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Original Research Article

Modification of WHO diagnostic criteria for gestational diabetes: implications for classification of hyperglycemia in pregnancy

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ABSTRACT

Background: Low and medium income countries (LMICs) especially in sub-Saharan Africa face unique challenges in screening and diagnosing hyperglycaemia in pregnancy. The implications of applying the 2013 WHO modifications for assessing hyperglycaemia in pregnancy in low resource settings are not known. We evaluated the significance of these recent changes in classification of hyperglycaemia among pregnant Nigerian women.

Methods: We reviewed the records of Oral glucose tolerance test conducted on 600 pregnant women at the Jos University Teaching Hospital (JUTH) between July 2012 and June 2016. The collected data were analyzed using Statistical Package for Social Sciences version 18 (SPSS Inc., Chicago, IL, USA). Test for association was done using Fisher's exact test. $P < 0.05$ was set as the level of significance.

Results: The results show that 15.9%, 20.2% and 15.7% of the women had GDM according to WHO (1999), IADPSG and WHO (2013) diagnostic criteria respectively while 4.8% of the women had DM in pregnancy by WHO 2013 criteria. Overall, 30.2% and 23.9% of women who were classified as GDM by WHO 1999 criteria and IADPSG criteria respectively were qualified to be classified as DM in pregnancy according to the WHO 2013 criteria.

Conclusions: The recent Modifications by the WHO 2013 guideline for classifying hyperglycemia in pregnancy may create non-uniform interpretation of OGTT. The confusion in classifying hyperglycemia among pregnant women referred between health centres may become more pronounced. There is an urgent need for a streamlined globally acceptable approach to assessing and classifying hyperglycemia in pregnant women.

Keywords: Gestational diabetes mellitus (GDM), Oral glucose tolerance test, Risk factors for GDM, Universal screening, WHO Criteria

INTRODUCTION

Gestational Diabetes Mellitus (GDM) is the most common form of hyperglycaemic disorders in pregnancy. GDM and other forms of hyperglycaemia in pregnancy is associated with increased risk of maternal and foetal complications.^{1,2} The incidence of GDM and diabetes in

pregnancy is increasing globally in tandem with the global rise in obesity and type 2 diabetes mellitus (T2DM).³

Unfortunately, the highest rise in the incidence of obesity, diabetes and other non-communicable diseases are expected to occur in low and medium income countries (LMICs) especially in sub-Saharan Africa.^{3,4} This

portends grave implications for the prevalence of GDM and diabetes in pregnancy in Nigeria as in other LMICs with large population of women in the reproductive age group. This maternal health challenge is compounded by poor health infrastructure that characterizes LMICs.

One of the difficulties of managing GDM and hyperglycaemia in pregnancy is the absence of local guidelines backed by evidence from local studies. Indeed, the global perspective of assessing or classifying hyperglycaemia in pregnancy is rather chaotic. There is an obvious lack of consensus on the criteria for diagnosing GDM.^{5,6} There are also several other contentious issues on diagnosis of GDM including but not limited to: the appropriate glucose load, number of time points and the ideal time for screening/diagnosis.⁶

Although there are genuine efforts attempting to harmonize the diagnostic criteria, these efforts have been

undermined by sparse localized studies to validate suggested diagnostic criteria.^{7,8} The result is that classification of hyperglycaemia in pregnancy has been left to the discretion of practicing physicians and obstetricians who often rely on recommendations by local diabetic or obstetric associations.⁵

The 1999 version of World Health Organization's (WHO) criteria has been widely used in Nigeria due to the absence of a national consensus for screening and diagnosis of GDM or hyperglycaemia in pregnancy.^{6,9,10}

However, in 2013, WHO revised its recommendations for classifying hyperglycaemia taking into cognizance the issues raised by the International Association of Diabetes in Pregnancy Study Groups (IADPSG) recommendations.¹¹⁻¹³ The WHO 2013 modifications along with common diagnostic criteria for GDM are summarised in table 1 below.

Table 1: Diagnostic criteria for GDM.

