Diabetes Mellitus Interagency Coordinating Committee (DMICC)

Diabetes Prevention: A National Priority

DMICC Meeting of November 10, 2009

Welcome and Goals of the Meeting

Dr. Judith Fradkin, DMICC Chair, welcomed members and noted that the timing of the meeting was auspicious, coinciding closely with the publication of the 10-year Diabetes Prevention Program (DPP) follow-up paper, which showed continued delay of type 2 diabetes for both lifestyle and metformin, and less need for anti-hypertensive and lipid-lowering medications in the lifestyle group. The long-term data should also prove helpful in refining estimated cost-effectiveness of the intervention.

Dr. Fradkin thanked Dr. Ann Albright, Centers for Disease Control and Prevention (CDC), for organizing today's DMICC meeting. In her introductory comments, Dr. Albright reported on a June meeting that included Indiana University, CDC, and NIH to discuss policy issues surrounding translation of the DPP into widespread clinical practice. She emphasized the importance of such efforts to realize the potential of the DPP to save lives and reduce the burden diabetes places on our health care system. The meeting served to highlight the importance of:

- Increased messaging with regard to risks, diagnosis, and treatment of pre-diabetes
- Incentives and re-imbursement for prevention treatment
- Developing key community infrastructure for delivering prevention efforts
- Developing training/credentialing programs, which are often necessary for re-imbursement by payers, and can be valuable for ensuring intervention quality

A white paper on the meeting is currently in production.

Diabetes Prevention: What Is Known—David Williamson, Ph.D., Emory University

Dr. Williamson noted the lifetime risk of developing some type of diabetes is about 33 percent for males, and 39 percent for females, making it one of the most common serious health conditions on the planet. The annual incidence rate comes to just about 1 percent per year. Thus, if a 100 percent effective diabetes prevention intervention were offered to everyone, regardless of relative risk, the number needed to treat (NNT) to prevent one case of diabetes per year would be 100, making the intervention fairly inefficient. In contrast, offering the intervention to only those at highest risk—those with both impaired fasting glucose (IFG) and impaired glucose tolerance (IGT)—would reduce the NNT to 26 people, making it quite

efficient. However, two-thirds of the people who develop diabetes per year do not have both IFG and IGT, so restricting the intervention substantially limits its potential for preventing disease.

Dr. Williamson noted, however, that while IFG and IGT both tend to gradually rise with age, progression to diabetes is typically preceded by a sharper increase in both measures. Studies in different British civil servants and in Pima Indians found that a sudden rise in one measure or the other was highly predictive of progression to diabetes within 6 years. Thus, a health care system which carefully tracked blood glucose control could identify people who are in the midst of transition to diabetes, and therefore most in need of preventative intervention. Dr. Williamson also pointed out that even when it does not progress to diabetes, pre-diabetes is not a benign state: it confers a 50 to 60 percent increase in risk of total mortality, 150 percent increase in cardiovascular disease (CVD) deaths, and an 8 percent prevalence of retinopathy.

Dr. Williamson drew attention to the XENDOS trial of orlistat for weight loss in obese individuals. Among participants with IGT, orlistat was effective for reducing diabetes. However, among the obese participants without IGT, orlistat had no impact on diabetes risk. In contrast, participants enrolled in the DPP were all at particularly high diabetes risk, with an annual incidence in the placebo group of 11 percent. So although the intervention was 58 percent effective, not 100 percent, it was necessary to treat just 6.9 of the participants with the lifestyle intervention to prevent 1 case of diabetes every 3 years. Thus, although promoting weight loss in obese individuals may have substantial benefit overall, diabetes prevention efforts will be most efficient when delivered to those with the highest risk.

Importantly, the DPP interventions—both metformin and lifestyle—were similarly effective in all racial/ethnic groups tested, and significantly blunted the excess risk conferred by certain genetic combinations. These data suggest the interventions are likely to be effective at preventing diabetes for just about anyone at high risk of the disease. Dr. Williamson also highlighted the other health benefits observed with the DPP lifestyle intervention, such as the reduction in CVD risk factors despite lower use of medicines to control them directly, which would be expected to help offset costs for payers.

