

Application of Continuous Glucose Monitoring and Automated Insulin Delivery technologies for Pregnant Women with Type 1 Diabetes, Type 2 Diabetes or Gestational Diabetes Mellitus: An International Consensus Statement

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Abstract

Insulin resistance increases after the first trimester of pregnancy, leading to glycaemic challenges for women with pregestational type 1 diabetes (T1D) or type 2 diabetes (T2D). Additionally, it can promote hyperglycemia in pregnant women without T1D or T2D, who develop gestational diabetes mellitus (GDM). Whilst the majority (>95%) of women with diabetes deliver healthy babies, maternal dysglycaemia can have consequences for the mother and their 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 (RCTs) before and during pregnancy. However, compelling data reports the benefits of CGM use in T1D, and increasing data reports on AID systems in pregnancies complicated by T1D. Appropriate CGM glucose thresholds for diagnosis of GDM, as well as the recommended time in range treatment targets for routine management of GDM and T2D, still need to be determined. The recommendations herein emphasise the value of using CGM during preconception and pregnancy for women with pregestational T1D, to reduce pregnancy complications. Recommendations also include the use of AID systems in women with pregestational T1D, to improve glycaemic management during preconception, during pregnancy and delivery, and in the postpartum period.

This consensus statement has been endorsed by ADJ Diabetes Brazil, Advanced Technologies & Treatments for Diabetes, American Association of Clinical Endocrinology, American College of Diabetology, American Pharmacists Association, Association of Diabetes Care & Education Specialists, Australasian Diabetes in Pregnancy Society, Australian Diabetes Society, Australian Diabetes Educators Association, Brazilian Diabetes Society, Breakthrough T1D, Centre for Chronic Disease (India), Diabetes Australia, Diabetes India, European Association for the Study of Diabetes, European Board and College of Obstetrics and Gynaecology, Indian College of Obstetricians and Gynaecologists, International Association of Diabetes and Pregnancy Study Groups, International Diabetes Federation, International Federation of Gynaecology and Obstetrics, Japan Diabetes Society, Research Society for the Study of Diabetes India, the Society for Obstetric Medicine India, and the World Organization of Family Doctors. The American College of Obstetricians and Gynecologists supports the value of this clinical document as an educational tool, July 2025.

Introduction

Pregnant women with pregestational type 1 diabetes (T1D) or early-onset type 2 diabetes (T2D), and women with gestational diabetes mellitus (GDM) are at increased risk for obstetric and neonatal complications.^{1–4} Substantial progress has been made to ensure that women with any type of diabetes have healthier pregnancies, with therapeutic advances including insulin analogues and continuous glucose monitoring (CGM) technology.^{1–4} Automated insulin delivery (AID) systems have (where available) become the standard of care for people with T1D outside of pregnancy and are increasingly used before and during T1D pregnancy.⁵ As diabetes technology evolves, the safety and efficacy data supporting use in pregnancy is growing.⁵ In order 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 optimal care of women with pregestational T1D or T2D during pregnancy, and women with GDM. 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,² or other technologies (such as apps or smart pens), are outside of the scope of this consensus paper.

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, recognizing that inclusivity and consideration of additional medical and social needs for this group require unique attention.⁶

Methods

The diaTribe Foundation, a non-governmental organisation, invited healthcare professionals (HCPs) with expertise using CGM and AID in diabetes in pregnancy to participate in a consensus panel that complied with the ACCurate Consensus Reporting Document (ACCORD) criteria.⁷ We used a Nominal Group Technique (NGT) methodology, combining brainstorming, discussion and refinement of ideas.⁸ The NGT methodology is designed to allow each participant to voice their views at each distinct stage, 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 of different continents (from Europe,

North-America, Australia, Asia, Africa and South-America). All authors of this article are members of the consensus writing group. People living with diabetes (including those 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, HM, JH and ML created a compendium of topics for consideration by the writing group, who 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 consensus meeting, prior to the ATTD conference in March 2025. Each recommendation was separately 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.

Search Strategy

We performed 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 October 2025 (Appendix P2 & P3). The PRISMA flow diagram for this process is shown on Appendix P4.

