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## The role of continuous glucose monitoring in the diagnosis and management of gestational diabetes mellitus

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Gestational diabetes mellitus (GDM) is the most common metabolic disorder in pregnancy, traditionally diagnosed using the oral glucose tolerance test (OGTT) and managed via self-monitoring of blood glucose (SMBG). However, both methods have limitations, including poor reproducibility, discomfort, and limited ability to detect glycaemic variability. Continuous glucose monitoring (CGM) offers a promising alternative by providing 24-hour glucose profiles and identifying glycaemic excursions missed by SMBG. CGM shows potential for early detection of subclinical dysglycaemia, improved diagnostic accuracy when combined with clinical risk scores, and improved patient satisfaction. Although randomised controlled trials (RCTs) have reported mixed results regarding perinatal outcomes, CGM is associated with improved glycaemic control, reduced gestational weight gain, and high user acceptability. Nocturnal hyperglycaemia identified by CGM may predict fetal overgrowth. Integration with telemedicine may further personalise care. Further large, robust, RCTs are needed to confirm CGM's clinical value and guide its broader implementation in GDM.

### Introduction

Gestational diabetes mellitus (GDM) is the most common metabolic disorder of pregnancy, affecting between 5% and 25.5% of pregnancies worldwide [1]. GDM carries significant health risks for both mothers and newborns, including pre-eclampsia, caesarean section, preterm delivery, macrosomia, shoulder dystocia, neonatal hypoglycaemia, admission to neonatal intensive care unit and stillbirth [2]. A large systematic review and meta-analysis of 156 studies involving 7506,061 pregnancies found that, in women not requiring insulin, GDM was associated with higher odds of caesarean delivery (OR 1.16), preterm birth (OR 1.51), and large for gestational age (LGA) infants (OR 1.57) [3]. In insulin-treated women, neonatal intensive care unit admission was more common (OR 2.29) [3]. A UK case-control study (291 stillbirths; 733 controls) showed that unscreened women at developing GDM had a 44% higher risk of late stillbirth (aOR 1.44), whereas screening eliminated this excess risk (aOR 0.98) [4]. Raised fasting plasma glucose ( $\geq 5.6$  mmol/L) without GDM diagnosis increased late stillbirth risk fourfold (aOR 4.22), while diagnosis and management removed the excess risk (aOR 1.10) [4].

Effective treatment, typically beginning with dietary and lifestyle modifications, and where necessary, pharmacological therapy such as metformin and insulin, provides clear benefits for both mother and child [5]. A meta-analysis of eight randomised controlled trials (RCTs) and one non-randomised study of late-diagnosed GDM has shown that GDM treatment lowered the risk of primary

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caesarean delivery by 5.3%, shoulder dystocia by 1.3%, macrosomia by 8.9%, LGA infants by 8.4%, NICU admission by 2%, and birth injury by 0.2% [6]. Early intervention has also proven beneficial [7]. The TOBOGM trial randomised 802 women at risk before 20 weeks of gestation and found that immediate treatment reduced composite adverse perinatal outcomes (birth at < 37 weeks' gestation, birth trauma, birth weight of  $\geq 4500$  g, respiratory distress, phototherapy, stillbirth or neonatal death, or shoulder dystocia) from 30.5% to 24.9% [7]. Overall, these findings confirm that GDM increases maternal and neonatal risks, but effective screening, early diagnosis, and timely treatment markedly improve outcomes for both mother and child [5].

Currently, the oral glucose tolerance test (OGTT) remains the internationally accepted gold standard for diagnosing GDM, usually performed between 24 and 28 weeks of gestation [5]. Following diagnosis, management typically involves self-monitoring of blood glucose (SMBG) to guide dietary and pharmacological interventions [5]. While OGTT and SMBG have been the cornerstone of GDM care, they have notable limitations in terms of accuracy, patient comfort, and the ability to capture dynamic nature of glucose metabolism during pregnancy [7–12].

In recent years, continuous glucose monitoring (CGM) has emerged as a promising alternative for the diagnosis and management of GDM [13–15]. Using a small subcutaneous sensor, CGM measures interstitial glucose levels electrochemically every few minutes, providing a comprehensive glucose profile over 24 h [16]. This enables the detection of important glycaemic patterns, such as postprandial spikes and nocturnal fluctuations, that are often missed by traditional methods like SMBG and OGTT [16]. While CGM is still gaining traction in the context of GDM, its use is already well established in pregnancies complicated by type 1 diabetes, where its use has resulted in improved glycaemic control, increased time in target glucose ranges, reduced variability, fewer hypo- and hyperglycaemic episodes, and improved maternal and neonatal outcomes [15,17,18].

Unlike SMBG, which measures glucose in capillary blood, CGM reflects interstitial glucose and may be subject to a physiological lag when glucose levels are changing rapidly [19]. As a result, a CGM reading may not always be directly equivalent to a fingerstick value at the same time point, particularly after times of rapid change in glucose such as after meals or during hypoglycaemia [19]. This distinction has implications for treatment decisions in GDM: women need clear guidance on how CGM metrics, such as time-in-range, could be used alongside or in place of SMBG targets when adjusting therapy [19].

This chapter reviews the current evidence on the use of CGM in GDM, comparing it with conventional diagnostic and monitoring methods. It addresses the challenges associated with current standards and evaluates CGM's potential to enhance diagnostic accuracy and improve maternal and neonatal outcomes. Additionally, it explores both patient and clinician perspectives.

#### *Limitations of current standards in GDM diagnosis using the OGTT*

In the United Kingdom, routine screening for GDM is typically conducted using the OGTT between 24 and 28 weeks of gestation, however first trimester testing may be recommended for those who are deemed high risk, for example a previous history of GDM [5]. Women with a negative initial screen undergo repeat OGTT between 24 and 28 weeks of gestation [5,8]. Although the OGTT is widely used, it presents several practical and clinical challenges [2,9].

