

Diagnosing gestational diabetes mellitus: implications of recent changes in diagnostic criteria and role of glycated haemoglobin (HbA1c)

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ABSTRACT

Gestational diabetes mellitus (GDM; approximately 5% of pregnancies) represents the most important risk factor for development of later-onset diabetes mellitus. We examined concordance between GDM diagnosis defined using the original 1999 World Health Organization (WHO) criteria and the more recent 2013 WHO criteria and 2015 National Institute for Health and Care Excellence (NICE) criteria. We studied two groups: a case-control group of 257 GDM positive and 266 GDM negative cases, and an incident cohort 699 GDM positive and 6,231 GDM negative cases. In the incident cohort, GDM prevalence was 3.7% (WHO 1999 criteria), 11.4% (NICE 2015 criteria) and 13.7% (WHO 2013 criteria). Our results showed that a significant number of additional cases are detected using the more recent NICE and WHO criteria than the original 1999 WHO criteria, but these additional cases represent an intermediate group with 'moderate' dysglycaemia (abnormal blood glucose levels). Our results also show that use of these newer criteria misses a similar group of intermediate cases that were defined as GDM by the 1999 WHO criteria and that glycated haemoglobin in isolation is unlikely to replace the oral glucose tolerance test in GDM diagnosis.

KEYWORDS: Clinical guidelines, concordance, gestational diabetes mellitus, glycated haemoglobin, HbA1c, NICE, World Health Organization

Introduction

Identification of type 2 diabetes mellitus (T2DM) in high-risk groups is a UK Diabetes National Service Framework priority.¹

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Gestational diabetes mellitus (GDM) represents the single largest risk factor for future development of full T2DM. It affects around 5% of pregnancies and is particularly prevalent in high-risk groups (eg overweight/obesity, family history of diabetes, previous large-for-gestation babies, non-Caucasian ethnicity).² In women with GDM, 35–60% will develop T2DM within 10–20 years after the index pregnancy.^{3–6} Furthermore, children born to mothers with GDM have an increased risk of obesity and abnormal glucose tolerance, both of which are established risk factors for the development of T2DM later in life.^{2,7} Therefore, accurate and early assessment of glycaemic status during pregnancy is not only essential in identifying dysglycaemia for antenatal management, but is equally important in facilitating targeted follow-up and proactive intervention in this young, generally healthy population.

In 2013, the World Health Organization (WHO) produced updated guidelines for the diagnosis of GDM.⁸ These replaced earlier recommendations from the WHO that were published in 1999⁹ and, by their own admission, were not evidence-based.⁸ The 2013 WHO guidelines draw on the conclusions of the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study (and follow the recommendations of the International Association of Diabetes and Pregnancy Study Groups (IADPSG)),^{10,11} focusing on cut-offs for screening for GDM based on pregnancy outcomes. While these guidelines aimed to provide a more evidence-based consensus to GDM screening, there remain some concerns about their impact on services, including whether the additional women identified using this approach include a number of women with 'mild GDM' whose pregnancy outcomes might not warrant the additional burden of this approach to screening.¹² In 2015, the UK National Institute for Health and Care Excellence (NICE) issued separate recommendations, which sought to take into account recent publications examining the potential impact of the 2013 WHO guidance.¹³

An additional factor is the rising use of glycated haemoglobin (HbA1c) as a diagnostic tool following the publication of the WHO criteria for the diagnosis of T2DM.¹⁴ The role of HbA1c in pregnancy is more challenging, not least because traditional cut-offs may not be appropriate given the physiological changes that occur during pregnancy, including increased erythrocyte turnover.¹⁵ However, its ease of use compared with the standard oral glucose tolerance test (OGTT) makes it an attractive alternative, at least as an initial screening tool.¹⁶

In this study, we aimed to assess the impact of the new 2013 WHO and 2015 NICE guidelines on the diagnosis of GDM in a large UK teaching hospital. We examined concordance between the 1999 WHO, 2013 WHO and 2015 NICE criteria, and explored the characteristics of the discordant cases. We also assessed the potential of HbA1c as an initial screening tool.

