DIABETES MELLITUS INTERAGENCY COORDINATING COMMITTEE OPPORTUNITIES FOR COLLABORATION IN EFFORTS TO REDUCE HEALTH DISPARITIES

Natcher Building, Conference Room F1/F2
National Institutes of Health Campus
Bethesda, Maryland
11:00 a.m. – 1:00 p.m.
February 8, 2008

SUMMARY MINUTES

WELCOME

Sanford Garfield, Ph.D., DMICC Executive Secretary, Senior Advisor, Biometrics and Behavioral Science, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH)

Dr. Garfield welcomed participants and asked everyone to introduce themselves. He noted that some members would be joining the meeting via telephone. Dr. Garfield introduced Dr. Judith Fradkin, Director of the NIDDK Division of Diabetes, Endocrinology, and Metabolic Diseases and Chair of the Diabetes Mellitus Interagency Coordinating Committee (DMICC) and invited her to give an update on issues addressed in previous DMICC meetings and an overview of current issues.

UPDATE ON PAST DMICC ISSUES

Judith Fradkin, M.D., Director, Division of Diabetes, Endocrinology and Metabolic Diseases, NIDDK, NIH

National Diabetes Coordinator

A bill has been introduced in the U.S. House of Representatives (HR 4836, introduced by Rep. Jay Inslee D-Washington) to create a National Diabetes Coordinator position. This will have a major impact on the DMICC, which currently is the venue for coordination across the U.S. Department of Health and Human Services (DHHS) and other agencies (e.g., the Veterans Health Administration [VHA]). It is thought that the coordinator would work out of the Office of the DHHS Secretary, although details on this and on resources for the position have not been made clear. Dr. Fradkin asked that DMICC members demonstrate that the DMICC is the appropriate vehicle for coordination across the federal agencies. She has been contacting institutes and centers (ICs) that currently do not have members on the DMICC to ask whether they would like to appoint representatives to the DMICC.

Dr. Ann Albright commented that she has been working with partners, such as Novo Nordisk, to help make partnerships related to DMICC activities more visible. Dr. Fradkin added that a representative from Novo Nordisk spoke at the previous DMICC meeting regarding their interest in supporting the NIDDK Diabetes Action Plan.

Update on the Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial

At a January 2007 meeting, the DMICC discussed possible clinical trials that NIDDK should consider, given that few ongoing trials will end in the next few years. One of these, the ACCORD trial, released interim findings this week. The findings indicated that excess deaths occurred in the arm of the trial targeting "intensive" reductions in Hb-A1c (meant to approach normal [Hb-A1c = 6.0–6.9] as closely as possible) compared with the arm of the trial targeting "moderate" reductions in hemoglobin-A1c (HbA1c) (Hb-A1c reductions to between 7.0–7.9). To alleviate concern among participants, everyone in the trial now has been placed in the intervention group targeting moderate reductions in Hb-A1c. This emphasizes a notion that has been coming to the forefront in guidelines published by the American Diabetes Association (ADA) and supported by NIDDK's National Diabetes Education Program (NDEP)—treatment targets should be individualized, particularly in subpopulations. The ACCORD treatment arm that had excess mortality was characterized by a mean age of 62 years, duration of diabetes of at least 10 years, and a prior cardiac event or multiple cardiovascular disease (CVD) risk factors. In addition, their Hb-A1c was above target levels (the mean was 8.2); these ACCORD participants exhibited a rapid decrease in glycemic control, which may have contributed to the excess mortality.

Psychoactive Drugs and Type 2 Diabetes

In September 2006, the DMICC held a meeting on diabetes and psychoactive drugs, specifically some of the atypical antipsychotic drugs that have been associated with obesity and type 2 diabetes (T2D). NIDDK has developed a PAR (Program Announcement with multiple receipt dates, referral, or review) with the National Institute of Mental Health (NIMH) to study this issue.

In the December issue of *Diabetes Care*, results from the program for older adults based in primary care (PROSPECT) trial indicated that in a subgroup of trial participants with diabetes, a substantial decrease in mortality occurred in patients treated with antidepressants (Bogner HR et al., *Diabetes Care* 2007). This subgroup may not have been specified in advance; therefore, the implications are unclear. Dr. Jose Caro, a former member of the NIDDK advisory council, and others from Eli Lilly and Company will be meeting with NIDDK staff on February 19 at 1:00 p.m. at Two Democracy Plaza to discuss diabetes and depression. Representatives from NIMH and the National Institute on Aging (NIA) have been invited; anyone else from the DMICC is welcome to attend.

Special Funding Program for Type 1 Diabetes and American Indians

Funds have been approved for the special program for type 1 diabetes (T1D) and the program for American Indians. NIDDK has issued a request for application (RFA) for an award called the T1D Pathfinder Award, modeled on an NIH Roadmap Initiative called the New Innovator Award.

