

The urgent need for universally applicable simple screening procedures and diagnostic criteria for gestational diabetes mellitus – lessons from projects funded by the World Diabetes Foundation

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Background: To address the risks of adverse pregnancy outcomes and future type 2 diabetes associated with gestational diabetes mellitus (GDM), its early detection and timely treatment is essential. In the absence of an international consensus, multiple different guidelines on screening and diagnosis of GDM have existed for a long time. This may be changing with the publication of the recommendations by the International Association of Diabetes and Pregnancy Study Groups. However, none of these guidelines take into account evidence from or ground realities of resource-poor settings.

Objective: This study aimed to investigate whether GDM projects supported by the World Diabetes Foundation in developing countries utilize any of the internationally recommended guidelines for screening and diagnosis of GDM, explore experiences on applicability and usefulness of the guidelines and barriers if any, in implementing the guidelines. These projects have reached out to thousands of pregnant women through capacity building and improvement of access to GDM screening and diagnosis in the developing world and therefore provide a rich field experience on the applicability of the guidelines in resource-poor settings.

Design: A mixed methods approach using questionnaires and interviews was utilised to review 11 GDM projects. Two projects were conducted by the same partner; interviews were conducted in person or via phone by the first author with nine project partners and one responded via email. The interviews were analysed using content analysis.

Results: The projects use seven different screening procedures and diagnostic criteria and many do not completely adhere to one guideline alone. Various challenges in adhering to the recommendations emerged in the interviews, including problems with screening women during the recommended time period, applicability of some of the listed risk factors used for (pre-)screening, difficulties with reaching women for testing in the fasting state, time consuming nature of the tests, intolerance to high glucose load due to nausea, need for repeat tests, issues with scarcity of test consumables and lack of equipment making some procedures impossible to follow.

Conclusion: Though an international consensus on screening and diagnosis for GDM is welcome, it should ensure that the recommendations take into account feasibility and applicability in low resource settings to ensure wider usage. We need to move away from purely academic discussions focusing on sensitivity and specificity to also include what can actually be done at the basic care level.

Keywords: *gestational diabetes mellitus; diagnostic test; maternal health; screening; barriers; guidelines; low resources settings; pragmatic approach; prevention*

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The global burden of diabetes continues to rise and is now estimated at 366 million people; three quarters live in the developing world (1). One approach to prevent the rising burden of diabetes is to focus attention on the early origins of health (2) and address the issue of gestational diabetes mellitus (GDM), defined as any degree of glucose intolerance with onset or first recognition during pregnancy (3, 4). It is well known that women with undiagnosed or poorly managed GDM as well as their infants are at increased future risk of developing type 2 diabetes (5–7) if preventive measures are not taken. In instances where lifestyle modifications or pharmaceutical intervention are implemented, studies have shown that it is possible to prevent or delay the onset of type 2 diabetes in high-risk individuals (8–10), including women with a history of GDM (11, 12). Addressing GDM thus constitutes a window of opportunity for early intervention and reduction of the future burden of type 2 diabetes.

Additionally other compelling reasons for addressing GDM include the elevated risk of adverse pregnancy outcomes, including maternal- and peri-natal mortality, obstructed labour, infections, spontaneous abortion, congenital abnormalities and macrosomia (13–16). Furthermore, women with a history of GDM are also at increased risk of future cardiovascular disease (17, 18).

The prevalence rate of GDM in general is said to reflect the prevalence of impaired glucose tolerance (IGT) in young reproductive women as well as the background prevalence of type 2 diabetes in the given population (19). Data from developed countries show prevalence rates of GDM ranging from less than 1 to 20% (20). Studies from developing countries are sparse, but studies from Pakistan, Sri Lanka, Ethiopia, South Africa, Nigeria, Iran, Thailand and India have found prevalence rates between 0.6 and 18.9% (21–32). In addition to ethnic differences, the variation in prevalence rates may be due to the use of different screening procedures and diagnostic criteria, how long back the studies were done, maternal age, parity, pre-pregnancy weight and BMI, and whether the studied population reside in urban or rural areas. Nonetheless, with rapid urbanisation, changing diets, decreasing physical activity, the trend towards delayed marriage and older maternal age as well as the growing epidemics of obesity and type 2 diabetes, the prevalence of GDM may very well be on the rise (33). In countries where appropriate care for obstetrical emergencies is lacking, unrecognized GDM may have particularly severe consequences for the health and well-being of the mother. Haemorrhage, hypertensive disorders, obstructed labour and infection/sepsis are among the leading global causes of maternal mortality (34). GDM and hypertension are linked directly or indirectly to all of them. The need for detecting and diagnosing GDM to ensure timely treatment is therefore widely recognised as highly important; however, there is

no international consensus on how to do it. This may now be changing with the publication of the recommendations by the International Association of Diabetes and Pregnancy Study Groups (IADPSG). However none of these guidelines take into account evidence from, or ground realities of, resource poor settings.