Methods

Patients

The evaluation examined two groups of pregnant women. The first group represented a case-control study consisting of 605 pregnancies in 528 women (mean age 29.7 ± 5.8 years) at high risk of GDM recruited from the University Hospital of North Midlands between January 1999 and March 2007. Antenatal OGTT data was available for 523 of these pregnancies. Using locally-derived criteria in use at the time (a modified version of the 1999 WHO criteria, OGTT cut-offs: fasting ≥ 6.1 mmol/L, 2-hour ≥ 7.8 mmol/L) comprised 257 cases with confirmed GDM by OGTT and 266 controls with normal baseline and 2-hour OGTT results.

The second group comprised a cohort of 6,930 incident pregnancies in women (mean age 28.5 ± 5.6 years) identified from clinical biochemistry laboratory records at the University Hospital of North Midlands for whom OGTT was performed to test for GDM between February 2010 and December 2013. These consisted of 5,246 requested by GPs, 48 hospital inpatients, 1,626 who attended outpatient antenatal clinics and 10 of unknown source. Using the same criteria as above, these comprised 699 cases with confirmed GDM by OGTT and 6,231 with normal baseline and 2-hour OGTT results.

Data were collected as part of audits of current practice against the guidance; therefore, ethics approval and informed consent was not required.

Oral glucose tolerance testing

As per standard practice, antenatal OGTTs were performed using a 75 g glucose load with plasma glucose measurements at baseline (0 minutes) and 2 hours post glucose load. A baseline sample for HbA1c was also routinely collected.

Definitions of GDM and categorisation of HbA1c measurements

For the purposes of the comparisons, GDM was defined using three approaches (Table 1):

- 1 the original 1999 WHO criteria⁹
- 2 the revised 2013 WHO criteria⁸
- 3 the 2015 NICE criteria.¹³

Patients were then categorised into four subgroups based on these criteria:

- 1 normal baseline/normal 2-hour results
- 2 raised baseline/normal 2-hour results
- 3 normal baseline/raised 2-hour results
- 4 raised baseline/raised 2-hour results.

HbA1c measurements were categorised using the WHO cut-off of 42 mmol/mol (6.0%).¹⁴

Table 1. Definitions of gestational diabetes mellitus

	1999 WHO criteria	2015 NICE criteria	2013 WHO criteria
Baseline (fasting) plasma glucose, mmol/L	≥ 7.0	>5.6	≥ 5.1
and/or 2-hour plasma glucose, mmol/L			
	≥ 7.8	≥ 7.8	≥ 8.5

*2013 WHO criteria baseline and 120-minute values only

NICE = National Institute for Health and Care Excellence; WHO = World Health Organization

Statistical analysis

Statistical analyses were performed using Stata (version 12, Stata Corporation, College Station, Texas, USA). Fisher's exact tests were used to compare classification groups using the different criteria. Comparison of median HbA1c concentrations between groups was performed using the Mann-Whitney U test while Chi-squared tests were used to compare proportions of cases with an HbA1c ≥ 42 mmol/mol ($\geq 6.0\%$) between categories.

Results

Comparisons between criteria for GDM diagnosis

We first examined the effect of the different GDM diagnostic criteria on the classification of cases within the case-control group (Table 2A) and cohort study group (Table 2B), using the four subgroups we defined.

As expected, compared with the original 1999 WHO criteria, the 2015 NICE criteria increased the proportion of cases in subgroups 2 and 4 ($\chi^2_3=91$; $p<0.001$) in the case-control group (Table 2A). Comparisons between the 2015 NICE criteria and the 2013 WHO criteria also showed significant differences, with the latter identifying more cases in subgroups 2 and 4, but less in group 3 ($\chi^2_3=69$; $p<0.001$). Compared with the 1999 WHO criteria, the revised 2013 WHO criteria had a more marked impact on the distribution ($\chi^2_3=235$; $p<0.001$). However, the overall number of cases defined as GDM (subgroups 2–4) were similar across the three criteria (1999 WHO = 47.8%, 2015 NICE = 55.4%, 2013 WHO = 49.7%).