This will allow NIDDK to supply 5 years of support for investigator-initiated research, and funding for all 5 years can be provided in 1 year. This will allow NIDDK to support investigator-initiated research at a time when continued funding for multiple year awards is not guaranteed because of budget constraints. NIDDK will meet with the NIH leadership to see whether NIDDK can provide a similar multiyear funding effort in Fiscal Year 2009 that would not be limited to NIH new investigators. This would allow NIDDK to support paradigm-shifting research.

On April 29–30, 2008, NIDDK will hold a clinical research planning and evaluation meeting with external experts in diabetes and endocrinology who have been invited to evaluate each of NIDDK's large efforts in clinical research related to T1D, including TRIALNET, ITN, islet transplantation, SEARCH, TEDDY, TRIGR, and other efforts.

GOALS OF THE MEETING

Dr. Fradkin

Dr. Fradkin commented that the goal of today's meeting is to focus on opportunities for DMICC members to interact and build on current and planned efforts to eliminate health disparities related to diabetes by fostering a more integrated approach. The presentations will make everyone aware of efforts and specific components of programs being conducted by DMICC ICs, and will encourage participants to think about opportunities for collaborations. She asked that the presentations minimize details about programs and focus instead on potential collaborative opportunities, with some time for discussion.

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 provided information about programs receiving HRSA funding, including the HRSA diabetes collaboration with the Centers for Disease Control and Prevention (CDC), which includes a focus on health disparities. She described the Bureau of Primary Health Care Services (BPHCS), which includes approximately 15 million participants, 927,349 of whom have diabetes. Participants in the BPHCS are predominately economically disadvantaged (92 percent live below 200 percent of the poverty level), 40 percent of participants are uninsured, and 64 percent are racial or ethnic minorities (35 percent Hispanic, 23 percent African American, 3.5 percent Asian Pacific Islanders, 1.1 percent American Indian/Alaska Natives, and 36.6 percent are non-Hispanic Caucasian). In addition, most BPHCS participants are women, participants include more than 807,000 are migrant/seasonal agricultural workers, and 828,000 are homeless individuals.

Dr. Fradkin asked Dr. Raggio-Ashley if she was able to identify opportunities for researchers to create partnerships with these health care centers. Dr. Raggio-Ashley responded that recent articles in the *New England Journal of Medicine* and other peer-reviewed journals have described the diabetes collaborative. The data are available for use and the centers generally

have relationships with local universities where research is conducted. There are opportunities for collaboration with the centers, but each center is an independently run entity.

If CDC or NIH wanted to collaborate with the centers to conduct a program on people with diabetes, Dr. Garfield asked whether the funding would go through HRSA or another agency. Dr. Raggio-Ashley responded that it could be done either way. HRSA can be a venue for communicating with the centers, or other agencies can contact the centers directly. For example, a large number of nutritionists are associated with the centers. If a researcher proposed a collaboration with a center to conduct a health care study, making use of the nutrition resources at the centers, this could be done.

Dr. Fradkin added that it sounds as if the centers may be a resource for opportunities to collaborate on training. Also, there may be opportunities to participate in joint meetings with HRSA or the centers. Dr. Raggio-Ashley said she is planning a large HRSA annual meeting in June and this may be an opportunity to discuss collaborating.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

Barbara A. Bartman, M.D., M.P.H., Medical Officer, Center for Outcomes and Evidence, Agency for Healthcare Research and Quality (AHRQ)

Dr. Bartman presented information on AHRQ and its mission to improve the quality, safety, efficiency, and effectiveness of health care for all Americans. Many AHRQ programs focus on health disparities; these include the National Healthcare Quality and Disparities Reports, which track 13 diabetes measures at the national level (http://www.ahrq.gov/qual/measurix.htm), the Diabetes Resource Guide and Workbook (http://www.ahrq.gov/qual/diabqualoc.htm), and the Diabetes Cost Calculator (http://www.nbch.org/CHVC/calculator/index.cfm). Ongoing programs also involve disparities collaborations, such as Improving Hispanic Elders' Health: Community Partnerships for Evidence-Based Solutions, which involves collaboration with the Agency on Aging (AoA), CDC, the Centers for Medicare and Medicaid Services (CMS), HRSA, and eight community teams from Houston, San Antonio, Lower Rio Grand Valley, Los Angeles, San Diego, Chicago, New York, and Miami (http://www.academyhealth.org/ahrq/elders/). AHRQ also participates with CDC and Healthcare Cost and Utilization Project (HCUP) state partners on State Snapshots, a program that includes sections on state-level disparities in diabetes and the costs of diabetes (http://statesnapshots.ahrq.gov/statesnapshots/diabetes.jsp?menuId=20&state=).