Criteria	Glucose Load	Glucose threshold (mmol/L)			
		Fasting glucose	1 hour glucose	2 hour glucose	3 hour glucose
WHO (1999)	75g	≥7.0		≥7.8	
WHO (2013) GDM	75g	5.1-6.9	10.0	8.5-11.0	
WHO (2013) DM in pregnancy	75g	≥7.0		≥11.1	
IADPSG*	75g	≥5.1	10.0	≥8.5	
NICE** ¹⁴	75g	≥5.6		≥7.8	
Canadian Diabetes Association ¹⁵	75g	≥5.3	10.6	≥8.9	
Carpenter and Coustan *** ¹⁶	100g	≥5.3	10.0	≥8.6	≥7.8
National Diabetes Data Group*** ¹⁷	100g	≥5.8	10.6	≥9.2	≥8.0

*International Association of Diabetes in Pregnancy Study Groups (IADPSG)- Adopted by several organisations including American Diabetes Association (ADA)¹⁸, **NICE- National Institute for Health and Care Excellence, ***Carpenter and Coustan; National Diabetes Data Group (NDDG)- Adopted by the American College of Obstetrics and Gynaecology (ACOG).¹⁹ ***Carpenter and Coustan; National Diabetes Data Group (NDDG) require 2 or more abnormal values for diagnosis, the others require 1 or more abnormal value(s) for diagnosis.

The 2013 WHO guidelines made allowance for one hour post glucose load and reduced the cut-off of fasting glucose and increased the cut-off of two-hour glucose. Furthermore, the 2013 modification capped the degree of glucose intolerance that can be classified as GDM and introduced the concept of overt diabetes in pregnancy. In effect, the WHO reclassified hyperglycaemia in pregnancy as: either GDM or overt Diabetes in pregnancy.

LMICs face unique challenges in screening for hyperglycaemia in pregnancy.²⁰⁻²² The implications of applying the 2013 WHO modifications on the prevalence of GDM, the management of hyperglycaemia and the resulting pregnancy outcome is not known. The capacity for adopting and managing the consequences of implementing the new WHO guidelines is critical for health care services all over the world and particularly in

LMICs with very limited resources for screening and treatment. Local approaches for diagnosing and monitoring of major non-communicable diseases and their risk factors have been encouraged.^{23,24}

Consequently, the burden of hyperglycaemia in pregnancy will need to be evaluated by local health services to determine the best strategy for testing and treating hyperglycaemia in pregnancy. In this study, we reviewed the records of women screened for GDM in our centre to evaluate the significance of these recent changes in classification of hyperglycaemia among pregnant Nigerian women.

METHODS

The records of Oral glucose tolerance test conducted on pregnant women at the department of chemical pathology

of Jos University Teaching Hospital (JUTH) between July 2012 and June 2016 were reviewed. A total of 600 records were reviewed. After excluding all cases of repeat testing and missing records, 540 cases were studied.

The study population consisted of women at various gestational age who were referred for diagnostic Oral glucose tolerance test (OGTT). Referral for OGTT was generally prompted by presence of one or more risk factors for GDM. However, some Obstetric units in JUTH practice universal screening. The study population thus reflects the full spectrums of GDM risk factors (from absent risk factors to multiple risk factors), glucose tolerance in pregnancy (from normal to mildly abnormal to GDM) and gestational age at testing (from early first trimester to late third trimester).

Data obtained from the records included age, gravidity and gestational age at testing (from last menstrual period, or ultrasonography), weight, height and blood pressure. Information regarding risk factors for GDM such a history of DM in first degree relatives, previous fetal macrosomia, maternal obesity (>90 kg) and previous intrauterine fetal death, previous GDM, which were obtained at testing.

The relevant clinical examinations and medical, obstetrical or family history pertaining to GDM risk factors were obtained at the time of OGTT prior to determination of glucose tolerance status. All OGTTs were performed in the morning after overnight fast, with venous blood samples drawn for the measurement of serum glucose at 0 hour, 1 hour and 2 hours post 75g glucose load. Glucose measurement was carried out on comparable assay methods on Roche Hitachi 902, Cobas C111 and Reflotron analyzers during the period under review. Following OGTT, the women were classified as normal glucose Tolerance (NGT), GDM or diabetes in pregnancy (DM) based on existing diagnostic criteria see table 1 above.

The collected data were compiled, tabulated, and analyzed using Statistical Package for Social Sciences version 18 (SPSS Inc., Chicago, IL, USA). Test for association was done using Fisher's exact test. P <0.05 was set as the level of significance.

Institutional review board statement: This study was reviewed and approved by the Ethics Committee of the Jos University Teaching Hospital.