Dr. Williamson suggested that policy implications from his perspective include the need for affordable community programs for delivery of evidence-based lifestyle intervention to high-risk persons; accurate, timely identification and referral of high risk persons by clinicians; and the economic and public health impact of prevention programs directly related to level of risk among program participants for health care payers/purchasers.

As an example of a way that a broad-based DPP-like program is being implemented, Dr. Williamson drew attention to a program funded by the Australian government that pays for a lifestyle intervention delivered to people between 40 and 49 years of age, with referral from their

health care providers, based on a composite risk score that must be confirmed by a 2-hour oral glucose tolerance test (OGTT).

Translating Diabetes Prevention: The Y Experience—David Marrero, Ph.D. and Ronald Ackermann, M.D., M.P.H., Indiana University School of Medicine

Drs. Marrero and Ackermann presented their work on translating the DPP. Dr. Marrero began by focusing on the questions that faced the translational research community at the end of the DPP: what should be the structure and content of the intervention, who should be targeted with the intervention, and how can it be designed to allow it to be scaled nationally, if successful? He noted specific barriers to DPP dissemination, including the need to screen for the target population using a blood test, which is not available in non-clinical settings, and which is not included in routine medical practice by all practitioners. In addition, payers must be confident that their intervention has similar effectiveness to the original DPP model, despite the fact that the delivered intervention will have to be adapted to a community setting to limit the costs relative to the intense, original DPP model. Further, it must be widely available to meet expected demand.

Dr. Marrero emphasized that even though it had been found to be cost-effective, the intensity of the DPP intervention (one-on-one coaching for 16 sessions over 24 weeks to train, problem-solve, and set goals) seemed impractical for widespread dissemination. But because it was so effective, they sought to maintain fidelity of the core principles, to adopt practical solutions for barriers, to minimize costs, and to carefully ascertain cost-benefit. Among their efforts was DEPLOY, a study designed to test the feasibility and effectiveness of training YMCA employees to deliver a group-based version of the DPP lifestyle intervention in YMCA branch facilities. YMCAs proved to be an attractive avenue for the approach: they are non-profit, seeking only to recover costs, and do not turn away people for inability to pay; there are 2,600 YMCAs nationally, with 42 million U.S. families located within 3 miles of a YMCA; and they have a history of national health program roll outs.

Dr. Marrero and colleagues designed a matched pair, group randomized YMCA diabetes prevention pilot. Participants:

- Were adult
- Were overweight/obese
- Had casual capillary blood glucose in the range of 110 to 199 mg/dL
- Had an ADA Risk Score ≥ 10
- Were allocated based on YMCA site for screening

The intervention group was offered a group-based version of the DPP delivered by trained YMCA staff, while those in the control group were given basic advice and other YMCA

programs. Mailings went to 45,000 households within 5 kilometers of 2 community YMCAs. Of the 578 people attending the screening event, 94 found to be at high risk for diabetes were enrolled, 47 to each group. At both 4 to 6 and 12 to 14 months, the participants in the intervention group showed weight loss (-6 percent) comparable to that observed in the DPP. Participants also decreased their total cholesterol levels by 21.6 mg/dL and 13.5 mg/dL at 4 to 6 and 12 to 14 months, respectively. Further dissemination of the approach has included training 22 YMCA staff in Indianapolis, 75 in Minnesota, 16 in Louisville, KY, 14 in Washington State, and a plan to train 20 in New York.

Going forward, Dr. Marrero emphasized the need for: standardization to ensure fidelity of content, maximize the probability of effective outcomes, and ensure the curriculum is updated or modified in a systematic, evidence-based way; training that is responsive to variation in trainee experience and background; and linkage to payment structures/reimbursement for the facilities and personnel delivering the intervention. Dr. Marrero identified several policy implications stemming from the work: a group based version of the DPP offers a feasible and effective means to achieve healthful lifestyle change; YMCAs offer a promising channel for national dissemination; and a national instructor training/recognition program is needed. Future research implications include the need to demonstrate capacity for delivering the intervention nationally.

