

Federal Initiatives To Address Gestational Diabetes Mellitus (GDM) Diabetes Mellitus Interagency Coordinating Committee (DMICC) Meeting

**March 28, 2013
Draft Meeting Summary**

Welcome and Goals of the Meeting—Judith Fradkin, M.D., Chair, DMICC, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH)

Dr. Judith Fradkin welcomed DMICC members that were present in person and by conference telephone. She commented that there has been an enhanced appreciation for the effects of the neonatal environment on the risk of the development of diabetes in the offspring as well as the degree to which GDM is a risk factor for subsequent development of type 2 diabetes in the mother. The obesity epidemic has contributed to a large increase in the rate of GDM, which is compounded by changes in diagnostic criteria. The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) recently held a consensus conference, *Diagnosing Gestational Diabetes Mellitus*, to evaluate the state of the science regarding GDM. Dr. Fradkin welcomed Dr. Catherine Spong, Associate Director for the NICHD's Division of Extramural Research, to discuss the results of the conference.

Report from the NIH GDM Consensus Development Conference—Catherine Spong, M.D., NICHD, NIH

Dr. Spong explained that GDM is a carbohydrate intolerance that is first diagnosed during pregnancy. GDM occurs in approximately 7 percent of pregnancies and carries an annual economic burden of \$636 million. Because of its prevalence, its link to the rise of obesity, and its adverse consequences for pregnancy and longer term outcomes for the mother and offspring, GDM has become a health priority. She noted that the screening and diagnosis procedures for GDM differ between the United States and internationally. The United States uses a two-tiered screening system: if blood glucose levels remain at or above 135 mg/dL 1 hour after a 50 g oral glucose tolerance test (OGTT), a second test (a 3-hour, 100 g OGTT or a fasting plasma glucose test) is performed. The international standard calls for one test (a 2-hour, 75 g OGTT).

Several controversies surround GDM, including the question of who should be screened, how GDM should be diagnosed, and the benefits of treatment. In the United States, almost all pregnant women are screened because the criteria are broad, although the U.S. Preventative Task Force (USPTF) does not recommend this practice. (Note: since Dr. Spong's presentation, [USPSTF has recommended](#) such screening.) Some evidence exists that treatment of GDM diagnosed under current criteria improves health outcomes for the mother and baby. In particular, although primary outcomes in two studies did not improve upon treatment of GDM, secondary outcomes, such as macrosomia and shoulder dystocia, did improve. The impetus for redefining diagnostic criteria comes from findings of the international Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) study, which showed a continuous association between glucose levels and adverse pregnancy outcomes. However there is no specific blood glucose level above which complication danger markedly increases. For example, a blood glucose level of 70 to 80 mg/dL is currently considered normal, but worse pregnancy outcomes are found at 80 mg/dL than at 70 mg/dL. The American Diabetes Association (ADA) endorsed new criteria for the diagnosis of GDM based on pregnancy outcomes, although no data are available that treatment at these new levels improves outcome. If adopted, these standards would double GDM diagnoses, with important implications for health resource utilization. Therefore, it is critical to determine whether the evidence indicates that treating more women would improve outcomes.

Dr. Spong explained that the consensus conference did not address whether GDM screening should occur, but rather addressed seven specific questions in consideration of the ideal diagnostic threshold for GDM and whether the diagnostic criteria should be changed. The seven questions and the panel's conclusions include:

- (1) What are the current screening and diagnostic approaches for GDM, what are the glycemic thresholds for each approach, and how were these thresholds chosen? The panel identified the criteria and glucose thresholds for the diagnosis of GDM based on the literature as well as several national and international association standards.
- (2) What are the effects of various GDM screening/diagnostic approaches for patients, providers, and the U.S. health care system? Moving to a one-step test raises concerns for patients, including the implications of fasting and the management and monitoring of the increased number of diagnosed individuals. Providers can expect a 30 percent increase in workload and the capacity of the U.S. health care system would be affected.
- (3) In the absence of treatment, how do health outcomes of mothers who meet various criteria for GDM and their offspring compare with those who do not? HAPO data show that as maternal hyperglycemia increases, so too does the likelihood of adverse outcomes (preeclampsia, large for gestational age (LGA) or macrosomia, shoulder dystocia, and birth injury, Cesarean delivery, hyperbilirubinemia, hypoglycemia, respiratory distress syndrome, and maternal risk for type 2 diabetes following pregnancy.)
- (4) Does treatment modify the health outcomes of mothers who meet various criteria for GDM and their offspring? Limited data demonstrate that maternal treatment reduces the risk of hypertensive disorders (by 40 percent), shoulder dystocia (by 60 percent), and macrosomia (by 50 percent).
- (5) What are the harms of treating GDM, and do they vary by diagnostic approach? Potential harms include patient anxiety and an increased risk of inductions to avoid LGA. Given the variability of the 2-hour glucose tolerance test, there might be an increase in false positives for the one-step approach.
- (6) Given all of the above, what diagnostic approach(es) for GDM should be recommended, if any? The panelists supported maintaining the current diagnostic approach, for GDM. Specific panelist quotes include: "there is not sufficient evidence to adopt a one-step approach;" "[lowering the threshold for GDM diagnoses] would increase the prevalence of GDM and the corresponding costs without demonstration of improvements in the most clinically important health and patient-centered outcomes"; "given potential benefits of one-step approach, resolution of the uncertainties associated with its use would warrant reconsideration" Dr Spong emphasized that these are statements by the panelists, however, and do not represent official government policy.
- (7) What are the key research gaps in the diagnostic approach of GDM? Many research gaps were identified. The panelists acknowledged that "given the potential benefits of the one-step approach, resolution of the uncertainties associated with its use would warrant reconsideration."

At the conclusion of the consensus conference, the panel supported maintaining the current diagnostic approach for GDM.

The HAPO and LIFE-Moms Studies—Barbara Linder, M.D., Ph.D., NIDDK, NIH

Dr. Barbara Linder described two large studies that address the effects of diabetes and obesity during pregnancy on mothers and offspring in the perinatal period and beyond. Clear evidence indicates that diabetes and obesity during pregnancy lead to subsequent metabolic abnormalities and complications in the offspring. The original HAPO study was designed to understand whether glucose levels lower than the traditional threshold for GDM were associated with adverse perinatal outcomes, including birth weight, adiposity, and umbilical cord C-peptide. The more than 25,000 women recruited comprised an ethnically and racially diverse group. All women had standard GDM screening by OGTT. Women diagnosed as having GDM were removed from the study. The OGTT results were blinded to the women recruited without GDM, as well as to their obstetricians

The results of the HAPO study demonstrated a continuous rise in adverse outcomes (e.g., birth weight, adiposity, and hyperinsulinemia) with increasing glucose levels. Importantly, no threshold or inflection point was identified. The objectives of the follow-up study are to determine whether maternal glucose levels lower than those considered diagnostic of GDM are associated with measures of adiposity in their offspring 8 to 12 years later or an increased risk of type 2 diabetes or obesity in the mothers over the same time period. The researchers will recruit 7,000 mother-offspring dyads from the original HAPO cohort to track a variety of anthropometric measures, including BMI, body composition and blood pressure, as well as OGTT to diagnose prediabetes or type 2 diabetes.

The Lifestyle Interventions for Expectant Moms (LIFE-Moms) study is a trans-NIH effort that will enroll overweight or obese pregnant women to determine how to promote normal weight gain during pregnancy. Each of the seven clinical sites within the consortium is testing a unique lifestyle intervention to control gestational weight gain or influence maternal metabolic profiles, but common core measures and outcomes will be evaluated so that direct comparisons across trials can be made. Outcomes, such as weight, OGTT, waist measurements, and blood pressure will be assessed at baseline and then at several times during pregnancy. Most of the sites will collect and store placental tissue that will be available for future analysis. Infants will be assessed at delivery, 6 months, and 1 year of age to understand how weight gain in pregnancy affects risk for adverse outcomes in infants. The LIFE-Moms study is expected to help researchers learn how to break the cycle of diabetes.

