DRAFT STATEMENT
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CONSENSUS DEVELOPMENT CONFERENCE STATEMENT

National Institutes of Health Consensus Development Conference:
Diagnosing Gestational Diabetes Mellitus Conference
March 4–6, 2013

National Institutes of Health (NIH) consensus statements are prepared by independent panels of health professionals and public representatives on the basis of (1) the results of a systematic literature review prepared under contract with the Agency for Healthcare Research and Quality (AHRQ), (2) presentations by investigators working in areas relevant to the conference questions during a 2-day public session, (3) questions and statements from conference attendees during open discussion periods that are part of the public session, and (4) closed deliberations by the panel during the remainder of the second day and morning of the third. This statement is an independent report of the panel and is not a policy statement of NIH or the Federal Government.

The statement reflects the panel's assessment of medical knowledge available at the time the statement was written. Thus, it provides a "snapshot in time" of the state of knowledge on the conference topic. When reading the statement, keep in mind that new knowledge is inevitably accumulating through medical research, and that the information provided is not a substitute for professional medical care or advice.

Introduction

Gestational diabetes mellitus (GDM) is a condition of carbohydrate intolerance of varying severity that begins or is first recognized during pregnancy and is one of the most common complications of pregnancy. In some cases, GDM is actually type 2 diabetes that has not previously been diagnosed, but, for most patients, the glucose intolerance disappears soon after delivery. The prevalence of GDM varies because of different screening and diagnostic criteria, populations, race, ethnicity, age, and body composition. Using current testing criteria in the United States, GDM prevalence is estimated to be between 5 percent and 6 percent, affecting approximately 240,000 of the more than 4 million births occurring annually. Multiple studies have shown increases in GDM among diverse populations during the 1990s and early 2000s. This observed increase in GDM nationally is consistent with changes in known risk factors for

GDM: advanced maternal age, family history of diabetes, and higher body mass index. All of these risk factors have increased in the past 20 years; for example, more than 20 percent of women in the United States are now obese as they enter pregnancy. GDM is more common among certain ethnic groups—such as African American, Asian, Hispanic, and Native American women—compared to non-Hispanic white women. These high-risk groups are not evenly distributed in the United States, with some regions facing a far greater burden.

Adverse short- and long-term health outcomes for both the mother and her offspring have been associated with the diagnosis of GDM. For the mother, these outcomes include gestational hypertension (pregnancy-induced high blood pressure) and preeclampsia (high blood pressure developed in pregnancy). The mother is also at increased risk for the later development of type 2 diabetes and other long-term metabolic complications. Excess glucose crosses the placenta and can cause adverse fetal effects. Fetal hyperinsulinemia (high levels of insulin in the blood) can lead to excess fetal size (increased risk of shoulder dystocia [large infant shoulder that requires additional obstetric manipulation] and cesarean delivery), increased respiratory distress syndrome, and neonatal metabolic conditions.

At this time, most obstetrical providers in the United States screen for GDM with a 50g glucose challenge test (GCT, measuring serum glucose 1 hour after a woman drinks a 50g oral glucose drink) followed by an oral 100g glucose tolerance test (OGTT, in which four blood samples are drawn over a 3-hour period after a woman drinks 100g glucose) if needed. This two-step approach has been recommended by the American College of Obstetricians and Gynecologists.

Depending on which GCT cutoff is chosen, 14 percent to 23 percent of patients will require the diagnostic OGTT.

Despite the near uniformity of current practice in the United States, a number of controversies remain: the value of routine screening, the most appropriate method and glycemic thresholds for diagnosis, and the effects of treatment on the short- and long-term outcomes for women and their children. For example, in 2008 the U.S. Preventive Services Task Force (USPSTF) determined that "the current evidence is insufficient to assess the balance between the benefits and harms of screening women for GDM either before or after 24 weeks' gestation." At the same time, others support liberalizing the definitions, which would categorize more pregnant women as having GDM. The International Association of Diabetes and Pregnancy Study Groups (IADPSG) has proposed a one-step approach (fasting, 1-hour and 2-hour glucose measurements), where GDM is diagnosed by one abnormal value. This strategy would increase the number of women labeled as GDM two- to threefold and could increase personal and societal costs. Therefore, clear evidence of substantive benefits from the IADPSG approach is needed to justify a change to that diagnostic technique.