The test requires patients to fast overnight, consume a non-physiological glucose load, and undergo serial venous blood samples over two hours to assess plasma glucose levels [8]. This test is time-consuming and frequently associated with unpleasant side effects, including headache, nausea, dizziness, and vomiting, contributing to test incompleteness [9]. In addition, the glucose load used in the OGTT does not reflect normal dietary intake and may not reflect an individual's glycaemic response, particularly in populations with diets rich in carbohydrate [9]. There is insufficient evidence to define precise diagnostic thresholds for OGTT conducted in early pregnancy (before 20 weeks), complicating clinical interpretation of results at this stage [9].

Another major concern with the OGTT is its poor reproducibility [10]. The OGTT demonstrates significant intra-individual variability, leading to a substantial proportion of false-positive and false-negative results [7,10]. For example, the Treatment of Booking Gestational Diabetes Mellitus (TOBOGM) study found that up to one-third of women diagnosed with early GDM through a standard OGTT did not meet diagnostic criteria when retested later in pregnancy, raising concerns about overdiagnosis and overtreatment [7]. Such inconsistencies can result in women with normoglycaemia being subjected to unwarranted dietary restrictions, frequent monitoring or pharmacological treatment, leading to increased anxiety, greater burden on healthcare resources, and elevated costs [12]. Conversely, women with high-carbohydrate diets may be underdiagnosed, as the OGTT may not sufficiently challenge their glucose metabolism to reveal dysglycaemia [12]. This may delay necessary treatment, increasing the risk of adverse maternal and neonatal outcomes [12].

Another study highlighting the unreliability of the OGTT found that when two tests were conducted within the same week, results were consistent in only 27–80% of cases, with fasting glucose levels varying by as much as 30% [20]. Similarly, one study reported that approximately 25% of women who initially tested positive for GDM were later found to be negative upon repeat testing [10]. This variability is even more pronounced during pregnancy due to fluctuations in glucose regulation, further calling into question the reliability of the OGTT as a diagnostic tool for GDM [11].

Additional barriers to OGTT exist in remote areas, for example, among some Australian population, where personal aversion to glucose load and logistical difficulties accessing laboratory services reduce uptake [21]. Therefore, there is an urgent need for a novel diagnostic test for GDM that offers improved tolerability, greater patient acceptability, and enhanced diagnostic accuracy [22].

#### *Limitations of current standards in GDM management via SMBG*

SMBG remains the standard of care for monitoring glycaemic control following a diagnosis of GDM, however its effectiveness is hindered by several practical and clinical limitations [23]. A prospective cohort study involving 91 women with GDM found that only

61.5 % adhered to at least 80 % of recommended SMBG checks [23]. Suboptimal adherence was associated with factors such as reduced socioeconomic status, non-white ethnicity, higher baseline HbA1c, and a family history of diabetes [23]. This suboptimal adherence was associated with poorer outcomes, including increased rates of pre-eclampsia and elevated HbA1c at delivery, despite increased insulin therapy [23]. Furthermore, the accuracy of SMBG data is compromised by unreliable logbook entries, which raises questions about the validity of the data used to guide clinical decisions [23].

SMBG also fails to capture the full range of glycaemic fluctuations throughout the day [12,24,25]. It typically involves intermittent capillary glucose measurements that may miss significant glycaemic excursion, for example, glucose readings one or two hours after meals, may miss peak levels, potentially underestimating postprandial hyperglycaemia [26]. Snacks consumed between meals, which can account for 20–25 % of daily caloric intake, are often not measured [25]. Overnight glycaemic variations, which may affect pregnancy outcomes, are overlooked [24]. These limitations suggest that SMBG may offer an incomplete picture of glycaemic control during pregnancy, highlighting an urgent need for novel glucose monitoring methods [23].

### *The role of CGM in the diagnosis of GDM*

Recent evidence suggests CGM may be a more sensitive and informative diagnostic tool than the conventional OGTT for identifying GDM, particularly in its early or subclinical stages [27]. A large prospective study involving 768 pregnant women found that those who later developed GDM already had higher mean glucose levels, increased glycaemic variability, and reduced percentage time in range for glucose sensor (3.5–7.8 mmol/L) as early as 13 weeks of gestation, well before diagnosis by OGTT at 24 weeks [27]. These women spent significantly more time above glucose thresholds of 6.7 and 7.8 mmol/L, both during the day and night across all trimesters [27]. CGM metrics, particularly time spent above 7.8 mmol/L, were strong predictors of later GDM diagnosis (area under the curve [AUC] 0.81) [27]. The average CGM wear time was 68 days, with good tolerability reported [27].

This study further identified that time spent above 7.8 mmol/L in the second trimester moderately predicted adverse neonatal outcomes such as LGA and hypertensive disorders of pregnancy (AUROC 0.58) [28]. Time above this threshold at 13–14 weeks retained predictive value for GDM diagnosis (AUROC 0.74) [28]. When matched for specificity with OGTT, CGM demonstrated comparable sensitivity for predicting LGA and hypertensive disorders of pregnancy, emphasising its potential utility as an early screening tool [28]. Ongoing studies such as Maternal Glucose in Pregnancy (MAGIC) and Glycaemic Observation and Metabolic Outcomes in Mothers and Offspring (GO MOMs) are investigating the role of CGM in early pregnancy screening and refining diagnostic criteria [14,29].

Several small observational studies confirmed CGM's ability to detect abnormal glycaemia in women with normal OGTT results [30–35]. In a prospective study involving 99 pregnant women (46 with GDM diagnosed via OGTT and 53 with normal OGTT results), seven days of CGM revealed abnormal glycaemic patterns in 33 women with normal OGTT [30]. Among these, 21 initiated diet therapy and 12 required insulin based on subsequent SMBG [30]. These women had elevated post-breakfast glucose levels and spent more time outside target glucose range, despite having similar average glucose levels to those diagnosed with GDM [30]. Although neonatal outcomes were similar between groups, the small sample size limited the power to detect significant differences [30]. These findings suggest CGM has the potential to reveal undiagnosed glycaemic abnormalities [30].

