

# Application of continuous glucose monitoring and automated insulin delivery technologies for pregnant women with type 1, type 2, or gestational diabetes: an international consensus statement



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Insulin resistance increases after the first trimester of pregnancy, leading to glycaemic challenges for women with pregestational type 1 diabetes or type 2 diabetes. Additionally, insulin resistance can promote hyperglycaemia in pregnant women without type 1 diabetes or type 2 diabetes, who develop gestational diabetes. Although most (>95%) women with diabetes deliver healthy babies, maternal dysglycaemia can have consequences for the mother and child, including prenatal, perinatal, immediate, and long-term postnatal complications. Diabetes technologies, such as continuous glucose monitoring (CGM) and automated insulin delivery (AID) systems can aid in optimising glycaemia outside of pregnancy. These novel technologies have not been extensively tested in large randomised controlled trials before and during pregnancy. However, compelling data report the benefits of CGM in type 1 diabetes, and increasing data report on AID systems in pregnancies complicated by type 1 diabetes. Appropriate CGM glucose thresholds for the diagnosis of gestational diabetes and the recommended time in range treatment targets for the routine management of gestational diabetes and type 2 diabetes still need to be determined. The recommendations in this Consensus Statement emphasise the value of CGM during preconception and pregnancy for women with pregestational type 1 diabetes in reducing pregnancy complications. Recommendations also include the use of AID systems in women with pregestational type 1 diabetes to improve glycaemic management during preconception, during pregnancy and delivery, and in the postpartum period. This Consensus Statement has been endorsed by 24 societies and groups.

## Introduction

Pregnant women with pregestational type 1 diabetes or early onset type 2 diabetes and women with gestational diabetes are at increased risk of obstetric and neonatal complications.<sup>1–4</sup> Substantial progress has been made to ensure that women with any type of diabetes have healthy pregnancies, with therapeutic advances including insulin analogues and continuous glucose monitoring (CGM) technologies.<sup>1–4</sup> Automated insulin delivery (AID) systems have (when available) become the standard of care for people with type 1 diabetes outside of pregnancy, and are increasingly used before and during type 1 diabetes pregnancy.<sup>5</sup> As diabetes technology evolves, the safety and efficacy data supporting the use of AID systems in pregnancy is growing.<sup>5</sup> To distil the several outcomes and clinical applications proposed for diabetes technologies during pregnancy with diabetes, a clinical consensus panel was convened to make evidence-based recommendations for the optimal care of women with pregestational type 1 diabetes or type 2 diabetes during pregnancy and for women with gestational diabetes. This International Consensus Statement focuses on CGM and AID systems as diabetes technologies that have the potential to be used in pregnancy to improve outcomes in women with diabetes. Other aspects of a multitargeted approach to the management of diabetes in pregnancy,<sup>2</sup> or other

technologies (such as apps or smart pens), are outside of the scope of this Consensus Statement.

This Consensus Statement uses the terms woman or mother to minimise misrepresentation of health statistics and cross-cultural communication barriers, and maintain visibility of the unique needs, experiences, and rights that come with pregnancy, birthing, and breastfeeding. The discussion herein also applies to people who do not identify as women, but are pregnant or have given birth, recognising that inclusivity and consideration of medical and social needs for this group require additional unique attention.<sup>6</sup>

This Consensus Statement has been endorsed by the ADJ Diabetes Brazil, Advanced Technologies and Treatments for Diabetes, the American Association of Clinical Endocrinology, the American College of Diabetology, the American Pharmacists Association, the Association of Diabetes Care and Education Specialists, the Australasian Diabetes in Pregnancy Society, the Australian Diabetes Society, the Australian Diabetes Educators Association, the Brazilian Diabetes Society, Breakthrough T1D, the Centre for Chronic Disease (India), Diabetes Australia, DiabetesIndia, the European Association for the Study of Diabetes, the European Board and College of Obstetrics and Gynaecology, the Indian College of Obstetricians and Gynaecologists, the International Association of Diabetes and Pregnancy

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Study Groups, the International Diabetes Federation, the International Federation of Gynaecology and Obstetrics, the Japan Diabetes Society, the Research Society for the Study of Diabetes India, the Society for Obstetric Medicine India, and the World Organisation of Family Doctors. The American College of Obstetricians and Gynecologists supports the value of this clinical document as an educational tool.

## Methods

The diaTribe Foundation—a non-governmental organisation—invited health-care professionals with expertise in the use of CGM and AID in diabetes during pregnancy to participate in a consensus panel that complied with the Accurate Consensus Reporting Document (ACCORD) criteria.<sup>7</sup> We used the nominal group technique, combining brainstorming, discussion, and refinement of ideas.<sup>8</sup> The nominal group technique is designed to allow every participant to voice their views at all distinct stages, and to agree or disagree within the overall group structure. Opinion leaders were drawn from academic institutions and diabetes, obstetric, and primary care associations globally. The writing group was selected to be multidisciplinary, and included representatives from different continents (Europe, North America, Australia, Asia, Africa, and South America). All authors of this Consensus Statement are members of the consensus writing group. People living with diabetes (including individuals with experience of having diabetes in pregnancy) and family members outside of academia were also invited. Participation in the writing group was voluntary and not remunerated. KB, JH, ML, and HRM created a compendium of topics for consideration by the writing group, who in turn provided two rounds of objective feedback (at in-person and online meetings in March, 2024, November, 2024, and January, 2025). A consolidated draft manuscript and recommendations based on this feedback were further developed and refined at the International Consensus on Diabetes Technology in Pregnancy meeting in March, 2025, before the Advanced Technologies and Treatments for Diabetes conference, also in March, 2025. Each individual recommendation was discussed until a consensus was reached, with 100% of the consensus group voting in agreement. These discussions, with feedback from external reviewers and international professional associations, were used to further refine the consensus document over multiple drafts following the March 2025 meeting. The final draft was then approved by all members of the writing group.

## General discussion

### Access and equity in the use of diabetes technologies

Disparities in diabetes care for some groups are long standing and have increased in the past decade.<sup>9–11</sup> Access to diabetes technologies, including previous forms such as self-monitoring of blood glucose (SMBG), varies

substantially in different settings due to disparate market access, health systems, and other factors.<sup>12,13</sup> Even within countries, studies have consistently shown 50% lower rates of access to diabetes technology among individuals with diabetes and low socioeconomic status compared with individuals in the highest quartiles of socioeconomic status, as well as among some racial and ethnic groups.<sup>14–20</sup> Addressing disparities in diabetes technology use might improve population-level glycaemic outcomes—widespread implementation of CGM has shown that health inequalities can be overcome, including population-level improvements in maternal and fetal health.<sup>21</sup> In this context, we acknowledge that the implementation of some recommendations might be more difficult for some populations within high-income countries, in most low-income and middle-income countries, and in conflict zones. In every situation, systems-level intervention is needed to improve access and health literacy in the use of diabetes technologies for healthy maternal and perinatal outcomes.

### Pregnancy is an insulin-resistant state

With advancing gestation after the first trimester, increases in insulin resistance and delayed insulin absorption (or reduced insulin secretion in type 2 diabetes) can result in high blood glucose concentrations.<sup>22–25</sup> During pregnancy, diabetic ketoacidosis is a life-threatening emergency for both the mother and fetus, with high rates of stillbirth associated with diabetic ketoacidosis (160/1000 pregnancies) occurring mainly in women with pregestational type 1 diabetes (1–2% of pregnancies).<sup>26</sup> However, stillbirth associated with diabetic ketoacidosis can also occur in pregestational type 2 diabetes (0·1%)<sup>26</sup> and in gestational diabetes (0·02%).<sup>27</sup> Beyond insulin management, meeting recommended glycaemic targets, avoiding hyperglycaemia, and the use of ketone monitoring are key to reducing diabetic ketoacidosis events in type 1 diabetes pregnancies; however, ketone monitoring is not routinely recommended in type 2 diabetes or gestational diabetes. Continuous ketone monitoring devices are currently in development,<sup>28</sup> including sensors with dual CGM and continuous ketone monitoring capability, but the role of ketone monitoring (eg, during sickness) is unknown during pregnancy.

### CGM to support general diet and physical activity recommendations

Pregnant women with diabetes are counselled regarding healthy behaviours, including a balanced diet inclusive of proteins, whole grains, healthy fats, fruits, and vegetables, along with regular physical activity, to improve health and optimise glycaemia.<sup>29</sup> Randomised controlled trials (RCTs) and crossover trials of nutritional-based or exercise-based interventions have focused on women with gestational diabetes, with little high-quality data in pregestational type 1 diabetes or type 2 diabetes.<sup>30</sup> These studies have

reported mixed results, including a moderate effect on fasting plasma glucose (FPG) and/or postprandial plasma glucose (PPG).<sup>30,31</sup> Studies on physical activity for lowering FPG and/or PPG<sup>30,32,33</sup> have generated inconsistent results. The use of CGM allows pregnant women to see the real-time relationship between glucose concentrations, diet, and physical activity.

### Integrating CGM data into the care of pregnant women with diabetes

CGM systems enable individuals with diabetes to track glucose fluctuations in real time and react to them as needed. Cloud-based platforms allow CGM data to be shared with a clinical team instantaneously, and can allow for rapid response times to questions or concerns from the individual CGM user.<sup>34</sup> Ideally, CGM data would be integrated into electronic health records, including ambulatory glucose profiles—the standard modality for viewing aggregated CGM data (typically 7–14 days).<sup>35</sup> Ambulatory glucose profile reports offer data visualisation for non-pregnant women and only some offer customisation for pregnancy-specific glucose goals. With a history of incorporating new consensus metrics and methods of visualising CGM data,<sup>36</sup> the ambulatory glucose profile report should include options to view the pregnancy-specific time in range (TIRp) of 3·5–7·8 mmol/L (63–140 mg/dL), which is widely used in type 1 diabetes pregnancy since an international consensus statement in 2019.<sup>37</sup> This inclusion would support patients and clinicians to make necessary therapy adjustments specific for diabetes pregnancy care, although CGM glucose thresholds for the diagnosis and management of type 2 diabetes and gestational diabetes still need to be determined. Notably, discrepancies currently exist in the metrics generated by different CGM sensors and depend on the comparator method used, indicating the need for industry-wide standards and comparator harmonisation such that CGM metrics can be interpreted consistently.<sup>38,39</sup>

### Integration of diabetes technology in the workflow of the diabetes and pregnancy care team

With increased availability and acceptability of CGM, many women will have access to this technology in pregnancy, either via prescription or over the counter. CGM and AID systems are advantageous in that they facilitate remote access to daily glycaemic pattern profiles, along with insulin delivery data for AID systems. Integration of these systems and the data they provide into clinical practice and office workflows will ideally require a multidisciplinary approach, including nursing and midwifery staff, pharmacists, diabetes care and education specialists, advanced practitioners, obstetricians, and other physicians. Importantly, CGM devices should be validated for use during pregnancy or should at least meet the US Food and Drug Administration integrated CGM performance criteria.<sup>40,41</sup> CGM integration

into pregnancy care will require user education on how to best use the technology, such as understanding alerts or alarms and trend arrows and the effects of diet and physical activity on glucose concentrations. Furthermore, education of health-care teams who are less familiar with the use of diabetes technologies (including primary care) or who might have a supporting role in preconception, antenatal, and postnatal care of women with diabetes is an essential component of implementing the consensus recommendations.