In this paper we present the findings from a mixed method explorative study conducted to investigate whether GDM projects supported by the World Diabetes Foundation (WDF) in developing countries utilize any of the internationally recommended guidelines/recommendations on screening and diagnosis of GDM; explore their experiences on the applicability and usefulness of the guidelines and barriers if any, in implementing these guidelines/recommendations. These projects have reached out to a total of 98,836 pregnant women through capacity building and improvement of access to GDM screening and diagnosis in the developing world and therefore provide a rich field experience on the applicability of the guidelines in resource poor setting (personal communication with Dr Anil Kapur/WDF data on record).

Methodology

From its establishment in 2002 to end-2010, WDF granted support to 253 projects. All applications from these projects were screened for the keywords ‘GDM’, ‘gestation’, ‘pregnan’ and ‘mother’. Project applications that contained one or more of these keywords were then examined in more detail to ensure that they actually include components or activities related to gestational diabetes. Projects where women with a history of GDM were included in the target group together with persons with other risk factors for type 2 diabetes (e.g. obesity, family history of diabetes), but with no specific objectives related to GDM, and projects where GDM was included in the training curriculum, but otherwise was not a component of action of the project were excluded. This resulted in 14 projects and national programmes specifically addressing the screening, diagnosis and care for women with GDM in low and middle income countries targeting thousands of pregnant women.

Of these 11 had begun implementation as of March 2011 and were thus included in this study. A specially designed questionnaire was sent to the project partners together with a letter asking the partner to participate in an interview. As two projects were implemented by the same institution 10 responded to the questionnaire. All 10 project partners agreed to participate in the interview as well; three of the interviews were conducted face-to-face, six were conducted via telephone and one replied to the questions in writing via email. Participation in the study was voluntary and prior to conducting the interview the purpose of it was explained to the respondents and consent to participate in the interview obtained. The nine project partners that were interviewed face-to-face or via

telephone also consented to have the interview audio recorded. Being questionnaire and interview based without use of human biological material, the study was exempt from ethics approval according to Danish law as confirmed upon enquiry by the Danish Biomedical Research Ethics Committee.

Questionnaire

The primary purpose of the questionnaire was to answer the first part of the objective: do the projects utilise guidelines and if so, which ones. A number of guidelines recommend different criteria and approaches for screening and diagnosis of GDM (Table 1). Most of them recommend use of glucose challenge tests, wherein pregnant women are subjected to an oral glucose solution and blood samples are drawn at different time intervals;

except the American Diabetes Association (ADA) which prior to 2010 recommended a non-challenge test. The questionnaire was designed to obtain information about the screening procedure, diagnostic criteria and cut off values used; as well as get an understanding of the challenges and barriers in implementing the guidelines in the local context in terms of ethnic and cultural issues, resources and capacity. These issues were further investigated in the interviews.

Interviews

A semi-structured interview-guide investigating barriers and challenges related to screening and diagnosis of GDM as well as the rationale for selecting the employed criteria was used for the interviews. The interview-guide was developed by KKN and AK based on peer-reviewed

Table 1. Overview of recommendations for screening procedures and diagnostic criteria for GDM