In a pilot study involving 87 women between 24 and 28 weeks of gestation, CGM was rated significantly more acceptable than the OGTT, with 81 % of participants scoring the experience 5 out of 5, compared with just 27 % for the OGTT ( $p < 0.001$ ) [31]. The study also explored diagnostic discrepancies using a triangulation approach that integrated CGM metrics, total risk scores (TRS), and CGM variability scores (CGMSV) [31]. Among 55 women deemed to have normal glucose tolerance by OGTT and triangulation, 28 were confirmed true negatives [31]. However, five women (9 %) were identified as false negatives, having normal OGTT results but elevated CGMSV and TRS score, while six women (11 %) were classified as false positives, having abnormal OGTT results but normal CGMSV and TRS metrics [31]. These findings suggest that OGTT may produce both false positive and false negative results, and they underscore the need to incorporate additional diagnostic tools such as CGM, risk scoring systems, and ultrasound measures [31].

Another prospective study involving 73 pregnant women (40 with GDM and 33 with normal glucose levels) evaluated the performance and acceptability of CGM over seven days, alongside SMBG [32]. CGM was generally well received, with 75 % of participants rating it as highly acceptable, though 15 % experienced mild skin irritation [32]. For analytical purposes, only three days of CGM data (excluding the OGTT day) were included to minimise bias [32]. Women with GDM demonstrated significantly higher mean glucose levels (5.53 vs 5.06 mmol/L), greater glycaemic variability (mean amplitude of glycaemic excursions [MAGE] 2.33 vs 1.73), and more time above the target range ( $> 7.8$  mmol/L) during the day (67 % vs 30 %) [32]. Among 34 women undergoing OGTT, only six were confirmed true positives by both CGMSV and combined demographic risk factor scores (CDRFS), while 11 were likely false positives, and one with a negative OGTT appeared to be a probable false negative [32]. Machine learning models trained on CGM data predicted OGTT outcomes with 80 % accuracy, suggesting that combining CGM metrics with clinical risk profiles may significantly enhance diagnostic precision [32]. However, further research is needed to define CGM-based diagnostic thresholds independent of OGTT [32].

In a larger prospective study, 136 pregnant women underwent a 2-step GDM screening before 30 weeks of gestation and wore a blinded CGM device (Dexcom G6 Pro) for 10 days when they took the OGTT [33]. GDM was diagnosed in only 2 individuals (2.2 %) using the 2-step method; however, CGM identified that 17 participants (18.5 %) spent  $\geq 10$  % of the time above the target glucose range ( $> 7.8$  mmol/L) [33]. This subgroup experienced significantly higher rates of adverse neonatal outcomes (63 % vs 18 %;  $p = 0.001$ ), including neonatal hypoglycaemia (47 % vs 14.5 %) and longer hospital stays (4 vs 2 days), compared with those who remained within the target range [33]. No significant differences in maternal outcomes, such as gestational weight gain, hypertensive disorders, or delivery method, were observed between the groups [33]. The study suggests that exceeding 10 % of time above the

**Table 1**  
Randomised controlled trials of CGM in GDM management.

Trial / Country	Sample size	Population	Intervention	Main Outcomes
DipGluMo (Germany, single-centre, open-label) [37]	302	Women with GDM, aged 18–45; lower mean BMI; ethnically mixed (68% White)	rt-CGM (Dexcom G6) vs SMBG	No difference in composite adverse perinatal outcomes (OR 1.02; 95% CI 0.63–1.66).
GlucoMOMS (Netherlands, multicentre, open-label) [38]	300	Insulin-treated women with T1DM (n = 109), T2DM (n = 82), GDM (n = 109)	Intermittent retrospective CGM vs SMBG	Outcomes not stratified by diabetes type. Macroemia incidence: 31.0% (CGM) vs 28.4% (SMBG); RR 1.06 (95% CI 0.83–1.37). HbA1c comparable between groups.
Malaysia (single-centre, open-label) [39]	50	Insulin-treated GDM	Retrospective CGM (6-day sensor at 28, 32, 36 weeks) vs SMBG	HbA1c rise lower in CGM group (+1 vs +3 mmol/mol; p = 0.024). Final HbA1c lower at 37 weeks (33 vs 38 mmol/mol; p < 0.006). 92% in CGM achieved HbA1c ≤ 39 mmol/mol vs 68% controls (p = 0.012). No severe hypoglycaemia.
FLAMINGO (Europe, single-centre, open-label) [41]	100	Women with GDM	Flash CGM vs SMBG	No difference in mean glucose. CGM group had greater reductions in fasting (p = 0.027) and postprandial (p = 0.034) glucose. Macroemia incidence lower with CGM (4.1% vs 20%; OR 5.63, 95% CI 1.16–27.22). No difference in insulin initiation.
China (single-centre, open-label) [43]	106	Women with GDM	CGM vs SMBG	No significant differences in obstetric/neonatal outcomes. Excessive GWG less frequent in CGM group (33% vs 56%; p = 0.039). Earlier CGM initiation linked with lower weight gain (p = 0.017).
China (single-centre, open-label) [44]	154	Well-controlled GDM (HbA1c < 6%)	CGM vs SMBG	TIR and HbA1c before delivery similar. More optimal GWG with CGM (60% vs 40%; p = 0.046). Lower neonatal birthweight (3124 g vs 3292 g; p = 0.015). No differences in adverse outcomes. SMBG was lower cost.
Singapore (pilot RCT) [40]	206	Early pregnancy, women at risk of GDM	Unblinded CGM feedback vs masked CGM	No significant difference in GDM incidence (21.5% vs 14.9%). Glucose values higher in unblinded group at 1 h and 2 h, but differences not significant.
Saudi Arabia (single-centre, open-label) [45]	130	Women with GDM	Short-term rt-CGM (~67 hrs) vs SMBG	HbA1c, fasting and postprandial glucose, and pregnancy outcomes were similar. CGM improved short-term glucose variability (p = 0.016–0.034), but not long-term outcomes.
United States (single-centre) [42]	40	Women with GDM	rt-CGM vs blinded CGM (4 weeks)	No difference in mean glucose, time in range, or maternal/neonatal outcomes.
Finland (single-centre) [46]	73	Women with GDM	CGM vs SMBG	More women in CGM group initiated pharmacotherapy (31% vs 8%; p = 0.015). No significant differences in maternal or neonatal outcomes.

target glucose range on CGM, even in the absence of positive OGTT, is associated with poorer neonatal outcomes [33].