Dr. Ackermann then spoke on the economics of diabetes prevention. For a medical intervention to be not just cost-effective, but actually cost-saving, he said, there must be: a practical way to identify people at high risk for avoidable costs; an intervention that can successfully prevent those costs and that is accessible to those expected to benefit; and intervention costs that are lower than the costs avoided. He noted that, although the DPP lifestyle intervention was found to be highly "cost-effective," that did not make it cost-saving. Indeed, it was sufficiently expensive and labor intensive that it would be effectively impossible to deliver it to the many millions of Americans who would stand to benefit. But if the costs of the intervention can be lowered far enough, they could be offset by the money saved through reduced need for other health care spending. He calculates that delivering the DPP lifestyle intervention to 100 high-risk 50-year-old people for 3 years would be expected to prevent 15 new cases of type 2 diabetes; avoid $91,400 in health care costs; prevent 162 missed work days; avoid the need for blood pressure/cholesterol medications in 11 people; and add the equivalent of 20 perfect years of health. Furthermore, short-term costs of care for people at high risk of diabetes can include treatments for cardiovascular events and other obesity-related treatment; and if they progress to diabetes, costs for self-management education, durable medical equipment and supplies, new medications to control glycemia and cardiac risk factors, increased utilization of tests and health care visits, and management of acute complications like hypoglycemia.

So the potential to avoid costs by preventing diabetes is considerable. And because the direct program cost of a YMCA-style group intervention come to about $13 per person per month compared to about $94 for the original DPP, Dr. Ackermann reported, it seemed reasonable to explore whether the YMCA approach could actually be cost saving, particularly when offered to

those with the highest disease risk—people with both IGT and elevated fasting blood glucose (FBG) (essentially the criteria for enrollment in the DPP). Dr. Ackermann reported that this segment of the population—about 11.8 million Americans—has an estimated 42 percent chance of developing type 2 diabetes within the next 7.5 years, and a 13.6 percent chance of experiencing a CVD event within 10 years.

Dr. Ackermann then presented estimated cost and savings data for various models for delivery of DPP-like interventions. Over 15 years, the original version of the DPP would eliminate a cumulative $6,000 of health care costs per participant, but the cumulative costs would be higher—almost $10,000 in 2008 dollars. Switching the format to a group context, but continuing to employ physicians to deliver it would allow cost savings in 9-10 years. However, assuming it were just as effective, a group intervention delivered by lay community members, as in the YMCA program, would be cost-saving almost immediately. He suggested that there is very good reason to hope that the YMCA program will be as effective as the DPP, because improvement in risk factors has been similar. What if the YMCA program ultimately proves less efficacious than the original DPP lifestyle intervention? If the goal is to break even within 2 years and to achieve cost savings thereafter, that would be achieved if the YMCA model were 58 percent as effective at preventing diabetes and health care costs as the original DPP lifestyle approach.

An expanded version of the YMCA study, titled RAPID, has enrolled 180 participants so far. Dr. Ackermann noted that study enrollment tripled within 3 weeks of moving from FBG-based screening for risk to using HbA1c, because health care providers were performing the latter test more routinely. The new study has 14 active instructors, at 8 YMCA locations as well as 3 groups receiving the intervention from YMCA instructors outside of YMCAs.

Dr. Ackermann highlighted several policy implications for clinical practice, which included: greater feasibility of detecting high-risk individuals using HbA1c than traditional tests; the promise of clinic-community partnerships; the need for practical tools to guide implementation by practices; the need for a quality monitoring program to track or reward the prevention process or achieved outcomes. Highlighted policy implications for payers/purchasers included the finding that direct support of community-based intervention may be an effective means of achieving short-term diabetes prevention, superior intermediate outcomes, and cost savings. Important future clinical research and evaluation issues include pilot testing of future quality monitoring or incentives programs, as well as of health information technology and other tools for integrating clinic-community partnerships. From the perspective of payers and purchasers, he noted the importance of a behavioral economics approach to inform payment models so as to incentivize identification and enrollment of the target demographic, and to promote program access, participation, and positive outcomes.

