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Gestational diabetes mellitus: evaluating the implications of applying international research into national policy and practice

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ORIGINAL

Background

Gestational diabetes mellitus (GDM) broadly denotes a dysregulation of glucose metabolism. However, there is a growing body of evidence exploring the complexity and heterogeneity of GDM as a diagnosis, which may include sub-phenotypes (Powe et al 2020). GDM is currently the most common medical complication in pregnancy, and the global prevalence is increasing with rising maternal age and obesity (Kim et al 2019, McIntyre et al 2019, Ye et al 2022). Estimations of prevalence vary widely depending on screening approach, diagnostic criteria and the population studied, overt prevalence, and social and cultural determinants of risk (Zhu & Zhang 2016, Sweeting et al 2024). The global prevalence of GDM is estimated to be 14 per cent when endorsing the International Association of Diabetes and Pregnancy Study Groups (IADPSG) criteria; however, the universal application of these criteria remains disputed (Wang et al 2022). A recent scoping review highlighted the global disparity in screening, diagnosis and management of GDM (Stedman et al 2024). Any association between GDM and adverse outcomes in pregnancy is likely to reflect the screening approach and diagnostic criteria used.

GDM has a strong impact on public health, with maternal and neonatal morbidities that encompass not only the perinatal period but also extend into later life (Souza & Iser 2022). Untreated GDM results in women being more likely to experience pre-eclampsia, caesarean birth or stillbirth, while babies are more likely to be born prematurely, macrosomic or large for gestational age (LGA) (Meek et al 2015, Ye et al 2022). These neonatal morbidities are, in turn, associated with birth injury, respiratory distress, hypoglycaemia and admission to neonatal intensive care units (NICU) (Ye et al 2022).

Outcomes could also be influenced by differences in maternal demographics including ethnicity, and social and cultural characteristics. Ethnic differences in the prevalence of GDM are particularly important in view of the associated socioeconomic, cultural and biological influences on risk (Sweeting et al 2024). The variance in approaches for the screening and diagnosis of GDM, and a lack of local, national and global consensus, makes comparing data on GDM challenging (McIntyre et al 2018, White et al 2023).

This paper will explore considerations when study demographics, screening and diagnostic approaches vary from the UK guidelines, population and health care systems in the context of GDM.

Global variance

For decades, there have been two different rationales for seeking a diagnosis of GDM. When glycaemic testing was introduced in the 1960s, the primary rationale was to identify women at risk of type 2 diabetes after pregnancy. However, in more recent years, the glycaemic threshold for diagnosis is dependent on the likelihood of adverse outcome in the current pregnancy (White et al 2023, Sweeting et al 2024).

Globally, there is no one single screening criterion or diagnostic method that is universally accepted and the variance in approaches makes accurately calculating the prevalence of GDM difficult (McIntyre et al 2019, Souza & Iser 2022). Such variance in approaches often results in diverse and contradictory responses from governing bodies and institutions, making international comparisons difficult (Hiéronimus & Le Meaux 2010, McIntyre et al 2019). There is also concern that current screening strategies do not reflect the heterogeneity of GDM as a condition (Saravanan et al 2020). Following the seminal hyperglycaemia and adverse pregnancy outcomes (HAPO) study, the IADPSG introduced new diagnostic thresholds that were based on an increase of 1.75 times in the primary outcomes (IADPSG Consensus Panel 2010).

The revised thresholds were lower and stricter than previously used and, as a result, the incidence of GDM would almost certainly increase alongside enhanced care provision and associated interventions (White et al 2023).

The World Health Organization (WHO) has since adopted and universally recommends these guidelines (WHO 2014). In recent years, there has been increasing acceptance of the IADPSG criteria (Cheung & Moses 2018, Hod et al 2019). However, a lack of research evidencing an effective reduction of either neonatal or maternal morbidities has meant many health care systems have chosen not to adopt these guidelines over concerns for the medicalisation of pregnancy, an increase in clinical capacity and limited cost effectiveness (Saravanan et al 2020; Sweeting et al 2024).