Another study involving 119 pregnant women using CGM during OGTT found that 86 % of those diagnosed with GDM by OGTT would have also met diagnostic criteria using CGM [34]. Furthermore, among the 91 women who were not diagnosed with GDM via OGTT, CGM correctly identified 59 % as non-GDM cases, reinforcing CGM's potential role in clinical practice [34].

Similarly, CGM in early pregnancy may offer predictive value for later GDM diagnosis [35]. A prospective study involving 103 overweight or obese Asian women demonstrated that early CGM metrics outperformed traditional risk models in predicting GDM (AUC 0.952 vs 0.722) and also correlated with higher rates of caesarean delivery and LGA infants [35].

In summary, CGM shows considerable promise as both a diagnostic and prognostic tool for GDM, offering greater sensitivity than the OGTT in detecting subclinical glycaemic abnormalities and reducing false negative and positive diagnoses [27,31]. When combined with clinical risk models, machine learning, and additional modalities such as ultrasound, CGM enables a more personalised and accurate approach to GDM detection [31,32]. Furthermore, CGM is better tolerated by pregnant women, potentially enhancing engagement and compliance with care [31,36]. While current evidence highlights CGM has the potential to transform GDM screening, large-scale RCTs are still needed to establish diagnostic standards and guide clinical protocols [13].

### *The role of CGM in GDM management: Randomised controlled trials and evidence overview*

RCTs have sought to evaluate the efficacy of CGM in improving pregnancy outcomes, but results to date have been mixed (Table 1) [37–46].

DipGluMo, a large RCT involving 302 women with GDM, compared real-time CGM (rt-CGM) with SMBG [37]. Participants in the rt-CGM group used a Dexcom G6 system (sensor and transmitter with smartphone app or receiver) throughout pregnancy, with a target glucose range of 3.5–7.8 mmol/L [37]. In the SMBG group, participants measured capillary glucose six times daily (before and 1 h after meals) with targets of  $\leq 5.3$  mmol/L fasting/preprandial and  $\leq 8.0$  mmol/L 1-hour postprandial [37]. To allow comparison of time-in-range (TIR) between groups, the SMBG arm was fitted with a blinded CGM sensor, with data downloaded independently [37].

The primary outcome, a composite of adverse perinatal events (LGA infants, macrosomia, polyhydramnios, neonatal hypoglycaemia, and stillbirth), did not differ significantly between groups (36 % rt-CGM vs 35 % SMBG) [37]. Although more women in the rt-CGM group received insulin (55 % vs 45 %), insulin was started significantly later than in the SMBG group (mean gestational age 31.8 vs 30.6 weeks;  $p = 0.02$ ) [37]. Other outcomes, such as pre-eclampsia, preterm birth, and neonatal intensive care admissions, were similarly low and comparable across both groups [37]. Notably, time-in-range in late pregnancy was significantly higher in the SMBG group (96.9 % vs 92.2 %;  $p = 0.02$ ), though a high rate (43 %) of participants in SMBG who refused at least one CGM session complicates this interpretation [37]. While rt-CGM did not demonstrate superior clinical benefits, rt-CGM was preferred by participants, who rated it significantly easier to use (mean score 8.7 vs 7.2;  $p = 0.001$ ) [37]. Despite its methodological strengths such as a robust design and high retention, the trial's findings may not be generalisable as it was conducted at a single university hospital and had a relatively homogeneous population with lower average BMI, though most major ethnicities were represented (White 68 %, African 12 %, Asian 10 %, Hispanic 6 %, Mixed 3 %) [37].

Another multicentre RCT conducted across 23 Dutch centres, GlucoMOMS, evaluated the impact of intermittent retrospective CGM on pregnancy outcomes in 300 insulin-treated pregnant women with type 1 ( $n = 109$ ), type 2 ( $n = 82$ ), or GDM ( $n = 109$ ) [38]. They did not separate out the types of diabetes in their analysis, so the effect in women with GDM could not be clearly ascertained [34]. There were no significant differences in macrosomia incidence and HbA1c levels between both CGM and SMBG groups [38]. However, pre-eclampsia was significantly lower in the CGM group (3.5 % vs 18.4 %; RR 0.30, 95 % CI 0.12–0.80), particularly among women with type 1 diabetes, although adherence to CGM was limited (66 %) due to device discomfort and perceived burden of use [38]. The strengths of the study include its large sample size, inclusion of all diabetes types, and broad generalisability, though high dropout in the CGM group, lack of blinded CGM in controls, and a prolonged recruitment period were limitations [38]. These findings suggest intermittent CGM may not be warranted for routine antenatal care, however rt-CGM and closed-loop systems warrant further research [38].

Evidence continues to suggest that tighter glucose targets and improved overnight glucose control may be essential for optimal outcomes in GDM [39]. A smaller open-label trial of 50 insulin-treated GDM patients showed that CGM users had a significantly smaller increase in HbA1c by 37 weeks compared to those using SMBG (+1 mmol/mol vs. +3 mmol/mol,  $P = 0.024$ ) [39]. CGM group had lower final HbA1c ( $33 \pm 4$  mmol/mol vs.  $38 \pm 7$  mmol/mol,  $P < 0.006$ ), and a greater proportion achieved optimal HbA1c  $\leq 39$  mmol/mol without severe hypoglycaemia (92 % vs. 68 %,  $P = 0.012$ ) [39]. This supports CGM as an effective tool for improving glycaemic control [39].