National Diabetes Education Program (NDEP) Post-GDM-related Activities—Joanne Gallivan, M.S., R.D., NDEP, NIH

Ms. Joanne Gallivan, Director for the NDEP, discussed NDEP efforts during the past year to raise awareness of the future health risks that having GDM places on both mother and child, as well as the steps that can be taken to mitigate risks. In 2012, Drs. Steven Gabbe, Mark Landon, and Judith Fradkin co-authored a commentary for publication in the Association of Obstetricians and Gynecologists' *Green Journal*. The commentary entitled, "[Promoting Health After Gestational Diabetes: A National Diabetes Education Program Call to Action](#)," included a call to action to improve the rate of postpartum screening to identify women with or at risk for type 2 diabetes; provide early treatment and prevention interventions for high risk women; and counsel mothers with a history of GDM that their offspring are also at risk and might also benefit from early interventions to improve their health and lower their risk for subsequent obesity or diabetes.

Other NDEP media outreach efforts occurred in May 2012 for Mother's Day and National Women's Health Week. The NDEP conducted promotional outreach via traditional and social media channels, which attracted the attention of many organizations and media outlets to extend the reach of NDEP messages. These activities resulted in more than 85 placements across the country, including the *Washington Post*, and promotion of NDEP post-GDM messages by organizations including Healthy Mothers Healthy Babies Coalition, Nelle & Lizzy (a company specializing in jewelry for mothers) and Curves, a fitness company. The NDEP has reviewed several of its publications in the past year to ensure

that people with limited literacy skills can better understand health information and use the information to make good decisions about health and medical care. For example, NDEP reviewed and revised its tip sheet, “It’s Never too Early to Prevent Diabetes,” to apply principles of plain language and health literacy. The revised tip sheet, available in English and Spanish, is now entitled, “Did You Have Gestational Diabetes When You Were Pregnant?” In May 2012, the NDEP hosted a webinar, “Promoting Health After Gestational Diabetes,” featuring Dr. Robert Ratner, Chief Scientific and Medical Officer for the American Diabetes Association. Nearly 200 partners attended the webinar. The NDEP provides resources and outreach tools to interested partners, including public service announcements, web banners, presentations, tip sheets, and videos focused on behavior change. NDEP partners may adapt these materials for their audiences.

Reports on Activities of Other Government Agencies: Centers for Disease Control and Prevention (CDC)—Mark Eberhardt, Ph.D., Michelle Owens-Gary, Ph.D., and Shin Kim, M.P.H. Dr. Mark Eberhardt mentioned that the CDC’s National Center for Health Statistics (NCHS) was working with state health departments to include GDM on birth certificates. Currently, 33 states report GDM, but the goal is to have all 50 states reporting by 2014.¹

Ms. Shin Kim, representing CDC’s Division of Reproductive Health, discussed the CDC’s GDM surveillance and research efforts. Routine population-based surveillance of GDM is limited to birth certificate, hospital discharge, and Pregnancy Risk Assessment Monitoring System (PRAMS) data, and each of which are less than ideal due to deficiencies of accessibility, quality, and/or completeness. The CDC has ongoing efforts to validate and improve the quality of GDM data from these sources.

The CDC is conducting research on postpartum screening and prevention of type 2 diabetes. At 6 weeks postpartum, 3 to 14 percent of women with GDM will have overt diabetes, and an additional 17 to 25 percent will have impaired fasting glucose levels. Notably, less than 50 percent of women with GDM return for postpartum glucose testing. The CDC is collaborating with Case Western Reserve University to evaluate a procedure for monitoring postpartum glucose with an OGTT within 72 hours of delivery. To reduce the risk of developing type 2 diabetes for women with GDM, the CDC is investigating the effectiveness of lifestyle interventions designed to achieve weight loss and increase physical activity.