Informed consent statement: This study used anonymous clinical data that were obtained from patient's medical records after obtaining due approval from the Ethics Committee of the Jos University Teaching Hospital.

RESULTS

The study consists of 540 women with mean (SD) age of 31.4±5.2 years, 27.6% of whom are 35 or more years old.

The mean EGA at testing was 27.5 weeks. About 11% of the women were tested in the first half of pregnancy. Most of the women were tested within the conventional 24-28 weeks of pregnancy (42%) or >28 weeks (41.7%). About 10.8% of the women were grand-multiparous. More than three-quarters of the women had at least one risk factor for GDM while almost one quarter of the women had no risk factors. The mean glucose levels and anthropometric parameters are shown in Table 2.

Table 2: General characteristics of the participants.

Variable	Frequency (%), Mean±SD
Age (Years)	31.4±5.2
<35	371 (72.4%)
≥35	149 (27.6%)
EGA at testing (weeks)	27.5±6.1
≤20	61 (11.3%)
<24	88 (16.3%)
24-28	227 (42.0%)
>28	225 (41.7%)
Parity	
0	96 (17.8%)
1-4	386 (71.4%)
≥5	58 (10.8%)
Risk Factors	
One or more	411 (76.1%)
None	129 (23.9%)
Biochemical Indices	
0 hour glucose (mmol/L)	4.3±1.1
1 hour glucose (mmol/L)	7.1±2.5
2 hours glucose (mmol/L)	6.4±2.2
Anthropometric Indices	
Weight	81.9±17.3
Height	1.6 ±0.1

Data for continuous variables are mean±SD; Categorical variables are presented as percentages

Table 3 shows the OGTT time points and their interactions for the diagnosis of GDM/DM in pregnancy according to WHO (1999), IADPSG and WHO (2011) diagnostic criteria. The results show that 15.9%, 20.2% and 15.7% of the women had GDM according to WHO (1999), IADPSG and WHO (2013) diagnostic criteria respectively. Also, 4.8% of the women would have been diagnosed of DM in pregnancy by WHO 2013 criteria.

Using fasting glucose cut-off, 15.9% and 13.7% of women meet the criteria for GDM by IADPSG and WHO (2013) diagnostic criteria whereas only 2.2% were diagnosed of GDM by WHO 1999 criteria. Using 1hr glucose alone, 10.6% of women were diagnosed as GDM in both the IADPSG and WHO (2013) diagnostic criteria.

The proportion of women who met the 2hr glucose cut-off was much lower with the IADPSG and WHO (2013) diagnostic criteria; 11.9% and 7% respectively. However, it was higher with the WHO 1999 criteria (15.9%). The

proportion of women that met cut-off of two time points (depending on the combination of time points) ranged from 8.0%-8.7% by the IADPSG and 4.1% -5.9% by

WHO (2013) diagnostic criteria. Only 7.2 % and 2.8% of the women met all three time points cut-off for IADPSG and WHO (2013) diagnostic criteria respectively.

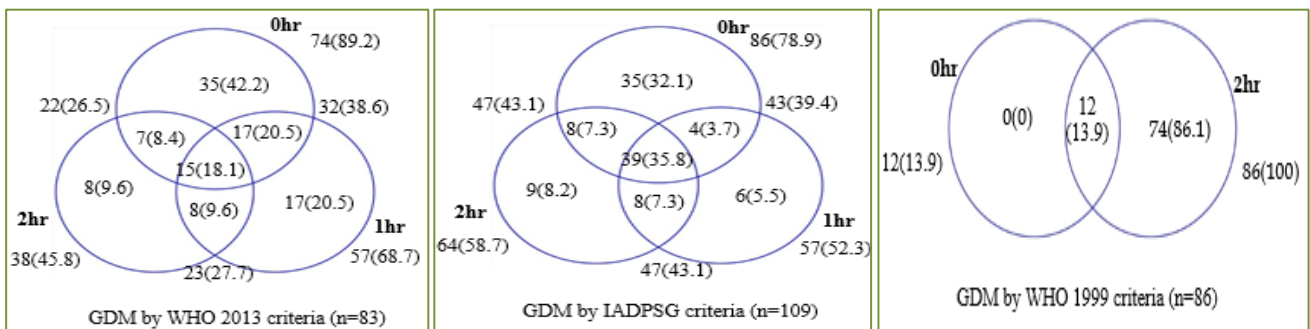
Table 3: OGTT- time points meeting GDM/DM criteria across all gestational age (n=540).