The National Institutes of Health Consensus Development Program is designed to address controversial questions of public health importance when there may be discordance between clinical practice and the available evidence. Consensus Development Conferences address targeted, carefully defined questions, which prompt a thorough review of the available evidence and solicit presentations from subject matter experts. An objective panel then concludes with a Consensus Statement, which addresses the critical questions.

By necessity, this panel, Diagnosing Gestational Diabetes Mellitus, cannot address every controversy surrounding GDM and will focus on diagnosis. However, the panel is cognizant of the fact that most health care providers in the United States currently screen, and will continue to screen, for this common complication. The panel also is aware that health care providers will continue to monitor and treat most patients based on whatever diagnosis of GDM is used, and that those will be expensive undertakings, with potentially negative consequences for those falsely categorized as having GDM. Although those facts may flavor deliberations, the panel will concentrate on the diagnosis of GDM, not on the merits of routine screening or on issues of treatment and its effects. Simultaneously, the USPSTF will re-examine the issue of routine screening. In combination, the panel hopes to clarify an approach to GDM that may resolve key controversies.

1. **What are the current screening and diagnostic approaches for gestational diabetes mellitus, what are the glycemic thresholds for each approach, and how were these thresholds chosen?**

Testing for diabetes in pregnancy has been a routine part of obstetric practice since O'Sullivan published results for the oral glucose tolerance test in pregnancy more than 40 years ago.[1] Currently, most practices use either a one-or two-step approach to GDM diagnosis.

Two-step approaches, proposed by the National Diabetes Data Group (NDDG) and Carpenter & Coustan (C-C) are commonly used in the United States and involve the administration of a

screening 50g glucose challenge test (50g GCT) to the patient without regard to fasting (first step). If the plasma glucose level measured 1 hour after the load is less than a selected cutoff (usually 130, 135, or 140 mg/dL), the woman is considered GDM-negative, and no further testing is required. If the glucose level is greater than the cutoff, then a diagnostic test (second step) is needed to confirm the diagnosis of GDM. This second step involves a 100g oral glucose tolerance test (100g 3-hour OGTT) given while the patient is fasting; the fasting 1-, 2-, and 3-hour post-load glucose levels are measured and compared with recommended diagnostic criteria (C-C or NDDG cutoffs) to confirm or reject the diagnosis of GDM (Table 1). The two-step approaches were not developed to diagnose diabetes in pregnancy per se, but rather to identify women at risk of developing diabetes mellitus later in life.

Table 1: Criteria and glucose thresholds for the diagnosis of GDM

Approach	Criteria*	Fasting mg/dL	1-hour mg/dL	2-hour mg/dL	3-hour mg/dL
Two-Step (100g load)	C-C	95 (5.3mmo/L)	180 (10.0mmol/L)	155 (8.6mmol/L)	140 (7.8mmol/L)
	NDDG	105 (5.8mmol/L)	190 (10.5mmol/L)	165 (9.1mmol/L)	145 (8.0mmol/L)
One Step (75g load)	WHO	110 (6.1mmol/L)		140 (7.8mmol/L)	
	IADPSG	92 (5.1mmol/L)	180 (10mmol/L)	153 (8.5mmol/L)	

* C-C = Carpenter & Coustan; NDDG = National Diabetes Data Group; WHO = World Health Organization; IADPSG = International Association of Diabetes and Pregnancy Study Groups

Single-step approaches proposed by the World Health Organization (WHO) and IADPSG are commonly used outside of the United States to diagnose GDM. In the single-step approach, a

75g oral glucose tolerance test (75g 2-hour OGTT) is administered to the fasting woman. Using the WHO approach, fasting and 2-hour post-load glucose levels are measured, and using the IADPSG approach, fasting, 1-hour, and 2-hour glucose levels are evaluated against recommended criteria to confirm or refute the diagnosis of GDM. Table 1 summarizes the GDM diagnostic glycemic cutoffs for these criteria. Distinctions between the WHO and the IADPSG are (1) the WHO requires one or more abnormal values and the IADPSG considers any single abnormal value as diagnostic of GDM, and (2) the IADPSG consensus cutoffs are the only ones that are based on pregnancy outcomes (glucose values associated with a 1.75-fold increase in selected adverse pregnancy outcomes).