Dr. Michelle Owens-Gary discussed the translational efforts through the CDC’s National Diabetes Prevention Program, which targets people with prediabetes, including women with a history of GDM for the prevention of type 2 diabetes. The CDC also is working to address GDM through its partnership with the National Association of Chronic Disease Directors and the Gestational Diabetes Collaborative (GDC). The goals of the GDC are to engage a multistate partnership with 10 states and three tribes, identify and validate routinely collected GDM data, identify gaps in the quality of GDM prevalence data, develop interventions to improve access to care, increase postpartum follow up, and enhance collaboration among public health programs.

One initial GDC effort involved the validation of GDM data from birth certificate, hospital discharge, and PRAMS data, which found that GDM diagnosis and documentation were inconsistent. This is concerning because women might not be tested for diabetes due to the lack of GDM documentation and clinicians might not perceive a need to follow them. The GDC is helping the states to increase the accuracy and documentation of GDM diagnoses. The GDC also developed reminder mailings for postpartum visits, which resulted in an increase from 41 to 70 percent for postpartum diabetes testing. The GDC developed the first statewide reports on the burden of GDM, is assessing knowledge gaps, and is supporting the training and education of health care providers and women.

¹ Dr. Eberhardt provided a later update that most if not all jurisdictions will be reporting GDM by the end of 2014; if one or two states do not meet this goal, they will begin collecting GDM information in 2015.

Closing Comments—Judith Fradkin, M.D., Chair, DMICC, NIDDK, NIH

Dr. Fradkin expressed appreciation to the speakers and DMICC members for the stimulating discussion. The next DMICC meeting in May 2013 will focus on bariatric surgery following an NIH conference that will consider important unanswered research questions on the topic. Dr. Fradkin suggested several additional ideas for future meetings, including a focus on childhood diabetes and surveillance efforts. The National Institute on Aging is organizing a meeting to consider unanswered research questions about diabetes in the elderly; the meeting organizers will be invited to present a summary of the meeting to the DMICC. A participant commented that research indicates that intestinal flora might play a role in the outcomes of bariatric surgery and suggested that probiotics might be an interesting topic for a future DMICC meeting. Dr. Fradkin thanked the DMICC members for their participation, including their suggestions and comments, and adjourned the meeting.

For general information about the history, goals, membership, and activities of the DMICC, please see the [DMICC web page](#) or the publication, “[DMICC: Coordinating the Federal Investment in Diabetes Programs To Improve the Health of Americans.](#)”

Speakers

Ms. Gallivan, NDEP
Dr. Linder, NIDDK
Dr. Spong, NICHD

Dr. Alvilés-Santa, NHLBI
Dr. Bourcier, NIAID
Dr. Chavez, NIMH
Dr. Conroy, NIBIB
Dr. Dankwa-Mullan, NIMHD
Dr. Dutta, NIA
Dr. Gao, NIAAA
Dr. Heindel, NIEHS
Dr. Khalsa, NIDA
Dr. Krasnewich, NIGMS
Dr. Kugler, DOD
Dr. Li, NHGRI
Dr. Parks, FDA
Dr. Post, DOA
Dr. Rosenblum, NCATS
Dr. Shen, NEI
Dr. Wasserman, NINR
Dr. Wong, NIDCD

DMICC Members Attending

Dr. Fradkin, NIDDK, Chair
Dr. Roberts, NIDDK, Executive Secretary
Dr. Atkinson, NIDCR
Dr. Bartman, AHRQ
Dr. Eberhardt, CDC
Dr. Feibus (for Dr. Pogach), VHA
Dr. Frant, NLM
Dr. Grave, NICHD
Dr. Graves, CSR
Dr. Roman, CMS

DMICC Members Not Attending

Dr. Albright, CDC
Dr. Alekel, NCCAM