Screening

Screening strategies range between universal screening and risk-based screening, using either one- or two-step approaches (Saravanan et al 2020). Risk-based screening is particularly supported in Europe, and is currently endorsed by the National Institute for Health and Care Excellence (NICE) (NICE 2020, White et al 2023). Risk-based screening is selective and aims to curb the cost of screening by limiting screening to high-risk populations and areas of high prevalence (Hiéronimus & Le Meaux 2010). However, the proportion of women with GDM who are not diagnosed by selective screening ranges from between three and 50 per cent (Hiéronimus & Le Meaux 2010). Risk-based screening is a poor predictor of women with GDM and is greatly reliant on questions asked by practitioners, alongside the woman's ability to recollect her own or family history (Farrar et al 2017a, White et al 2023). As a result, estimated prevalences may be prone to a margin of error. The differing risk factors and population demographics result in variance across populations and proportions of populations screened (Farrar et al 2017a). This variance appears not only when comparing international policies but also between local hospitals. Murphy et al (2016) found that, despite all hospitals endorsing NICE guidance, each hospital had a specific policy for screening for GDM, as well as its own diagnostic criteria. National variation in diagnostics remits further highlights the disparities when screening for or diagnosing GDM.

In addition, not all women who screen positive for risk factors will go on to appropriately receive screening for GDM (Murphy et al 2016). In a cohort of 650 women who had identifiable GDM risk factors, according to the NICE guidelines, only 395 (60.8 per cent) were appropriately screened (Murphy et al 2016). Overall, compliance was poor but ethnicity was the risk factor most likely to be missed, with 66.3 per cent of women from ethnic groups at risk not being screened appropriately (Murphy et al 2016). The reason for non-compliance with guidelines is yet to be fully understood but could justify the argument for universal screening (Murphy et al 2016). There is a significant impact from failing to follow through on testing. Women who fulfil NICE screening criteria but are not tested for GDM have a 44 per cent higher rate of late stillbirth (Stacey et al 2019). Women who are diagnosed with GDM and possess the associated risk factors are more likely to experience pregnancy complications and adverse outcomes, in comparison to their counterparts that do not have risk factors (Minschart et al 2021).

Although approaches differ, there is global agreement that screening for GDM and subsequent treatment should occur routinely at 24–28 weeks' gestation (Sweeting et al 2024). That said, emerging evidence suggests there could be rationale to undertake screening at an earlier gestation (Saravanan et al 2020). Lifelong consequences for neonates, as a result of exposure to maternal hyperglycaemia, may have already developed by 28 weeks of gestation (Saravanan et al 2020). Evidence of hyperglycaemia before 24 weeks' gestation is associated with significantly increased risk for perinatal mortality, neonatal hypoglycaemia and insulin therapy (Immanuel & Simmons 2017). An early abnormal result could represent an early diagnosis of GDM or otherwise undiagnosed overt diabetes (Minschart et al 2021). In the context of early hyperglycaemia, and in light of an obesity epidemic, it is highly likely that increasing numbers of GDM diagnoses are in fact cases of undiagnosed, overt diabetes (McIntyre et al 2019). Identifying women with severe hyperglycaemia in early pregnancy allows for earlier intervention and time to achieve adequate glycaemic control (Saravanan et al 2020).

Testing and diagnosis

The identification of GDM promotes future observation and screening for morbidities in later life for both mother and baby, which, without the initial diagnosis, might go undetected. Diagnosis may be accomplished using clinical risk factors, biochemical testing or a combination of both (White et al 2023). Testing methods have evolved with time, yet continue to differ widely between countries and guidelines (Minschart et al 2021, White et al 2023). The WHO, IADPSG and some European guidelines support a one-step strategy with a 75g glucose load (Li-Zhen et al 2019). NICE also recommends this strategy but differs in adopting a selective screening approach instead of universal screening (Li-Zhen et al 2019). Alternative two-step testing is supported by many institutions. including the American Diabetes Association (ADA), American College of Obstetricians and Gynecologists (ACOG) and Canadian Diabetes Association (CDA) (Sweeting et al 2022).

Two-step testing includes risk-factor based approaches to identify women who then directly undergo an oral glucose tolerance test (OGTT) or using a non-fasted glucose challenge test (GCT) to determine who will progress to an OGTT (Sweeting et al 2024). Using the GCT is advantageous, in that it can be performed without maternal fasting, is usually better tolerated and can be easily implemented in primary care (Minschart et al 2021). Table 1 demonstrates the variance in glucose load, timing of postprandial blood glucose and the diagnostic limits that have been adopted in recent years by various stakeholders.