2. What are the effects of various diabetes mellitus screening and diagnostic approaches for patients, providers, and U.S. health care systems?

Patients

Changing to a test that requires a fasting blood glucose and an increased wait time of 2 hours is an additional burden for pregnant women. In addition, the fasting state may be difficult and uncomfortable for some women.

Adopting the IADPSG criteria would substantially increase the proportion of women diagnosed with GDM. The diagnosis of GDM carries considerable inconvenience for patients. They must self-monitor their blood glucose levels several times a day and carefully monitor what they eat. They will need to meet with a registered dietitian and/or a diabetes educator, resulting in

additional appointments. Also, (and despite a lack of clear efficacy), they often undergo fetal testing such as non-stress testing and additional obstetric ultrasounds. These extra procedures and provider visits require extra time and create additional challenges regarding transportation, child care, or work and may result in additional out-of-pocket costs. These problems are likely enhanced for vulnerable populations.

Providers

Increasing the proportion of women with GDM by two- to threefold has considerable implications for health care providers. Two randomized clinical trials saw an increase in either prenatal visits or visits to a health care provider. These visits would require additional clinical resources as well as the services of registered dietitians and diabetes educators. In one study of two large hospitals in Australia, it was estimated that the workload would increase approximately 30 percent if new diagnostic criteria for GDM were implemented. One estimate is that the IADPSG criteria would result in 450,000 more patient education visits, 1 million more clinic visits, and 1 million more prenatal testing appointments each year in the United States.

U.S. Health Care Systems

Adopting the IADPSG criteria for the diagnosis of GDM would increase the proportion of women with GDM with attendant implications for hospitals and health care systems. The additional outpatient visits and testing described above also will affect hospitals and payers. There may be capacity constraints relating to additional volume of laboratory tests. Other more

difficult to quantify factors include increased time spent on labor and delivery suites due to inductions and increased time spent in postpartum rooms due to more frequent cesarean deliveries.

Published results suggest that direct medical and patient time costs would both be higher if the IADPSG protocol were adopted. In 2009, it was estimated that the annual cost in the United States for the care of GDM would increase from $636 million to $2 billion. Economic analyses that weigh the tradeoff between costs, health benefits, and potential harms vary widely and do not provide sufficient information to compare the various approaches, likely due to uncertainty regarding the health benefits of increased diagnosis of GDM.

3. In the absence of treatment, how do health outcomes of mothers who meet various criteria for gestational diabetes mellitus and their offspring compare with those who do not?

Many high-quality studies have evaluated maternal and fetal outcomes among women with untreated GDM compared to those without GDM. Although these studies employed various diagnostic criteria, several findings have been consistent. In terms of maternal outcomes, studies have shown that a diagnosis of GDM increases risks of cesarean delivery, preeclampsia, and gestational hypertension.

In terms of fetal outcomes, methodologically strong studies have shown a continuous relationship between increasing glucose levels and increasing incidence of large-for-gestational

age infants and infants with macrosomia (a condition in which the newborn is significantly larger than average). In addition, a consistently higher risk of shoulder dystocia has been found among women with a diagnosis of GDM compared to those without GDM; shoulder dystocia can lead to rare but important outcomes such as brachial plexus injury. Some studies report neonatal hypoglycemia (low blood glucose) and hyperbilirubinemia (excess bilirubin in the blood) among neonates born to women with GDM, although the evidence supporting these associations has not been consistent. A relationship between GDM and subsequent childhood obesity has been found in some but not all studies. The effect on longer term outcomes in the offspring, including type 2 diabetes mellitus, is unclear.

The Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) study demonstrated that the magnitudes of maternal and fetal risks increase with the severity of maternal hyperglycemia (low blood glucose). The HAPO study evaluated glucose tolerance at 24 to 32 weeks during pregnancy in 25,505 pregnant women from 15 centers in 9 countries, providing information on a heterogeneous, multinational, ethnically diverse group of women. For women with less severe hyperglycemia during pregnancy, increasing maternal glucose levels were related to increased infant birth weight, body fat, and cord C-peptide (a measure of insulin resistance in the infant) above the 90th percentile, and increased primary cesarean delivery rates. In addition, these women also had increased risks for premature delivery, preeclampsia, shoulder dystocia or birth injury, and hyperbilirubinemia. Neonatal hypoglycemia and admissions to neonatal intensive care units also were more common in infants born to mothers diagnosed with GDM.

Of note, these risks have been defined using the traditional two-step approach. Milder forms of GDM diagnosed through newer strategies may not be associated with these adverse outcomes to the same degree as noted in prior studies.

4. Does treatment modify the health outcomes of mothers who meet various criteria for gestational diabetes mellitus and their offspring?

Very few well-designed, high-quality studies have attempted to estimate the benefit of treatment of GDM compared with no treatment. These treatments included self-blood glucose monitoring, medical nutrition therapy, and insulin in some patients. Criteria for the diagnosis of GDM varied. Women with more severe forms of GDM were not included in the studies.

Maternal Outcomes

Treatment of GDM reduced the risk for hypertensive disorders of pregnancy by approximately 40 percent. Shoulder dystocia risk was reduced with treatment by approximately 60 percent; however, as shoulder dystocia was a rare event, the absolute risk changed from only 3.5 percent (untreated) to 1.5 percent (with treatment). Another consistent finding among the studies was that the treatment of GDM did not increase the risk of cesarean delivery.

Results were not consistent among studies for maternal weight gain and risk for induction of labor; therefore, the panel could draw no conclusions on the effect of treatment on these two maternal outcomes. Evidence was lacking or insufficient to conclude whether there is an effect

of treatment of GDM on birth trauma, body mass index at delivery, and long-term maternal outcomes including type 2 diabetes mellitus, obesity, and hypertension.

Fetal, Neonatal, and Child Outcomes

A pooled meta-analysis of five randomized clinical trials found a 50 percent reduction in macrosomia in infants born to mothers who received treatment for GDM, although the absolute difference in mean birth weight was less than 150g in the two largest studies. Similarly, randomized trials have demonstrated that infants of mothers who received treatment for GDM were less likely to be large for gestational age (absolute risk reduction 6 percent). Randomized trials, however, have not shown a decrease in neonatal hypoglycemia in response to maternal treatment of GDM. There are no sufficient data available to conclude whether treatment of GDM modifies neonatal morbidities such as prematurity, admission to neonatal intensive care units, or mortality. More studies are needed to evaluate the long-term metabolic outcomes (obesity and risk of type 2 diabetes mellitus) of children born to women with GDM.

The panel strongly recommends caution when applying these results to clinical practice for several reasons. First, participants in clinical trials typically are highly motivated individuals who are eager to adhere to even complex protocols in academic medical center venues with very favorable staff-to-patient ratios. These factors are not usually present in the average clinical practice. Second, not all treatments employed in current daily practice were studied. Oral anti-diabetic agents, such as glyburide and metformin, are notable in their absence. Third, differing thresholds for criteria to diagnose GDM may change the size of the effect of the treatments for

the entire group in unpredictable ways. Milder forms of GDM may not benefit from treatment. Finally, application of treatments purely for the sake of the benefits without regard for the costs would be inappropriate.

5. What are the harms of treating gestational diabetes, and do they vary by diagnostic approach?

A potential harm of increased diagnosis of mild GDM is patient anxiety. It is generally accepted that patients experience short-term stress and anxiety when receiving a new diagnosis of a serious condition, including GDM, which could adversely affect their health. Nonetheless, it is unclear if long-term stress and anxiety are increased. In part, this is due to a paucity of data. Also, it is possible that women may adapt to their diagnosis with diabetes management, thereby decreasing their anxiety level. In addition to anxiety, women with a diagnosis of GDM have reported feelings of loss of control, shock, depression, fear, and disappointment.

Few studies directly addressed the emotional impact of screening for and diagnosis of GDM. One study noted a lower sense of well-being, less positive experience of their pregnancy, and more concern about their health in women with GDM compared to those without the condition. Another group noted that women with GDM had increased concern about their baby's health and their own health as well as a fear of losing personal control over their health. Also, the over-diagnosis of GDM may lead to the "medicalization of pregnancy," which transforms an otherwise normal pregnancy into a disease.