Organisation	Type of test	Glucose load (g)	Cut-off points	Who should be screened?
WHO 1999 (40)*	One-step	75	FPG \geq 126 mg/dl (7.0 mmol/l) 2 h \geq 140 mg/dl (7.8 mmol/l)	Not mentioned
ADA 2003 (36)	Fasting or random non-challenge test in general. The OGTT recognised as a valid test.	NA	FPG $>$ 126mg/dl (7.0 mmol/l) Random $>$ 200 mg/dl (11.1 mmol/l)	Selective
ADA 2010 (37)**	Two- or one-step	50 (GCT) and 100 (OGTT)	GCT: \geq 140 mg/dl (7.8 mmol/l) OR \geq 130 mg/dl (7.2 mmol/l) OGTT: FPG \geq 95 mg/dl (5.3 mmol/l) 1 h \geq 180 mg/dl (10.0 mmol/l) 2 h \geq 155 mg/dl (8.6 mmol/l) 3 h \geq 140 mg/dl (7.8 mmol/l)	Selective
ADA 2011(51)*	One-step	75	FPG \geq 92 mg/dl (5.1 mmol/l) 1 h \geq 180 mg/dl (10.0 mmol/l) 2 h \geq 153 mg/dl (8.5 mmol/l)	Universal
IADPSG 2010 (35)*	One-step	75	FPG \geq 92 mg/dl (5.1 mmol/l) 1 h \geq 180 mg/dl (10.0 mmol/l) 2 h \geq 153 mg/dl (8.5 mmol/l)	Universal
Fifth International Workshop Conference on GDM 2007 (38)**	Two- or one-step	50 (GCT) and 75 OR 100 (OGTT)	GCT: \geq 140 mg/dl (7.8 mmol/l) or \geq 130 mg/dl (7.2 mmol/l) OGTT: FPG \geq 95 mg/dl (5.3 mmol/l) 1 h \geq 180 mg/dl (10.0 mmol/l) 2 h \geq 155 mg/dl (8.6 mmol/l) 3 h \geq 140 mg/dl (7.8 mmol/l)– 3 h only measured for 100 g OGTT	Selective
NICE 2008 (39)*	One-step	75	FPG \geq 126 mg/dl (7.0 mmol/l) 2 h \geq 140 mg/dl (7.8 mmol/l)	Selective

*One or more of the listed values for the OGTT must be found to make a diagnosis of GDM. ** Two or more of the listed values for the OGTT must be found to make a diagnosis of GDM.

articles identified through a literature search in pubmed on barriers to GDM detection, treatment and follow-up, previous reported challenges mentioned by WDF project partners and certain broad issues, e.g. cultural barriers, which required further exploration as little information on these was available in the existing literature. The questions in the interview-guide were mainly open-ended and fairly broad to encourage the respondents' own point of view and not just confirming the views of the researchers, e.g. 'From a health system point of view, what are the main barriers for ensuring early and proper diagnosis and management of women with GDM?'.

The interviews were recorded and transcribed in their full length to ensure transparency, and content analysis was used to analyse the data. The interviews and questionnaires were coded using categories for the different topics that were revealed in the data. The categories were then reviewed by KKN to make sure that no overlapping categories described the same phenomena, and subsequently organised into core themes describing the problems encountered with the screening procedures and diagnostic criteria. In the present paper we report issues related to screening and diagnosis of GDM.

Results

Two of the 11 projects reported that screening and diagnosis of GDM were not a key activity and were excluded. In this paper we report on the experiences from a total of eight project partners implementing nine GDM projects in India, Cuba, Sudan, Cameroon, Kenya and China. The projects are listed in Table 2.

Screening procedures and diagnostic criteria used

Variations in approach to detection and diagnosis of GDM were found among the projects included in this study (Table 3). One project, 06-207 Sudan, uses the non-challenge method recommended by ADA before 2010. The project from Karnataka, India (08-381) uses the two-step approach with 75 g OGTT, but the most widely used test among the WDF supported GDM projects is the one-step challenge test. Thus, five (04-067, 08-312, 09-436, 10-517, 10-551) of the nine projects rely on a one-step challenge test to screen and diagnose GDM. Finally, a fourth approach is also being utilised by the projects in Cuba (06-196) and Cameroon (07-278) and in low resource settings by the project in China (10-517); here pregnant women are subjected to a non-challenge test and depending on the result of the test, women undergo a 75 g OGTT. In Cuba, all abnormal readings are subjected to an OGTT whereas in Cameroon, only women with readings in the borderline area are subjected to an OGTT while women with high glucose levels in the non-challenge test are immediately diagnosed with GDM without having the OGTT performed.

The difference in diagnostic criteria employed by the projects is, however, not only centred on the type of test used, but also on the cut-off values for diagnosis. Further, as illustrated in Tables 1 and 3 some projects follow the procedure from a guideline, but do not necessarily use the exact same cut-off values and vice versa. The project from Cameroon (07-278) for instance does not follow the exact procedure recommended by IADPSG, but it does employ the cut-off values recommended by IADPSG. Moreover, a couple of the projects use cut-off values that are not recommended in any of the listed guidelines.

Selective versus universal screening

Just as there is divergence in the tests and cut-off points recommended by various technical organisations and employed by the WDF projects, there is also disagreement over whom to screen. The most recent, the IADPSG, recommends universal screening, i.e. all pregnant women to be screened for GDM (35). However, the ADA (prior to 2011), the Fifth International Workshop Conference on GDM and the National Institute for Health and Clinical Excellence all recommend that the decision of whom to screen be taken based on risk factor assessment, i.e. selective screening (36–39); thus, only women with one or more of specified risk factors should be offered testing for GDM. Seven of the nine projects, apply universal screening whereas two projects, Kenya (09-436) and Sudan (06-207) only screen pregnant women with one or more risk factors. The risk factors that are assessed are listed in Table 4.