Translating Diabetes Prevention: Indian Health Service (IHS) Implementation—Kelly Acton, M.D., IHS

Dr. Acton described an IHS DPP translation demonstration project as implemented in dozens of Indian and Alaska Native communities throughout the United States. The project recently completed recruitment, so Dr. Acton focused on design, preliminary data, lessons learned, and feedback from the sites. She drew attention to the 2002 reauthorization of the Special Diabetes Program for Indians, which directed IHS to develop a competitive grant program to demonstrate diabetes prevention, and also to address its cardiovascular complications. The law further required evaluation of the program.

The Request for Applications (RFA) for the demonstration project was issued in 2004, a planning phase began in 2005, and activities are expected to be completed in 2010. The research is being conducted in 36 American Indian/Alaska Native communities throughout the country. The project was designed to recruit and screen to identify people with elevated FBG and IGT; teach the 16 session DPP Lifestyle Balance Curriculum in group sessions to those enrolled; provide individual coaching on weight loss strategies and goals, physical activity, and diet; organize community-based activities; and measure weight loss, physical activity, nutrition, and diabetes prevention as outcome variables. During the planning year, grantees were oriented to the project and its requirements, and trained in the empirical foundation for the project and its basic activities, as well as in data collection methods. They were also involved in collaborative planning of the core elements, the evaluation process, and community awareness and prevention activities. DPP personnel who worked with American Indian sites in the original study participated in the planning meetings, and provided training and recommendations to project staff. The collaborative approach was modeled on the Institute for Healthcare Improvement's Collaboratives series, which encouraged participating teams to work together, with experts sharing basic information, teams sharing experience and knowledge, and collaborative development of program features. American Indian participants in the original DPP also shared their experiences, to help provide inspiration for both staff and participants in the demonstration project.

Recruitment is followed by a baseline assessment, the 16 session DPP curriculum, a follow-up assessment, and further assessments at 1 and 2 years. The lifestyle coaching and community-based activities are planned to extend from the curriculum phase through the final assessment. In addition to participant demographic and health data, data for the evaluation phase are also being collected on the providers, their programs, organizations, and communities to help identify factors influencing success. A cost analysis will also be performed. Data are submitted from the sites every week, via 12 types of participant forms and 8 types of grantee forms.

Almost 4,000 individuals signed consent forms, and 3,329 completed a baseline assessment. Recruitment is complete, and the first 689 participants have already completed their year 2 assessment. Average weight loss was greatest right after the curriculum was actively delivered,

but has been maintained fairly well for those who have completed all assessments. Improvements in diet, physical activity, and some other health measures have also been observed.

Dr. Acton discussed keys to program success, including the importance of tailoring materials and messaging for local communities. Lessons learned include reducing the number of forms, and pilot testing of forms and questionnaires; clearly defining timelines and concepts such as "baseline" for lay staff; having databases ready and tested prior to data collection; and the need to hire early. Many programs were found to be highly successful both in process measures and outcomes. A few less successful programs were marked by a number of characteristics, such as lack of provider buy-in and community support; unwillingness to accept prevention as care; unwillingness to accept pre-diabetes as a diagnosis; difficulty accessing patient records or scheduling labs; unavailable space; staff turnover and re-training; changes in tribal leadership resulting in loss of support; and leader/provider knowledge deficit with respect to pre-diabetes.