### Impact of diabetes technology on maternal mental health

Women with diabetes face heightened risks of mental health issues during pregnancy and the postpartum period, including depression, anxiety, and stress—largely due to the added burden of living with a chronic condition.<sup>42–45</sup> Diabetes technology might either ease or increase this burden, and research suggests that some women can have disturbed sleep,<sup>46</sup> increased anxiety, and symptoms of depression with CGM use,<sup>47</sup> whereas others can have benefits that include reduced stress, diabetes distress, and fear of hypoglycaemia, as seen in observational studies outside of pregnancy.<sup>48–51</sup> The impact of diabetes technology can vary by type of diabetes in pregnancy. Ultimately, the application of diabetes technology should be tailored to individual needs, balancing the impact on mental health with diabetes management and outcomes.

### Diabetes technology in type 1 diabetes during pregnancy

#### Prepregnancy care in type 1 diabetes

Maternal glycaemia is a modifiable risk factor, and avoiding hyperglycaemia before conception reduces the risks of congenital malformations and miscarriage.<sup>3,52</sup> Maintaining target glycaemia during pregnancy reduces complications attributed to fetal hyperinsulinaemia, including preterm births, large for gestational age (LGA) infants, and neonatal care admissions.<sup>3,53</sup> The HbA<sub>1c</sub> target should be less than 7·0% (<53 mmol/mol) during preconception or less than 6·5% (<48 mmol/mol), if feasible, during pregnancy (table 1).<sup>3,29,56</sup> CGM systems have become the standard of care for managing type 1 diabetes during pregnancy.<sup>3,29,37,56,57</sup> International consensus targets recommend a TIRp of 3·5–7·8 mmol/L (63–140 mg/dL) more than 70% of the time (table 1).<sup>37,58</sup> Evidence that the use of pregnancy-specific glycaemic targets with CGM during preconception can improve pregnancy outcomes is currently scarce.

AID systems use an algorithm, insulin pump, and CGM sensor to provide glucose-responsive insulin delivery with user-initiated pre-meal insulin boluses.<sup>59–61</sup> Specific data on AID systems in the preconception period are insufficient, but data from outside of pregnancy have indicated that AID systems support reaching glycaemic goals, leading to a 12% higher time in range (TIR) of

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Measures	Aim
HbA <sub>1c</sub> when planning pregnancy	HbA <sub>1c</sub> which reflects glycaemic concentrations over the past 3–4 months <7.0% (<53 mmol/mol); <6.5% (<48 mmol/mol) if feasible
HbA <sub>1c</sub> first trimester	NA <6.5% (<48 mmol/mol)
HbA <sub>1c</sub> second and third trimester	NA <6.0% (<42 mmol/mol) <sup>54</sup>
Percentage of sensor data obtained	The proportion of obtained versus total possible data collected by the CGM device; provides a measure of confidence in all data-derived metrics ≥70% of data during the collection period <sup>38</sup>
TIR when planning pregnancy	Percentage of time spent between 3.5 mmol/L and 7.8 mmol/L (63–140 mg/dL) for pregnancy if possible or between 3.9 mmol/L and 10.0 mmol/L (70–180 mg/dL) otherwise >70% of time per day (ie, 16 h 48 min)
TIRp	Percentage of time spent in consensus target glucose range in pregnancy—ie, between 3.5 mmol/L and 7.8 mmol/L (63–140 mg/dL) >70% of time per day (ie, 16 h 48 min)† from as early as possible following pregnancy confirmation
TBRp <3.5 mmol/L (63 mg/dL)	Percentage of time spent with glucose <3.5 mmol/L (<63 mg/dL) <4% of time per day (1 h)
TBR <3.0 mmol/L (54 mg/dL)	Percentage of time spent with glucose <3.0 mmol/L (<54 mg/dL) <1% of time per day (15 min)
TARp >7.8 mmol/L (140 mg/dL)	Percentage of time spent with glucose >7.8 mmol/L (>140 mg/dL) <25% of time per day (6 h)‡
Mean sensor glucose	Mean 24-h glucose concentration calculated across all recorded sensor glucose readings Suggested mean sensor glucose of 6.0–6.7 mmol/L (108–120 mg/dL), based on expert opinion (evidence level E)
GMI	A measure of short-term glucose concentrations that can be used to predict long-term glucose exposure; GMI is expressed in the same units as HbA <sub>1c</sub> (eg, as a percentage or mmol/mol) for comparative purposes, but they are usually not identical No international consensus target, but <42 mmol/mol is suggested, which is similar to (but not equivalent to) a HbA <sub>1c</sub> of 6.0%
CV	Dynamic GV expressed as percentage CV and calculated as follows: 100 × (SD divided by mean glucose) ≤36% of glucose variability in type 1 diabetes; <sup>38</sup> ≤30% in type 2 diabetes (NCT04972955) <sup>55</sup>
TIRp intrapartum	Percentage of time spent in consensus target glucose range—between 3.5 mmol/L and 7.8 mmol/L (63–140 mg/dL)—during labour and delivery >70% of time intrapartum
TIR postpartum	Percentage of time spent in consensus target glucose range—between 3.9 mmol/L and 10.0 mmol/L (70–180 mg/dL)—following delivery >70% of time per day

CGM=continuous glucose monitoring. CV=coefficient of variation. GMI=glucose management indicator. GV=glucose variability. NA=not applicable. SD=standard deviation. TARp=pregnancy time above range. TBR=time below range. TBRp=pregnancy time below range. TIR=time in range. TIRp=time in range in pregnancy. \*HbA<sub>1c</sub> is known to be an inconsistent marker of glycaemia during pregnancy, emphasising the value of CGM metrics. †Percentage of TIRp is specific for pregnant women with type 1 diabetes. Percentage of TIRp for pregnant women with type 2 diabetes and gestational diabetes should probably be more than 70%, but the exact amount is unknown due to a scarcity of data. ‡Percentage of TARp is specific for pregnant women with type 1 diabetes. Percentage of TARp for pregnant women with type 2 diabetes and gestational diabetes should be much less than 25%, but the exact amount is unknown due to a scarcity of data.

Table 1: HbA<sub>1c</sub> and CGM targets for pregnant women with type 1 diabetes\*

3.9–10.0 mmol/L (70–180 mg/dL) than continuous subcutaneous insulin infusion (CSII) pumps or multiple daily injections (MDI).<sup>59,60,62</sup> AID systems should be initiated before pregnancy if possible to optimise preconception glycaemia.<sup>2</sup> AID systems with evidence of clinical effectiveness from larger RCTs in pregnancy should preferably be used (panel 1; table 2).<sup>70,71,78</sup> However, given that half of pregnancies in women with pregestational diabetes are unplanned,<sup>80</sup> AID systems proven to optimise antenatal glycaemia should be started as soon as pregnancy is verified—usually at 7–8 weeks gestation.

### Pregnancy care in type 1 diabetes

The CONCEPTT trial, including 325 women with type 1 diabetes (215 pregnant and 110 planning pregnancy), showed that real-time CGM leads to a significantly higher TIRp than SMBG, with reductions in LGA infants, neonatal intensive care unit admissions, and severe neonatal hypoglycaemia.<sup>1</sup> CGM use also reduces hypertensive disorders of pregnancy<sup>81,82</sup> and offers important cost savings, with improved neonatal outcomes.<sup>66–69,83</sup> Therefore, the use of CGM is

recommended for pregnant women with type 1 diabetes (panel 1).<sup>29,57,83</sup>

The use of open-loop CSII does not improve glycaemia or pregnancy outcomes compared with MDI,<sup>84–90</sup> and higher rates of LGA infants have been reported in some studies.<sup>89,91–93</sup> In the CONCEPTT trial, MDI users had lower rates of gestational hypertension, neonatal hypoglycaemia, and neonatal intensive care unit admissions than CSII users.<sup>94</sup> RCTs and observational studies also indicate that the use of CSII compared with MDI results in higher gestational weight gain,<sup>84</sup> highlighting the challenge of optimising CSII settings, especially from the second trimester onwards, when insulin resistance increases.<sup>95,96</sup>

Sensor-augmented pump (SAP) therapy refers to the use of CSII and CGM together in an open-loop configuration. With partial AID functionality, the pump can be used in low-glucose-suspend mode or suspend-before-low mode, in which insulin delivery is suspended for up to 2 h once a preset hypoglycaemic threshold is reached or predicted to be reached (no automated corrections are made for hyperglycaemia). By contrast, when in the predictive low-glucose-suspend mode,

insulin delivery is suspended when an algorithm predicts hypoglycaemia within the next 30 min, with basal insulin restored once hypoglycaemia is corrected. When tested, both SAP and partial AID were safe and effective in minimising maternal hypoglycaemia,<sup>97–99</sup> but no improvements in TIRp or pregnancy outcomes were observed.