Performing an OGTT on all pregnant women is recommended by most organisations, including NICE (NICE 2020, Sweeting et al 2024). However, the OGTT is now being questioned as the primary means of diagnosing GDM; novel biomarkers such as maternal lipids or continuous glucose monitoring are just some of the suggested future diagnostic tests (Sweeting et al 2019, Saravanan et al 2020). The OGTT can be affected by biological variances, processing delays and factors associated with pregnancy, including difficulty fasting (Daly et al 2016). Although the OGTT is problematic, it remains the gold standard diagnostic tool for GDM (Sweeting et al 2024). Other glycaemic measures, such as fasting glucose or HbA1c, have major limitations and are not routinely supported by NICE to diagnose GDM (NICE 2020, Sweeting et al 2024). While the WHO adopts the IADPSG glycaemic thresholds, it does not recommend any specific screening approach for GDM (WHO 2014).

Table 1. Screening and diagnostic criteria

Criteria	Universal/ selective	One/two step	Glucose load	Fasting result	1-hour	2-hour	3-hour
ADIPS[1]	Universal	One	75G fasted	>5.1mmol/l	>10.0mmol/l	>8.5mmol/l	
FIGO[2]	Universal	One	75G fasted	>5.1mmol/l	>10.0mmol/l	>8.5mmol/l	
IADPSG[3]	Universal	One	75G fasted	>5.1mmol/l	>10.0mmol/l	>8.5mmol/l	
WHO[4]	Universal	One	75G fasted	>5.1mmol/l	>10.0mmol/l	>8.5mmol/l	
ADA[5]	Universal	One	75G fasted	>5.1mmol/l	>10.0mmol/l	>8.5mmol/l	
		Two	50G non-fast		7.2-7.8mmol/l		
			100G fasteda	>5.3mmol/l	>10.0 mmol/l	>8.6 mmol/l	>7.8 mmol/l
ACOG[6]	Universal	Two	50G non-fast		7.2-7.8mmol/l		
			100G fasteda	>5.3mmol/l	>10.0 mmol/l	>8.6 mmol/l	>7.8 mmol/l
CDA[7]	Universal	One	75G fasted	>5.1mmol/l	>10.0mmol/l	>8.5mmol/l	
		Two[b]	50G non-fast		>7.8mmol/l		
			75G fasted	>5.3mmol/l	>10.6mmol/l	>9.0mmol/l	
NICE[8]	Selective	One	75G fasted	>5.6mmol/l		>7.8mmol/l	

1: Nankervis et al (2013); 2: Hod et al (2015); 3: IADPSG consensus panel (2010); 4: WHO (2014); 5: ADA (2024); 6: ACOG (2018); 7: Canadian Diabetes Association Clinical Practice Guidelines Expert Committee (2013); 8: NICE (2020).

[a] two abnormal results required for diagnosis

[b] preferred approach by the CDA

Cost-effectiveness, sensitivity and specificity

Universal screening is somewhat simpler in comparison to risk-based screening; however, while a comprehensive list of risk factors may reduce the costs of screening, it could also result in missed diagnoses and therefore not be cost-effective (Hiéronimus & Le Meaux 2010). The cost-effectiveness of managing GDM is a balance between the increased costs of screening and treatment in relation to preventing adverse maternal and neonatal outcomes (Sweeting et al 2024). A systematic review in 2019 assessed the cost-effectiveness of screening and treatment for GDM based on six studies. However, only one study was UK based (Fitria et al 2019). Analyses varied with regard to costs included in treating GDM, for example, lifestyle choices, pharmaceuticals, blood glucose monitoring, assessing fetal wellbeing and induction of labour (IOL) (Mo et al 2021). Fitria et al (2019) concluded that GDM treatment could be considered cost-effective under certain circumstances, but universal screening for GDM is not justifiable.