OGTT-Time points meeting GDM/DM criteria (hour)	WHO (1999) criteria	IADPSG criteria	WHO (2013) criteria	
			GDM	DM in pregnancy
0	12 (2.2%)*	86 (15.9%)	74 (13.7%)	12 (2.2%)
1	N/A	57 (10.6%)	57 (10.6%)	N/A
2	86 (15.9%)	64 (11.9%)	38 (7.0%)	26 (4.8%)
0 and 1	N/A	43 (8.0%)	32 (5.9%)	N/A
0 and 2	13 (2.4%)	47 (8.7%)	22 (4.1%)	13 (2.4%)
1 and 2	N/A	47 (8.7%)	23 (4.3%)	N/A
0,1 and 2	N/A	39 (7.2%)	15 (2.8%)	N/A
0 only	0	35 (6.5%)	35 (6.5%)	0
1 only	N/A	6 (1.1%)	17 (3.1%)	N/A
2 only	74 (13.7%)	9 (1.7%)	8 (1.5%)	0
GDM	86 (15.9%)	109 (20.2%)	83 (15.4%)	-
DM in pregnancy	N/A	N/A	-	26 (4.8%)

* Percentages of all subjects (n=540); N/A: Not applicable

In Figure 1, fasting glucose was the most frequently met criteria for GDM/DM followed by 2hr glucose (Note that 26 women were diagnosed as DM in pregnancy by 2hr

glucose in WHO 2013 criteria, see table 2). Using the WHO 1999 GDM criteria, all the women who were diagnosed of GDM met the 2hours cut-off. Also, all who met the fasting cut-off also met the 2 hours cut-off.



* Percentages of GDM subject

Figure 1: Venn diagram showing Interaction of OGTT time points for the GDM diagnosis.

Using fasting glucose alone for diagnosis would have excluded 86.1%, 21.1% and 10.8% of women diagnosed as GDM using the WHO 1999, IADPSG and WHO 2013 criteria. Although the absolute number of women that met the 1 hour cut-off remained were the same (57), the relative proportion of women who diagnosed of GDM by meeting the 1 hour cut-off alone increased from 5.5% in the IADPSG criteria to 20.5% in the WHO 2013 criteria.

In Table 4, the proportion (percentage) of GDM (WHO 1999) and GDM (IADPSG) that meet the criteria for DM

in pregnancy (WHO 2013) is depicted across gestational age at OGTT. Overall, 30.2% of women who were classified as GDM by WHO 1999 criteria were qualified to be classified as DM in pregnancy according to the WHO 2013 criteria. Also, 23.9% of women who were classified as GDM by IADPSG criteria were qualified to be classified as DM in pregnancy according to the WHO 2013 criteria. The proportion is particularly higher in the first half of pregnancy where as much as one-third to half of the women diagnosed as GDM would have been classified as DM in pregnancy. Table 5 shows that there

was no significant association between GDM risk factors and GDM diagnosed by “IADPSG” the current WHO

(2013) criteria or even DM in pregnancy according to WHO 2013 criteria (P>0.05).

Table 4: Proportion (percentage) of GDM (WHO 1999) and GDM (IADPSG) that meet criteria for DM in pregnancy (WHO 2013).

	GDM (WHO 1999)	GDM (IADPSG)	GDM (WHO 2013)	DM in Pregnancy (WHO 2013)	% of GDM (WHO 1999 that meet DM in pregnancy criteria (WHO 2013)	% of GDM (IADPSG) that meet DM in pregnancy criteria (WHO 2013)
All subjects	86	109	83	26	26/86 (30.2)	26/109 (23.9)
≤ 20	8	12	8	4	4/8 (50)	4/12 (33.3)
< 24	15	19	15	4	4/17 (23.5)	4/19 (21.1)
24-28	24	41	35	6	6/24 (25)	6/41 (14.6)
>28	45	49	35	14	16/45 (35.6)	16/49 (32.7)

However, there was significant association between having GDM risk factors and being diagnosed with GDM by WHO 1999 criteria [P=0.008; OR= (1.2-4.7)]. Also, 12.8% to 25.1% of women with GDM (depending on diagnostic criteria) do not have any risk factors.

Table 5: Association of GDM and risk factors for GDM using Fisher’s Exact Test.