#### Evidence from randomised controlled trials

Most commercially available AID systems have not yet been robustly evaluated in pregnancy (table 2); however, two RCTs have tested the CamAPS FX and the MiniMed 780G AID systems in pregnant women with type 1 diabetes (table 2).<sup>70,71</sup> Notably, most women studied to date have been White. The CamAPS FX system is licensed for use globally in pregnancy, whereas the MiniMed 780G system is currently licensed only within Europe. The AiDAPT RCT compared CamAPS FX with standard care (MDI or open-loop CSII with CGM) in 124 pregnant women with type 1 diabetes, with an inclusion criteria of HbA<sub>1c</sub> of 6·5–10% (48–86 mmol/mol).<sup>70,100,101</sup> The use of CamAPS FX significantly increased the baseline-adjusted mean TIRp (10·5%—ie, an additional 2·5 h; 68·2% AID vs 55·6%), regardless of baseline HbA<sub>1c</sub> and previous technology use.<sup>70</sup> A TIRp of more than 70% was attained throughout pregnancy in 47% of patients in the AID group compared with 11% in the standard of care group. CamAPS FX users had lower rates of hypertensive disorders, less gestational weight gain,<sup>70</sup> and self-reported positive pregnancy experiences.<sup>102</sup>

The CRISTAL study randomly assigned 95 pregnant women with type 1 diabetes, comparing the MiniMed 780G AID system versus standard care with MDI or with open-loop CSII or partial AID and any CGM system,<sup>71,103</sup> with no lower HbA<sub>1c</sub> limit for inclusion. AID use did not improve the overall TIRp compared with standard care (66·5% vs 63·2%), but improved the overnight TIRp by 24 min (+6·58%), reduced the time below range in pregnancy (TBRp) by 19 min, and improved treatment satisfaction.<sup>71</sup> In contrast to real-world studies,<sup>104</sup> excess gestational weight gain was significantly lower in MiniMed 780G users compared with standard insulin therapy.<sup>71</sup> The algorithm performed well overnight, but often required assisted carbohydrate administration (adding so-called fake carbohydrates) with meals—further refinement is needed for use later in pregnancy. AID is also likely to be cost-saving compared with standard care.<sup>105</sup> The AiDAPT and CRISTAL trials were not powered for pregnancy outcomes.

The pilot PICLS RCT compared the MiniMed 670G as a hybrid closed loop AID system with the same device used as an SAP system in 23 women.<sup>75</sup> The mean glucose was significantly higher and the TIRp tended to be lower but this was not statistically significant ( $p=0\cdot17$ ) in the third trimester with AID functionality. Hypoglycaemia fear improved for AID users.<sup>106</sup> Assistive techniques were used, such as so-called fake

#### Panel 1: Recommendations for using diabetes technology in pregnant women with type 1 diabetes and those planning pregnancy

Each of the recommendations in this consensus have been assigned a level of supporting evidence (ie, A, B, C, or E) that adheres to the evidence-grading system of the American Diabetes Association Standards of Medical Care in Diabetes (appendix p 5).<sup>29</sup>

- Glycaemia should be optimised when planning pregnancy to reduce the risk of pregnancy complications (A).<sup>55,63,64</sup> The use of continuous glucose monitoring (CGM) is recommended for all women with type 1 diabetes\* to optimise glycaemia before pregnancy to reduce pregnancy complications (A),<sup>1</sup> such as reduced admissions to neonatal intensive care units, reduced incidence of large for gestational age infants and lowered occurrence of neonatal hypoglycaemia. CGM should be used to reach and maintain a time in range of 3·9–10·0 mmol/L (70–180 mg/dL)—more than 70% per day before pregnancy, targeting an HbA<sub>1c</sub> of <7·0% (<53 mmol/mol) or <6·5% (48 mmol/mol) if feasible (A).<sup>1,65</sup>
- CGM use during pregnancy results in important cost savings, or is cost neutral, compared with self-monitored blood glucose testing, with improved neonatal health outcomes (A).<sup>66–69</sup>
- Automated insulin delivery (AID) systems with randomised controlled trial (RCT) evidence for use in pregnancy and showing clinically relevant benefits in glycaemia are recommended for use by women with type 1 diabetes intending to conceive, starting preconception (A).†<sup>70–72</sup>
- AID systems with evidence from RCTs in pregnancy and showing clinically relevant benefits compared with standard insulin therapy and CGM are recommended for women with type 1 diabetes during pregnancy,† preferably those showing clinically relevant improvements (5% time in range in pregnancy [TIRp] increase daily), with pregnancy-specific glucose target settings, with systems that can adapt to changes in insulin sensitivity or a pregnancy-specific algorithm (A).<sup>70–72</sup> These systems can support improvements in TIRp of 3·5–7·8 mmol/L (63–140 mg/dL), with improved glycaemia overnight, a reduction in hypoglycaemia, and less burden for the user.
- AID systems with evidence from RCTs and showing clinically relevant benefits in glycaemia outside pregnancy, but with little or no evidence of benefit in pregnancy, might be considered preconception (B), and potentially continued in selected women with type 1 diabetes during pregnancy when used with assistive techniques and by experienced health-care teams (B).† Systems with an appropriately low glucose target setting and clinically relevant benefits in glycaemia (at least a 5% TIRp improvement) should preferably be used (E).<sup>29</sup>
- Continued use of AID systems during delivery and immediately postpartum can allow the user and an experienced health-care team to maintain tight glycaemia without increased risk of time below range and is advantageous in that therapy does not need to be switched to manual insulin delivery or intravenous insulin infusion intrapartum (B).<sup>73,74</sup>
- AID systems can be safely used in early and late postpartum, with improved glycaemia compared with standard insulin therapy (A).†<sup>75–77</sup>
- We recommend providing pregnant women with type 1 diabetes using AID systems and their health-care team with instructions for AID system management during labour and delivery, and postpartum in the third trimester (E).

\*People using CGM devices should also always have access to blood glucose meters (BGMs). People who are taking insulin and using BGMS should be encouraged to check their blood glucose concentrations when appropriate, based on their insulin therapy. †For all insulin pump users, pregnant women using AID systems should be vigilant regarding the risks of diabetic ketoacidosis, during times of hyperglycaemia, sickness, vomiting, or diarrhoea. Pregnant women should be provided with ketone monitoring equipment and be reminded to always carry spare insulin pump supplies and insulin pens.

carbohydrate boluses and exiting AID functionality See Online for appendix overnight, as needed.<sup>75,107</sup> As this AID system was a first-generation device, it is no longer available in most countries.

	Data in pregnancy and approval	Suggested pump settings and features for pregnancy <sup>†</sup>
<b>CamAPS FX</b>	Cambridge treat-to-target adaptive MPC with mylife YpsiPump; DANA Diabecare RS, and DANA-i insulin pumps (with Dexcom G6/G7 or FreeStyle Libre 3 CGM); recommended customisable glucose targets of between 4·4 mmol/L and 5·5 mmol/L (80–100 mg/dL) during pregnancy; ease-of-function to temporarily increase glucose target by approximately 2·5 mmol/L (45 mg/dL) and stop insulin delivery when glucose <7·7 mmol/L (<139 mg/dL); boost function to temporarily increase insulin delivery by approximately 35% (until target is reached)	Data from RCT available; <sup>70</sup> approved in >15 countries (UK, across Europe, Australia, New Zealand, USA [algorithm is approved but no compatible pump is commercially available], and Canada)
<b>Diabeloop</b>	Diabeloop Generation 1 algorithm with Dexcom G6 CGM; customisable glucose targets of between 5·5 mmol/L and 7·2 mmol/L (99–130 mg/dL); adaptable features include aggressiveness in hyperglycaemia (conditions the administered boluses when glucose >10 mmol/L [ $>180 \text{ mg/dL}$ ]), aggressiveness in normoglycaemia (conditions the basal rate provided by the system when glucose values are between 3·8 mmol/L and 10 mmol/L [ $70\text{--}180 \text{ mg/dL}$ ]), and aggressiveness at breakfast, lunch, and dinner (conditions the amount of bolus in every intake); carbohydrate-to-insulin ratios and insulin sensitivity cannot be adapted	No data available from RCT; no pregnancy indication
<b>iLet</b>	Adaptive closed-loop algorithm with Dexcom G6 or Dexcom G7; customisable glucose targets of between 6·1 mmol/L and 7·2 mmol/L (110–130 mg/dL) in 0·6 mmol/L (10 mg/dL) increments, listed as lower, usual, and higher	No data available from RCT; no pregnancy indication
<b>Medtronic MiniMed 670/770G</b>	Treat-to-target PID technology with insulin feedback with Guardian 3 CGM; non-customisable glucose target of 6·7 mmol/L (120 mg/dL); temporary target of 8·3 mmol/L (150 mg/dL)	Data from small, pilot RCT available; <sup>75</sup> no pregnancy indication
<b>Medtronic MiniMed 780G</b>	PID technology with insulin feedback with the most advanced SmartGuard technology, with Guardian 3 or 4, Simplera, and Abbott Instinct CGM; customisable glucose target of 5·5–6·7 mmol/L (99–120 mg/dL) in 0·6 mmol/L (10 mg/dL) increments; temporary target of 8·3 mmol/L (150 mg/dL)	Data from RCT available; <sup>71</sup> European conformity mark (CE) for use in type 1 diabetes pregnancy in Europe
<b>Omnipod 5 (SmartAdjust)</b>	MPC algorithm with Dexcom G6 CGM, Dexcom G7 CGM, or FreeStyle Libre 2-Plus CGM; customisable glucose targets of between 6·1 mmol/L and 8·3 mmol/L (110–150 mg/dL) <sup>‡</sup> in 0·6 mmol/L (10 mg/dL) increments	No data available from RCTs; no pregnancy indication
<b>Tandem:tslimX2 or Tandem Mobi with Control-IQ or Control-IQ+ technology</b>	Treat-to-range MPC algorithm with Dexcom G6 CGM, Dexcom G7 CGM, and FreeStyle Libre 3-Plus CGM; non-customisable target range options; responsive to user basal rate and sensitivity adjustments; sleep activity range of 6·2–6·7 mmol/L (112–120 mg/dL), which can be used for 24 h, with optional exits to regular control of the IQ activity target range of 6·8–8·8 mmol/L (112–160 mg/dL) or the exercise activity range of 7·8–8·8 mmol/L (140–160 mg/dL)	RCT data available; <sup>72,78</sup> no pregnancy indication

(Table 2 continues on next page)

(Continued from previous page)