Problems encountered with using recommended screening procedures and diagnostic criteria in low resource settings

Table 5 shows the core themes that address problems encountered with using recommended screening procedures and diagnostic criteria.

Pregnant women do not necessarily attend antenatal care in 24–28th weeks of gestation

The various guidelines listed in Table 1 recommend screening for GDM in the 24th to 28th weeks of gestation. They all also note that efforts, typically in the form of risk assessments, should be made at the first prenatal visit to detect and diagnose potential overt diabetes, i.e. undetected pre-gestational diabetes (35–40). Almost all projects reported that they screen women between the 24th and 28th weeks of gestation or at least that this is what their protocol states. From the interviews it became clear that it is not always possible to screen during this period.

“Most of our mothers attend the antenatal clinic quite late, maybe after the 28th week, and this is something which the department of reproductive health are trying to address by sensitising them to

Table 2. Overview of projects included in review¹

WDF project number	Country	Project title	Implementing partner	Collaborating partners	Project period
04-067	India, Tamil Nadu	<i>Gestational diabetes mellitus – awareness creation, prevention and control in the community</i>	Dr V. Seshiah Diabetes Care and Research Institute	Department of Public Health and Preventive Medicine, Tamil Nadu; The Municipal Corporation of Chennai; Local NGOs and women's self help groups	August 2004– January 2010
06-196	Cuba	<i>Completion of the diabetes and pregnancy services network in all the provincial capitals in Cuba</i>	Instituto Nacional de Endocrinología; Hospital Ginecobstétrico 'Ramón Glez. Coro'	The Maternity and Infant Program; the National Group of Obstetrics and Gynaecology; the National Group of Endocrinology; the National Committee on Diabetes and Pregnancy	August 2007– October 2012
06-207	Sudan	<i>Gestational diabetes mellitus control project</i>	Sudan Fertility Care Association	UNFPA Sudan Country Office; Federal Ministry of Health	June 2007– August 2012
07-278	Cameroon	<i>Improving screening, management, and outcome of gestational diabetes in urban and rural Sub Saharan Africa</i>	Institute of Health and Society, University of Newcastle	Cameroon Burden of Diabetes Project; Ministry of Health	October 2008– August 2012
08-312	India, Tamil Nadu	<i>Extension of project on gestational diabetes mellitus – awareness creation, prevention and control in the community</i>	Dr V. Seshiah Diabetes Care and Research Institute	Centre for Health Education and Development; Department of Public Health and Preventive Medicine, Government of Tamil Nadu	August 2008– July 2012
08-381	India, Karnataka	<i>Addressing gestational diabetes mellitus in a rural and tribal population of Mysore District, India</i>	Swami Vivekananda Youth Movement	Prashasa Health Consultants Pvt Ltd	March 2009– March 2012
09-436	Kenya	<i>Mainstreaming Comprehensive Diabetes Care in Kenya</i>	Ministry of Public Health and Sanitation; The Kenya Diabetes Management and Information Centre	The Kenya Diabetes Association; the Kenya Diabetes Study Group; Kenya Diabetes Educators; the World Health Organization	August 2009– March 2015
10-517	China	<i>China GDM centres – establishment and training dissemination</i>	Peking University First Hospital	Ministry of Health of China; Novo Nordisk (China)	November 2010– August 2013
10-551	India, Punjab	<i>Gestational diabetes in Punjab</i>	Deep Hospital	Jagran Pehel; Sri Rama Charitable Hospital; Iqbal Hospital; Novo Nordisk; Steno Diabetes Center; Health Strategies International; Government Medical Colleges in Patiala, Amritsar and Faridkot; Municipal Corporation in Ludhiana; Department of Health and Family Welfare in Ludhiana; Copenhagen University; University of California, San Francisco	January 2011– April 2013