AHRQ programs on comparative effectiveness research also offer the opportunity for collaboration. These include programs at the Evidence-Based Practice Centers and Developing Evidence to Inform Decisions about Effectiveness research center (referred to as DEcIDE), a program that includes effectiveness research on bariatric surgery in patients with T2D or gestational diabetes. DEcIDE also assesses the pharmacogenetics of metformin and research gaps in diabetes treatment. The Centers for Education and Research on Therapeutics (CERTs) program is a national initiative to increase awareness of the benefits and risks of new, existing, or combined uses of therapeutics through education and research. CERTs are studying the impact of risperidone on the development of diabetes in children.

Other collaborative activities include a program with CDC, the Diabetes Primary Prevention Initiative 4; the National Health Plan Disparities Collaborative; the Medicaid Care Management Learning Network; the Health Plan Disparities Collaboratives; practice-based research networks; and Accelerating Change and Transformation in Organizations and Networks (ACTION), an integrated delivery system network.

The Effective Health Care Challenge is an initiative to address the question, what is effective health care? Dr. Bartman described the areas of study that will address choosing the right care for the right person at the right time. Stakeholders will have an opportunity for input, as will experts and the public.

Discussion

Dr. Pogach asked for clarification on the study of genetics and metformin. Dr. Bartman responded that individual differences in genetic profiles can result in individual differences in the rate at which metformin is metabolized; therefore, some individuals may benefit more from the use of other drugs. Dr. Pogach noted that this sounds like something that should be in the NIH pipeline. Dr. Bartman said that this study is being directed by a researcher at AHRQ who has an interest in pharmacogenetics. Dr. Fradkin commented that this study on pharmacogenetics meshes with the Diabetes Prevention Program (DPP) and could be an area for collaboration

CENTERS FOR DISEASE CONTROL AND PREVENTION

Ann Albright, Ph.D., R.D., Chief, Diabetes Prevention and Control Program, California Department of Health Services, Division of Diabetes Translation, National Center for Chronic Disease Prevention and Health Promotion, CDC

Dr. Albright reviewed the mission and programs of CDC's Division of Diabetes Translation. Primary functions are to track the diabetes burden, conduct applied translation research to prioritize effective interventions, develop and maintain state-based diabetes prevention and control programs, and implement National Program Initiatives, including the NDEP and the Native Diabetes Wellness Program.

Dr. Albright described the CDC programs on reducing health disparities that are amenable to collaboration, including the following.

- The U.S.–Mexico Border Project, which includes diabetes surveillance and interventions using community health workers.
- The Translating Research into Action for Diabetes (TRIAD) study, the largest healthcare delivery study on diabetes in the country.
- The Diabetes Primary Prevention Initiative (DPPI), a program to translate the DPP into action that is being conducted in collaboration with state-based diabetes programs.
- The Diabetes Prevention Pilot Collaborative with HRSA, a study examining the primary prevention of diabetes in community health centers.

- SEARCH for Diabetes in Youth, the only epidemiologic study of diabetes and youth in the country.
- The National Diabetes Surveillance System.
- Project DIRECT, a community-based participatory research study among African Americans in North Carolina. Results of the project will inform decisions about the next project with African Americans with and at risk for diabetes.

Opportunities for collaboration include the County Level Diabetes Prevalence Estimates Project, the National Kidney Initiative, the Vision Health Initiative, and the NDEP. She encouraged participants to look at these initiatives to see where they may want to collaborate.

Discussion

Dr. Garfield commented that diabetes prevention initiatives are found in many agencies. For example, the Indian Health Service has a diabetes prevention initiative among American Indian tribes, in which NIDDK is involved. HRSA has a demonstration project for diabetes prevention. It would be nice if this meeting resulted in collaboration on a topic rather than having five or six separate agencies continue to focus separately on the same topic. Dr. Albright agreed that this is an important reason to collaborate on such initiatives. Translation for the DPP is an example; many agencies would benefit from taking part in this initiative. As a follow-up to a recent meeting, CDC has agreed to hold a primary prevention conference as a recommendation from their primary prevention expert panel meeting. DMICC members will be invited to the conference and participate in discussions about next steps in primary prevention and ways to share the workload.

CENTERS FOR MEDICARE AND MEDICAID SERVICES

Sheila H. Roman, M.D., M.P.H., Senior Medical Officer, Center for Medicare Management, Centers for Medicare and Medicaid Services (CMS)

Dr. Roman described CMS initiatives and opportunities for collaboration on diabetes care for patients. CMS is primarily a payer in the healthcare system, so its efforts in diabetes are generally part of other demonstration efforts for chronic care management that are legislatively mandated, such as monitoring how chronic healthcare is delivered or how it can become more efficient. CMS's Quality Improvement Roadmap includes strategies to work through partnerships and alliances, and includes many demonstration and pilot projects on chronic care of which diabetes is one of the designated conditions of interest.