**Sequel Twiist and open source systems (do-it-yourself APS—eg, Loop) and Android APs)**

Data in pregnancy and approval	Suggested pump settings and features for pregnancy*
MPC algorithm with Dexcom G6 CGM or Dexcom G7 CGM or Freestyle Libre; fully customisable glucose targets; low user-set targets can be temporarily activated before meals to increase insulin delivery before eating to help with postprandial glucose rises; programme custom temporary override settings for future use (eg, post-meal high of 120–130% for 2–3 h); safety settings are individually set by user	No data from RCTs, no pregnancy indication Personalised glucose targets; recommended daytime target of 50–55 mmol/L (90–99 mg/dL) before 16 weeks gestation; if glucose variability is low, a night-time target of 50 mmol/L (90 mg/dL) or less can be considered; after 16 weeks gestation consider lower targets; liberally use post-meal high custom override; consider if pre-meal target provides better results than pre-meal bolusing since bolusing shuts off the lower pre-meal target; for Loop users, consider using the Lollipop (30 min) food absorption time at meals after 16 weeks gestation; consider increasing the auto-bolus—microboluses from the default of 40% if user regularly misses food boluses; learn new system features and complete training modules or review system-specific resources before implementing new feature updates during pregnancy

Adapted from Benhalima et al.<sup>79</sup> For all systems, availability differs across regions, with differences in algorithms according to differing regulatory requirements and other regional factors. AID=automated insulin delivery; APS=artificial pancreas system. CGM=continuous glucose monitoring. GWC=gestational weight gain. MPC=model predictive controller. PID=proportional integral derivative. RCT=randomised control trial. \*For all systems, pump settings (basal rates, carbohydrate-to-insulin ratios, insulin sensitivity factors, and active insulin time) should be adjusted for manual and automated modalities as appropriate for the stage of pregnancy and individualised care. †Safe meal bolus refers to a meal bolus amount that is adjusted downwards due to various factors that the algorithm considers, such as hypoglycaemia risk prediction within the next 4 h, active insulin on board, and total daily insulin dose. #FDA approved change to 5.6–8.3 mmol/L (100–150 mg/dL) anticipated in the USA in the first half of 2026. \$Reverse correction refers to a calculated dose of insulin lower than that strictly derived from the carbohydrate-to-insulin ratio when the glucose concentration is below the target range at the time of carbohydrate announcement. ¶The so-called super bolus technique was initially promoted by John Walsh for the use of insulin pumps in non-pregnant populations. To avoid late hypoglycaemia when strengthening the carbohydrate-to-insulin ratios, the basal rates should be reduced during the late postprandial period.<sup>83</sup> ||The Loop algorithm is now commercially available with the Sequel<sup>TM</sup> system.

**Table 2: Algorithm and glucose targets of the available AID systems and suggested settings for pregnancy**

The CIRCUIT RCT included 88 pregnant women with type 1 diabetes and gestation less than 14 weeks and a baseline HbA<sub>1c</sub> of 7.4%, comparing the Tandem t:slim X2 pump with Control-IQ versus standard care with MDI or open-loop CSII, both with CGM (table 2).<sup>72</sup> The outcomes indicated a significantly greater TIRp from 16 weeks to 34 weeks gestation in the AID group compared with the MDI or open loop with CGM group (65.4% vs 50.3%, respectively, with a mean adjusted difference of 12.5%; p<0.001). The percentage TBRp was also reduced for AID users (mean adjusted difference of -1.0%), as was the time above range in pregnancy (TARp) (mean adjusted difference of -11.5%). A case series with the t:slim X2 pump with Control-IQ or Basal IQ showed them to be safe during pregnancy,<sup>108–110</sup> with less burden than partial AID therapy in previous pregnancies.<sup>108</sup> No RCTs have been done in pregnancy with Diabeloop, Omnipod 5, or iLet AID systems. Two case series with the Omnipod 5 system reported a TIRp of between 56% and 82%, with the highest TIRp reached by manually exiting AID overnight.<sup>111,112</sup>

**Evidence from real-world studies**

Although data from RCTs is the gold standard for framing clinical recommendations (appendix p 5), real-world evidence can provide important insights. Several systematic reviews and meta-analyses have examined the use of AID during type 1 diabetes pregnancy.<sup>113–115</sup> These meta-analyses included large RCTs and observational data up to September, 2024. These meta-analyses showed that AID systems outperformed standard care in nocturnal TIRp and time spent at less than 63 mg/dL. Two of three meta-analyses<sup>113,114</sup> concluded a glycaemic benefit of AID versus standard insulin therapy. However, these meta-analyses did not have power to evaluate pregnancy outcomes as none of the RCTs on AID in pregnancy were powered on pregnancy outcomes and the sample size was small.

A case series and observational studies with mostly MiniMed 780G and Tandem t:slim X2 Control-IQ showed that they could be safely used in pregnancy: increased TIRp and less burden were observed compared with previous pregnancies that used SAP therapy, or when compared with a group on MDI or open-loop pump therapy, although a TIRp of more than 70% was not reached in all women throughout gestation.<sup>116–120</sup> A real-world cohort study of 112 pregnant women with type 1 diabetes in Spain,<sup>104</sup> comparing MDI with AID (again mostly MiniMed 780G and Tandem t:slim X2 Control-IQ) in women with a median HbA<sub>1c</sub> of 48 mmol/mol (6.5%) at the first antenatal visit, indicated that MDI users had a greater reduction in HbA<sub>1c</sub> in the second trimester than AID users (-0.56% vs -0.20%), although no between-group significant difference existed in HbA<sub>1c</sub> in any trimester. Moreover, no significant differences were observed in TIRp between the groups, and AID users had less TBRp and

lower glycaemic variability in the second and third trimesters. However, AID users had more gestational weight gain (difference of 3·2 kg) and higher rates of macrosomia, although not significantly higher when adjusted for maternal weight gain or third trimester HbA<sub>1c</sub>.<sup>104</sup> These study outcomes could have been affected by selection bias, as women might have been offered AID systems due to difficulties in reaching glycaemic goals or based on the personal preferences of women and their health-care providers. For example,<sup>104</sup> AID users had a longer diabetes duration compared with the MDI group, which can be associated with reduced achievement of tight glycaemia and more likely use of AID therapy. Another real-world study<sup>121</sup> comparing different AID systems in 137 pregnant women with type 1 diabetes (62% on MiniMed 780G, 27·7% on CamAPS FX, and 10·2% on Tandem Control-IQ) indicated a significantly lower HbA<sub>1c</sub> ( $-4\cdot8\text{ mmol/mol}$ ) by the third trimester in CamAPS FX and Tandem Control-IQ users, and a 5·9% higher TIRp in the second trimester in CamAPS FX compared with MiniMed 780G. In addition, the adjusted odds ratio for LGA infants was lower in women using CamAPS FX (0·25) or Tandem Control-IQ (0·10) compared with MiniMed 780G users. Selection bias cannot be excluded due to the observational design. No information was available on the use of temporary system settings (such as sleep mode in Tandem Control-IQ, boost in CamAPS FX, or the use of assistive techniques, such as fake carbohydrates in MiniMed 780G), which could provide important additional insights into system use.

A non-controlled observational study of ten women on at-home use of a pregnancy-specific algorithm, with low daytime (4·4–6·0 mmol/L [80–108 mg/dL]) and nighttime (4·4–5·6 mmol/L [80–100 mg/dL]) glycaemic targets, reported an increase in the TIRp from 64·5% (with SAP or partial AID) to 78·6% (with AID;  $p=0\cdot002$ ) from 14 weeks to 32 weeks until delivery, with a reduction in hypoglycaemia.<sup>122–125</sup> This system is not commercially available, and the absence of a control group precludes conclusions on a causal effect. Data on unregulated, open-source artificial pancreas systems is limited to case reports of pregnant women with strong diabetes self-management skills, showing potential benefits in women with type 1 diabetes, but again limited by an absence of control groups.<sup>120,126–129</sup>

The consensus panel recommends the use of AID systems with evidence of benefits from large RCTs (panel 1).<sup>70,71,72,130–132</sup> AID systems with at least a 5% (72 min) increase in daily TIRp are recommended to achieve clinically relevant benefits for obstetric and neonatal outcomes.<sup>133</sup> The lowest glucose targets and strictest AID settings should be used to reach optimum glucose concentrations in most circumstances (table 2). Insulin-to-carbohydrate ratios should be strengthened in pregnancy to accommodate increasing insulin resistance and delayed insulin absorption (table 2). Boluses should

initially be given 10–15 min before meals, but might need to be given up to 30 min before in late pregnancy, depending on the AID system used (table 2). Educational resources to support women using AID systems during pregnancy and experienced health-care staff should be accessible to optimise care.<sup>134,135</sup> Support should be individualised and intensified as needed to ensure that the woman is able to operate the device effectively. Due to delayed insulin absorption later in pregnancy, with increasing insulin doses and increased risk of blockage of infusion sets, changing the infusion sets more frequently is often necessary (at least every 3 days, especially later in pregnancy).<sup>2</sup>

High values for HbA<sub>1c</sub>, TIRp, average glucose, glucose management indicator, and glycaemic variability metrics, as well as low TIRp values (all reflecting maternal hyperglycaemia) are associated with increased pregnancy complications.<sup>58,133,136–150</sup> An observational cohort study of 117 women with either type 1 diabetes (58%) or type 2 diabetes (42%)<sup>149</sup> described optimal pregnancy outcomes with a TIRp of either 66% or 71% depending on the method of calculation, which is consistent with the international TIRp recommendation for CGM use in pregnancy (table 1).<sup>151,152</sup> A target for mean glucose could also be useful,<sup>140,153</sup> as mean glucose is highly correlated with overall glycaemia and is a modifiable determinant of fetal hyperinsulinaemia (table 1).<sup>140,154</sup> Some experts suggest tighter overnight TIRp targets; however, to date, no evidence exists supporting the use of different daytime versus nighttime targets (table 1). Notably, studies not using AID systems used SMBG glucose targets to optimise therapy, and the sole use of CGM-derived targets was not tested in RCT settings.