¹For more information on the projects please see www.worlddiabetesfoundation.org

Table 3. Screening procedure and diagnostic criteria used in the projects

WDF project number	Country	Test used	Cut-off values	Universal or selective	Approximate number of pregnant women screened for GDM
04-067	India, Tamil Nadu	75 g OGTT	<i>Plasma glucose</i> 2 h OGTT \geq 140 mg/dl (7.8 mmol/l)	Universal	12,056
06-196	Cuba	Fasting non-challenge test confirmed by a 75 g OGTT	<i>Plasma glucose</i> Fasting \geq 100 mg/dl (5.6 mmol/l) 2h OGTT \geq 140 mg/dl (7.8 mmol/l)	Universal	25,066
06-207	Sudan	Random non-challenge test	<i>Blood glucose</i> \geq 120 mg/dl (6.7 mmol/l)	Selective	7,551
07-278	Cameroon	Fasting non-challenge test with borderline cases confirmed by 75 g OGTT	<i>Blood glucose</i> Fasting $>$ 92 mg/dl (5.1 mmol/l) Fasting: 80–92 mg/dl (4.4–5.1 mmol/l) \rightarrow OGTT <i>Plasma glucose</i> 1-h OGTT \geq 180 mg/dl (10.0 mmol/l) 2-h OGTT \geq 153 mg/dl (8.5 mmol/l)	Universal	12,000
08-312	India, Tamil Nadu	75 g OGTT (irrespective of fasting or non fasting)	<i>Plasma glucose</i> 2 h \geq 140 mg/dl (7.8 mmol/l)	Universal	12,500
08-381	India, Karnataka	50 g GCT confirmed by 75 g OGTT	<i>Plasma glucose</i> GCT \geq 130mg/dl (7.2 mmol/l) \rightarrow OGTT Fasting \geq 92 mg/dl (5.1 mmol/l) 1 h OGTT \geq 180mg (10.0 mmol/l) 2 h OGTT \geq 153 mg/dl (8.5 mmol/l)	Universal	2,054
09-436	Kenya	75 g OGTT	<i>Plasma glucose</i> Fasting \geq 126 mg/dl (7.0 mmol/l) 2 h OGTT \geq 140 mg/dl (7.8 mmol/l)	Selective	NA
10-517	China	75 g OGTT OR Fasting non-challenge test confirmed by 75 g OGTT	<i>Plasma glucose</i> Fasting \geq 92 mg/dl (5.1 mmol/l) \rightarrow OGTT 1-h OGTT \geq 180 mg/dl (10.0 mmol/l) 2-h OGTT \geq 153 mg/dl (8.5 mmol/l)	Universal	26,459
10-551	India, Punjab	75 g OGTT	<i>Plasma glucose</i> 2-h OGTT \geq 140 mg/dl (7.8 mmol/l)	Universal	1,150

Table 4. Overview of risk factors used for selective screening

	Risk factors which should be determined
<i>WDF project number</i>	
06-207 Sudan	Overweight, obesity, pre-gestational diabetes, family history of diabetes, history of GDM, diagnosis of PCOS, previous baby weighing > 4 kg, history of unexplained stillbirth, history of baby with birth defect, glucosuria, high blood pressure, history of repeated, unexplained abortions.
09-436 Kenya	Age >25 years, BMI > 25 kg/m ² , history of GDM, history of glucosuria, previous baby weighing >4 kg, history of poor obstetric outcome, family history of diabetes, known impaired glucose tolerance, known diabetic fasting glucose, grand multipara.
<i>Organisation</i>	
American Diabetes Association 2003 (36)	Obesity, age >25 years, member of ethnic group with average or high prevalence of GDM, family history of diabetes, history of abnormal glucose tolerance, history of poor obstetrical outcome.
American Diabetes Association 2010 (37)	Obesity, history of GDM, previous baby that was large-for-gestational age, presence of glucosuria, diagnosis of PCOS, family history of type 2 diabetes, age >25 years, member of ethnic group with average or high prevalence of GDM, history of abnormal glucose tolerance, history of poor obstetrical outcome.
Fifth International Workshop Conference on GDM 2007 (38)	Obesity, family history of type 2 diabetes, history of GDM, previous history of impaired glucose metabolism, previous history of glucosuria, age >25 years, low or high birth weight, history of poor obstetric outcome, member of ethnic group with average or high prevalence of GDM.
NICE 2008 (39)	BMI >30kg/m ² , previous baby weighing ≥ 4.5 kg, history of GDM, family history of diabetes, member of ethnic group with high prevalence of diabetes (South Asian, Black Caribbean or Middle Eastern).

come to the clinic as soon as they discover they are pregnant so that they can be followed up and in case of any complication necessary action is taken.”
Respondent from Kenya.