CMS's demonstration and pilot projects aim to benefit patients with chronic conditions such as diabetes and encompass a broad range of mandated initiatives, such as those on informatics, telemedicine and patient education demonstration projects, case management demonstration projects, care management, and various projects related to Medicare practice and efficiency.

Diabetes care measures included in CMS demonstration projects include HbA1c management and control, blood pressure management, lipid management, low-density lipoprotein cholesterol level measurement, urine protein testing, and eye and foot exams. CMS operates pay-for-

reporting (P4R) programs, such as the Hospital Quality Initiative, which considers quality measures for inpatient and hospital outpatient care, physician voluntary quality reporting programs, and physician resource use programs. There are additional opportunities for collaboration in the Hospital-Acquired Conditions and Present on Admission Indicator program, which could address the issue of glycemic control in hospital patients discussed at a previous DMICC meeting.

The 2008 Physician Quality Reporting Initiative (PQRI) includes many measures related to diabetes control, as well as measures that assess comorbid conditions related to outcomes from diabetes care. For example, PQRI measures include HbA1c control in T1D and T2D, high blood pressure control, presence or absence of diabetic retinopathy and management of the condition, and measures related to foot care.

Dr. Roman presented diabetes goals included in the Government Performance and Results Act (GPRA)—screening for retinopathy, and testing for Hb1Ac and lipids. To meet GPRA requirements, CMS must show that rates of progress in physician practice for each goal is compared year-to-year. The CMS Quality Improvement Organization (QIO) program goals related to diabetes, as stated in the eighth Statement of Work (SOW), will require collection of statewide rates for the same measures as the GPRA national goals. Statewide goals also will include a measure of cultural competency training at the physician practice level. The ninth SOW will include a state-focused target of the bottom 50 percent on diabetes measures, which will include implementation of diabetes self-management training approved by CMS.

A focus on diabetes disparities reduction measures and evaluation also will be included in the ninth SOW, which could be an area in which CMS will look for collaboration. The program will emphasize preventive care for populations with diabetes, will use community health workers and/or certified diabetes educators to improve outcomes in underserved populations of Medicare beneficiaries with diabetes, and will be awarded to a subset of QIOs based on population or need. The measurement of success of the diabetes disparities reduction program will be based on the percentage of targeted participating practices actually recruited and the relative improvement rates in HB1Ac testing, lipid testing, and eye exams.

CMS is in a position to collect large amounts of data through its demonstration and pilot programs. Much of these data are administrative and chart-extracted; this allows a significant opportunity for collaboration to use these data for other purposes if the data were to be funded to be housed in a common data warehouse.

Discussion

Dr. Fradkin asked whether the QIOs just measure disparities or also take concrete steps to reduce disparities. Dr. Roman responded that in the 9th SOW the performance measures for diabetes specifically addresses the reduction of disparities.

Dr. Fradkin asked participants to focus on opportunities for collaboration related to health disparities at this meeting; the DMICC meeting on April 1 will focus on collaborations regarding translation. She commented that presenters are providing information related to collaborations

for both health disparities and translation. She suggested that it may make sense to build on this meeting such that presenters at the April 1 meeting present one or two ideas for specific projects involving collaborations across components of the DMICC, rather than repeating descriptions of many of the same ongoing efforts in the context of translation. She said that Dr. Garfield would send information about this to DMICC members for the April 1 meeting.

INDIAN HEALTH SERVICE

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

CAPT. Brown provided a presentation on behalf of Kelly Acton, representative from IHS to the DMICC. The IHS has a long history of collaboration, and ongoing programs and projects offer opportunities for continued and new collaborations. The IHS has 333 Special Diabetes Programs for Indians (SDPI) community-directed grant programs since 1997 for the treatment and prevention of diabetes. These programs are individually designed to meet the needs of the communities in which they are implemented, and many of these programs are collaborating with various entities including state and local health departments, universities, and local schools and private businesses.

In addition, 66 SDPI targeted demonstration projects focus specifically on two areas, the primary prevention of diabetes (36 grantees) and CVD risk reduction in people with diabetes (30 grantees). All of the programs follow the same intervention with minor local adaptations. The programs are in the 3rd year of their grant (the 2nd year of intervention), and already are showing some success in their interventions, such as decreases in weight and body mass index and improvements in glycemic control and blood pressure. Dissemination of this information offers an opportunity for collaboration.

The IHS Standards of Care for Diabetes have been in existence since 1986, and are updated every 2 years based on updated evidence; they are not meant to supplant the ADA guidelines, but are adapted to the specific populations served by the IHS. These Standards may serve as a model for others working to develop similar materials for other special populations. In addition, the IHS has measured its performance on these Standards of Care with an annual audit called the IHS Diabetes Care and Outcomes Audit since 1986. Results from the audit are used by local, regional, and national organizations for quality improvement efforts and to track trends in diabetes care over time. The audits allowed, for example, the IHS to discover the reduction of HbA1c levels that started in 1996 (9.1 percent average HbA1c levels) and continued to 2007 (7.82 percent average HbA1c levels).

