atkins provided sample information on Maryland from the Diabetes Care Quality Performance web tool to exemplify the types of comparisons available using data from the states. Examples of the Innovations web tool also were shown.

Challenges in addressing the quality of diabetes care within the context of all chronic diseases are being defined. Many patients have multiple chronic conditions and risk factors aside from diabetes, such as CVD and hypertension. Interactions between conditions and multiple medications and/or treatments make it difficult to determine the impact of interventions. There also often is a tension between treatment goals, as well as conflicts between healthcare providers. These factors add a complexity for addressing quality care.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Tanya Pagan Raggio-Ashley, M.D., M.P.H., FAAP, Director, Division of Medicine and Dentistry, Health Resources and Services Administration (HRSA)

Dr. Raggio-Ashley began her presentation by commenting that the Health Resource and Services Administration (HRSA) envisions optimal health for all, supported by a health care system that assures access to comprehensive, culturally competent, quality care. The HRSA goal is to improve health care access, health outcomes, and quality of care. In addition, the bureau works to eliminate health disparities, improve the public health and health care systems, enhance the ability of the health care system to respond to public health emergencies, and achieve excellence in management practice.

HRSA is involved in many diabetes-related activities, including those for direct services and education and training. For direct services, HRSA funds projects for primary health care, the Office of Minority Health, Office of Quality, Office of Planning and Evaluation, Maternal Child Health Bureau, and the Diabetes and the Elderly Project. In education and training, HRSA has the Bureau of Health Professions, which funds projects for children's graduate medical education, training in primary care medicine and dentistry, National Research Service Awards in Primary Care, and area health education centers for nursing. Each of these components has programs related to diabetes care and service.

The HRSA Health Centers serve patients of all ages and those from many ethnic and racial backgrounds. The Bureau of Primary Care Health Services serves approximately 15 million persons nationally—almost 1 million of them with diabetes—at 1,002 health centers. The Bureau provides primary care (medical, oral and behavioral health), podiatry and optometry, and discounted pharmaceuticals through 340b pharmaceutical programs. The Bureau generates nearly 3 million visits, or approximately 3.18 encounters per patient, annually; collaborates with State Diabetes programs; and partners with the Diabetes Collaborative to improve and assess quality of care.

In 2006, the Health Disparities Collaborative was comprised of 800 Federally-qualified Community Health Centers that focused on improvement in chronic disease care, including diabetes, asthma, CVD, and depression; 634 centers serving 300,000 patients were involved in diabetes treatment and prevention programs. Change packages for diabetes improvement are available to all health centers.

Other HRSA projects include the Center for Quality, which assesses agency-wide performance measures, including the diabetes measure of HbA1c, and the HIV–AIDS Bureau, which affords diabetes-related primary care for patients with HIV–AIDS. HRSA also has funded a series of projects with the Public Health Data Standards Consortia on the bi-directional exchange between safety net provider electronic health records systems and public health information systems. An upcoming project will build on the Robert Wood Johnson Foundation Common Ground Project in Wisconsin; one of its focal points will be diabetes.

Dr. Fradkin commented that there appear to be opportunities for NIDDK and HRSA to collaborate, especially with regard to the maternal centers. Dr. Raggio-Ashley responded that the maternal centers are an important initiative for understanding gestational diabetes, as well as T1D among children. She said that diabetes can be devastating in minority communities because minority women tend to have less treatment or get treatment later than non-minority women; this

also appears to be true for minority children. HRSA has been looking at this issue for some time and would welcome consideration of collaborations among Federal agencies.

INDIAN HEALTH SERVICE

Tammy L. Brown, M.P.H., R.D., CAPT. USPHS, Nutritional Consultant, Division of Diabetes Treatment and Prevention, Indian Health Service (IHS)

CAPT Brown presented an update of diabetes programs within the Indian health care system.. The latest prevalence data on diabetes among American Indians and Alaska Natives (AI/AN) indicate that the prevalence of diabetes is increasing across all tribal communities, in all age groups and in both men and women. There are regional differences in rates of diagnosed diabetes across the 12 Indian Health Service (IHS) Administrative Areas. In 2004, the age-adjusted diabetes prevalence in AI/AN adults was highest in the Tucson Area (southwestern U.S.) at 26.7% and lowest in the Alaska Area at 6.1%. Whereas in 2004, compared with 1997, the highest rate of increase in age-adjusted prevalence of diabetes in AI/AN adults occurred in the Alaska Area at 55% and was lowest in Tucson Area at 12%. Although diabetes is also increasing in the U.S. population as a whole, the increase in the AI/AN population is even more dramatic. Between 1997 and 2004, the prevalence of diagnosed diabetes increased by 45 percent in all major regions (all ages) served by the Indian Health Service. Mortality rates from diabetes remains approximately 3-fold higher in AI/AN than among the U.S. population at large.

