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EDITORIAL

Testing for Gestational Diabetes Mellitus: International Federation of Gynecology and Obstetrics Recommendations

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THE ISSUE: PROBLEMS OF MULTIPLE CRITERIA

Global health care organizations and professional bodies have advocated a plethora of diverse algorithms for screening and diagnosis of gestational diabetes mellitus (GDM). Unfortunately, even the endocrine, diabetes, and obstetric associations within particular countries often used markedly dissimilar protocols and cut-off values for screening and diagnosis of GDM. These recommendations for GDM were criticized for lacking validation, as they were developed based on tenuous data; the results of expert opinions were biased owing to economic considerations or were convenience oriented,[1] thereby creating confusion and uncertainty among care providers. One underlying, yet fundamental problem, as shown consistently by several studies including the Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) study, is that the risk of poor pregnancy outcomes associated with hyperglycemia is continuous with no clear inflection points.[2-6]

It is, therefore, clear that any set of criteria for the diagnosis of GDM proposed will need to evolve from a consensus approach, balancing risks and benefits in particular social, economic, and clinical contexts.[7] In 2010, the International Association of Diabetes in Pregnancy Study Groups (IADPSG) proposed consensus-derived cut-off values for fasting, 1-hour, and 2-hour 75-g oral glucose tolerance test (OGTT) threshold values, defining GDM based on odds ratio thresholds of 1.75 in comparison with the mean, for markers of diabetic fetopathy [large for gestational age (LGA), excess fetal adiposity, and fetal hyperinsulinemia] in the multinational observational HAPO study.[8] These criteria have been widely accepted and recently adopted by the World Health Organization (WHO) and the American Diabetes Association (ADA).[9,10] However, LGA and fetal adiposity are also dependent on factors other than maternal glucose alone. For example, using the 2-hour glucose cut-off value of 8.5 mmol/L (153 mg/dL) selected by the IADPSG may not be as efficient in identifying women at risk for fetal overgrowth as those identified by a 2-hour glucose value corresponding to that at a slightly lower odds ratio of 1.5 compared with the mean. The latter corresponds to the older, WHO criteria 2-hour value of 7.8 mmol/L (140 mg/dL).

Apart from the different cut-off values, the lack of consensus among the different professional bodies for an algorithm for screening and diagnosis of GDM is perhaps an even larger problem. Despite repeated pleas for a single process and criteria,[11] the ideal protocol for the diagnosis of GDM continues to be debated.

Universal *vs* Selective Testing

Selective testing based on clinical risk factors for GDM evolved from the view that in populations with a low risk of GDM, subjecting all pregnant women to a laboratory test was not considered cost-effective. Traditionally, the risk factor-based approach was popular in Europe. Some of the aforementioned risk factors used were age and body mass index (BMI) (at varying thresholds); ethnicity; polyhydramnios; macrosomia (current or past pregnancy); GDM in the past; unexplained stillbirth; type II diabetes

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mellitus (T2DM) in a first-degree relative; and polycystic ovary syndrome. The Toronto Tri-hospital Gestational Diabetes Project[12] developed a scoring system based on maternal age, BMI, and race. However, variations in risk factors have resulted in different approaches, generally with poor sensitivity and specificity. The major problem of risk factor-based screening is its high demand on the health care providers with more complex protocols for testing, which result in lower compliance by both patients and health care providers.

Given the high rates of hyperglycemia in pregnancy in most populations and that selective testing based on known risk factors has poor sensitivity for the detection of GDM, it seems appropriate to recommend universal rather than risk factor-based testing. This approach is strongly recommended by the International Federation of Gynecology and Obstetrics (FIGO) and is particularly relevant to low-, low–middle-, and middle-resource countries, where 90% of all cases of GDM are found and ascertainment of risk factors is poor owing to low levels of education and awareness, and poor record keeping. In many of these countries, there is little justification for selective testing, as they also have ethnic populations considered to be at high risk.[13]

In 2010, the IADPSG proposed screening of all pregnant women with a single-step 75-g OGTT.[8] This position has since been supported by the ADA and the International Diabetes Federation (IDF).[14] However, there continues to be a lack of uniformity of testing protocols within and between hospitals in the same city, county, and country,[15] let alone internationally.