Short-term CGM use has also shown promise in reducing adverse outcomes [41]. The FLAMINGO RCT compared CGM flash glucose monitoring (CGM-FGM) to SMBG in 100 pregnant women diagnosed with GDM between 24 and 28 weeks of gestation and found no significant difference in mean glucose levels [41]. However, CGM users achieved greater reductions in fasting ( $-0.69$  mg/dl vs.  $2.52$  mg/dl,  $p = 0.027$ ) and postprandial glucose levels ( $-1.01$  mg/dl vs.  $1.93$  mg/dl,  $p = 0.034$ ) [41]. Although there were no significant differences in insulin use and birthweight percentiles between CGM and SMBG groups, the CGM group had a significantly lower incidence of fetal macrosomia compared to SMBG (4.1 % vs. 20 %, OR 5.62, 95 % CI 1.16–27.22) [41]. Participants also demonstrated better dietary compliance, with improved EAT scores at follow-up (37 vs. 34,  $p = 0.017$ ) [41]. CGM identified more nocturnal hypoglycaemia episodes than SMBG (15 vs. 2/month) [41]. Despite the short duration of follow-up, these findings suggest CGM-FGM may enhance glycaemic control and reduce fetal macrosomia [41].

A separate RCT in China with 106 women assessed the impact of CGM versus SMBG on maternal and neonatal outcomes [43]. Although there were no statistically significant differences in glycaemic control, CGM users gained significantly less weight during pregnancy ( $13.56 \text{ kg} \pm 2.81 \text{ kg}$  vs.  $14.75 \text{ kg} \pm 2.91 \text{ kg}$ ,  $P = 0.004$ ) and had lower rates of excessive gestational weight gain (33.3% vs. 56.4%,  $P = 0.039$ ) [43]. While neonatal outcomes such as LGA infants, caesarean section rates and neonatal hypoglycaemia did not differ significantly, early CGM initiation may offer advantages in maternal weight gain management [43]. The study was limited by its small sample size, lack of blinding, incomplete sensor data and lower incidence of perinatal complications, which may have limited statistical power to detect significant differences [43].

In a similar trial involving 154 Chinese women with well-controlled GDM (HbA1c levels below 6%), no significant differences were found between the CGM and SMBG groups in time in range, mean blood glucose, glucose variability, or HbA1c before delivery [44]. However, the CGM group achieved more favourable gestational weight gain (GWG) (59.7% vs 40.3%,  $p = 0.046$ ) and lower infant birth weights ( $3123.79 \text{ g}$  vs  $3291.56 \text{ g}$ ,  $p = 0.015$ ) [44]. No significant differences were observed in rates of adverse maternal or neonatal outcomes [44]. CGM incurred significantly higher costs (¥2250 vs ¥752.4) and offered limited added benefit in glycaemic control for this low-risk population [44]. The study's findings may have limited applicability to women with higher baseline HbA1c, and data completeness was affected by COVID-19 pandemic [44].

Further evidence from a pilot RCT in Singapore explored whether rt-CGM feedback could reduce the incidence of GDM when initiated early in pregnancy [40]. Although CGM was well accepted and viewed as motivational, no statistically significant difference in GDM incidence was observed between groups [40]. While unblinded users showed trends towards better glycaemia control with greater time-in-range percentages, poor adherence to regular scanning and lack of behavioural changes limited the CGM's effectiveness [40]. The findings suggest that CGM feedback alone, without structural education or lifestyle guidance, is not sufficient to influence GDM outcomes, and future studies should incorporate earlier CGM use with comprehensive support strategies to influence maternal outcomes meaningfully [40].

In a Saudi Arabian RCT involving 130 pregnant women with GDM, researchers assessed whether a single short-term application of rt-CGM shortly after diagnosis could serve as an educational and motivational tool [45]. While rt-CGM significantly improved short-term glucose variability, there were no significant differences in HbA1c, fasting/postprandial glucose, insulin use, or pregnancy outcomes such as birthweight, macrosomia, or neonatal hypoglycaemia [45]. Approximately half the participants reported behaviour changes due to CGM, and nearly half had treatment plans adjusted [45]. The trial underscores the acceptability of rt-CGM and its potential as an educational aid, though its limited duration (approximately 67 h) and small sample size limited the ability to detect broader clinical benefits [45].

Similarly, a single-centre RCT involving 40 women with GDM in United States compared rt-CGM to blinded CGM for four weeks [42]. There were no significant differences in the mean glucose levels or pregnancy outcomes [42]. These results suggest that while rt-CGM may be more informative, it did not provide clinical benefit over blinded monitoring or SMBG in this short-term, small study [42].

An RCT in Finland comparing CGM with SMBG in 73 pregnant women with GDM found that CGM identified more women requiring anti-hyperglycaemic treatment than SMBG [46]. Of those using CGM ( $n = 36$ ), 31% (11 women) were started on medication (8 on insulin, 2 on metformin, and 1 on both) compared to just 8% (3/37) in the SMBG group ( $p = 0.0149$ ) [46]. Despite the difference in treatment initiation, there were no significant differences in maternal or neonatal complications [46]. The study suggests CGM may detect the need for medication in GDM more effectively or earlier, however, further large-scale trials are required [46].

A recent meta-analysis of six RCTs, involving 482 women with GDM, highlighted the benefits of CGM over traditional SMBG [13]. CGM use was associated with lower HbA1c (mean difference:  $-0.22$ ; 95% CI:  $-0.42$  to  $-0.03$ ), reduced gestational weight gain (mean difference:  $-1.17$ ; 95% CI:  $-2.15$  to  $-0.19$ ), and lower neonatal birth weights (mean difference:  $-116.26 \text{ g}$ ; 95% CI:  $-224.70$  to  $-7.81 \text{ g}$ ) [13]. However, CGM did not significantly reduce the incidence of neonatal macrosomia compared to SMBG [13]. Limitations of the meta-analysis included the use of older CGM models and small sample sizes, and most trials used CGM intermittently rather than continuously [13].