Table 5. Overview of themes that address problems encountered with using recommended screening procedures and diagnostic criteria in low resource settings

Themes	Respondents mentioning/ total number of respondents
Pregnant women do not necessarily attend antenatal care in the 24th to 28th weeks of gestation	4/8
GDM risk factor assessments may not be useful or valid	5/8
Women are not always fasting when they come to the health facility	4/8
Tests are time consuming and may need to be repeated	4/8
Nausea associated with concentrated glucose solution	2/8
Scarcity of test consumables and lack of equipment	4/8

Often pregnant women do not attend antenatal care until late in pregnancy and screening women for GDM in the 24th to 28th weeks and assessing the risk for overt diabetes early on can therefore not always be done. If women do attend antenatal care prior to the 24th week it is not always certain that they will return between the 24th and 28th weeks to have the test performed. To avoid getting encumbered with the challenge of screening women in the 24th to 28th week of pregnancy, some projects (08-312, 07-278) conduct the test whenever women first present for antenatal care regardless of gestational week. Many projects, however, make efforts to create awareness on the need to attend antenatal care in time through community health workers, mass media and other communication channels.

GDM risk factor assessments may not be useful or valid
The majority of projects employ universal screening for GDM because of poor applicability of the risk factors for GDM mentioned in the recommendations. All guidelines listed in Table 4, for instance, list being a member of an ethnic group with average and/or high prevalence of diabetes as a risk factor that should trigger screening for GDM. This in general includes South Asians, black Caribbean, and those of Middle Eastern descent (39). In other words in a number of low and middle income

countries a majority of pregnant women should be screened for GDM because of their ethnicity.

“Most western studies indicate that Indian ethnicity increases the risk for gestational diabetes. Since all our women are of Indian origin by default all of them are at higher risk of GDM.” Respondent from Karnataka, India.

Another issue is the doubtful validity of the risk factors listed in Table 4 in various local contexts that the WDF projects operate in. The project in Cameroon (07-278), for instance, carried out a currently unpublished pilot study of 920 women and found that the risk factors were very weak in picking up women with GDM and thus by using risk factor-based screening a number of women with GDM could not be detected. This finding is supported by statements from other partners as well. Two possible explanations for this are revealed in the interviews. First of all, some projects, especially from India, reported that obesity is not a very good indicator for GDM as many of the Indian women are small and thin yet have high rates of GDM.

“Typically with this risk factor screening we will be missing a lot of women. These women are thin, they are small and low weight, they were not obese but GDM positive, so the BMI does not reflect that much. Nor does the family history because when she says that nobody in her family has diabetes I suspect it is because nobody has been tested, it is not that nobody has. So relying on risk factors is going to be very difficult.” Respondent from Tamil Nadu, India.

The second problem is underreporting of diabetes among first-degree relatives, high birth weight in a previous pregnancy or history of poor pregnancy outcomes. Women are often uncertain of these issues and the pool of undetected diabetes is so high that negative family history is an unreliable marker of lower risk. In Cameroon (as well as other places) it was not only the unreliability of family history of diabetes and previous birth weight as risk markers that were problematic, but also risk factors related to previous pregnancies.

“When you start looking at data on previous pregnancy it is amazing the number of “I don’t know” answers that we had for things like different outcomes of pregnancy or different things that could have happened in the pregnancy that can be used as risk factor for gestational diabetes in the current pregnancy. There were so many “No” or “I don’t know” that the sensitivity of risk factors was not good at all.” Respondent from Cameroon.

Yet, the project partners currently using risk-factor based screening (06-196, 09-207, 09-417) reported they had no difficulties in using them as women in their area in general are able to respond to questions related to risk factor assessment. However the problems with risk factors highlighted above clearly show that they are unreliable.

Projects that reported problems with risk factor assessment for screening decided to take the universal screening approach.

Women are not always fasting when they come to the health facility

Most screening and diagnostic tests require that women should be fasting 8–14 h when undergoing GDM testing. Ensuring that women present for the test in the fasting state is a challenge for many projects.

“We tell them to come in fasting but they do not come fasting, because they typically believe that a pregnant woman should not be fasting for many hours. If she lives really near the health centre and she comes in time – by 7.30 in the morning – that is okay for fasting, I guess. But if she lives far off by the time she reaches the health centre it will be 10.30 in the morning and that means she has been fasting overnight for more than 12 hours and I don’t think she is going to do it. So these women tend to eat something during the travel, so they don’t report to us in the fasting state.” Respondent from Tamil Nadu, India.

Many respondents stated that a significant proportion of women attending antenatal care clinics are not fasting. Due to the belief that a pregnant woman should not be fasting for many hours, they often consume something on the way even if asked to come fasting. Poor access also means that they may not come back soon enough for a repeat visit if asked to come back fasting and the opportunity for testing may be lost. The IADPSG notes that in many settings it can be impractical for the woman to attend in the fasting state, but this is only stated in relation to the first prenatal visit when testing for overt diabetes (35). The issue of women not coming in the fasting state led the project in Karnataka, India (08-381) to use the GCT for screening because this can be done irrespective of the women being fasting.