A Payer's View: Centers for Medicare & Medicaid Services (CMS)—Marc Hartstein, CMS

Mr. Hartstein noted that CMS was historically charged to pay for services that are deemed medically necessary and reasonable for existing disease or injury states, and only recently began covering some types of preventive medicine, including vaccines and diabetes screening tests, among others. He emphasized that preventive care coverage by CMS is generally limited to what is required under statute. However, individuals can appeal for national coverage, which CMS may agree to cover if it is deemed "medically reasonable and necessary." Diabetes screening tests (FBG and OGTT) and diabetes self-management training, for example, are benefits mandated under statute for people with certain specific risk factors or conditions. Mr. Hartstein reviewed the specific conditions that must be met in order to receive coverage for these benefits. Medical nutrition therapy (MNT) is another statutory benefit available to people who have been diagnosed with diabetes or chronic renal insufficiency; this benefit includes an initial nutrition and lifestyle assessment, and 3 hours of one-to-one nutrition therapy services in the first year, and 2 hours for each subsequent year. He described DSMT and MNT as models for how CMS might cover diabetes prevention if given the authority to do so. Other benefits he listed for those with diagnosed diabetes were: foot care, A1c tests, glaucoma screening, influenza and pneumococcal immunizations, blood glucose self-testing equipment, therapeutic shoes, insulin pumps and the insulin used in the pumps.

In order to illustrate CMS requirements for provision of care, Mr. Hartstein then described two benefits that are not tied to a diagnosis of diabetes: cardiac rehabilitation and pulmonary rehabilitation. He noted that, in contrast to a program such as group diabetes prevention at YMCAs, these benefits are mandated by statute and are restricted to patients with a higher degree of disease severity. They also require physician prescription and supervision, and are not

community-based. Indeed, he noted that YMCAs are not currently recognized as Medicare providers or suppliers, and moreover YMCAs would not meet the statutory reimbursement requirements related to physician standards and supervision. Thus, coverage of a service delivered by a community-based organization would be unprecedented for the Medicare program.

A Payer's View: Private—Deneen Vojta, M.D., UnitedHealth Group (UHG)

Dr. Vojta described her company's three level approach to diabetes management: tertiary prevention to reduce poor outcomes in high-risk diabetes patients with poor blood glucose control; secondary prevention to achieve better health outcomes for those whose disease is better controlled; and primary prevention to reduce conversion to diabetes among those at high risk. She emphasized that when considering coverage for particular interventions, the emphasis is on what is both evidence-based and scalable—the plan generally should not cover anything that would only be available to a fraction of members who would be eligible. The DEPLOY model of a scalable, evidence-based intervention to achieve primary preventions is therefore an attractive one to UHG. She noted that the company's web-based billing platforms would potentially work well for non-standard providers such as the YMCA. At the same time, their electronic health systems would help them identify participants who stand to benefit from such a program and make it possible for the company to track outcomes and identify problems if a particular YMCA, for example, were not achieving expected results. Thus, for UHG, the problem becomes one of actually scaling up the program and achieving implementation in their markets. Because, as described by other speakers, the necessary scaling appears to be under way, Dr. Vojta envisioned that UHG could employ an incentive system where, for example, payment is tied to attending early sessions, as well as later sessions, and to achieving weight loss, so that all three would be necessary for full payment.

The Role of Federal Agencies and Lessons Learned

Agency for Healthcare Research and Quality (AHRQ): Dr. Barbara Bartman discussed ongoing diabetes work being supported by AHRQ, recommending the AHRQ website (http://www.ahrq.gov/) for more detailed information on funding opportunities. She noted that most AHRQ diabetes-related work pertains to treatment and testing, rather than prevention, but the recently American Recovery and Reinvestment Act (ARRA)-enlarged comparative effectiveness research (CER) program may fund prevention studies. In particular, she drew attention to the Clinical and Health Outcomes Initiative in Comparative Effectiveness (CHOICE) and the Innovative Adaptation and Dissemination of AHRQ Comparative Effectiveness Research Products (iADAPT) grant programs. Although neither is specific to diabetes, she said, diabetes is specified as a priority condition for research applications. She also noted AHRQ's Effective

Healthcare Program, which does systematic reviews as well as larger, observational studies using claims databases or registries, for example. This program manages the Diabetes Multi-Center Research Consortium, which performs CER pertinent to care for diabetes and some related conditions.