### Intrapartum and immediate postpartum care in type 1 diabetes

Guidelines recommend intrapartum glucose concentrations of 4·0–7·0 mmol/L (72–126 mg/dL) to reduce the risk of neonatal hypoglycaemia.<sup>155–157</sup> However, studies suggest that persistent maternal hyperglycaemia during the second and third trimesters and LGA, indicative of sustained fetal hyperinsulinaemia, are strongly associated with neonatal hypoglycaemia.<sup>156,158–160</sup> Therefore, targeting intrapartum glycaemia might not reverse sustained fetal hyperinsulinaemia.<sup>161</sup> A pragmatic approach with intrapartum glycaemic targets of 5·0–8·0 mmol/L (90–144 mg/dL) has been suggested to minimise maternal hypoglycaemia.<sup>156</sup> For some, continuation of CSII (including full or partial AID) intrapartum can help attain in-target glycaemia during this period.<sup>162–165</sup> Insulin sensitivity increases immediately after delivery; therefore, insulin doses should be reduced 50% or more postpartum compared with late third trimester doses, often 20% lower than before pregnancy, with further reductions in women who are breastfeeding.<sup>156,166,167</sup>

Observational data from 27 women showed that the use of the precursor of CamAPS FX maintained tight glycaemia intrapartum and early postpartum.<sup>73</sup> Case series with the Tandem t:slim X2 pump with Control-IQ showed that the target TIRp could be maintained intrapartum.<sup>110,117</sup> Compared with routine care, MiniMed 780G use was associated with a higher TIRp intrapartum (63·1% vs 71·5%), without an increased TBRp, and with a more than 85% TIR of 3·9–10·0 mmol/L (70–180 mg/dL) in the early postpartum period (table 3).<sup>74</sup>

Avoiding the need to switch mode of insulin therapy before delivery empowers women to manage their glucose concentrations and reduces health-care costs and staff burden.<sup>163,164</sup> Antenatal counselling and training

for health-care professionals and pregnant women are crucial (panel 1). Suggestions for implementing AID intrapartum are listed in table 3.

#### Late postpartum care in type 1 diabetes

For breastfeeding women, insulin doses are approximately 20% lower compared with prepregnancy,<sup>169–172</sup> potentially increasing the risk of night-time hypoglycaemia if insulin doses are not appropriately reduced.<sup>170,171,173</sup> The CLIMB study in 18 women using MiniMed 670G/770G with early (6–10 days postpartum) or delayed (12 weeks postpartum) AID use reported less maternal hypoglycaemia<sup>76</sup> and a small decrease in glucose after night-time breastfeeding was reduced with AID

	Suggested settings intrapartum	Suggested settings postpartum
<b>CamAPS FX</b>		
RCT data available intrapartum and up to 6 months postpartum <sup>168</sup>	Increase glucose target to 5·5–6·0 mmol/L (99–108 mg/dL); insulin-to-carbohydrate ratios of between 1:12g and 1:15g	Glucose target of 6·0 mmol/L (108 mg/dL) and use so-called ease-off as required; mean postpartum glucose target was 6·0 mmol/L (108 mg/dL) in the AiDAPT postpartum study; insulin-to-carbohydrate ratios of between 1:12g (non-breastfeeding) and 1:15g (breastfeeding)
<b>Diabeloop</b>		
No data available	No recommendation due to absence of evidence	Adapt glucose targets between 5·5 mmol/L and 7·2 mmol/L (99–130 mg/dL); adapt aggressiveness in hyperglycaemia, normoglycaemia, and at meals, as needed
<b>iLet</b>		
No data available	No recommendation due to absence of evidence	Adapt glucose targets between 6·1 mmol/L and 7·2 mmol/L (110–130 mg/dL) as needed
<b>Medtronic MiniMed 670/770G</b>		
No RCT data available intrapartum on automatic mode; RCT data available 3–7 days onwards until 6 months postpartum <sup>105,167</sup>	No recommendation due to absence of evidence	Glucose target of 6·7 mmol/L (120 mg/dL, non-customisable); active insulin time of 2–3 h
<b>Medtronic MiniMed 780G</b>		
RCT data available intrapartum and early postpartum <sup>161</sup>	Glucose target can most frequently remain at 5·5 mmol/L (99 mg/dL); increase as needed to a glucose target of 6·1 mmol/L or 6·7 mmol/L (110 mmol/L or 120 mg/dL); active insulin time of 2 h; increase insulin-to-carbohydrate ratios by at least 50%	Glucose target can most frequently remain at 5·5 mmol/L (99 mg/dL); increase as needed to a glucose target of 6·1 mmol/L or 6·7 mmol/L (110 mmol/L or 120 mg/dL); temporary target of 8·3 mmol/L (150 mg/dL) is rarely needed; active insulin time of 2 h; increase insulin-to-carbohydrate ratios by at least 50% (and an average increase by 80% is needed when breastfeeding)
<b>Omnipod 5 (SmartAdjust)</b>		
No data available	No recommendation due to absence of evidence	Adapt glucose targets between 6·1 mmol/L and 8·3 mmol/L (110–150 mg/dL); might benefit from resetting the pump to prepregnancy settings or spending some time in manual mode before resuming automation
<b>Tandem t:slim X2 or Tandem Mobi with Control-IQ or Control-IQ+ technology</b>		
Data available from a case series; <sup>72,109</sup> RCT ongoing <sup>107</sup>	Sleep activity range of 6·2–6·7 mmol/L (112–120 mg/dL) during labour and delivery	Sleep activity function can often be continued if postpartum profile is activated;* if frequent hypoglycaemia or fear of postpartum hypoglycaemia then Control-IQ without an activity target range of 6·2–8·8 mmol/L (112–160 mg/dL) can be used with sleep activity overnight or, if needed, temporary use of the exercise activity range of 7·7–8·8 mmol/L (140–160 mg/dL) can be used
<b>Sequel Twiist and open source systems (do-it-yourself APS—eg, Loop† and Android APS)</b>		
Little data available; case reports	Set up two custom temporary overrides for delivery (50% and 75% of insulin needs, with a target of 5·5 mmol/L [99 mg/dL] enabled indefinitely) in advance, but do not activate until needed based on glucose, stage of labour, and mode of childbirth	Change target to 6·1–7·5 mmol/L (110–135 mg/dL) postpartum; continue temporary overrides until postpartum settings* are activated; if Android APS experience is very limited, consider the following setting adjustments: stop dynamic insulin sensitivity factor, reduce the maximum units per hour and maximum total insulin on board by around 25–50% compared with the pregnancy values, and reduce the so-called maximum allowed bolus by 25–50%

AID=automated insulin delivery. APS=artificial pancreas system. RCT=randomised control trial. \*For systems with setting-based algorithms (ie, Control-IQ, open source), basal rate, carbohydrate ratios, and insulin sensitivity settings should be weakened after delivery or immediately before delivery of the neonate (whichever is practical) to an individualised postpartum profile. The general principles for calculating an individualised postpartum profile are as follows: if prepregnancy pump settings were optimised and are known, then adjust all settings to be at least 20% weaker than the prepregnancy setting (more for breastfeeding). Alternatively, use settings that are at least 50% less aggressive than the end of pregnancy pump settings. For systems that have the option of multiple pump profiles (ie, Control-IQ, Android APS), users should programme a postpartum profile well in advance of delivery and activate it immediately after delivery. For systems (Loop 1·0–3·0) that do not have the option of multiple pump profiles, the postpartum profile will need to be programmed postpartum (basal rates, carbohydrate-to-insulin ratios, correction factors, and glucose targets). †The Loop algorithm is now commercially available with the Sequel Twiist system.

Table 3: Available data and suggested intrapartum and postpartum settings for the available AID systems

versus SAP use.<sup>76</sup> In the PICLS study involving 23 women with type 1 diabetes, AID use was resumed 3–7 days postpartum, with a similar postpartum TIR of 3·9–10·0 mmol/L (70–180 mg/dL) between groups and a trend towards a lower TBR of less than 3·9 mmol/L (<70 mg/dL) with AID.<sup>75</sup> The AiDApT extension trial continued CamAPS FX use throughout pregnancy, labour, birth, and up to 6 months postpartum, with a significantly improved TIR compared with intensive insulin therapy with CGM (72% with AID vs 54% with standard intensive therapy).<sup>101</sup> These studies support the continued use of AID postpartum (panel 1).<sup>101</sup> Suggestions for postnatal glucose targets and settings are shown in tables 1 and 3.

### **Diabetes technology in type 2 diabetes during pregnancy**

Women with pregestational type 2 diabetes reported higher rates of complications, such as pre-eclampsia, LGA, and small for gestational age neonates, as well as more congenital malformations and higher perinatal mortality compared with women without diabetes.<sup>174</sup> Pregnant women with type 2 diabetes also tend to be older, have higher BMI, and receive less frequent prepregnancy and antenatal care than women with pregestational type 1 diabetes.<sup>3</sup> Although women with type 2 diabetes can more often reach glycaemic targets compared with women with type 1 diabetes during pregnancy,<sup>3</sup> the rates of stillbirth and perinatal mortality are higher in type 2 diabetes, suggesting that lower glucose targets might be needed.<sup>3</sup> Non-glycaemic determinants, such as socioeconomic deprivation, prepregnancy BMI, coexistent medical conditions, and gestational weight gain should also be considered.

#### **Prepregnancy care in type 2 diabetes**

For women with type 2 diabetes, a preconception HbA<sub>1c</sub> target of less than 6·5% (<48 mmol/mol) is recommended to reduce congenital anomalies; however, a pregnancy HbA<sub>1c</sub> target of less than 6·0% (<42 mmol/mol) might be more applicable to reduce the rates of perinatal mortality, pre-eclampsia, preterm birth, LGA, and neonatal intensive care unit admissions.<sup>29,175</sup> Therapies showing safety in pregnancy should preferentially be used, which means insulin is often needed to reach preconception glucose goals.<sup>29</sup> CGM can be a useful tool, as it is associated with a reduced HbA<sub>1c</sub>, an increased TIR, and reduced hypoglycaemia in non-pregnant adults with type 2 diabetes.<sup>176</sup> In a pilot study,<sup>177</sup> preconception use of CGM in women with prediabetes or type 2 diabetes was associated with positive changes in weight and fitness and with an increased time between 3·9 and 7·8 mmol/L (70–140 mg/dL), although adequately powered studies in prepregnancy and pregnancy are urgently needed.

#### **Pregnancy care in type 2 diabetes**

Evidence for the use of CGM during type 2 diabetes pregnancy is currently scarce, with no substantive RCT

data. Ongoing RCTs are examining the efficacy of CGM in women with type 2 diabetes (ISRCTN12804317 and NCT06628453). Three RCTs comparing CGM with SMBG during pregnancy have included few women with type 2 diabetes alongside women with type 1 diabetes and gestational diabetes.<sup>178–180</sup> All of the studies used older CGM systems episodically, and in one study, participants were masked to CGM data. Statistical power to evaluate the effectiveness of CGM in type 2 diabetes pregnancy was lacking in these studies.