Through the IHS Best Practices for Diabetes program, IHS developed 18 best practices for a wide array of topics, such as foot care, eye care, kidney preservation, and diabetes and youth. The program offers advice, technical support, and tools to local and national programs. IHS would welcome collaboration in its ongoing efforts to update and expand these Best Practices.

The Diabetes Education in Tribal Schools (DETS) project is a collaboration among the Tribal Leaders Diabetes Committee (TLDC), the IHS, NIDDK, CDC, and eight tribal colleges. DETS

is a science curriculum for grade levels K–12 that is being pilot-tested and will be disseminated throughout the nation. The theme of the curriculum is "Health is Life and Balance," and is meant to teach children about diabetes in a culturally relevant manner, encourage them to seek education in science and biomedical sciences, and increase their understanding of diabetes and the maintenance of a healthy lifestyle. The dissemination of DETS offers an opportunity to collaborate with various organizations at the local, regional, and state levels.

The IHS Division of Diabetes has a history of developing, testing and disseminating high quality, culturally-appropriate education materials. They have many collaborations in this area and would like to continue and expand these collaborations.

A signature aspect of the SDPI is the use of traditional and cultural approaches to transmitting information such as storytelling, talking circles and through other traditional practices. They will share these approaches as well as learn new approaches from others working with special populations.

The IHS Division of Diabetes has a strong, effective network. There is extensive sharing of information and expertise in both directions—local to regional to national headquarters. It allows for rapid translation of new findings and the spread of innovation throughout our system. This network would be an efficient way for outside organizations to share information about opportunities for collaboration with IHS, Tribal, and urban Indian health programs.

Finally, the IHS is a direct, primary-care agency. When new findings, tools, or proven strategies become available, it is important to provide this information to our communities so they can put it into practice. Figuring out how to translate the results from randomized controlled trials into the "real world" setting of rural Indian communities is a challenge, which is why the IHS strongly encourages the funding of more translational research and welcomes opportunities to collaborate and participate in this type of work.

Discussion

Dr. Garfield commented that CAPT. Brown made clear the types of disparities work and opportunities for collaboration in IHS programs. He asked DMICC members to consider how they can work with IHS in future collaborations.

U.S. FOOD AND DRUG ADMINISTRATION
Mary Parks, M.D., Director, Division of Metabolic and Endocrine Drug Products, U.S. Food and Drug Administration (FDA)

Dr. Parks discussed FDA collaborations with industry on diabetes drugs. Legislation sets the FDA mission, and thus the agency itself has limited projects that involve independent research activities. FDA does, however, have a role in making effective therapy available for T1D and T2D that is making an impact on society and giving physicians tools to reduce the diabetes burden. FDA will provide draft guidance for industry to give them a template for the development of T1D or T2D drugs and biologics. When this is released for public comment

later this year it is important for FDA to hear not only from industry and academia, but also from federal agencies with an interest in diabetes treatment and care. She encouraged DMICC members to consider commenting on the draft guidance.

Dr. Parks described FDA initiatives related to health disparities. The agency has required companies to provide effectiveness and safety data on racial and ethnic groups regarding therapies and other products. In her tenure at FDA, Dr. Parks has observed an increase in minority participation in clinical trials. For example, a recent industry submission for approval of a new drug had approximately 25 percent minority participants in the clinical trial. In the past, most trials included less than 10 percent minority participants. Some of the increase reflects the global nature of the industry's reach and the increasing use of targeted therapies. In addition, some companies are conducting clinical trials in countries other than the United States, such as Japan, and include only Asian participants; FDA has informed these companies that results from such trials should not be relied upon solely to request approval for the drug in the United States. Patient demographics need to reflect the general population of diabetics in the U.S.

One area of interest for those working in diabetes research is process that took place last year regarding rosiglitazone data suggesting an increased risk for cardiovascular ischemic events. FDA took rosiglitazone to an advisory committee to review data on the drug and to make recommendations on this risk, the marketability of the drug, or labeling/risk management. The events surrounding rosiglitazone have become a very hot political issue. Congress and the media have focused on HbA1c as a surrogate, criticizing whether this is an appropriate biomarker of drug benefit or for drug approval. Based on presentations given today, it appears that most people accept HbA1c as a surrogate.