General discussion

Access and equity in use of diabetes technology

Disparities in diabetes care for certain groups are long-standing and have increased in the last decade.^{9–10} Access to diabetes technologies, including older forms such as self-monitoring of blood glucose (SMBG), varies greatly across settings due to disparate market access, health systems, and other factors.^{12,13} Even within countries, studies have consistently demonstrated 50% lower rates of access to diabetes technology among individuals with diabetes and lower socioeconomic status, and among certain racial and ethnic groups.^{14–20} Addressing disparities in diabetes technology use may improve population level glycaemic outcomes, and widespread implementation of CGM has shown that health inequalities can be overcome, including population level improvements in maternal/fetal health.²¹ In this context, we acknowledge that the implementation of some recommendations may be harder for some populations within high-income countries, in most low and middle-income countries, and in

conflict zones. In each case, systems-level intervention is needed to improve access and health literacy in the employment of diabetes technologies for healthier 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 T2D) can result in higher glucose levels.²²⁻²⁵ During pregnancy, diabetic ketoacidosis (DKA) is a life-threatening emergency for both the mother and fetus, with high rates of stillbirth associated with DKA (160/1000 pregnancies), occurring mainly in women with pregestational T1D (1-2% of pregnancies),²⁶ but it can also occur in pregestational T2D (0.1%)²⁶ and in GDM (0.02%).²⁷ Beyond insulin management, meeting recommended glycaemic targets, avoiding hyperglycaemia, and use of ketone monitoring are critical to reducing DKA events in T1D pregnancies but ketone monitoring is not routinely recommended in T2D or GDM. Continuous ketone monitoring (CKM) devices are currently in development,²⁸ including sensors with dual CGM and CKM capability, but the role of ketone monitoring (during times of sickness, for example) 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 protein, whole grains, healthy fats, fruits and vegetables, along with regular physical activity, to improve health and optimize glycaemia.²⁹ Randomised controlled trials (RCTs) and crossover trials of nutritional or exercise-based interventions have focused on women with GDM, with limited high quality data in pregestational T1D or T2D.³⁰ These studies have reported mixed results, including a moderate effect on fasting plasma glucose (FPG) and/or postprandial plasma glucose (PPG).^{30,31} Studies on physical activity for lowering FPG and/or PPG^{30,32,33} have generated inconsistent results. The use of CGM allows pregnant women to see the real-time relationship between glucose levels, diet and physical activity.

Integrating CGM data into the care of pregnant women with diabetes

CGM systems enable individuals with diabetes to follow their glucose fluctuations in real time and react to them as needed. Cloud-based platforms allow CGM data to be shared with the clinical team in real time and may allow for quicker response times to questions or concerns from the individual CGM user.³⁴ Ideally, CGM data would be integrated into electronic health records, including ambulatory glucose profiles (AGP), the standard modality for viewing aggregated CGM data (typically 7-14 days).³⁵ AGP reports offer data visualization for non-pregnant women and only some offer customization for pregnancy-specific glucose goals. With a history of incorporating new consensus metrics and methods of visualizing CGM data,³⁶ it is imperative for the AGP report to include options to view the

pregnancy specific time in range (TIRp) of 3.5-7.8 mmol/L (63-140 mg/dL) that is widely used in T1D pregnancy since the International Consensus statement of 2019.³⁷ This would support patients and clinicians to make necessary therapy adjustments specific for diabetes pregnancy care, although CGM glucose thresholds for diagnosis and management of T2D and GDM still need to be determined. It is worth noting that discrepancies currently exist amongst the metrics generated by different CGM sensors, depending on the comparator method used, indicating an unmet need for industry-wide standards and comparator harmonization such that CGM metrics can be interpreted consistently.^{38,39}

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

With increased availability and acceptability of CGM, more women will have access to this technology in pregnancy, either via prescription or over the counter. CGM and AID systems have the advantage that they facilitate remote access to daily glycemic patterns profiles, along with insulin delivery data in the case of 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 at least meet FDA iCGM performance criteria.^{40,41} CGM integration into pregnancy care will require user education on how best to utilize the technology, such as understanding alerts/alarms and trend arrows, and the effects of diet and physical activity on glucose levels. Furthermore, education of healthcare teams who are less familiar with the use of diabetes technologies (including primary care), who may 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.⁴²⁻⁴⁵ Diabetes technology may ease or increase this burden – research suggests some women may experience disturbed sleep,⁴⁶ increased anxiety, and symptoms of depression with CGM use,⁴⁷ while others may experience benefits including reduced stress or diabetes distress, and lessened fear of hypoglycaemia, as seen in observational studies outside of pregnancy.⁴⁸⁻⁵¹ The impact of diabetes technology may vary by type of diabetes in pregnancy. Ultimately, 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 T1D

Maternal glycaemia is a modifiable risk factor and avoiding hyperglycaemia prior to conception reduces risks for congenital malformations and miscarriage.^{3,52} Maintaining target glycaemia during pregnancy reduces complications attributed to fetal hyperinsulinaemia, including preterm births, large for gestational age (LGA) infants, and neonatal care admissions.^{3,53} The HbA1c target should be at least <7.0% (<53 mmol/mol) during preconception, or <6.5% (<48 mmol/mol) if feasible, and lower during pregnancy (Table 1).^{3,29,54} CGM systems have become standard of care for managing T1D during pregnancy.^{3,29,37,54,55} International consensus targets recommend a TIRp of 3.5-7.8 mmol/L (63-140 mg/dL) >70% (Table 1).^{37,56} There is currently a lack of evidence that using the pregnancy-specific glycaemic targets with CGM during preconception can improve pregnancy outcomes.