### Future studies

Ongoing studies seek to address these gaps with more robust designs (Table 2) [47–51]. The CORDELIA trial, a multicentre RCT in Belgium, is evaluating the clinical and cost-effectiveness of CGM versus SMBG, including in early diagnosed GDM [47]. Primary outcomes include a composite of adverse pregnancy outcomes, and secondary endpoints explore the psychosocial effects of CGM use and defining optimal glycaemic targets [47].

Similarly, the GRACE trial aims to determine whether rt-CGM (Dexcom G6) improves maternal and neonatal outcomes in women diagnosed with GDM between 24 and 32 weeks of gestation [48]. This study, recruiting 372 women across multiple European centres, focuses on LGA infants as the primary end point, and secondary outcomes include neonatal hypoglycaemia, caesarean delivery, and shoulder dystocia [48]. Postnatal assessments include maternal HbA1c, neonatal biometry, and follow-up testing of maternal glucose metabolism at 8–16 weeks postpartum [48]. Although the trial has reached its completion date, results have not yet been published [48].

The RECOGNISE trial is a feasibility study designed to inform a larger RCT comparing intermittently scanned CGM with SMBG in women newly started on metformin or insulin [49]. The primary outcome is recruitment and retention rates, device adherence, data completeness, and the acceptability of intervention and trial design [49]. The study will also assess glycaemic control and maternal-fetal health outcomes [49]. Key strengths of the study include its inclusive recruitment strategy, engaging women from underserved

**Table 2**  
Ongoing RCTs of CGM in GDM.

Trial / Country	Sample size	Population	Intervention	Main Outcomes	Estimated Study duration
CORDELIA (Belgium, multicentre, open label) [47]	386	Women with early or standard-diagnosed GDM	Blinded-CGM vs SMBG	Primary: composite adverse pregnancy outcomes. Secondary: psychosocial effects of CGM, definition of optimal glycaemic targets, and cost-effectiveness.	2024–2027
GRACE (Europe, multicentre, open-label) [48]	372	Women with GDM diagnosed 24–32 weeks	rt-CGM (Dexcom G6) vs SMBG	Primary: LGA infants. Secondary: neonatal hypoglycaemia, caesarean delivery, shoulder dystocia, maternal HbA1c, neonatal biometry, maternal postpartum glucose metabolism (8–16 weeks).	2020–2025. Completed. Results pending.
RECOGNISE (UK, multicentre, open-label, feasibility trial) [49]	60	Women newly initiated on metformin or insulin	Intermittently scanned CGM vs SMBG	Primary: recruitment/retention, adherence, data completeness, acceptability. Secondary: glycaemic control, maternal-fetal outcomes. Strong focus on underserved/ethnically diverse populations and qualitative evaluation.	2022–2024. Completed. Results pending.
CAPO (USA, Connecticut, single-centre, open-label) [50]	65	Women with medication-managed GDM, 24–36 weeks	CGM vs SMBG	Primary composite: perinatal death, shoulder dystocia, macrosomia, NICU admission for neonatal hypoglycaemia, birth trauma. Secondary: caesarean section for labour arrest, hypertensive disorders.	2020–2024. Completed. Results posted.
University of Washington (USA) [51]	105	Women with GDM diagnosed < 28 weeks	rt-CGM (Dexcom G6) vs SMBG	Maternal and neonatal health outcomes (specific endpoints not yet detailed).	2021–2025. Study completed. Results posted.

communities, including ethnically diverse and non-English-speaking populations, and in-depth exploration of participant and clinician acceptability through qualitative interviews [49]. Criteria for progression to a full-scale multisite trial will be acceptability of participants and HCPs towards trial processes including recruitment, randomisation, outcome measures and follow-up [49].

Two ongoing US-based RCTs are investigating the effectiveness of CGM compared to GDM. The CAPO study, a single-centre trial in Connecticut, involves 80 women with medication-managed GDM between 24 and 36 weeks of gestation [50]. The primary composite outcome includes perinatal death, shoulder dystocia, macrosomia, NICU admission for neonatal hypoglycaemia, and birth trauma such as fractures or nerve palsy [50]. Secondary outcomes include rates of caesarean section for labour arrest and hypertensive disorders of pregnancy [50]. Running from 2020 to 2026, the study also explores whether CGM improves glycaemic control and patient adherence [50]. However, its relatively small sample size and single-site design may limit statistical power and generalisability [50]. A separate trial by the University of Washington involves 100 women diagnosed with GDM before 28 weeks of gestation, comparing the Dexcom G6 rt-CGM with SMBG [51]. The study aims to assess maternal and neonatal health outcomes, though specific endpoints are not clearly defined [51].

While CGM offers a more nuanced and continuous measure of glycaemia, its superiority over SMBG in improving perinatal outcomes remains uncertain [13,37–46,52]. Differences in study design, CGM modality (real-time vs retrospective), duration of monitoring, population risk profiles, and adherence all influence trial outcomes [13,37–46,52]. Collectively, these previous and ongoing trials represent an important step towards refining GDM management [13,47–51].