	Risk factor	No risk factor	p-value	Odd ratio
GDM (WHO 1999)	75 (87.2)	11 (12.8)	0.008	2.4 (1.2-4.7)
NGT (WHO 1999)	336 (74)	118 (26)		
GDM (IADPSG)	88 (80.7)	21 (19.3)	0.258	1.4 (0.8-2.4)
NGT (IADPSG)	323 (74.9)	108 (25.1)		
GDM (WHO 2013)	65 (78.3)	18 (21.7)	0.579	1.2 (0.7-2.1)
NGT (WHO 2013)	323 (74.9)	108 (25.1)		
DM (WHO 2013)	23 (88.5)	3 (11.5)	0.158	2.6 (0.6-8.5)
NGT (WHO 2013)	323 (74.9)	108 (25.1)		

NGT- Normal Glucose Tolerance

As much as a quarter of the women with GDM by WHO 2013 criteria do not have any risk factors. This fraction is lower with IADPSG criteria (about 1/5th)) and much lower with WHO 1999 criteria (about 1/8th). About 11.3% of women with diabetes in pregnancy do not have any risk factors.

DISCUSSION

The findings from this study show that GDM is common in Nigerian pregnant women particularly those with at

least one risk factor(s) for GDM. As much as 20% of women who underwent diagnostic OGTT were classified as GDM by the IADPSG criteria. This is consistent with previous reports from our centre and in tandem with the projection by the ADA.⁷

In spite of the WHO 1999 criteria having a lower 2-hours cut-off than the IADPSG criteria (7.8mmol/L vs 8.5mmol/L), the prevalence of GDM by IADPSG criteria was higher than the WHO 1999 with almost 5%. This difference therefore is mostly due to very low fasting glucose cut-off of IADPSG compared to the WHO1999 criteria (5.1mmol/L vs 7 mmol/L). The 1-hour cut-off introduced in the IADPSG criteria only contributed 5.5% to the diagnosis of GDM by IADPSG (in exclusion of fasting and 2-hours glucose cut-off). The fasting glucose on the other hand contributed 32.1% (in exclusion of 1 hour and 2-hours glucose cut-off).

In the light of current available data, the non-evidence-based diagnostic criteria for hyperglycemia in pregnancy recommended by the World Health Organization (WHO) in 1999 needed to be updated.¹¹ The modifications in the WHO 2013 criteria followed systematic reviews and aimed at aligning the diagnosis of GDM to the recommendations from the landmark Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study and therefore the ensuing IADPSG criteria.^{13,25} The WHO recommendation in 2013 however raised the concern that the definition of GDM included a wide range of glucose abnormalities such as Diabetes mellitus and impaired glucose tolerance (IGT) or impaired fasting glucose (IFG) as defined in non-pregnant adults and this has implications for management during and after pregnancy.

The WHO 2013 guideline therefore favoured a demarcation between diabetes and lesser degrees of glucose tolerance in pregnancy. Therefore, hyperglycemia first detected at any time during

pregnancy should be classified as either Diabetes mellitus in pregnancy or Gestational diabetes mellitus. In effect, the WHO 2013 criteria placed a ceiling on the IADPSG criteria for diagnosis of GDM so that women above this glucose upper limit were classified as diabetes mellitus in pregnancy rather GDM.

The study records, taking into account the current WHO 2013 guidelines, shows that 15.4% of all women reviewed had GDM this is similar to the prevalence by WHO 1999 criteria (15.9%) but almost a 5% reduction from the prevalence using the IADPSG criteria. It is also crucial to note that the balance represented women who had diabetes mellitus in pregnancy. To put it in another form, almost 5% of the women who would have been classified as GDM actually had Diabetes in pregnancy. The study records also show that as much as one-third to half of GDM diagnosis by the IADPSG and WHO 1999 criteria in the first half of pregnancy actually met the definition of DM in pregnancy as proposed by the WHO 2013.

Although we did not review the management of these patients, it is likely that a diagnosis of DM in pregnancy rather than GDM would have influenced the management strategy and may have impact on the pregnancy outcome.