AID systems use an algorithm, insulin pump and a CGM sensor to provide glucose-responsive insulin delivery with user-initiated premeal insulin boluses.⁵⁷⁻⁵⁹ There is insufficient specific data with AID systems in the preconception period, but data from outside of pregnancy have indicated that AID systems support achievement of glycaemic goals, leading to a 12% higher time in range (TIR) 3.9-10.0 mmol/L (70-180 mg/dL) compared to continuous subcutaneous insulin infusion (CSII) pumps, or multiple daily injections (MDI).^{57,58,60} Where possible, AID systems should be initiated before pregnancy, to optimise preconception glycaemia.² AID systems with evidence of clinical effectiveness from larger RCTs in pregnancy should preferably be used (Box 1, Table 2).⁶¹⁻⁶³ However, given that half of pregnancies in women with pregestational diabetes are unplanned,⁶⁴ AID systems proven to optimise antenatal glycaemia should be started as soon as pregnancy is confirmed, usually at 7 to 8 weeks gestation.

Pregnancy care in T1D

The CONCEPTT trial, including 325 women with T1D (215 pregnant, 110 planning pregnancy), demonstrated that real-time CGM leads to significantly higher TIRp compared to SMBG, with reductions in LGA infants, neonatal intensive care unit (NICU) admissions, and severe neonatal hypoglycaemia.¹ CGM use also reduces hypertensive disorders of pregnancy,^{65,66} and offers important cost savings with improved neonatal outcomes.⁶⁷⁻⁷¹ Use of CGM is therefore recommended for pregnant women with T1D (Box 1).^{29,55,71}

The use of open-loop CSII is not demonstrated to improve glycaemia or pregnancy outcomes compared to MDI⁷²⁻⁷⁸ and higher rates of LGA infants have been reported in some studies.^{77,79-81} In the CONCEPTT trial, MDI users had lower rates of gestational hypertension, neonatal hypoglycaemia and NICU

admissions than CSII users.⁸² RCTs and observational studies also indicate that use of CSII compared to MDI results in higher gestational weight gain (GWG).⁷² This highlights the challenge of optimising CSII settings, especially from the second trimester onwards when insulin resistance increases.^{83,84}

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, respectively (but no automated corrections are made for hyperglycaemia). In contrast, when in predictive low glucose suspend mode, insulin delivery is suspended when an algorithm predicts hypoglycaemia within the next 30 mins, with basal insulin restored once hypoglycaemia is corrected. When tested, both SAP and partial AID were safe and effective in minimising maternal hypoglycaemia,⁸⁵⁻⁸⁷ but no improvements in TIRp or pregnancy outcomes were obtained.

Evidence from randomized controlled trials

Most commercially available AID systems have not been robustly evaluated in pregnancy (Table 2), however two well-conducted RCTs have tested the CamAPS® FX and the MiniMed 780G® AID systems in pregnant women with T1D (Table 2).^{61,62} It should be noted that the majority of women studied to date have been White. The CamAPS® FX system is licensed for use globally in pregnancy, whereas the MiniMed 780G® system is licensed within Europe. The AiDAPT RCT compared CamAPS® FX to standard care (MDI or open-loop CSII with CGM) in 124 pregnant women with T1D, with an inclusion criteria of HbA1c 6.5-10% (48-86 mmol/mol).^{61,88,89} Use of CamAPS® FX led to a significant baseline-adjusted 10.5% increase (an additional 2.5 hours) in mean TIRp (68.2% AID vs. 55.6%), regardless of baseline HbA1c and previous technology use.⁶¹ TIRp >70% was achieved throughout pregnancy by 47% in the AID group compared to 11% in the standard of care group. CamAPS® FX users had lower rates of hypertensive disorders, less GWG,⁶¹ and self-reported positive pregnancy experiences.⁹⁰

The CRISTAL study randomised 95 pregnant women with T1D, comparing the MiniMed 780G® AID system versus standard care with MDI, or with open-loop CSII or partial AID and any CGM system,^{62,91} with no lower HbA1c limit for inclusion. AID use did not improve overall TIRp compared to standard care (66.5% vs. 63.2%) but improved overnight TIRp by 24 minutes (+6.58%), reduced time below range in pregnancy (TBRp) by 19 minutes and improved treatment satisfaction.⁶² In contrast to real-world studies,⁹² excess GWG was significantly lower in MiniMed 780G® users, compared to standard insulin therapy.⁶² The algorithm performed well overnight but often required assisted

carbohydrate administration (adding “fake carbohydrates”) with meals, and requires further refinement for use later in pregnancy. AID is also likely to be cost-saving compared to standard care.⁹³ Neither AiDAPT nor CRISTAL were powered for pregnancy outcomes.