### *CGM metrics and pregnancy outcomes*

Further insight into CGM's predictive value comes from a large prospective cohort study involving 1302 pregnant women diagnosed with GDM at around 26 weeks of gestation [53]. Participants underwent CGM for 14 days, with subsequent follow-up through to delivery [53]. The study found that increases in time above range (TAR), glucose area under the curve (AUC), and mean blood glucose (MBG) were significantly associated with higher risk of adverse outcomes [53]. In contrast, time below range was linked to a lower risk of LGA infants, while elevated TAR was positively associated with higher rates of neonatal intensive care unit (NICU) admissions [53]. The study also highlighted that overweight or obese women were at increased risk of hyperglycaemia and adverse pregnancy outcomes [53]. While the strengths of this study include a large sample size and detailed CGM profiling, the limitations of this study include its single-centre design, a homogenous Chinese population, and restriction to second-trimester data limits its generalisability [53]. Nonetheless, CGM metrics, particularly TAR and MBG, may serve as early predictors of adverse pregnancy outcomes in GDM, advocating for personalised glucose targets and the need for multi-ethnic interventional trials to confirm clinical utility [53].

Complementary evidence from a separate prospective cohort study in China involving 340 pregnant women demonstrated that CGM use significantly improved glycaemic metrics, including reduced variability [54]. These improvements were linked to lower incidences of pre-eclampsia, primary caesarean delivery, and reduced birth weights [54]. The mean amplitude of glycaemic excursions (MAGE) was positively associated with birth weight and adverse maternal outcomes, suggesting that managing glucose variability may be as crucial as maintaining glucose levels [54].

Emerging evidence suggests that the timing of dysglycaemia may be as important as overall glycaemic control in predicting adverse outcomes in GDM [24]. One study in particular demonstrated a stronger association between nocturnal hyperglycaemia and the risk of delivering an LGA infant [24]. In this prospective observational study involving 162 women with GDM, women underwent masked CGM for seven days between 30 and 32 weeks of gestation [24]. Women who delivered LGA infants had significantly higher mean glucose levels than those with appropriately sized babies (6.2 mmol/L vs. 5.8 mmol/L,  $P = 0.025$ ) [24]. Notably, traditional glycaemic metrics such as time in range, time above or below target, and glucose variability did not differ significantly between the groups ( $P > 0.05$ ) [24]. Through functional data analysis, elevated glucose levels were shown to be particularly high during the night (00:30–06:30), with a mean nocturnal glucose of  $6.0 \pm 1.0$  mmol/L versus  $5.5 \pm 0.8$  mmol/L ( $P = 0.005$ ) [24]. These findings suggest that nocturnal hyperglycaemia, often missed by SBMG, may play a pivotal role in excessive fetal growth [24]. The strengths of this study include an ethnically diverse cohort and the detailed glycaemic profiling, however its limitation lies in the monitoring window at 30–32 weeks of gestation which may not reflect glucose dynamics earlier or later in pregnancy [24]. Overall, these results suggest that the CGM has the potential to identify and manage nocturnal hyperglycaemia, potentially reducing the risk of LGA-related complications [24].

### *CGM and telemedicine integration*

The integration of downloadable glucose data with telemedicine represents a transformative model for managing GDM [55]. By providing detailed glycaemic data, CGM enables healthcare professionals to deliver tailored, data-driven interventions remotely [55]. This would not only enhance patient convenience but also allow for more timely and precise therapeutic adjustments [55]. A meta-analysis of 32 RCTs involving 5108 patients demonstrated the clinical benefits of telemedicine [51]. Patients in the telemedicine group showed significant improvements in glycaemic control, with reductions in HbA1c (mean difference [MD] =  $-0.70$ ,  $p < 0.01$ ), fasting blood glucose (MD =  $-0.52$ ,  $p < 0.01$ ), and 2-hour postprandial glucose (MD =  $-1.03$ ,  $p = 0.01$ ), compared to those receiving standard care [55]. Telemedicine was also associated with lower incidences of obstetric and neonatal complications [55]. These included reduced rates of caesarean section (relative risk [RR] = 0.82), neonatal hypoglycaemia (RR = 0.67), preterm birth (RR = 0.27), macrosomia (RR = 0.49), pregnancy-induced hypertension or preeclampsia (RR = 0.48), neonatal asphyxia (RR = 0.17), and polyhydramnios (RR = 0.16) [55]. Trial sequential analyses confirmed the stability and reliability of these findings,

highlighting the robust evidence supporting telehealth integration [55]. Further studies are required to assess the integration of CGM with digital health platforms in routine GDM management [55].

#### *Acceptability of CGM in clinical practice*

Patient and clinician acceptability is key to the successful integration of CGM into routine care [56]. Recent studies have shown that CGM is generally well tolerated and preferred over OGTT, which remains the current standard for GDM diagnosis [22,56]. In a pilot study, 81 % of participants rated CGM with the highest acceptability score compared to just 27 % for OGTT ( $p < 0.001$ ) [22]. Participants cited CGM's convenience, minimal invasiveness, and improved comfort as key benefits, particularly during early pregnancy when OGTT is often poorly tolerated [22].

The latest CGM devices, have further improved user experience by eliminating the need for finger-prick calibration and offering discreet, arm-worn sensors [31]. These features align with the WHO RE-ASSURED criteria, which promote diagnostic tools that are Real-time, Easy to use, Affordable, Sensitive, Specific, User-friendly, Rapid, Equipment-free, and Deliverable to end-users [31]. CGM meets most of these benchmarks and, crucially, offers a more patient-centred alternative to traditional testing [31].

Healthcare professionals also acknowledge CGM's potential, although confidence in OGTT remains high [22]. In one survey, 73 % of clinicians still supported OGTT, yet 66 % expressed concerns about its limitations, including cost, accessibility, and the absence of CGM-based diagnostic thresholds [22]. Encouragingly, neither patients nor clinicians rated any aspect of CGM such as sensor insertion or removal as 'very poor', underscoring its broad acceptability [22]. Continued research is required to validate CGM thresholds and integrate them into diagnostic algorithms [22].