Modification of the WHO 1999 to the 2013 criteria has given more prominence to the fasting glucose due to increased sensitivity of diagnosing GDM. Many centres still use the WHO 1999 criteria. In resource limited rural settings such as in LMICs, due to constraint in resources for testing, the use of fasting glucose (usually readings from glucometers) is quite common.^{23,24}

The inherent danger in this is highlighted in this study. Using fasting glucose alone for diagnosis of GDM by WHO 1999 criteria would exclude 86.1%. This can be explained by the high fasting glucose cut-off. In the IADPSG and WHO 2013 criteria as much as one in five (23/109) women would be misclassified as normal glucose tolerant if fasting glucose only is used. Although this misclassification rate in the IADPSG and WHO 2013 criteria is much reduced compared to using WHO 1999 criteria, it is worrisome that almost 40% (9/23) of those that would be misclassified actually had more severe glucose intolerance (DM in pregnancy in the WHO 2013 criteria). This may have potentially adverse consequences on maternal and fetal morbidity and mortality.

Furthermore, having at least one risk factor for GDM was significantly associated with increased odds for GDM by WHO 1999 criteria. There was however no significant association between risk factors and GDM or DM either by the IADPSG criteria or the WHO 2013 criteria. In fact, one in five of GDM women diagnosed by IADPSG criteria do not have any risk factors. Also about a quarter of all women diagnosed as GDM and more than 10% of women diagnosed as DM by the WHO 2013 criteria would be missed if they were screened only on the basis

of having GDM risk factors. This is critical for many centres in Nigeria and other LMIC countries who practice selective screening due to resource constraints.

Although the WHO 2013 criteria attempted to streamline the diagnosis of hyperglycemia in pregnancy in line with IADPSG recommendation, it would appear that the upward review of the 2-hour cut-off (from 7.8mmol/L to 8.5mmol/L) may have lost some sensitivity for GDM diagnosis. In this study, the 2-hour cut-off was the most sensitive for the WHO 1999 criteria. All women diagnosed with GDM by WHO1999 criteria met the 2-hour cut-off (sensitive=100%). By contrast the sensitivity of 2-hour glucose for diagnosis of GDM was 58.7% and 45.8% for the IADPSG and the WHO 2013 criteria respectively.

There has been concerns about the impact of the low fasting glucose cut-off (5.1mmol/L) on increasing the rate of diagnosis of GDM.^{7,26} The fasting glucose alone contributed to 32.2% and 42.2% of the diagnosis of GDM by the IADPSG and the WHO 2013 criteria respectively. By contrast a high fasting glucose cut-off of 7.0 mmol/L did not contribute at all to the diagnosis of GDM by WHO criteria. This suggest that although a fasting value of 7.0 mmol/L may be too high, 5.1 mmol/L should be considered too low with a tendency to high false positive rate.^{7,26}

In a recent publication, we canvassed for a combination of WHO (1999) and IADPSG criteria as a risk stratification tool for predicting adverse pregnancy outcome due to hyperglycemia in pregnancy.²⁷ We showed that women who met both criteria were more likely to have adverse pregnancy outcome than women who met only one of either criteria. Women who met only the IADPSG criteria were the least likely to have adverse outcome.²⁷

This study reinforces our notion that the weak association of adverse outcome with IADPSG-alone diagnosed GDM was due to a possible high false positive rate due mainly to the low fasting cut-off value. The current WHO 2013 guidelines may have incorporated this weakness in the classification of hyperglycemia in pregnancy. An appropriate cut-off may be close to the NICE value of 5.6 mmol/L.¹⁴ Almost 60% (43/74) of those who met the fasting cut-off in the current WHO (2013) criteria had fasting glucose between 5.1 mmol/L and 5.6 mmol/L. However, the clinical significance of any adjustment would however have to be confirmed taking into consideration the effect on pregnancy outcome. This should be a focus for future studies.

CONCLUSION

The recent Modifications by the WHO 2013 guideline for classifying hyperglycaemia in pregnancy has thrown up a unique challenge in the health care settings in Nigeria and other LMICs occasioned by the lack of consensus on the

appropriate diagnostic criteria to use. As aptly described by Agarwal, very commonly in LMICs this disparity is obvious between hospitals or centres and even within units in a hospital.⁵ Lack of uniform interpretation of OGTT coupled with varying treatment protocols among units within a given hospital may have potentially disastrous consequences. Also, the confusion in classifying hyperglycaemia among pregnant women referred between health centres is likely to become more pronounced unless a uniform diagnostic guideline is adopted. This study therefore underscores the urgent need for a streamlined global approach for assessing and classifying hyperglycaemia in pregnant women.

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