The case for universal testing (i.e., testing all pregnant women) with some biochemical test has its supporters.[16,17] However, among advocates of universal testing, there is a lack of uniformity in the approach to testing methodology.

The 50-g glucose challenge test (GCT) has been the most popular test for this purpose. This is part of the two-step algorithm (50-g GCT followed by the 100-g OGTT) still advocated by the ACOG, and offered as an alternative diagnostic strategy in the latest ADA guideline.

The one-step 75-g OGTT in all women is endorsed by the WHO, IDF, and many other organizations that agree with the recommendations of the IADPSG.

In the overall cost of providing care to women with GDM, the cost of administering a GTT to all pregnant women is likely to be minimal if the initial fasting GTT level result can be used to decide if the full GTT is needed.[18,19] In situations where women may not be able to come for testing in a fasting state, a single-step 75-g 2-hour nonfasting test, as used in India, may be applied.[20,21]

The FIGO initiative for GDM is meant to provide a practical guide for national associations to adopt and promote a uniform approach to testing, diagnosis, and management of GDM for all countries and regions based on their financial, human, and infrastructure resources.

- The FIGO adopts and supports the IADPSG/WHO/IDF position that all pregnant women should be tested for hyperglycemia during pregnancy using a one-step procedure.
- The FIGO encourages all countries and its member associations to adapt and promote strategies to ensure universal testing of all pregnant women for hyperglycemia during pregnancy.

Diagnostic Criteria

Diabetes in Pregnancy

The diagnosis of diabetes in pregnancy as defined by the WHO criteria[9] should be based on one or more of the following results recorded by routine testing at any time during the course of pregnancy:

- Fasting plasma glucose ≥7.0 mmol/L (126 mg/dL); and/or
- 2-hour plasma glucose ≥11.1 mmol/L (200 mg/dL) following a 75-g oral glucose load; or
- Random plasma glucose ≥11.1 mmol/L (200 mg/dL) in the presence of diabetes symptoms.

Additionally, the ADA also recommends hemoglobin A1c (HbA1c) (≥6.5%), confirmed by repeat testing, as sufficient to diagnose diabetes in the presence or absence of pregnancy.[10]

Gestational Diabetes Mellitus

As per the recommendation of the IADPSG (2010) and WHO (2013), the diagnosis of GDM is made using a single-step 75-g OGTT when one or more of the following results are recorded during routine testing, specifically between weeks 24 and 28 of pregnancy or at any other time during the course of pregnancy:

- Fasting plasma glucose 5.1 to 6.9 mmol/L (92–125 mg/dL);
- 1-hour post 75-g oral glucose load ≥10 mmol/L (180 mg/dL);
- 2-hour post 75-g oral glucose load 8.5 to 11.0 mmol/L (153–199 mg/dL)

- FIGO adopts the WHO (2013) criteria for diagnosis of diabetes mellitus in pregnancy.
- FIGO adopts the WHO (2013) and IADPSG (2010) criteria for diagnosis of GDM. Given the resource constraints in many low-resource countries, other strategies described herein are considered equally acceptable.
- FIGO suggests various options for diagnosis of GDM based on resource settings in Table 1.