There is good news in recent data from the Special Diabetes Program for Indians (SDPI). Diabetes care and preventive services have increased substantially since 1998; for example, the number of organized diabetes education programs has increased from 25 percent to 95 percent between 1998 and 2005 as a result of the SDPI funding. A signature aspect of the SDPI is its use of traditional cultural modes of transmitting information, such as storytelling, talking circles, and traditional practices. The SDPI also has enhanced collaborations and partnerships between IHS and tribal health programs, schools and worksites; for instance, linking with tribal social service programs to help implement diabetes awareness programs and improve access to needed community programs and services that help support diabetes prevention and treatment activities.

Treatment and monitoring of diabetes in AI/AN are important initiatives of the IHS. According to the 2007 IHS Diabetes Care and Outcomes Audit, 99 percent of AI/AN have T2DM, 53 percent of AI/AN with diabetes are being treated with oral agents, 19 percent are receiving oral agents plus insulin, 17 percent are receiving dietary therapy alone, and 10 percent are receiving insulin alone. Highlights of results from the IHS Diabetes Care & Outcomes audit include the following:

- Mean HbA1c has decreased in the AI/AN population from 9.0 percent (%) in 1996 to less than 7.8% in 2006, mainly due to new or enhanced diabetes awareness, education and treatment strategies.
- Mean triglyceride, total cholesterol, and low density lipoprotein levels also have decreased significantly during the same time period (mean LDL in 2006 is 101 mg/dl).

- Measures for kidney disease have been encouraging, with an increase in the use of ACE-inhibitors and a steady decline in the number of AI/AN with diabetes with any proteinuria (from 29% to 16% from 1996 to 2006).
- Diabetes self-management education has also increased significantly.

In addition to these successes in clinical outcomes above, CAPT Brown presented evaluation results from the SDPI from 1998–2006. Congress authorized the SDPI in 1997 for "the prevention and treatment of diabetes in American Indians and Alaska Natives." Now in its tenth year, the *Special Diabetes Program for Indians* is a $150 million per year grant program that provides funding for diabetes treatment and prevention services at 399 IHS, Tribal and Urban Indian health programs through 2008. Results of the evaluation include the following:

- Eighty-three percent of the SDPI programs focused on primary prevention; 67 percent on secondary prevention; and 32 percent on tertiary prevention.
- Primary prevention programs for children have increased from 10 percent before 1998 to 83 percent in 2005.
- Weight management programs in children have increased from 18 percent before 1998 to 67 percent in 2005.
- Collaborations with local school systems have increased from approximately 20 percent before 1998 to approximately 75 percent in 2006. School programs for healthy eating and physical activity have increased from 18 to 62 percent and 22 to 67 percent, respectively, from before 1998 to 2005.
- Safe environments for physical activity have increased from approximately 15 percent before 1998 to approximately 70 percent in 2006.
- Nutrition programs for families have increased from approximately 30 percent before 1998 to approximately 90 percent in 2006.
- Weight management programs for adults have increased from 28 percent before 1998 to 77 percent in 2005.
- Culturally-appropriate diabetes education programs have increased from approximately 35 percent before 1998 to approximately 92 percent in 2006.

The SDPI helped create diabetes treatment and prevention programs where none existed before, as well as enhance programs that were already in place. They are employing successful, proven strategies to address key areas of diabetes treatment and prevention across the entire life span to not only enhance the quality of life of people with diabetes, but also help the Indian health system achieve cost-effectiveness, realize cost-savings, and reduce the cost burden of diabetes in our communities.

The successes that have been achieved over the past decade represent only the beginning of what can achieved when Tribes, Urban programs and IHS work together as partners toward the shared goal of a diabetes-free future. It will be important that the program receive continued support during reauthorization hearings for the program in 2008.

UPDATE ON PLANS FOR T1D SPECIAL FUNDING PROGRAM
Dr. Fradkin

Dr. Fradkin reminded members that the *Type 1 Diabetes Strategic Plan* has been completed and is now posted on the NIDDK website at http://www2.niddk.nih.gov/AboutNIDDK/ResearchAndPlanning/Type1Diabetes/.

The Evaluation Report on the Special Statutory Funding Program for Type 1 Diabetes Research also has been completed. This Congressionally-mandated evaluation was overseen by statute by the DMICC and was based on various metrics, including bibliometric analysis, professional judgment, grantee assessment, NIH database analysis, and scientific accomplishments and progress. The evaluation report may be found on the NIDDK website at www.T1Diabetes.nih.gov/evaluation.

Dr. Fradkin said she would like to hold an External Advisory Committee (EAC) meeting in January or February 2008 to discuss major clinical projects. Areas of expertise needed are in T1D, diabetes clinical trials, and autoimmune disease. The EAC will advise NIDDK on prioritization and scope of projects related to the T1D Special Funding. Discussions will center on what can be done if funding does not continue or if funding is extended. This is an important issue for NIDDK. She suggested that if funding is extended, there may be the development of a Strategic Plan, the establishment of advisory groups on clinical research, autoimmunity and the beta cell, and diabetic complications. A request will be made to approve multi-year funding.

Dr. Fradkin thanked participants for their attendance and lively discussions. She gave special thanks to the speakers for the impressive list of diabetes-related activities being conducted at their Institutes and Centers.

The meeting adjourned at 12:10 p.m.