In a retrospective observational study comparing 82 pregnant women with type 2 diabetes who used CGM versus 278 who did not, CGM users had reduced odds of a composite neonatal adverse outcome, of preterm birth, and of neonatal intensive care unit admissions.<sup>181</sup> A pilot study in Australia showed that the use of intermittently scanned CGM is feasible in remote and diverse populations (75% Aborigines or Torres Strait Islander) with type 2 diabetes pregnancy (n=57), but with variable sensor usage.<sup>182</sup> In women with more than 50% use of CGM, each 1% increase in TIR was associated with a 4–5% reduction in the rates of neonatal complications.<sup>183</sup>

Large-scale, adequately powered trials of CGM use in pregnancy complicated by type 2 diabetes and studies assessing the relationship between CGM metrics and type 2 diabetes pregnancy outcomes are needed, including studies on the use of AID systems or connected insulin smart pens in type 2 diabetes pregnancies. Women with type 2 diabetes generally have lower HbA<sub>1c</sub> during pregnancy than women with type 1 diabetes, yet the rates of stillbirth and perinatal mortality are higher than those in type 1 diabetes.<sup>3</sup> Glucose is the single most important modifiable factor influencing these outcomes, suggesting that an increased TIRp might be needed for women with type 2 diabetes to improve these outcomes. As women with type 2 diabetes are increasingly using CGM before pregnancy, and often become pregnant while using CGM, the expert consensus recommendation is that CGM can be offered to women with type 2 diabetes during pregnancy (panel 2), based on available resources and individual preference. A high TIRp (>80%; panel 2) is suggested in pregnancy based on expert opinion, acknowledging the scarcity of solid evidence (level E evidence).

#### **Care during labour and delivery in type 2 diabetes**

Research is needed to identify the target glucose ranges during labour in women with type 2 diabetes, and to understand the impact of the use of diabetes technologies during labour in type 2 diabetes. As in type 1 diabetes, the decision to continue the use of any technologies during childbirth should be individualised, discussed with the mother, and determined before labour begins, considering the previous experience of the health-care team within the hospital setting and the knowledge and experience of the mother.<sup>161</sup>

## Postpartum care in type 2 diabetes

Data are especially needed to establish how diabetes technologies can help to avoid hypoglycaemia postpartum and can reduce the risk of neonatal hypoglycaemia. Despite the scarcity of data on optimising technology use postpartum for women with type 2 diabetes,<sup>185</sup> we suggest optimising the TIR to 3·9–10·0 mmol/L (70–180 mg/dL), similar to other non-pregnant women with type 1 diabetes) in the immediate postnatal period, while establishing breastfeeding and adapting to new routines.<sup>156</sup> The use of CGM could enhance glycaemia in this period by facilitating the attainment of a TIR of more than 70%.<sup>186</sup>

## Diabetes technology in gestational diabetes

Gestational diabetes is generally defined as hyperglycaemia, first detected during pregnancy, provided that overt diabetes has been excluded.<sup>187</sup> It is the most common medical complication of pregnancy, with a global prevalence of 14%.<sup>188</sup> Gestational diabetes is associated with increased risks of perinatal complications compared with women without hyperglycaemia, including pre-eclampsia, LGA, neonatal hypoglycaemia, and greater long-term maternal and offspring risks of type 2 diabetes and cardiovascular disease.<sup>189</sup> Gestational diabetes results from a chronic defect in β-cell compensation detected by routine glucose testing in pregnancy; however, the causes are varied, similar to diabetes outside of pregnancy.<sup>190</sup>

Management of gestational diabetes includes medical nutrition therapy with pharmacotherapy (generally insulin, or in some cases, metformin) if required and counselling on health-promoting behaviours to reach maternal glucose goals, alongside obstetric surveillance to monitor fetal growth.<sup>189</sup> A 2021 systematic review and meta-analysis of 3982 women reported that treatment for gestational diabetes diagnosed at 24–28 weeks gestation is associated with a lower risk of primary caesarean deliveries, macrosomia, LGA births, shoulder dystocia, birth injury, and admission to neonatal intensive care units compared with women with gestational diabetes who were not treated.<sup>191</sup> To date, a single treatment trial of early gestational diabetes exists, showing that early diagnosis and treatment in women before 20 weeks gestation modestly reduced the risk of a composite of serious perinatal complications (driven almost entirely by reduced neonatal respiratory distress) compared with deferred treatment.<sup>192</sup>

## Care during gestational diabetes

Evidence supporting specific SMBG-derived glucose targets in gestational diabetes is limited. The TARGET trial involving 1100 women showed a similar rate of LGA births for tighter targets, with an FPG of 5·0 mmol/L or less ( $\leq 90 \text{ mg/dL}$ ), 1-h postprandial of 7·4 mmol/L or less ( $\leq 133 \text{ mg/dL}$ ), 2-h postprandial of 6·7 mmol/L or less ( $\leq 120 \text{ mg/dL}$ ) versus less tight targets (FPG  $<5\cdot5 \text{ mmol/L}$

## Panel 2: Recommendations for using diabetes technology in pregnant women with type 2 diabetes and those planning pregnancy or women with gestational diabetes

Each of the recommendations in this consensus has been assigned a level of supporting evidence (ie, A, B, C, or E) that adheres to the evidence-grading system of the American Diabetes Association Standards of Medical Care in Diabetes (appendix p 5).<sup>29</sup>

### Type 2 diabetes in pregnancy

- Capillary blood glucose testing is recommended for all women with type 2 diabetes before and during pregnancy, along with education to reinforce consistent use (A).
- Based on the evidence of continuous glucose monitoring (CGM) use in non-pregnant type 2 diabetes populations, CGM can be used in preparation for pregnancy to help women with type 2 diabetes reach glycaemic targets (B).<sup>176,65,184</sup>
- CGM can be offered to women with type 2 diabetes during pregnancy, based on available resources and individual preferences, but little evidence of improved outcomes with CGM during type 2 diabetes pregnancy exists (E). Evidence to determine CGM metrics associated with optimal pregnancy outcomes for women with type 2 diabetes is insufficient. When CGM is used during type 2 diabetes pregnancy, a target of >80% time in range in pregnancy (TIRp)—ie, 3·5–7·8 mmol/L (63–140 mg/dL)—might be applicable, with <4% below 3·5 mmol/L (63 mg/dL) and <15% above 7·8 mmol/L (140 mg/dL); however, the most appropriate targets are unknown (E).

### Gestational diabetes

- Capillary blood glucose testing is recommended for all women with gestational diabetes, along with education to reinforce consistent use (A).
- CGM can be offered to women with gestational diabetes\* based on available resources and individual preferences, although evidence for improved outcomes is scarce (E).
- Evidence to determine CGM metrics associated with optimal pregnancy outcomes for women with gestational diabetes is insufficient. When using CGM in gestational diabetes, a target of >90% TIRp—ie, 3·5–7·8 mmol/L (63–140 mg/dL)—might be suggested (E); however, the most appropriate targets are unknown (E).

\*People using CGM devices should also always have access to blood glucose meters (BGMs). People who are taking insulin and using BGMs should be encouraged to check their blood glucose concentrations when appropriate, based on their insulin therapy.

[<99 mg/dL], 1-h postprandial <8·0 mmol/L [ $<144 \text{ mg/dL}$ ]), and 2-h postprandial <7·0 mmol/L [ $<126 \text{ mg/dL}$ ]).<sup>193</sup> Tighter targets did not reduce the risk of LGA infants, but were associated with a lower risk of a composite outcome of perinatal death, birth trauma, or shoulder dystocia. An increase in maternal haemorrhage, coagulopathy, embolism, and obstetric complications was balanced against these benefits.<sup>193</sup>

A 2023 Cochrane review reported low-certainty evidence that tighter glycaemic management (FPG  $\leq 5\cdot0 \text{ mmol/L}$  or  $\leq 5\cdot1 \text{ mmol/L}$  [ $\leq 90 \text{ mg/dL}$  or  $\leq 92 \text{ mg/dL}$ ] and PPG  $\leq 6\cdot7 \text{ mmol/L}$  or  $\leq 7\cdot4 \text{ mmol/L}$  [ $\leq 120 \text{ mg/dL}$  and  $\leq 133 \text{ mg/dL}$ ]) was potentially associated with reduced neonatal risk of death or severe infant morbidity, compared with less tight glycaemic management (FPG  $\leq 5\cdot3 \text{ mmol/L}$  or  $\leq 5\cdot8 \text{ mmol/L}$  [ $\leq 95 \text{ mg/dL}$  or  $\leq 104 \text{ mg/dL}$ ] and PPG  $\leq 7\cdot8 \text{ mmol/L}$  or  $\leq 8\cdot0 \text{ mmol/L}$  [ $\leq 140 \text{ mg/dL}$  or  $\leq 144 \text{ mg/dL}$ ])<sup>194</sup> but came with an increased maternal risk of hypertensive disorders of pregnancy. A systematic review of 34 observational studies (9433 women) reported that a FPG target of less than 5·0 mmol/L ( $<90 \text{ mg/dL}$ ) was associated with less

macrosomia, LGA births, neonatal hypoglycaemia, neonatal jaundice, and pre-eclampsia for women with gestational diabetes, again with a low certainty of evidence.<sup>195</sup> Although HbA<sub>1c</sub> is positively associated with perinatal complications in gestational diabetes,<sup>196</sup> the clinical utility of HbA<sub>1c</sub> in gestational diabetes is limited, since specific HbA<sub>1c</sub> thresholds do not have the sensitivity for predicting complications.<sup>197–199</sup>

### CGM metrics for monitoring glycaemia during gestational diabetes

Insufficient evidence exists for the use of CGM in the management of women with gestational diabetes; therefore, SMBG is the standard of care for glucose management in gestational diabetes (panel 2). A 2017 Cochrane review reported less gestational weight gain with CGM versus SMBG (mean difference -1.26 kg), based on low-certainty evidence.<sup>200</sup> A 2022 review of six trials (482 women) found similar benefits of CGM on gestational weight gain and an improvement in HbA<sub>1c</sub> and birthweight, based on low-certainty evidence.<sup>201</sup> A meta-analysis suggested that episodic use of CGM in gestational diabetes was associated with improved third trimester HbA<sub>1c</sub> and reduced LGA births.<sup>202</sup> The outcomes of the GRACE open-label RCT,<sup>203</sup> reported that 170 women diagnosed with gestational diabetes and assigned to use CGM had fewer LGA newborns compared with 175 women with gestational diabetes in the SMBG control group (3.5% vs 10.3%; p=0.014). The CGM group also had improved time in tight range (3.8–7.8 mmol/L (70–140 mg/dL). Further, adequately powered studies are needed to establish the clinical efficacy of CGM therapy in gestational diabetes (panel 3).