Discussion

Dr. Parks asked if there was a Memorandum of Understanding (MOU) between the FDA and the DMICC for information shared at this meeting. Dr. Fradkin commented that NIDDK/NIH has talked about having a MOU with the FDA entity that oversees medical devices. This was suggested by members of a working group and should be considered more broadly. Dr. Parks said that FDA plans to have an advisory committee discuss the drug approval process for diabetes. This would focus on when to ask for cardiovascular outcomes trials, and whether HbA1c level should continue to be used as an outcome rather than mortality outcomes. Anyone interested in diabetes research should have an interest in the decisions made at this meeting. In addition, the FDA is working internally to try to have more people with diabetes and minorities included in clinical trials so there can be a better understanding of interventions for these populations.

Dr. Fradkin added that HbA1c as a surrogate outcome was front and center in the media coverage regarding the release of results from the ACCORD trial this week. In terms of minority participation in clinical trials, NIH has had this as a priority for many years, although diabetes trials do not generally test only one drug, with the exception of metformin in DPP. There are few trials that test only one drug in minority populations.

NATIONAL CENTER ON MINORITY HEALTH AND HEALTH DISPARITIES
Francisco S. Sy, M.D., Dr.P.H., Director, Division of Extramural Activities and Scientific Programs, National Center on Minority Health and Health Disparities (NCMHHP), NIH

Dr. Sy presented information on programs of the NCMHHP and opportunities for collaboration. NCMHHP is organizing a trans-NIH health disparities forum in December 2008 at the new Gaylord Hotel on the DC waterfront. Information will be forthcoming as the date draws closer. He also indicated that Dr. Garth Graham, the DMICC representative from the DHHS Office of Minority Health, had planned to attend today's meeting to present information on collaboration between CDC and NIH regarding health disparities research. He was unable to attend, but a steering committee and expert groups on obesity, mental health, chronic diseases including diabetes, and the environment have been established, and the expert groups are meeting every 2 weeks.

NCMHHP runs two programs that offer opportunities for collaboration. The first is the Centers of Excellence Program, which supports biomedical, behavioral, and social research, and provides research training for members of "health disparity populations." There are 53 centers across the nation. Funding is provided through P20 and P60 award mechanisms and awards are issued for up to 5 years. Administrative and Research Cores are required for the award; the Community Outreach and Research Training Cores are optional. Other ICs may cosponsor these awards, but they are issued for research on health disparities and are not specific to diabetes. It is up to awardees to decide what disease they will target within the health disparities paradigm. Currently, 53 centers are funded under this mechanism, with approximately 30 percent focused on diabetes. The next cycle for this RFA will begin sometime in February with a receipt date in mid-2008; awards will be made in 2009.

The NCMHHD Community-Based Participatory Research (CBPR) Program also is available for collaboration. The goal of this program is to support community intervention research studies using CBPR principles and methods to reduce and eliminate health disparities in any disease or condition of major concern to the community with an emphasis on racial and ethnic minorities. This program consists of three phases. The first phase is a 3-year research planning grant began in 2005 and will end in 2008. There are 25 grantees, of which seven focus on diabetes. The second phase is a 5 year intervention research grant that will begin in 2008 and end in 2013 and is open to collaboration for behavioral and medical intervention projects at the community level. The receipt date was August 2007 with an award date in February. The third phase is a 2-year dissemination research grant that will be developed from 2013 to 2016. The 2-year dissemination grants will be awarded to those organizations that successfully complete phase two intervention projects.

Discussion

A participant asked whether support will be continued after the 3- and 5-year award periods. Dr. Sy responded that this decision would be made at the end of the original award periods.

Dr. Raggio-Ashley commented that HRSA is participating in the Federal Health and Research Collaborative and also participates in an Interagency Health Disparities Collaborative in which diabetes serves as a venue for health disparities.

VETERANS HEALTH ADMINISTRATION
Leonard M. Pogach, M.D., M.B.A., National Program Director, Diabetes, Veterans Administration National Program, East Orange Veterans Affairs Medical Center, VHA

Dr. Pogach described the systematization of quality improvement and quality innovation for people with diabetes in the VHA system. He expressed the strong commitment of the VHA for ending all racial, gender, and age health disparities. Diabetes among veterans has increased from approximately 561,000 of 2,923,000 clinical users in 1998 to an estimated 1,250,000 of ~5,200,000 clinical users in 2008. People with diabetes are predominately male (97 percent), older (59 percent are more than 65 years old), and economically challenged. Among younger veterans, there are more women and minorities. Multiple comorbid conditions, both physical and mental, generally occur in the VHA population.

VHA initiatives focus on disparities because minorities are such a large part of the population receiving care in the system. It is difficult to separate translation activities from disparities. Dr. Pogach referred participants to the VHA website, where information on disparities can be found (http://www1.va.gov/health/AboutVHA.asp). The website also has resources on systematizing quality by Dr. Cooper-Smith published in *Health Affairs* in 2007.

Dr. Pogach described VHA initiatives that include collaborative or partnership aspects. These include the following.