Table 1: Options for diagnosis of GDM based on resource settings

		Strategy		
Setting	*Who to test and when*	*Diagnostic test*	*Interpretation*[a]	*Grade*
Fully resourced settings	All women at booking/ first trimester	Measure fasting plasma glucose (FPG), random blood glucose (RBG), or HbA1c to detect diabetes in pregnancy		1|+++O
	24−28 weeks	If negative: Perform 75-g 2-hour OGTT		
Fully resourced settings serving ethnic populations at high risk[b]	All women at booking/ first trimester	Perform 75-g 2-hour OGTT to detect diabetes in pregnancy		2|+OOO
Any setting (basic): Particularly medium- to low-resource settings serving ethnic populations at risk	All women between 24 and 28 weeks	Perform 75-g 2-hour OGTT		1|+++O

FPG: Fasting plasma glucose

[a]Interpret as per IADPSG/WHO/IDF guidelines unless stated otherwise.

[b]Asians are at high risk of hyperglycemia during pregnancy, which may include previously undiagnosed diabetes. The proportion of previously undiagnosed diabetes is highest in the youngest age group, particularly among women.[22] In Asian populations, FPG and HbA1c have much lower sensitivity to diagnose diabetes than the 2-hour postglucose value.[23] In a study of 11 Asian cohorts, more than half of the diabetic subjects had isolated postchallenge hyperglycemia.[24] In a study in China, 46.6% of the participants with undiagnosed diabetes (44.1% of the men and 50.2% of the women) had isolated increased 2-hour plasma glucose levels after an OGTT.[25] Therefore, the need to identify postprandial hyperglycemia seems especially relevant in Asian populations.

Resource-based Approach to Diagnosis

Implementation of guidelines is a constant challenge. The reality is that most low-resource countries around the world are unable to implement a GDM detection program based on a universal 75-g OGTT or rely on just high-risk women undergoing a 75-g OGTT. These challenges and barriers have been reviewed extensively.[28] The applicability of the IADPSG cut-off value for fasting glucose to diagnose GDM, especially in the first trimester, has been contested in a recent study from China.[29]

Recommendations that are rigid and impractical in real-life settings are unlikely to be implemented and, hence, may produce little or no impact. On the contrary, pragmatic, but less-than-ideal recommendations may produce significant impact owing to more widespread implementation.

The FIGO approach is three-pronged:

1. To promote, encourage, and advocate ideal evidence-based guidance;
2. To offer pragmatic options for resource-constrained situations based on local experience backed by less-than-optimal evidence;
3. To promote research aimed at improving the evidence base in both well-resourced and resource-constrained contexts.

The FIGO recommendations are based on available resources at country level and evidence of local practice. Countries worldwide fall into four resource categories. There are also variations seen within any country. An affluent country may have pockets of poorly funded care and, conversely, a low- or middle-resource country may have state-of-the art care in the private sector for a selected few.

High-resource countries: Countries or regions, such as Canada, Western Europe, Japan, South Korea, USA, etc.

Upper middle-resource countries: Countries, such as Brazil, China, Colombia, Hungary, Malaysia, Mexico, Romania, South Africa, Turkey, etc.

Low middle-resource countries: Countries, such as India, Indonesia, Pakistan, Nigeria, Egypt, Vietnam, etc.

Low-resource countries: Countries, such as Bangladesh, Nepal, Cambodia, Kenya, Tanzania, Uganda, Ethiopia, Congo, etc.

Risk Models

If a country cannot afford any laboratory testing, risk models are available. Many have been advocated from studies in Canada,[12] Denmark,[30] Thailand,[31] and Vietnam.[32] They use a permutation of various clinical risk factors, including age, BMI, family history of diabetes mellitus, GDM in past pregnancies, LGA newborns, and glycosuria. Their widespread applicability in large settings in low-resource countries has not been tested and is not recommended by FIGO.

Eight low- and middle-resource countries – India, China, Nigeria, Pakistan, Indonesia, Bangladesh, Brazil, and Mexico – account for 55% of the global live births (70 million live births annually) as well as 55% of the global burden of diabetes (209.5 million), and should be key targets for any focused strategy on addressing the global burden of GDM pregnancies.