As expected, the proportion of GDM positive cases (subgroups 2–4) was much lower in the cohort study group than the case-control study group (Table 2B). In the case-control study group, the distribution across the four subgroups was more similar when classified by the 2015 NICE criteria ($\chi^2_3=202$; $p<0.001$) than the 2013 WHO criteria ($\chi^2_3=867$ $p<0.001$) when compared with the 1999 WHO criteria. Overall, there were 3.7 times the number of GDM positive cases when classified by the 2013 WHO criteria (13.7%) than the 1999 WHO criteria (3.7%: $\chi^2_1=53$, $p<0.001$), with the 2015 NICE showing a prevalence similar to that when using the 2013 WHO criteria (11.4%).

Concordance between criteria

We next examined the concordance between the criteria in the definition of GDM. These are described firstly for the

Table 2. Comparison of criteria for classifying gestational diabetes mellitus (GDM)**A – Case control study**

			1999 WHO criteria, n(%)	2015 NICE criteria, n(%)	2013 WHO criteria, n(%)
GDM negative	Subgroup 1 (normal baseline/normal 2-hour results)	275 (52.2)	233 (44.6)	263 (50.3)	
GDM positive	Subgroup 2 (raised baseline/normal 2-hour results)	6 (1.1)	47 (9.0)	109 (20.8)	
	Subgroup 3 (normal baseline/raised 2-hour results)	228 (43.6)	163 (31.2)	65 (12.4)	
	Subgroup 4 (raised baseline/raised 2-hour results)	14 (2.7)	79 (15.1)	86 (16.4)	
B – Cohort study					
GDM negative	Subgroup 1 (normal baseline/normal 2-hour results)	6,257 (96.3)	6,138 (88.6)	5,983 (86.3)	
GDM positive	Subgroup 2 (raised baseline/normal 2-hour results)	11 (0.2)	130 (1.9)	564 (8.1)	
	Subgroup 3 (normal baseline/raised 2-hour results)	625 (9.0)	493 (7.1)	194 (2.8)	
	Subgroup 4 (raised baseline/raised 2-hour results)	37 (0.5)	169 (2.4)	189 (2.7)	

*2013 WHO criteria classification based on baseline and 120-minute values only

case-control study group (Table 3A–C) and then for the cohort study group (Table 3D–F).

Table 3A shows that, in the case-control study group, there was high concordance between the 1999 WHO criteria and the 2015 NICE, with only 42 additional patients being classified with GDM by the 2015 NICE criteria. These cases had a median HbA1c (36 mmol/mol); this is more similar to those classified as GDM positive by both criteria (37 mmol/mol) than those classified as GDM negative (30 mmol/mol).

Table 3B shows the concordance between the original 1999 WHO and the revised 2013 WHO criteria in the case-control study group. Comparing the two criteria, 112/523 (21.4%) cases showed discordant results. Interestingly, compared with those classified as normal by both criteria, both groups where results were discordant demonstrated a higher median HbA1c (both $p<0.001$, Mann-Whitney U test) and proportion with an HbA1c \geq 42 mmol/mol ($p<0.001$ for normal/GDM versus normal/normal; $p=0.001$ for GDM/normal versus normal/normal). There were no significant differences in median HbA1c ($p=0.636$, Mann-Whitney U test) or proportion with a HbA1c \geq 42 mmol/mol ($p=0.425$) between the two discordant groups (normal/GDM versus GDM/normal) although values were generally higher in those classified as GDM positive by the 2013 WHO than the 1999 WHO criteria (Table 3B).

Table 3C illustrates the assessment of concordance between the 2013 WHO criteria and the 2015 NICE criteria. The 70 discordant results (13.4%) had intermediate characteristics in terms of median HbA1c compared with those positive by both criteria. However, those classified as GDM positive by the NICE (2015) but not the WHO (2013) criteria had a median HbA1c (36 mmol/L) and proportion with HbA1c greater than 42 mmol/mol (8.2%) more similar to those positive by both criteria (37 mmol/mol and 24.1%, respectively).

Examining data from the cohort study group (Tables 3D–F) showed that the concordance between the 1999 WHO and 2015 NICE criteria was again high, with only 1.7% additional patients being classified with GDM by the 2015 NICE criteria (Table 3D). As with the case-control study group, these discordant cases had a median HbA1c (37 mmol/mol) more similar to those classified as GDM positive by both criteria

(38 mmol/mol, $p=0.318$) than those classified as GDM negative by these criteria (34 mmol/mol, $p<0.001$). Furthermore, the proportion of cases with a HbA1c above 42 mmol/mol (17.7%) was also similar in this discordant group to those classified as GDM positive by both criteria (22.6%, $p=0.229$) while the proportion in those classified as GDM negative by both criteria was only 2.5%.