The economic evaluation of a screening policy should not only consider the cost of the screening test itself but also the costs related to potential adverse events that may ensue in the absence of screening or as a result of poor sensitivity (Hiéronimus & Le Meaux 2010). As Monaghan et al (2021:1) write:

'*The proportion of subjects correctly given a positive assignment out of all subjects who are actually positive for the outcome, indicates how well a test can classify subjects who truly have the outcome of interest*.'

If the potential harm of a missed diagnosis is the priority, screening tests with a high sensitivity are favoured, often at the expense of specificity (Donovan et al 2013). However, if the harm of incorrectly diagnosing a condition prevails, a screening test with high specificity is preferred (Donovan et al 2013).

'*The proportion of subjects correctly given a negative assignment out of all subjects who are actually negative for the outcome, indicates how well a test can classify subjects who truly do not have the outcome of interest*.' (Monaghan et al 2021:1)

The GCT has long been used in combination with the OGTT, either 75g or 100g depending on diagnostic criteria; however, data are lacking with regard to sensitivity and specificity when used in accordance with the IADPSG/WHO criteria (Benhalima et al 2018). While the alternative of a one-step approach could result in a more timely diagnosis and therefore earlier treatment, concern for a diagnosis following one abnormal result does ensue, particularly given the poor reproducibility of the OGTT (Cundy et al 2014, Benhalima et al 2018).

Treatment and intervention

Aside from lifestyle interventions, methods for optimal management are yet to be identified, as contemporary data on the outcomes associated with untreated GDM are limited, given the ethical implications associated with withholding treatment (White et al 2023, Sweeting et al 2024). Dietary adjustments and physical activity are the primary treatments for GDM but where glycaemic control is not achieved, pharmacotherapy may be warranted (McIntyre et al 2019, Mustafa et al 2021). Randomised controlled trials (RCTs) and recent meta-analyses have indicated lifestyle interventions are largely unsuccessful at preventing GDM for the majority of at-risk women and, instead, management strategies should be individualised, focusing on individual pathogenesis to achieve optimum impact of intervention (Egan & Simmons 2019, Saravanan et al 2020).

Pharmacotherapy is principally insulin but oral glycaemic agents are used in certain countries (McIntyre et al 2019). Metformin is commonly used and generally considered both safe and effective in treating GDM, with fewer maternal and neonatal adverse outcomes in comparison to insulin (Bidhendi Yarandi et al 2021). However, the use of oral agents varies internationally, given that little data exist regarding the long-term impact for the baby (Sweeting et al 2024). A recent systematic review and meta-analysis concluded that, despite 42 RCTs comparing outcomes in accordance with pharmacological intervention, continued poor-quality research, small sample sizes and a high risk of bias mean that the most effective pharmacological treatment is still unknown (Farrar et al 2017b).

Behboudi-Gandevani et al (2021) suggest that successfully managing even mild GDM can result in a reduction of adverse outcomes. Continuous glucose monitoring can result in earlier detection of hyperglycaemia and therefore improved glycaemic control, less maternal weight gain and lower infant birthweight (García-Moreno et al 2022). However, there were no differences when exploring the impact on pre-eclampsia, caesarean birth, gestational age at birth, neonatal hypoglycaemia, admission to NICU or mortality (García-Moreno et al 2022).

Fetal surveillance is a common theme among international guidelines, including cardiotocography and biophysical profile from 38 weeks' gestation; however, evidence is limited to suggest that use of such tests prevents fetal compromise and stillbirth (Sweeting et al 2024). Monitoring fetal growth in women with GDM (particularly those with a high BMI) guides possible interventions such as IOL (Sweeting et al 2024). A recent systematic review and meta-analysis determined that there is an absence of robust evidence to guide the use of IOL at different gestational weeks in GDM (Luo et al 2023). Studies exploring the impact of IOL on adverse maternal and neonatal outcomes yield inconsistent results (Luo et al 2023). International variations in population demographics, screening and diagnostic criteria mean that the benefits and risks of IOL therefore remain unclear (Luo et al 2023). The studies included originated from the US, Canada, Italy and Israel, with all but one study using a two-step approach to diagnose GDM and therefore are not reflective of the UK provision of care where NICE guidelines have been adopted.