- VHA-Department of Defense (DOD) development and use of evidence in explicit clinical care guidelines with risk stratification (glycemic is rated highest in North America based on the use of the AGREE instrument, and significantly higher than ADA).
- VHA-DOD-IHS Tele-retinal imaging project complete; deployed in the VHA.
- VA-DHHS HealthierUS Veterans.
- Implementation of MOVE! Weight Loss Program.
- Preservation Amputation Care and Treatment Program.
- Telemedicine (home-based).
- Identification of individuals with chronic kidney disease using eGFR in computerized records.
- National Diabetes and High Risk Foot Registries with linked demographic, code, laboratory, and medications that can produce customized reports and track continuity of care.
- Nationwide Monitoring of Glycemia in hospital setting (currently ICUs).
- Five Million Lives High Alert Medications: Insulin

All of these initiatives offer opportunities for collaborations.

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

Dr. Fradkin focused on NIDDK's large, multicenter clinical trials on T2D, all of which emphasize recruitment of minority populations that are disproportionately affected. She highlighted decision points in the timeline for the trials when funding decisions offer the opportunity for collaborations. These trials have been conducted in partnership with CDC, which provides a cost-effectiveness component.

The HEALTHY middle school program for diabetes prevention will conclude in June 2008. HEALTHY was designed to be an intervention trial for reducing obesity and improving impaired fasting glucose in this population. The trial has produced a large amount of population-based data on African American and Hispanic adolescents; a follow-up component may be added to the trial after June.

Treatment Options for type 2 Diabetes in Adolescents and Youth (TODAY) is a clinical trial that is investigating the best way to treat T2D in adolescents. The trial is still in its recruitment phase, but will include a collection of genetic samples from a population that is at the highest risk of T2D and includes African Americans, Hispanics, and Native Americans. The genetic component will be a tremendous resource that offers an opportunity for collaboration with parties interested in this aspect of the trial.

The DPP, which has been completed, included 45 percent minority participants. The DPP reported that metformin and lifestyle interventions worked well across all groups. The DPP Outcomes Study (DPPOS) will hold an advisory meeting on February 15 to discuss 5-year data after the close of DPP; the group also will review data on event rates. A recommendation will be made to NIH after the DPPOS meeting on whether to continue to follow these patients for another 5 years. The DPPOS is being co-funded by other NIH institutes and centers, and Dr. Fradkin requested their continued support in working with NIDDK on this initiative.

The Action for Health in Diabetes (Look AHEAD) study includes approximately one-third minority participants and currently is in progress.

Dr. Fradkin also presented an update of information regarding the National Diabetes Information Clearinghouse. A few new things may be useful to DMICC members who have initiatives relevant to minority populations. Many diabetes researchers and health providers have become aware that many of the laboratories providing HbA1c tests have found interference with these tests in people with variant hemoglobin (e.g., African Americans with the sickle-cell trait and Southeast Asians with variant hemoglobin E). The Clearinghouse is providing information on this topic because some people with diabetes are being over- or undertreated based on miscalculated levels of glycemic control. Also, misdiagnoses are occurring because their HbA1c levels are being used inappropriately to diagnose diabetes in people with variant hemoglobin. Dr. Fradkin recalled a visit to an Oakland, California, health center that services mostly minority patients; she found that the HBA1c test was being used even though it is not valid for some of the African Americans using the clinic. This experience highlights the importance of getting this

information out to health care providers and systems. Information on this topic may be found on the Clearinghouse website at http://diabetes.niddk.nih.gov/dm/pubs/traitA1C/index.htm.

The Clearinghouse also just launched a website that contains information in Spanish on each of the topics related to NIDDK—diabetes, kidney and urologic diseases, and digestive diseases. This website is available at http://diabetes.niddk.nih.gov/index_sp.htm.

Dr. Fradkin encouraged DMICC members to attend a conference on diabetes and obesity disparities that will be held June 30–July 1, 2008, at the Natcher Conference Center on the NIH campus. The conference will focus on issues related to health care systems, patient factors, research design issues, and next steps. Information on the conference will be distributed to DMICC members in the next few months.

Discussion

Dr. Parks asked if Dr. Fradkin could provide names of laboratories that perform assays that are more relevant to patients with the sickle-cell trait. Dr. Fradkin responded that Qwest Diagnostics is one of the largest laboratories that performs the HbA1c tests, which are not valid for some members of minority populations. Qwest conducts approximately one-fourth of all HbA1c tests in the United States, but they are in the process of implementing a new diagnostic test that will test for hemoglobin variants. The National Glyco-Hemoglobin Standardization Program website (http://www.ngsp.org/) has information on which assays are standardized and which are not. Dr. Parks indicated that she is not sure if FDA is scrutinizing companies that ask for approval for these diagnostic tests, but this is an area that will be looked at carefully in the future.