CDC: Dr. Ann Albright reported on four "levers" CDC is using to promote diabetes prevention, in cooperation with several of the previous speakers. Lever 1 is to train a cadre of master trainers and lifestyle interventionists for delivery of DPP-like interventions through the Diabetes Training and Technical Assistance Center, set up for this purpose under contract with Emory University. She underlined the need expressed by previous speakers for well-trained and accredited providers in order to achieve scaling efforts with fidelity to the intervention as adapted by Drs. Marrero and Ackermann. Lever 2, therefore, is a recognition program for accreditation analogous to longstanding CDC laboratory accreditation programs that will assure payers that the services they are covering maintain fidelity to proven methods. State-based Diabetes Prevention and Control Programs will have an important role to play by helping collect data on programs, monitor quality, and provide support. Lever 3 is setting up model sites in several states, that will serve as locations for the intervention, places where the methods can be observed, and laboratories to problem-solve during the scaling process. Public dollars will be used at first in these initial sites, with the expectation of moving to private funding in time. Lever 4 is to improve understanding and awareness of pre-diabetes, including encouraging health care providers to talk about the condition with patients. The CDC is working with a contractor to develop materials for the campaign, which will focus on geographic areas near to the model sites. Feedback from the model sites may help to refine the education effort. She emphasized the interest of CDC in working with other federal partners toward the overall goal of scaling availability of the DEPLOY curriculum.

National Diabetes Education Program (NDEP): Ms. Joanne Gallivan reminded the group that the NDEP's *Small Steps. Big Rewards. Prevent type 2 Diabetes* campaign was developed after the initial DPP results were announced, to help people at risk for diabetes to make healthful changes to their lifestyles. The materials have also been tailored for specific high-risk audiences, for example with the *Paso a Paso* campaign in Spanish. The campaigns include materials for both health care consumers and health care providers. The materials have been updated and expanded several times, as more data become available. NDEP assessed public knowledge about diabetes prevention issues through a recent survey. She noted that not only is family history of diabetes a serious risk factor for the disease, but also the surveys identify it as a factor that resonates with people: thus, NDEP has featured messaging about family diabetes history with increasing prominence in culturally-tailored campaign materials and public service announcements. The survey also found an increase in general awareness of the term "pre-diabetes," as a health condition, particularly among adults between 45 and 64 years of age. Ms. Gallivan concluded by noting that NDEP now has an on-line inventory of tools, research articles

and programs available to help people achieve and maintain lifestyle change, developed in collaboration with Dr. Marrero and others.

Health Resources and Services Administration (HRSA): Dr. Deborah Willis-Fillinger noted a variety of HRSA efforts affecting diabetes care, primarily for people who already have the disease. These include Federally Qualified Health Centers; Migrant Health Centers; Rural Critical Access Hospitals; HIV AIDS Clinics; Maternal Child Health Bureau-Title V programs; training for health professionals; Children's Hospitals Graduate Medical Education Payment Program; Diabetes Learning Collaboratives; and HRSA Core Measures—Hemoglobin A1c. Dr. Willis-Fillinger noted that for the approximately 1 million people with frank diabetes treated at Community Health Centers, HRSA is focusing on the Institute of Medicine's Priority Conditions for Improvement. In particular, these include: a HRSA clinical core performance measure for HbA1c, in which the Centers submit annual reports on their patients' A1c values; a Quality Improvement Toolkit, in development, that will include core measure implementation materials developed through the Institute for Healthcare Improvement Breakthrough Collaborative, including diabetes tools; continued monitoring and analyzing data submitted by participants in the Community Health Center Diabetes Collaborative; and supporting the Patient Safety and Clinical Pharmacy Services Collaborative, which is creating community health center teams to co-manage patients with diabetes. She expressed her appreciation for the preceding presentations on diabetes prevention, and the sense that representatives from high-performing community health centers involved in current diabetes programs may be very interested in becoming group diabetes prevention trainers. State primary care associations, which have experience with group coaching, may also be interested either in the trainer or the master trainer content.