Despite inconsistent recommendations regarding the gestation at the point of IOL, several international bodies, including NICE, continue to recommend IOL to improve pregnancy outcomes and reduce adverse morbidities (NICE 2020, Luo et al 2023). A recent Cochrane review concluded that there are few studies exploring the impact of interventions such an IOL or elective caesarean birth but the data that do exist show no clear difference in the maternal and neonatal morbidities examined (Martis et al 2018).

Morbidities and UK reliability

Country of study origin, obesity prevalence, maternal populations, screening and clinical approaches significantly contribute to heterogeneity between studies assessing pregnancy complications; therefore, the risk of adverse outcomes varies between studies as a result (White et al 2023). Some outcomes associated with GDM are not necessarily morbid but can result in an increased likelihood for other morbidities (Hiéronimus & Le Meaux 2010). For example, fetal macrosomia may not be considered a morbidity but the associated maternal morbidities include caesarean section and severe perineal trauma (Vieira et al 2020).

A systematic review of 26 studies showed a greater risk of caesarean delivery, LGA, preterm birth, hypertension, mortality, pre-eclampsia, shoulder dystocia, IOL and insulin use in women diagnosed with early GDM compared with those diagnosed with late GDM (Hannah et al 2022). Only one study was from the UK and used WHO 1999 diagnostic criteria, which are no longer reflective of the current NICE (2020) approach. Larger studies with standardised approaches are required to accurately determine the global impact of early GDM (Hannah et al 2022).

Ye et al (2022) found that in comparison to a non-diabetic cohort, there was an increased risk of preterm birth, caesarean section and LGA babies when women required pharmacological intervention but not insulin. For women who did require insulin therapy, there was an increase in the rates of LGA, respiratory distress and admission to NICU (Ye et al 2022). A recent scoping review determined that admission to NICU at term gestation may be a potential outcome irrespective of pharmacological intervention, but again highlighted the difficulty in study comparison as a result of the variance in GDM protocols and demographic representation (Stedman et al 2025). Across the 156 studies in the Ye et al (2022) systematic review and meta-analysis, women were divided into two cohorts (GDM and non-GDM), in accordance with the individual diagnostic criteria used; 72.6 per cent of women were diagnosed with GDM using criteria other than WHO, Carpenter and Coustan or IADPSG (Ye et al 2022). With such variance in criteria used, there is a possibility that some women in the GDM cohort may have been considered non-GDM in another study and this would impact the outcomes and findings. Equally, with 18.4 per cent of studies being undertaken in low-income countries, it is unlikely that the provision of care is reflective of the UK and therefore caution should be taken when considering the relatability of results.

Future results

Standardised diagnostic criteria are crucial to accurately assess national and regional prevalence of GDM (Paulo et al 2021). However, while stakeholders continue adopting a glucocentric approach, achieving a standardised approach appears unlikely. Due to international variation in practices, heterogenous maternal populations and continued scrutiny of the oral glucose tolerance test as a screening process, there is considerable interest in finding alternative methods to diagnose GDM (White et al 2023). Standardised screening, diagnostic and treatment approaches might be pragmatic but, in view of the disparities earlier discussed, validation studies are needed with careful consideration of socioeconomic status and the heterogeneity of GDM as a condition (Sweeting et al 2024).

Despite great interest in developing risk stratification for women with GDM, there are few studies evaluating a spectrum of non-glycaemic variables to identify sub-phenotypes (Francis et al 2023). Developing accurate composite risk scores has the potential to result in a more cost-effective approach to screening and intervention, while optimising outcomes for both mothers and babies (Saravanan et al 2020). One recent study explored the use of machine learning to identify women who were likely to develop GDM (Artzi et al 2020). Findings suggested that a computational model derived from electronic health records accurately predicted high-risk women who would benefit from early intervention to reduce the potential for both maternal and neonatal complications (Artzi et al 2020). Saravanan et al (2020) also propose significant development in the data collected in relation to GDM; improving the accuracy of coding and increasing the number of key variables would enable the development of a dataset that could be used for future machine-learning studies similar to the study by Artzi et al (2020).

Unless a universal approach is adopted, significant heterogeneity is likely in any future systematic reviews and meta-analyses, and any meaningful comparison is unlikely to be achieved. Future research should carefully consider this potential and design studies that can enable policy development that responds to individual population needs (Saravanan et al 2020).

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