Recommended TIR targets for management of gestational diabetes still need to be determined. Although women with gestational diabetes can achieve a higher TIRp than women with type 1 diabetes, it does not appear to translate into reduced LGA births<sup>202,204–207</sup> or improvements in other perinatal outcomes.<sup>208–210</sup> Mean sensor glucose—a marker of average glucose concentrations—is associated with excess fetal growth in gestational diabetes.<sup>202,204–207,211</sup> A cohort study of 1302 women in China with gestational diabetes found mean sensor glucose and TARp to be associated with a composite outcome of preterm births, LGA births, fetal distress, premature rupture of membranes, and neonatal intensive care unit admission.<sup>206</sup> Additionally, TIRp, TARp, area under curve, mean amplitude of glycaemic excursion, and mean sensor glucose were positively associated with LGA births, whereas TBRp was inversely associated with LGA births.<sup>206</sup> However, the characteristics of these women (such as low BMI) are not representative of wider gestational diabetes cohorts, and mean sensor glucose concentrations were low even for women at the highest risk of complications.<sup>206</sup> In a secondary analysis of the DiGest RCT with a limited sample of 361 women with gestational diabetes,<sup>212</sup> a mean glucose concentration of less than 6.1 mmol/L (<110 mg/dL) was suggested as a therapeutic target for the management of gestational diabetes. Evidence to suggest a mean glycaemia target for gestational diabetes is insufficient.

Several large RCTs powered on pregnancy outcomes and comparing CGM with SMBG in gestational diabetes are ongoing or have been completed.<sup>5</sup> The first large RCT powered on pregnancy outcomes, namely the DipGluMo trial,<sup>213</sup> did not show an improvement in maternal

### Panel 3: Priorities for future research

#### Type 1 diabetes

- More evidence is needed on whether automated insulin delivery (AID) systems can improve maternal and neonatal pregnancy outcomes. Data from large national audits, registries, or meta-analyses could provide more information on pregnancy complications since the introduction of AID systems.
- More research is needed to establish whether the current proposed consensus glucose targets for pregnancy are adequate, should differ according to the trimester, or should be lower overnight compared with daytime.
- More data are needed to determine the most appropriate continuous glucose monitoring (CGM) glycaemic targets at preconception to improve pregnancy outcomes.
- More evidence is needed on the most appropriate target for mean glucose in pregnancy, as this metric might help to further improve pregnancy outcomes.
- More research is needed on the timing of the bolus when AID systems are used in pregnancy.

#### Type 2 diabetes

- Data are needed on what glycaemic targets should be used at preconception and during pregnancy to optimise pregnancy outcomes in women with type 2 diabetes.
- Large studies adequately powered on pregnancy outcomes are needed to establish whether the use of CGM can reduce the risk of pregnancy complications in women with type 2 diabetes.
- Studies that investigate the relationship between CGM metrics and type 2 diabetes pregnancy outcomes are needed.
- Research is needed to identify target glucose ranges during labour in women with type 2 diabetes, and to understand the impact of using diabetes technology during labour in type 2 diabetes.
- Data are needed on how to optimise diabetes technology use postpartum for women with type 2 diabetes.
- Large studies are needed to assess the use of AID systems or connected insulin pens in type 2 diabetes pregnancies.

#### Gestational diabetes

- Understanding the value of CGM in the screening, diagnosis, and management of gestational diabetes is needed.
- Recommended CGM treatment targets for routine management of gestational diabetes need to be determined.
- Adequately powered studies on pregnancy outcomes are needed to establish whether the use of CGM can reduce the risk of pregnancy complications in women with gestational diabetes, including in early gestational diabetes.
- Research is needed to identify target glucose ranges during labour in women with gestational diabetes.
- More data are needed to establish whether CGM can be useful postpartum to screen for glucose intolerance (and whether it can replace the burden of the oral glucose tolerance test) and to identify who is at the highest risk of developing an adverse metabolic profile in the long term.

complications or perinatal outcomes in 156 women with CGM compared with the use of SMBG in 143 women with gestational diabetes. The TIRp was slightly higher with SMBG compared with CGM (96·9% vs 92·2%) later in pregnancy, although women preferred using CGM.<sup>213,214</sup> A 2025 single-centre RCT in 111 participants with gestational diabetes, which was not powered on pregnancy outcomes, reported a higher TIRp in the CGM group compared with SMBG (93% [SD 6] vs 88% [SD 14]), taking into account the low compliance with SMBG in the control group.<sup>215</sup>

Since clear evidence for CGM is scarce, SMBG is the standard of care for the management of gestational diabetes. However, based on expert opinion, CGM can be offered to women with gestational diabetes based on available resources and individual preferences, although evidence for improved perinatal outcomes is lacking. Acknowledging the scarcity of strong evidence, a suggestion based on expert opinion is made—in line with international consensus targets<sup>37</sup>—that if CGM is used in gestational diabetes, a target TIRp of more than 90% and a TARp of less than 10% could be used (level E; panel 2). RCTs evaluating the use of CGM in women with gestational diabetes are urgently needed, including CGM treatment targets and associations with perinatal outcomes.

#### CGM in the diagnosis of gestational diabetes

A large prospective observational study, Glucose Levels Across Maternity (GLAM), examined the association of CGM-derived glycaemic patterns with perinatal outcomes in a cohort of 768 women enrolled before 17 weeks gestation.<sup>216</sup> Gestational diabetes was diagnosed with an oral glucose tolerance test (OGTT) at 24–28 weeks gestation. CGM-measured glucose values were slightly higher than OGTT-based glucose concentrations.<sup>217</sup> The GLAM study showed an increased mean sensor glucose of 6·4 mmol/L (SD 1·2) versus 5·8 mmol/L (SD 1·0; 115 mg/dL [SD 22] vs 104 mg/dL [SD 18]) and a decreased TIRp (84% vs 94%) from 13 weeks to 14 weeks gestation in women subsequently diagnosed with gestational diabetes at 24–28 weeks gestation.<sup>218</sup> A second trimester TARp of more than 7·8 mmol/L (>140 mg/dL) best predicted gestational diabetes at 24–28 weeks gestation, with an area under the receiver-operating characteristic curve of 0·81.<sup>218,219</sup> The ongoing observational study Glycaemic Observation and Metabolic Outcomes in Mothers and Offspring study (GO MOMs) will provide further insights into early pregnancy glycaemia and comparisons between CGM and OGTT data.<sup>168</sup>

#### CGM-derived thresholds for identifying gestational diabetes based on outcome associations

The GLAM study also showed positive associations between CGM glucose metrics and pregnancy complications.<sup>216</sup> LGA births and hypertensive disorders of pregnancy were associated with slightly higher mean

sensor glucose (5·7 mmol/L [102 mg/dL] vs 5·6 mmol/L [100 mg/dL] for LGA [ $p=0\cdot01$ ] and 5·7 mmol/L [102 mg/dL] vs 5·5 mmol/L [99 mg/dL] for hypertensive disorders [ $p<0\cdot001$ ]). Percentage time more than 6·7 mmol/L (>120 mg/dL) and more than 7·8 mmol/L (>140 mg/dL) were also positively associated with LGA births and hypertensive disorders of pregnancy, respectively.<sup>208,218</sup> However, the absolute difference in mean sensor glucose in women with and without perinatal complications was small, highlighting the difficulty of defining clinical treatment thresholds.

#### Intrapartum care in gestational diabetes

No studies have evaluated CGM targets during labour and delivery in women with gestational diabetes. The American College of Obstetricians and Gynecologists recommends 6·1 mmol/L (110 mg/dL) as the upper glucose target for intrapartum glucose for women with gestational diabetes.<sup>220</sup> Most data supporting these targets are derived from studies on women with pre-existing diabetes rather than gestational diabetes.<sup>155–157</sup>

Women with gestational diabetes on high doses of insulin might require increased glucose monitoring and active insulin dose titration. However, an RCT on intrapartum management in 76 women with gestational diabetes,<sup>54</sup> comparing tight (hourly glucose testing and treatment if glucose is <3·3 mmol/L [<60 mg/dL] or >5·6 mmol/L [>100 mg/dL]) versus liberal targets (4-h glucose measurement and treatment if glucose is <3·3 mmol/L [<60 mg/dL] or >6·7 mmol/L [>120 mg/dL]) showed no difference in initial neonatal glucose concentrations, but lower mean neonatal glucose concentrations with tight glycaemic management in the first 24 h.<sup>54</sup>

#### Postpartum glucose in gestational diabetes

Most women can stop pharmacotherapy after delivery. Checking the postpartum blood glucose concentrations before discharge from hospital is useful to identify women with persisting diabetes in need of pharmacological management at discharge. However, no clear consensus exists on what test to do in the immediate postpartum period. OGTT is ideally carried out 6–12 weeks postpartum to assess glycaemic status,<sup>29</sup> but is often not conducted. Data are scarce on the use of CGM in the postpartum period to help identify women who are at higher risk of progression to diabetes, but studies are underway (NCT04972955).

#### Strengths and limitations

The consensus process and method that was used has strengths and limitations. Strengths include the international composition of the consensus panel and the considerable expertise reflected in the participants. Opinion leaders were represented from academic institutions, hospitals, and various diabetes, obstetric, and primary care associations globally. The patient voice was also represented. The nominal group technique

method was a strength, allowing each participant the opportunity to contribute at several points in the development of the consensus, such that all voices were able to contribute effectively. Limitations included that the selection of the consensus panel was not systematised or in any way randomised—rather it was founded in their clinical experience in the application of diabetes technology in pregnancy complicated by diabetes. This selection process might have introduced bias. A further limitation is that the literature database searches were largely based on publications in English and relied on published studies, rather than a wider investigation of case-based and non-English language resources.