#### *Tackling health inequalities with CGM*

Women from socioeconomically disadvantaged backgrounds, and those of Black or South Asian ethnicity, are disproportionately affected by GDM and often face barriers to care [57]. Diagnostic methods like OGTT may exacerbate these disparities, given their poor tolerability and demanding logistical requirements [57]. A multi-centre UK study involving 1906 pregnant women revealed that 32.3 % failed to attend OGTT appointments altogether, with non-attendance highest among younger women, those from Black African backgrounds, and those with high parity or lower socioeconomic status [57]. Common barriers included test discomfort, mental health issues, transport difficulties, childcare demands, and scheduling conflicts [57]. The need for fasting, prolonged clinic attendance, and morning appointment availability further limits OGTT accessibility [57]. In contrast, CGM offers a less invasive, more flexible alternative that may be better suited to women facing these challenges [56].

In low-resource settings, CGM has also demonstrated potential [58]. A study in Uganda involving 28 pregnant women found that CGM could detect abnormal glucose patterns missed by OGTT [58]. Some women who tested negative on OGTT exhibited elevated glucose spikes, while others with initially positive OGTT results had CGM profiles similar to controls [58]. These women also had a significantly lower BMI (29.0 vs 36.3 kg/m<sup>2</sup>,  $p = 0.014$ ), suggesting that traditional OGTT thresholds may lead to overdiagnosis in leaner populations [58]. Despite CGM's potential, technical challenges such as underestimation of glucose levels (by 0.58 mmol/L on average) and sensor loss (21 % of cases) due to environmental conditions remain, but CGM holds promise for context-appropriate, equity-enhancing diagnostic pathways [22,56,58].

#### *Cost-Effectiveness of CGM in GDM*

Although CGM systems incur higher upfront costs compared to standard diagnostic tools, growing evidence suggests they may offer significant long-term cost savings by reducing maternal and neonatal complications [59]. In the UK, it is estimated that £9.5 million could be saved annually through the reduction of neonatal intensive care unit (NICU) admissions in women with type 1 diabetes using CGM [59]. Similar economic benefits may apply to GDM by lowering rates of costly outcomes such as caesarean section and NICU stays [60].

When accounting for staff time, phlebotomy, and patient monitoring over several hours, OGTT becomes considerably more resource-intensive [36,61]. Importantly, false GDM diagnoses have substantial cost implications [61]. A false positive GDM diagnosis may lead to over AUD \$6000 in unnecessary care, while false negatives can incur over AUD \$5500 in complications [61]. In this context, the higher upfront cost of CGM may be justified [61]. Further economic modelling is needed to fully understand CGM's value, particularly in reducing unnecessary interventions and improving maternal and neonatal outcomes [36,59,61].

#### **Summary**

CGM is an emerging tool in the diagnosis and management of GDM, offering more detailed glycaemic insights than traditional OGTT and SMBG [24]. CGM's ability to detect nocturnal hyperglycaemia and glycaemic variability, often missed by SMBG, may enable earlier identification of GDM and enable more personalised care [24]. While RCTs have produced mixed results with some showing no significant improvement in maternal-fetal outcomes, others have reported notable benefits, including reduced pre-eclampsia rates, lower gestational weight gain, improved HbA1c levels, and decreased fetal macrosomia [37–46,52]. A meta-analysis has reported that CGM results in modest improvements in HbA1c, reduced gestational weight gain, and lower neonatal birth weights [13]. When combined with telemedicine, CGM has been shown to reduce adverse maternal and neonatal outcomes such as caesarean section, neonatal hypoglycaemia, preterm birth, macrosomia and pre-eclampsia, highlighting its value in remote, data-driven care

models [55]. Patients and clinicians report high satisfaction with CGM, with many preferring it over the OGTT for its convenience and comfort [22,56]. However, inconsistent study designs, variations in CGM technology, and patient adherence limits its broad applicability [37–46,52]. Ongoing research aims to address these limitations [47–51]. Overall, CGM shows strong potential to improve GDM care by enabling early detection, personalised treatment, and broader access when integrated with telehealth and education [13]. For CGM to become a standard in modern maternity care, high-quality evidence, updated guidelines and equitable access will be essential [5,62,63].

### Research Agenda

- Trials are needed to assess the utility of CGM for early detection and management of gestational diabetes mellitus (GDM), particularly in the first and early second trimesters.
- The impact of CGM use on short- and long-term maternal and neonatal outcomes should be evaluated.
- The predictive value of CGM-derived metrics, such as nocturnal hyperglycaemia and time above range, requires further investigation.
- Comparative studies of CGM versus OGTT and SMBG in diagnostic accuracy and patient acceptability are needed.
- Trials integrating CGM with clinical risk scores and telemedicine platforms should be undertaken.
- Multi-ethnic, adequately powered randomised controlled trials are required to improve the generalisability of findings.
- The cost-effectiveness of CGM in GDM diagnosis and management should be assessed.
- Studies examining CGM-guided personalised treatment strategies and their impact on clinical outcomes are needed.

### Practice Points

- Gestational diabetes mellitus (GDM) is commonly diagnosed with the oral glucose tolerance test (OGTT) and monitored via self-monitoring of blood glucose (SMBG), both of which have limitations.
- Continuous glucose monitoring (CGM) provides detailed 24-hour glucose profiles, detecting glycaemic excursions missed by SMBG.
- CGM enables earlier detection of subclinical dysglycaemia and may improve diagnostic accuracy when combined with clinical risk scores.
- Use of CGM in GDM has been associated with improved glycaemic control, reduced gestational weight gain, and enhanced patient satisfaction.
- Nocturnal hyperglycaemia detected by CGM may serve as an early marker for fetal overgrowth.
- Integration of CGM with telemedicine platforms offers potential for more personalised and accessible diabetes care in pregnancy.
- Despite promising results, large, robust, and ethnically diverse randomised controlled trials are required to validate CGM's clinical impact on maternal and neonatal outcomes.

### Declaration of Competing Interest

Hui Wei Leow declares no competing interests relating to this work. Eleanor Scott has received honoraria for talks and workshops from Abbott Diabetes Care, Lilly Diabetes Care, and Ypsomed Diabetes Care. Karen Forbes declares no competing interests related to this work.

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