“Some protocols which recommended fasting glucose screening were hard for us to implement, because it is difficult for us to access women early in the morning in a fasting state. Either they are delayed in getting to the hospital or it is difficult for a health worker to reach their home early in the morning . . . We are doing the 50 g glucose challenge test which is done irrespective of the fasting state, because this is more practical.” Respondent from Karnataka, India.

However, other respondents spoke against the use of the GCT followed by OGTT for diagnosis as this two-step method was considered to be too troublesome compared to the one-step approach and it did not completely eliminate the need for women to be fasting for the second test. The project in Tamil Nadu, India (04-067 and 08-312), has developed another solution to

get around the problem of fasting and refer to their own research having shown that the 75 g glucose solution is a sufficiently large load on carbohydrate metabolism that having had a small meal previously does not make any difference to the results of the 2 h OGTT (41). Accordingly, the project now encourages health care providers to initiate the 2 h OGTT, even if the woman has had breakfast a few hours back. To be free of having to test women in the fasting state, the project has completely skipped measuring fasting plasma glucose. Likewise, the project in Punjab, India (10-551) is also mainly relying on the 2 h OGTT. While agreeing to a more simple approach, the respondent from Cameroon (07-278) additionally demands that GDM diagnostic criteria should be based on postprandial measurements without the need for a glucose challenge. One project (06-207 Sudan) is undertaking random non-challenge tests for both screening and diagnosis and is thus neither relying on the woman coming in a fasting state nor the process of a glucose challenge test. However, the ADA which included this approach in their 2003 guideline (36) no longer recommends this approach (37).

Test are time consuming and may need to be repeated

The amount of time required for the test is another challenge stressed by respondents. Only the non-challenge test does not require women to wait for the test to be completed. All challenge tests involve some degree of waiting after the administration of the glucose solution. Depending on the test it may take up to 3 h from the first, fasting, blood sample to the last sample drawn. Those tested with a one-step approach are subjected to a 2 h wait. Some women find this too long and leave even before the test is completed.

“There is also the issue of time . . . in the case there is someone, who is at risk, and you have to tell them to come, to wait for two hours, and come back and then you repeat the same. It is a challenge to them because they travel a long distance to go to the health facility. Some have to do 20 km to find the nearest health facility because they are scattered around the country. So the challenge is here how to keep the mothers for two hours.” Respondent from Kenya.

The respondent from the projects in Tamil Nadu, India (04-067 and 08-312) stressed the advantage of the one-step approach in comparison to the two-step approach, as the test can be performed in one day. Other projects (06-196, 07-278, 10-517 in low resource areas) are also trying to reduce the number of OGTTs performed to decrease the time and consumables used by only conducting the OGTT on women with abnormal or borderline fasting results. This approach does not save time for women with abnormal or borderline fasting results, but reduces the time spent on the test for women with normal results. In addition to the time spent for the test itself is

the waiting time at the health centre and time spent on transport to and from the health centre.

Nausea associated with concentrated glucose solution

It was also mentioned that drinking the concentrated glucose solution used in the OGTT makes many women nauseous, and some end up vomiting requiring repeat test on another day, thereby highlighting the need to make the solution palatable or reduce/eliminate the need for glucose challenge.

“Sometimes taking glucose may be very nauseating for pregnant mothers, and we don’t have the right sort of preparation for glucose to give to these mothers for eventual testing or the 2 hour glucose tolerance test.” Respondent from Kenya.

Scarcity of test consumables and lack of equipment

Finally, lack of necessary consumables and equipment were mentioned as major challenges.

“When we wanted the government centres also to adopt the testing in their antenatal care we realised that they do not have the consumables like the glucose powder or equipment for biochemical analysis of glucose, and there are frequent power cuts so they were not able to separate the plasma in time.” Respondent from Karnataka, India.

There is both the challenge of having a properly equipped laboratory for analysing the blood samples as well as the challenge of even having the consumables to perform the test, including the glucose solution. Most guidelines recommend measurements of venous plasma glucose, this requires that the necessary laboratory equipment to separate plasma is available at the health centres and trained staff available to perform the test; compared to the alternative use of capillary whole blood, which is typically measured with a glucometer.