Dr. Raggio-Ashley commented that she was impressed by the information in Spanish available at the NIDDK Information Clearinghouse website and noted that she will use it for the HRSA Hispanic elderly participants that she described earlier. She added that the issue of HbA1c variants is critical and should be an area of collaboration among the various agencies interested in diabetes treatment or trials. Dr. Fradkin responded that each interested party should try to influence providers of the HbA1c tests to offer HbA1c variant tests. This is especially true for insurance payers, such as CMS.

NATIONAL INSTITUTE OF NURSING RESEARCH
Paul Cotton, Ph.D., Program Director, Office of Extramural Programs, Health Behavior and Minority Health, National Institute of Nursing Research (NINR)

Dr. Cotton, presenting on behalf of Dr. Martha Hare, described opportunities for collaboration with the NINR. The NINR has programs in biobehavioral research; it encourages interdisciplinary research and actively seeks collaborations. At a previous DMICC meeting, Dr. Hare presented information on psycho-social research on children, adolescents, and families affected by T1D, including the coping skills training program by Dr. Margaret Gray at Yale University. Dr. Gray now is testing a web-based intervention.

NINR also conducts research via its intramural laboratories, and this also is open to collaborations. The intramural research programs include those focused on translational research in collaboration with NIDDK on diabetes and obesity and participation in many of the trans-NIH initiatives on implementation research and health. Opportunities for future research include studies of the metabolic syndrome, eating behaviors and physical activity, and applications of genomic research to patient behavior and clinical care.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
Peter Savage, M.D., Senior Advisor to the Director, NIDDK

Dr. Savage presented information on ongoing studies at the National Heart, Lung, and Blood Institute (NHLBI) and highlighted opportunities for collaboration on three new studies that are just beginning. Among ongoing studies, he noted the Strong Heart Study in American Indians. During early phases of the SHS, collaboration with the IHS and with the NIDDK in Phoenix, Arizona, was invaluable. This study has been very successful and has generated a family study, an obesity prevention study (Pathways Study), and a series of ongoing community studies.

An exciting new study just getting underway at the NHLBI is the Hispanic Community Health Study. This study is cosponsored by NIDDK, NINDS, NIDCD, NIDCR, NCMHD and NODS. The study will recruit participants from age 18 to 74 years who will be followed over time for occurrence of diseases such as obesity, heart disease, stroke and diabetes. The study also will attempt to measure the roles of cultural adaptation and multiple disparities on the incidence and prevalence of chronic disease. Recruitment will emphasize sampling several Hispanic populations: Mexican Americans, Puerto Ricans, Cuban Americans, and Central/South Americans. Examinations are expected to begin in the fall of 2008.

The Cardiovascular Research Network (CVRN) in community-based care is a project for conducting collaborative CVD research via short-term investigations of emerging public health issues concerning CVD and its risk factors. The CVRN is set up to take advantage of healthcare organizations with electronic medical records to get more up-to-date surveillance data on CVD, promote research in clinical practice, and assess the impact of new technologies. The CVRN will have approximately 7 million enrollees at 14 sites with some diversity, and will look at comprehensive health care. This project could easily incorporate a project related to diabetes.

The Systolic PRessure Intervention Trial (SPRINT) is a new joint project between NHLBI and NIDDK—a collaborative trial that is examining the impact on CVD and on chronic renal disease of lowering systolic blood pressure. The study will investigate the J-curve in blood pressure control.

Dr. Savage discussed the ACCORD clinical trial. This trial, which investigates the impact of intensive versus standard glucose control and of interventions to compare aggressive versus standard control of lipids and blood pressure, is a collaborative effort involving NHLBI, NIDDK, the National Eye Institute (NEI), CDC, and the VHA. He briefly discussed the recent

termination of the intensive glucose intervention arm in the trial because of excess deaths despite a trend toward reduction in total CVD events.

Several successful collaborations between NHLBI and NIDDK have taken place or are ongoing. Because of the importance of diabetes as a CVD risk factor, important opportunities exist for future joint efforts.

DISCUSSION AND GENERAL CONCLUSION
Dr. Fradkin

Dr. Fradkin asked members to begin planning for the April 1 meeting. From the presentations at today's meeting, she asked members to engage in conversations with other DMICC members so they can focus on discussing a few specific projects for collaboration at the April 1 meeting. For example, from Dr. Savage's presentation of information on the CVRN, it seems that there is overlap with the TRIAD, which is currently being reformulated. In addition, many of the things that AHRQ is doing seem to be projects that DMICC members should consider for collaborations.

Another idea for possible discussion at the April 1 meeting will be information on the HbA1c diagnostic measurement with respect to hemoglobin variants. This is an important issue for many DMICC organizations.

Dr. Fradkin thanked participants for making this an informative meeting, and requested that everyone take time between now and April 1 to talk with one another about potential collaborations.

The meeting adjourned at 1:10 p.m.