Table 3E shows the concordance between the original WHO and revised WHO criteria in the cohort study group. Comparing the two criteria, 680/6930 (9.8%) of cases showed discordant results. As with the case-control study group, compared with those classified as normal by both criteria, both groups where results were discordant demonstrated a higher median HbA1c (both $p<0.001$, Mann-Whitney U test) and proportion with an HbA1c \geq 42 mmol/mol (both $p<0.001$). The values were significantly higher in those classified as GDM positive by the 2013 WHO than the 1999 WHO criteria, compared with the reverse discordant group ($p<0.001$ for both median HbA1c level and proportion with a HbA1c \geq 42 mmol/mol).

Examining the characteristics of the discordant results between use of the 2015 NICE and 2013 WHO criteria (Table 3F) showed that 8.1% cases were discordant. Again, the discordant cases showed intermediate characteristics in terms of HbA1c although those classified as GDM by the 2013 WHO criteria, but not by the 2015 NICE criteria, had significantly higher median HbA1c (37 versus 35 mmol/L; $p<0.001$, Mann-Whitney U test) but not a higher proportion with a HbA1c $>$ 42 mmol/mol ($p=0.105$) than the other discordant group.

Potential role for HbA1c

Given the increased proportion with an HbA1c \geq 42 mmol/mol in the discordant cases, we then explored the potential role of HbA1c in the diagnosis of GDM using the cohort study data (Table 4). In this group, the sensitivity, specificity and negative predictive value of HbA1c were similar (irrespective of the criteria used). In terms of positive predictive value, of the 329 cases with a HbA1c \geq 42 mmol/mol, 46.2%, 52.6% and 60.8% of cases were classified as GDM positive by OGTT by the

Table 3. Concordance between criteria in the diagnosis of gestational diabetes mellitus (GDM)**A – Case-control study: 1999 WHO versus 2015 NICE**

1999 WHO*	2015 NICE*	Discordant?	n(%)	Median HbA1c, mmol/mol	Proportion with HbA1c≥42 mmol/mol
Normal	Normal	No	233 (44.6)	30	1.7%
Normal	GDM	Yes	42 (8.1)	36	16.7%
GDM	Normal	Yes	0	-	-
GDM	GDM	No	247 (47.3)	37	22.1%

B – Case-control study: 1999 WHO versus 2013 WHO

1999 WHO*	2013 WHO*	Discordant?	n(%)	Median HbA1c, mmol/mol	Proportion with HbA1c≥42 mmol/mol
Normal	Normal	No	213 (40.7)	31	1.4%
Normal	GDM	Yes	62 (11.9)	36	12.9%
GDM	Normal	Yes	50 (9.5)	34	8.2%
GDM	GDM	No	198 (37.9)	38	26.2%

C – Case-control study: 2015 NICE versus 2013 WHO

2015 NICE*	2013 WHO*	Discordant?	n(%)	Median HbA1c, mmol/mol	Proportion with HbA1c≥42 mmol/mol
Normal	Normal	No	213 (40.8)	30	1.4%
Normal	GDM	Yes	20 (3.8)	33	5.0%
GDM	Normal	Yes	50 (9.6)	36	8.2%
GDM	GDM	No	239 (45.8)	37	24.1%

D – Cohort study: 1999 WHO versus 2015 NICE

1999 WHO*	2015 NICE*	Discordant?	n(%)	Median HbA1c, mmol/mol	Proportion with HbA1c≥42 mmol/mol
Normal	Normal	No	6138 (88.6)	34	2.5%
Normal	GDM	Yes	119 (1.7)	37	17.7%
GDM	Normal	Yes	0	-	-
GDM	GDM	No	673 (9.7)	38	22.6%

E – Cohort study: 1999 WHO versus 2013 WHO

1999 WHO*	2013 WHO*	Discordant?	n(%)	Median HbA1c, mmol/mol	Proportion with HbA1c≥42 mmol/mol
Normal	Normal	No	5,780 (83.4)	33	2.0%
Normal	GDM	Yes	477 (6.9)	37	13.2%
GDM	Normal	Yes	203 (2.9)	35	7.4%
GDM	GDM	No	470 (6.8)	38	29.2%