To address these issues some projects are relying on or experimenting with measuring glucose in capillary whole blood simply because it is more feasible and gives immediate result. However, glucose levels in capillary whole blood are 10–15% lower than glucose levels in plasma (42, 43) and different values are therefore necessary for measurements in capillary whole blood and venous plasma. Some respondents reported that they therefore use a conversion; yet, this may not be ideal for diagnostic purposes as variation may be too great and unpredictable for the individual person that it may result in misclassification (44).

Furthermore, to address the issue of lack of consumables such as 75 g glucose solution for the OGTT, the respondent from Kenya mentioned that the project is experimenting with substituting glucose with equivalent glucose load from sugar-heavy beverages.

“It is a challenge to have the right 75 grams of glucose in all health facilities. We are trying to see if

we can recommend 300 ml of Sprite. One of the diabetes educators is working on this problem to see if we can deliver an equivalence of the 75 grams of glucose. Sometimes taking glucose may be very nauseating for pregnant mothers and we don't have the right sort of preparation for glucose to give to these mothers for the 2 hour glucose tolerance test.”

Respondent from Kenya.

Discussion

Protocols for screening and diagnostic tests, including their cut off values, are often based on evidence from scientific research carried out by well-resourced academic institutions. While it is necessary to create and define criteria and protocols under optimal conditions, the typical clinical settings in low and middle income countries with poor resources and high disease burden face conditions that are often far removed from these ideal settings. Therefore the feasibility of applying screening procedures and diagnostic criteria becomes questionable. Most guidelines fail to address the need and constraints of low resource settings where the demand for clear simple directions is the greatest. This was also evident in our study of nine WDF supported GDM projects in developing countries; these projects used seven different approaches to screening and diagnosing GDM, reflecting different versions and interpretations of at least six guidelines for screening procedures and diagnostic criteria.

In addition, we identified a number of problems related to the applicability of the major guidelines/recommendations for screening and diagnosing GDM. These include problems with screening women within the recommended time frame, reliability and applicability of the recommended risk factors, difficulties with testing in the fasting state, poor compliance with repeat testing, time consuming nature of the tests, intolerance to high glucose load due to nausea, lack of equipment and scarcity of test consumables at primary care settings.

Studies assessing the importance of risk factors for gestational diabetes have found similar inconsistent results (45). In developing countries the lack of knowledge and poor medical records negate the value of risk factors such as family history of diabetes or a history of adverse pregnancy outcome. The absence of obesity or knowledge of pre-pregnancy weight makes another risk marker redundant. Therefore, the poor applicability reported by many of the projects in this review is not particularly surprising. The IADPSG does not recommend selective screening (35). Yet, limited resources make it desirable to identify methods where the number of blood samples tested can be reduced. Some studies have investigated whether fasting plasma glucose can be used to assist in deciding if the pregnant woman should undertake the OGTT, however, they have shown inconsistent results (46–48). In addition to savings on the number of tests it may also reduce the time spent on

the test for some women. This, however, is difficult to implement as reaching women for testing while they are fasting is in itself a huge challenge.

Yet, given the relevance of maternal hyperglycaemia and GDM to poor pregnancy outcome and higher risk of future diabetes and other cardio-metabolic conditions, screening for GDM needs to be carried out more widely. To accomplish this, an easy to use, economical and reliable point of care screening and diagnostic test is required that can be used in the primary care setting in low resource countries. Until we have such a test, there is a need to develop greater evidence and consensus to simplify current procedures that can be applied in low resource settings. In fact, the issue of applicability is inherent in the key components and requirements for medical screening such as the availability of facilities for diagnosis and treatment and acceptability of the test by the population (49, 50). Currently, as shown in this article, it can be contested whether these requirements are met in low resource settings. Yet, the need for detection, diagnosis and treatment remains, whereby one needs to find a balance between screening procedures and diagnostic criteria with high sensitivity and specificity but low feasibility of application on the one hand against one that has moderate sensitivity and specificity but higher feasibility of use. Far too often the latter loses out in academic discussions at a great loss to public health. It is about time that we address this issue seriously.

Conclusion

While the IADPSG recommendations have tried to unify and simplify the screening procedure and diagnostic criteria for GDM, findings from this study indicate that in the present form, they are still not simple enough and easy to implement in low resource settings. With GDM prevalence rates likely to increase in developing countries there is an urgent need to establish screening procedures and diagnostic criteria for GDM which are simple, clearly understandable, feasible and offer options that can be used in different settings at the point of care. So while an international consensus on the screening procedures and diagnostic criteria for GDM is welcome it is imperative that such procedures and criteria are applicable in low resource settings to ensure wide usage. In other words, we need to move away from research focusing purely on sensitivity and specificity to testing the evidence in correlation with what can actually be achieved at the basic care level.

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