There is considerable variability in the 2-hour glucose tolerance test. Results may differ in as many as 25 percent of women if performed at different times. Thus, a one-step test is likely to result in more “false positive” results than a two-step test. In turn, positive tests will further increase cost, inconvenience, and anxiety.

The harms of medical therapy for GDM are well known. Medications such as insulin and anti-diabetic agents may cause hypoglycemia and other side effects. There are also obstetric “harms” associated with an increased risk of GDM.

One randomized controlled trial has shown higher induction of labor rates in women with GDM compared to normal controls. Women with GDM are more likely to undergo increased maternal and fetal monitoring. Subjective interpretation of ultrasound findings and fetal non-stress tests produces a high rate of false positives and is a factor in unnecessary induction of labor leading to failed inductions and cesarean delivery. Data regarding the effect of changing the diagnostic criteria for GDM on inductions are uncertain.

Cesarean rates may be higher in women given the diagnosis of GDM, and it is uncertain whether treatment can mitigate this increase. Cesarean delivery is associated with a higher rate of short- and long-term complications. There is concern about the rising cesarean rate by many groups; the present rate in the United States is 32.9 percent. Since the vaginal birth after cesarean rate is now less than 10 percent, most women who delivered by cesarean will again deliver by repeat cesarean. With each subsequent pregnancy, the rate of placenta previa (which occurs when an infant placenta partially or totally covers the mother’s cervix) and placenta accreta (a serious

pregnancy condition that occurs when blood vessels and other parts of the placenta grow too deeply into the uterine wall) increase dramatically. These conditions result in serious complications such as hemorrhage, infection, emergency hysterectomy, and even death.

A diagnosis of GDM may lead to more intensive neonatal care, potentially separating mother and infant. One study indicated that infants born to mothers with the diagnosis of GDM were more frequently admitted to an intermediate care nursery. It is important to note that protocols for increased surveillance vary among hospitals. There is theoretical risk for small for gestational age fetuses in patients treated for GDM; however, the two largest randomized clinical trials have not demonstrated this risk.

6. Given all of the above, what diagnostic approach(es) for gestational diabetes mellitus should be recommended, if any?

At present, GDM is commonly diagnosed in the United States using a 1-hour screening test with a 50g glucose load followed by a 3-hour 100g glucose tolerance test (a two-step approach) for those found to be abnormal on the screen. This approach identifies approximately 5 percent to 6 percent of the population as having GDM. The diagnostic threshold criteria for this test were originally predicated not on perinatal outcomes, but on the likelihood that a woman would develop diabetes mellitus several years subsequent to pregnancy. Subsequently, evidence has accumulated that the GDM identified by this system is associated with an increased risk of adverse maternal and perinatal outcomes.

In contrast, newly proposed diagnostic strategies rely on the administration of a 2-hour glucose tolerance test (a one-step approach). Each of these strategies is based on a one-step approach with a fasting component, a 75g glucose load, and 2 hours of testing. However, these tests differ on whether a 1-hour sample is included, whether two abnormal values are required, and the diagnostic cutoffs that are used. Most recently, the IADPSG has proposed diagnostic thresholds based on demonstrated associations between glycemic levels and an increased risk of obstetric and perinatal morbidities.

The panel considered whether a one-step approach to the diagnosis of GDM should be adopted in place of the two-step approach. The one-step approach offers certain operational advantages. The current two-step approach is not used other than during pregnancy and is largely restricted to the United States. There would be value in a consistent diagnostic standard across the lifespan within the United States and during pregnancy around the world. This unification would allow better standardization of best practices in patient care and comparability of research outcomes. The one-step approach also holds potential advantages for women and their health care providers as it would allow a diagnosis to be achieved within the context of one visit as opposed to two.

To determine whether the advantages of the one-step approach should lead to its adoption, several criteria need to be fulfilled:

- There should be evidence that the additional women who are identified by the one-step approach have an increased frequency of maternal and/or perinatal morbidities.

- There should be evidence that these morbidities can be decreased by intervention.