F – Cohort study: 2015 NICE versus 2013 WHO

2015 NICE*	2013 WHO*	Discordant?	n(%)	Median HbA1c, mmol/mol	Proportion with HbA1c≥42 mmol/mol
Normal	Normal	No	5,780 (83.4)	34	2.0%
Normal	GDM	Yes	358 (5.2)	37	11.7%
GDM	Normal	Yes	203 (2.9)	35	7.4%
GDM	GDM	No	589 (8.5)	39	26.8%

*Normal is defined as subgroup 1, while GDM is defined as subgroups 2–4 using the categorisation defined in the methods
HbA1c = glycated haemoglobin; NICE = National Institute for Health and Care Excellence; WHO = World Health Organization

1999 WHO, 2015 NICE and 2013 WHO criteria, respectively. These data suggest that, while a HbA1c≥42 mmol/mol detects marginally more GDM positive cases using the 2015 NICE or 2013 WHO criteria, use of HbA1c alone as a screening test to reduce the number of OGTTs would risk missing a significant number of GDM cases.

Discussion

It is unsurprising that our data show that implementation of the 2013 WHO criteria would result in more GDM cases compared with the 1999 WHO criteria. However, the magnitude of this increase (3.7-fold) would equate to a major

Table 4. Potential role of HbA1c as a screening tool for gestational diabetes mellitus (GDM). The performance of HbA1c \geq 42 mmol/mol to identify cases of GDM defined by the three criteria was assessed.

HbA1c \geq 42 mmol/mol	GDM positive by		
	1999 WHO	2015 NICE	2013 WHO
Sensitivity	152/673 (22.6%)	173/792 (21.8%)	200/947 (21.1%)
Specificity	6,080/6,257 (97.2%)	5,982/6,138 (97.5%)	5,854/5,983 (97.8%)
Positive predictive value	152/329 (46.2%)	173/329 (52.6%)	200/329 (60.8%)
Negative predictive value	6,080/6,601 (92.1%)	5,982/6,601 (90.6%)	5,854/6,601 (88.7%)

HbA1c = glycated haemoglobin; NICE = National Institute for Health and Care Excellence; WHO = World Health Organization

impact on workload for maternity services and is consistent with findings elsewhere.^{10,12,17–19} Mayo *et al*¹⁹ suggested that the 1-hour glucose value in the OGTT was the most significant determinant of increase in GDM cases using this criteria, suggesting that even this may be an underestimate. Indeed, the HAPO study suggested that, overall, around a third of GDM cases were diagnosed using the 1-hour value.¹⁰ While most studies indicate a major impact, Helseth *et al*¹⁸ showed that a ‘simplified IADPSG criteria’, which also excluded the 1-hour value, gave rise to a ‘moderate’ increase in GDM cases (prevalence 6.1–7.4%).

The characteristics of discordant cases

We also found that, of the discordant results, those diagnosed with GDM by the 2013 WHO criteria but not the 1999 WHO criteria had a higher proportion with a HbA1c \geq 42 mmol/mol and higher mean HbA1c than those discordant in the reverse (ie diagnosed with GDM by the 1999 WHO but not the 2013 WHO criteria). However, this latter group had values that remained significantly greater than those negative for GDM by both criteria. The findings were very similar between the two study groups and suggest that adoption of the 2013 WHO criteria may still miss some women at risk of dysglycaemia during pregnancy. Our data suggest that those additional cases identified by the 2013 WHO criteria have intermediate HbA1c levels (between those identified as GDM negative by both sets of WHO criteria and those that are positive). This may correspond to the group of women described by Long and Cundy¹² as having ‘mild’ GDM, who have less significant consequences and high cost:benefit ratios. Interestingly, similar intermediate HbA1c levels were observed in subgroups 2 and 3 (ie where only one of the baseline or 2-hour values was above the threshold) in the cohort study group, irrespective of the criteria used (mean HbA1c 36.3–37.5 mmol/mol). This highlights the challenges that adoption of any new protocol would bring; it will never be 100% accurate in at identifying the right cases. Hence, the choice of which criteria to adopt remains a balance between minimising pressure on stretched healthcare services and providing the optimum service for patients.¹²