## Conclusion

Strong evidence exists that CGM and AID can help women with type 1 diabetes to meet glycaemic targets during pregnancy and in the postpartum period. More evidence is needed to establish whether AID can also improve pregnancy outcomes. The evidence on CGM use in pregnant women with type 2 diabetes or gestational diabetes is limited, but preliminary observations indicate a potential for benefits, and larger RCTs are ongoing. More evidence is needed regarding the CGM glycaemic metrics and targets that should be recommended in pregnant women with type 2 diabetes and gestational diabetes. An extended summary of the gaps in evidence

and priorities for future research is provided in panel 3. Manufacturers of diabetes technologies should address their reporting systems to accommodate pregnancy-specific targets. Despite evidence supporting the application of diabetes technology in pregnancy with diabetes, inequity in the provision of CGM and AID systems during pregnancy persists, and intervention to improve access and health literacy in the use of diabetes technologies for healthier maternal and neonatal outcomes is needed.

## Contributors

All authors contributed equally to all aspects of the consensus process, both as participants in working groups framing the narrative and evidence base for type 1 diabetes, type 2 diabetes, or gestational diabetes, and for general discussion. As such, all authors participated in providing feedback on 24 serial drafts of the final manuscript. All authors have given their approval for this version to be published. KB, JH, ML, and HRM are the guarantors of this work and take full responsibility for the work as a whole.

## Declaration of interests

KB has received consulting fees from AstraZeneca and Eli Lilly; speakers fees from Novo Nordisk, AstraZeneca, and Mundipharma Medtronic; support for attending meetings or for travel from AstraZeneca and Novo Nordisk; grants or contracts from Medtronic, Novo Nordisk, Eli Lilly, AstraZeneca, Metagenics, and Abbott; has received equipment, materials, or drugs from Medtronic, Dexcom, Novo Nordisk, Abbott, and Lifescan; and is the recipient of a Senior Fellowship of The Flemish Research Foundation (1800225N). CD has received research funding from Dexcom, Abbott, and the Helmsley Charitable Trust; and has sat on data safety monitoring boards or advisory boards for Abbott and Dexcom. DA has received payment or honoraria from Abbott Diabetes Care and the diaTribe Foundation; and has declared a leadership or fiduciary role at DeDoc. AA has received grants or contracts from the National Institutes of Health (NIH), Breakthrough T1D, and the Helmsley Charitable Trust; has received payment or honoraria from the American Diabetes Association (ADA) and Breakthrough T1D; has received support for attending meetings or for travel from the International Society for Pediatric and Adolescent Diabetes, Advanced Technologies and Treatments for Diabetes (ATTD) conference, and ADA; and has declared a leadership or fiduciary role at ADA Health Disparities and T1DX-QI. TB has served on advisory panels for Novo Nordisk, Sanofi, Eli Lilly, AstraZeneca, Medtronic, Abbott, and Roche; has received honoraria for participating in speaker bureaus from Eli Lilly, Novo Nordisk, Medtronic, Abbott, Sanofi, Dexcom, Aventis, AstraZeneca, and Roche; has received research grant support to their institution from Abbott, Medtronic, Novo Nordisk, Sanofi, Novartis, Sandoz, Zealand Pharma, the Slovenian Research and Innovation Agency, the NIH, BreakthroughT1D, the Helmsley Foundation, and the European Union. RMB has received research support, has acted as a consultant, or has sat on the scientific advisory board for Abbott Diabetes Care, Ascensia, DexCom, Eli Lilly, Embecta, Insulet, Medtronic, Novo Nordisk, Roche Diabetes Care, Tandem Diabetes Care, and Sanofi; and their employer—non-profit HealthPartners Institute—contracts for his services: he receives no personal income from these activities. AC has acted as a consultant or has sat on the scientific advisory board for Novo Nordisk, Insulet, MannKind, and Zealand; and has declared clinical research investigator status for Novo Nordisk, Medtronic/Companion Medical, Insulet, Sanofi, Dexcom, Abbott, Eli Lilly, UnitedHealth, and Tandem Diabetes. LED has received research grant funding for investigator-initiated research from Diabetes Canada, Major Sciences Initiatives Competition, and the Alberta Diabetes Institute; has received research funding for investigator-initiated research from the Calgary Health Trust; was a speaker for Dexcom, but declares that the payment was made to their institution; and has received, at reduced cost, a loan of equipment from Dexcom, Tandem Diabetes Care, Medtronic, and Inter-analytics for investigator-initiated research funded by non-profit competitive funding agencies. DRF declares that their employer received consulting fees and payment

## Search strategy and selection criteria

We did a comprehensive literature search on MEDLINE, PubMed, and the Cochrane Library for articles published between Jan 1, 2008 (when the first data on CGM in pregnancy became available), and Oct 25, 2025 (appendix pp 2–3). The following search terms were used: “randomised controlled trial”, “randomised clinical trial”, “real world study”, “observational study”, “cohort study”, “continuous glucose monitoring”, “CGM”, “CGM metrics”, “intermittently scanned continuous glucose monitoring”, “isCGM”, “flash glucose monitoring”, “time in range”, “time below range”, “time above range”, “insulin pumps”, “sensor-augmented pump therapy”, “closed-loop therapy”, “closed-loop insulin delivery”, “CSII”, “automated insulin delivery”, “HbA1c”, “GMI”, “glycaemic control”, “hypoglycaemia”, “glycaemic variability”, “predictive low glucose suspend”, “pregnancy outcomes”, “pregnancy complications”, “delivery”, “intrapartum”, “breastfeeding”, “postpartum”, and “cost-effectiveness” in combination with the terms “pregnancy” and “diabetes”. Randomised control trials, real-world studies, observational studies, and cohort studies were included. If no other evidence was available, case reports and case series were also considered: otherwise, these were excluded. Only studies performed in humans and published in English were considered. The PRISMA flow diagram for the search process is shown in the appendix (p 4).

or honoraria from Embecta, Eli Lilly, Novo Nordisk, Abbott, and Medtronic; declares that Embecta, Eli Lilly, Novo Nordisk, and Abbott paid their employer for sitting on a data safety monitoring board or advisory board; and received support for attending meetings or for travel from Novo Nordisk. DI has received payment or honoraria from Dexcom, Abbott, Sanofi, Novo Nordisk, Insulet, Tandem, Eli Lilly, Sequel, and Medtronic. KK has received grants or contracts from AstraZeneca, Boehringer Ingelheim, Eli Lilly, Merck Sharp and Dohme, Novo Nordisk, Roche, Sanofi, Servier, Oramed Pharmaceuticals, Daiichi-Sankyo, and Applied Therapeutics; has received consulting fees and payment or honoraria from Amgen, AstraZeneca, Bristol Myers Squibb, Boehringer Ingelheim, Eli Lilly, Novo Nordisk, Sanofi, Servier, Pfizer, Roche, Daiichi-Sankyo, Embecta, and Nestle Health Science; is a member of KDIGO Indigo Type 2 Diabetes and CKD guidelines, a member of the Primary Care Study Group of the European Association for the Study of Diabetes, a council member for the Research Advisory Council at the Public Health Foundation of India, sits on the RSSDI International Advisory Board, India, is a member of the ADA Overcoming Therapeutic Inertia Advisory Group, is a board member for the European Association for the Study of Diabetes/European Foundation for the Study of Diabetes; and is also supported by the National Institute for Health Research (NIHR) Applied Research Collaboration East Midlands and the NIHR Leicester Biomedical Research Centre. CJL has declared that payment was made to their institution for grants from Tandem Diabetes, Insulet, Dexcom, Abbott, MannKind, Deka-TWIIST, NIH, the Helmsley Foundation, and Breakthrough T1D; has received consulting fees and support for attending meetings or for travel from Dexcom, Insulet, and Tandem Diabetes; and has sat on a data safety monitoring board or advisory board for the NIH and Breakthrough T1D. HRM declares that their institution was paid with a grant or contract from the NIHR Health Technology Assessment; received speaker fees from Abbott Diabetes Care, Dexcom, Eli Lilly, Medtronic, Novo Nordisk, Sanofi, and Ypsomed; received support for attending meetings or for travel from Ypsomed Australia and Dexcom; has declared a leadership or fiduciary role as the chair of the National Pregnancy in Diabetes audit; sits on the *Diabetes Care* and *Diabetologia* editorial board; and has received equipment from Abbott Diabetes Care for PROTECT. RN reports grants from Taisho Pharmaceutical, Ono Pharmaceutical, Mitsubishi, Nippon Boehringer Ingelheim, Arkaly, Kowa, and Abbott; and declares consulting fees or honoraria from Eli Lilly Japan, Novo Nordisk, Abbott, Sanofi, Japan Medtronic, Nippon Boehringer Ingelheim, Teijin, Kissei Pharmaceutical, Medtronic, and Astellas. SP has received research funding from Breakthrough T1D, the Helmsley Charitable Trust, the NIH, NIDDK, Dexcom, Medtronic MiniMed, the University of Colorado, and T1D Exchange; honoraria from the Children's Diabetes Foundation and the ADA; received support for attending meetings or for travel from the Children's Diabetes Foundation, the American College of Diabetology, Breakthrough T1D, and the ADDT conference; has received payment for sitting on a data safety monitoring board or advisory board for the Sansum Diabetes Research Institute; has declared an unpaid leadership or fiduciary role at the American College of Diabetology and the ADA. DS declared support for attending meetings or for travel from the conferences themselves as an invited speaker; has sat on a data safety monitoring board or advisory board for the Australian Commission on Safety and Health and the South Western Sydney Local Health District; has declared a leadership or fiduciary role at Diabetes Australia, ADIPS, and the Aotearoa Diabetes Foundation, New Zealand; has received equipment to their institution from Tandem and Abbott; and has received an educational grant to their institution from Abbott. JMY has received grants or contracts from CIHR, Diabetes Canada, the Health Sciences Foundation, Diabetes Research Envisioned and Accomplished in Manitoba, the Manitoba Medical Services Foundation, and the Winnipeg Foundation; has received support for attending meetings and has received equipment, materials, or drugs from Abbott, Dexcom, and Medtronic; and has a leadership or fiduciary role at Diabetes Canada and the Diabetes in Pregnancy Study Group. ÁGT has reported an unpaid leadership role in the Hungarian Diabetes Association and the Diabetes Pregnancy Study Group; has received grants from the Ministry of Innovation and Technologies of Hungary; has received consulting fees from Boehringer

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