A few examples of current approaches to diagnoses of GDM in different parts of the world, particularly from the large-burden countries where systematic testing for GDM is being implemented, are provided in Appendix 1. These examples have inspired FIGO's pragmatic options and guidance for resource-constrained situations.

Appendix 1: Alternative strategies as currently used in specified countries

China: Medium- to low-resource settings serving populations at high risk	All women at booking/ first trimester	Measure FPG to detect diabetes in pregnancy	>7.0 mmol/L or >126 mg/dL. FPG values between 5.6 and 6.9 mmol/L, (100−125 mg/dL) consider as GDM[18]	2|+OO
	24−28 weeks	If negative: Perform 75-g 2-hour OGTT *Or*		1|+++O
		To reduce number of OGTTs, measure FPG. Only in women with values between 4.5 and 5.0 mmol/L (81−90 mg/dL), perform 75-g 2-hour OGTT	Value >5.1 mmol/L or >92 mg/dL diagnostic of GDM	2|+OOO
Indian subcontinent: Medium- to low-resource settings serving rural/ semiurban/urban ethnic populations at high risk	All women at booking/ first trimester	Measure fasting or nonfasting 2-hour value after 75-g OGTT	Reading between 7.8 and 11.0 mmol/L or 140 and 199 mg/dL indicates GDM[19,20c]	2|+OOO
	24−28 weeks	If negative: Repeat test		
Latin America: Medium- to low-resource settings	All women at booking/ first trimester	Measure FPG to detect diabetes in pregnancy	>7.0 mmol/L or >126 mg/dL. FPG values between 5.6 and 6.9 mmol/L (100−125 mg/dL), consider as GDM	2|+OOO
	24−28 weeks	If negative: Perform 75-g 2-hour OGTT	75-g 2-hour glucose value >7.8 mmol/L or >140 mg/dL is diagnostic of GDM[d]	
UK: All settings	Selected women at booking/as soon as possible[e]	Perform 75-g 2-hour OGTT	FPG of 5.6 mmol/L or above or 2-hour plasma glucose of 7.8 mmol/L or above is diagnostic[f]	
	24−28 weeks	If negative: Perform 75-g 2-hour OGTT		
	Offered also to other women with risk factors for GDM[g]			

[c]Diabetes in Pregnancy Study Group in India (DIPSI) guideline.[8]

[d]Latin America Study Group.[26]

[e]Women with a past history of GDM or women with glycosuria of 2+ or above on one occasion or of 1+ or above on two or more occasions (as detected by reagent strip testing during routine prenatal care in the current pregnancy).

[f]National Institute for Health and Care Excellence (NICE).[27]

[g]BMI above 30 (calculated as weight in kilograms divided by height in meters squared), previous macrosomic baby weighing 4.5 kg or above, family history of diabetes, first-degree relative with diabetes, minority ethnic family origin with a high prevalence of diabetes.

COST-EFFECTIVENESS OF GDM TESTING AND MANAGEMENT

Apart from infrastructure and capacity constraints, implementation of universal testing for GDM is challenged by lack of good evidence to support cost-effectiveness in both the high- and low-resource countries. To facilitate decision-making, countries need reliable information on the cost and cost-effectiveness of GDM screening and treatment. Almost all cost-effectiveness analyses have assessed only short-term complications,[33] omitting consideration of reductions in long-term T2DM. A recent study from the USA evaluated the potential cost-effectiveness of new GDM screening criteria for both time periods.[34] Another study, based on the Gestational Diabetes Formulas for Cost-Effectiveness or the GeDiForCE Model[35] described in, showed that the interventions are "highly cost-effective" in both Indian and Israeli settings when long-term effects are taken into account.[36]

All countries have an obligation to implement the best GDM testing and management practices they can.

The FIGO acknowledges that for global progress to be made, India, China, Nigeria, Pakistan, Indonesia, Bangladesh, Brazil, and Mexico must be key targets for focused GDM attention.

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