Alternative approaches

The more recent 2015 NICE criteria represent a potential compromise relative to the 2013 WHO criteria in that it uses a lower value for the baseline plasma glucose in the standard OGTT.¹³ Our results show that, relative to the 1999 WHO criteria, this identified a small additional group of women

with higher HbA1c levels without increasing the overall workload as much as using the 2013 WHO criteria. Other groups have adopted other approaches in attempts to minimise misidentification of high-risk cases while making the workload more manageable. Cosson *et al*²⁰ proposed the use of a blood glucose threshold combination associated with a higher odds ratio of 2.0 (rather than 1.75 as proposed by the IADPSG) for neonatal disorders. This would translate into 75 g OGTT cut-offs of 5.3 mmol/L for the baseline value and 9.0 mmol/L for the 2-hour value for the diagnosis of GDM. In 2016, Hughes *et al*²¹ suggested the combination of fasting glucose, HbA1c and anthropometric measurements, such as waist circumference, might offer an alternative approach for identifying GDM cases. This raises the question of the role of HbA1c in pregnancy. Hughes *et al*²¹ suggest that it is limited when considered alone as a diagnostic tool for GDM, a view upheld by our data, by that of Lowe *et al*²² as part of the HAPO study findings and the findings of Ryu *et al*.²³ However, it is interesting to note that, in our cohort study group, a raised HbA1c of \geq 42 mmol/mol was better at identifying those diagnosed as GDM by the 2013 WHO criteria than by the earlier 1999 criteria, or even the more recent 2015 NICE criteria. HbA1c may, therefore, be best used as an addendum to current processes, rather than an alternative, and additional data are required to elucidate its effectiveness in this regard.

Study strengths and limitations

The study was limited in that the data was collected retrospectively; therefore, we were unable to collect 1-hour OGTT data in order to fully evaluate the impact of implementing the 2013 WHO criteria. The case-control data was collected some time ago and did not include all GDM cases. However, the case group appeared typical of cases at the hospital and similar in demographics to the later cases from the cohort study. Furthermore, it is important to note that, in two independent populations, data collected using different study designs provided very similar findings. This strengthens our confidence in the results and the conclusions. While the data were collected from a single centre, we have no reason to believe that our findings could not be replicated elsewhere in the UK. Other study data would support this.^{10,12,17–19}

Conclusions

Our findings illustrate the potential magnitude of the impact of implementing the 2015 NICE and 2013 WHO criteria for the diagnosis of GDM on the workload of maternity services

in a large UK teaching hospital, and on the general practice activity linked to it. They also indicate that the additional cases identified using the 2013 WHO criteria have intermediate dysglycaemia. It is yet to be determined if this additional case load will benefit clinically from early identification, so more research is required in this area. Adoption of the 2015 NICE criteria would have a similar impact on overall workload, but perhaps without missing as many with more significant dysglycaemia. Therefore, the implications for clinical practice are complex, both clinically and logistically. Implementation of the 2013 WHO criteria would change the volume of activity, but also the clinical characteristics of the GDM patient group. Certainly, the impact on workload may result in delayed implementation; audit data may be useful to explore which guidance centres have adopted (if at all) and the implications. The 2015 NICE criteria offer a more manageable compromise, but are less likely to be adopted outside the UK. This may lead to multiple variations being used, including other markers such as HbA1c. Clearly, the role of HbA1c in the diagnosis of GDM still has a long way to go and is only likely to have an impact in combination with other factors. ■

Conflicts of interest

The authors have no conflicts of interest to declare.

Author contributions

FWF and AAF conceived and designed the study; CJD, SAH and EH collected and assembled the data; FWF and AAF performed the data analysis and interpretation. AAF and FWF wrote the manuscript and all authors critically appraised the manuscript and gave final approval for publication.

Acknowledgements

This work received no external funding. It formed part of the internal audit programme at the University Hospital of North Midlands NHS Trust. The authors gratefully acknowledge the support of the Audit Department at the University Hospital of North Midlands for help in data collection tool design and collation of data for the case-control study group.

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