- There should be evidence that the benefits of the decrease in morbidities outweigh the harms incurred (including maternal, perinatal, and societal).

There is good evidence that increasing glycemic levels during pregnancy are associated with greater maternal and perinatal morbidities. There is no single cutoff below which these associations are absent. These associations have been best demonstrated for the outcomes of shoulder dystocia, cesarean delivery, macrosomia, large-for-gestational-age birth weight, neonatal adiposity, neonatal hypoglycemia, and elevated umbilical cord blood C-peptide. It is not as clear whether associations exist for other important outcomes such as brachial plexus palsy, perinatal mortality, childhood obesity, or subsequent maternal metabolic complications.

There also is evidence that treatment of women with GDM—diagnosed either by the one-step or two-step approach—may improve some outcomes. Outcomes that have been improved with treatment include the frequencies of macrosomia, large-for-gestational-age birth weight, shoulder dystocia, and hypertensive disease of pregnancy. Despite improvements in these intermediate outcomes, the frequencies of composite neonatal morbidity and cesarean delivery have not been consistently improved with treatment. Long-term outcomes for mothers and their offspring have not been improved in the few studies that have been performed.

The one-step approach, as proposed by the IADPSG, is anticipated to increase the frequency of the diagnosis of GDM by two- to threefold, to a prevalence of approximately 15 percent to

20 percent. There are several concerns regarding the diagnosis of GDM in these additional women. It is not well understood whether they will benefit from treatment, and if so, to what extent. Moreover, the care of these women will generate additional direct and indirect health care costs. Such costs include increased utilization of registered dietitians and diabetes educators, prenatal care visits, and fetal assessments with modalities such as ultrasound and prenatal testing. There is also evidence in some studies that the labeling of these women may have unintended consequences, such as an increase in cesarean delivery and more intensive newborn assessments. In addition, increased patient costs, life disruptions, and psychosocial burdens have been identified. Currently available studies do not provide clear evidence that a one-step approach is cost-effective in comparison with the current two-step approach.

Based on the above considerations, the panel believes that there are benefits from standardization within the United States and between the United States and the world with regard to the diagnostic approach to GDM. Nevertheless, at present, the panel believes that there is not sufficient evidence to adopt a one-step approach, such as that proposed by the IADPSG. The panel is particularly concerned about the adoption of new criteria that would increase the prevalence of GDM, and the corresponding costs and interventions, without clear demonstration of improvements in the most clinically important health and patient-centered outcomes. Thus, the panel recommends that the two-step approach be continued. However, given the potential benefits of a one-step approach, resolution of the uncertainties associated with its use would warrant reconsideration of this conclusion.

7. What are the key research gaps in the diagnostic approach of gestational diabetes mellitus?

The panel identified the following research needs for GDM diagnosis:

- Develop an approach to diagnosis in the United States that is more consistent with international diagnostic approaches. This requires further research to define the optimal strategy that will improve health in the most cost-effective manner.

- Determine whether the additional women categorized as having diabetes by the IADPSG model, who would be considered normal in the two-step strategy, accrue any benefit from treatment. This question would be best answered by a randomized controlled trial that, ideally, would use clinically important health and patient-centered outcomes.

- Conduct cost-benefit, cost-effectiveness, and cost-utility analyses to more fully understand the resource implications of changing the thresholds for a diagnosis of GDM.

- Given that the different approaches represent different burdens for patients, conduct research to understand patient preferences and the psychological consequences of the diagnosis of GDM.

- Perform well-conducted prospective cohort studies of the “real world” impact of GDM treatment on care utilization and practice patterns.

- Assess lifestyle interventions during pregnancy that may improve maternal and fetal outcomes in women with GDM.

- Assess the long-term impact that a label of GDM may have for future pregnancy planning, future pregnancy management, and future insurability.

- Conduct further study of the long-term metabolic, cardiovascular, developmental, and epigenetic (inherited changes in phenotype [appearance] caused by mechanisms other than changes in DNA) impact on offspring whose mothers have been treated for GDM.

- Assess interventions to decrease the subsequent risk of the occurrence of metabolic syndrome, diabetes, and cardiovascular disease in women with GDM.

A single standard for screening and diagnostic thresholds for GDM should be established by professional organizations.

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