The pilot PICLS RCT compared the MiniMed 670G® as a hybrid closed loop AID system to the same device used as a SAP system in 23 women.⁹⁴ Mean glucose was significantly higher and TIRp tended to be lower ($p=0.17$) in the 3rd trimester with AID functionality. Hypoglycaemia fear improved for AID users.⁹⁵ Assistive techniques were used such as using “fake carbohydrate” boluses and exiting AID functionality overnight as needed.^{94,96} As this AID system was a first-generation device, it is no longer available in most countries.

The CIRCUIT RCT included 88 pregnant women with T1D and gestation <14 weeks and a baseline HbA1c of 7.4%, comparing the Tandem t:slim X2 pump using Control IQ® versus standard care with MDI or open-loop CSII, both with CGM (Table 2).⁹⁷ The outcomes indicated a significantly greater TIRp from 16-34 weeks gestation in the AID group compared to the MDI/open loop with CGM group (65.4% vs 50.3%, a mean adjusted difference of 12.5%; $p<0.001$). Percentage TBRp was also reduced for AID users (mean adjusted difference -1.0%) as was TARp (mean adjusted difference -11.5%). A case series using the t:slim X2 pump with Control IQ® or Basal IQ® have shown them to be safe during pregnancy,⁹⁸⁻¹⁰⁰ with less burden compared to partial AID therapy in previous pregnancies.⁹⁸ There are no RCTs in pregnancy with Diabeloop®, Omnipod 5® or iLet® AID systems. Two case series using the Omnipod 5® system have reported TIRp between 56-82% with the highest TIRp achieved by manually exiting AID overnight.^{101,102}

Evidence from real-world studies

Although data from RCTs is the gold standard for framing clinical recommendations (Appendix P5), real-world evidence can provide important insights. Several systematic reviews and meta-analyses have examined the use of AID during T1D pregnancy.¹⁰³⁻¹⁰⁵ These meta-analyses included larger RCTs and observational data up to September 2024. These meta-analyses showed that AID systems outperformed standard care in nocturnal TIRp and time spent <63 mg/dL. Two out of three meta-analyses^{103,104} concluded a glycaemic benefit of AID versus standard insulin therapy. However, each meta-analysis lacked power to evaluate pregnancy outcomes as none of the current RCT’s on AID in pregnancy were powered on pregnancy outcomes and the sample size from RCT’s was still limited.

A small case series and observational studies with mostly use of the MiniMed 780G® and Tandem t:slim X2 control IQ® showed that they could be safely used in pregnancy with increased TIRp and less burden compared to previous pregnancies using SAP therapy, or when compared to a group with MDI or open-

loop pump therapy, although not all women could achieve a TIRp >70% throughout gestation.^{106–110} A Spanish real-world cohort study of 112 pregnant women with T1D,⁹² comparing MDI with AID (again, mostly MiniMed 780G® and Tandem t:slim X2 control IQ) in women with a median HbA1c of 48 mmol/mol (6.5%) at first antenatal visit, indicated that MDI users had a greater reduction of HbA1c in the second trimester (-0.56% vs. -0.20%), although there was no between-group significant difference in HbA1c in any trimester. Moreover, there were no significant differences in TIRp between groups, while AID users had less TBRp and lower glycaemic variability in the second and third trimesters. However, AID users had more GWG (difference of 3.2 kg) and higher rates of macrosomia, although this was not significantly higher when adjusted for maternal weight gain or third trimester HbA1c.⁹² These study outcomes could have been affected by selection bias, as women may have been offered AID systems due to difficulties in achieving glycaemic goals and/or based on the personal preferences of women and their healthcare providers. For example, in the Spanish study,⁹² AID users had a longer diabetes duration compared to the MDI group, which can be associated with reduced achievement of tight glycaemia and more-likely use of AID therapy. Another recent real-world study,¹¹¹ comparing different AID systems in 137 pregnant women with T1D (62% on MiniMed 780G, 27.7% on CamAPS FX and 10.2% on Tandem Control-IQ), indicated a significantly lower HbA1c (-4.8mmol/mol) by the third trimester in CamAPS FX and Tandem Control-IQ users, and a 5.9% higher TIRp in the second trimester with CamAPS FX compared to MiniMed 780G. In addition, women using CamAPS FX or Tandem Control-IQ had a lower adjusted odds ratio (OR 0.25 and 0.10, respectively) for LGA infants compared with MiniMed 780G users. Due to the observational design, selection bias cannot be excluded. No information was available on the use of temporary systems settings (such as sleep mode in Tandem Control-IQ, Boost in CamAPS FX or use of assistive techniques with fake carbs in MiniMed 780G), which could provide important additional insight into system use.

A non-controlled observational study of 10 women on at-home use of a pregnancy-specific algorithm, with lower 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 has reported an increase in TIRp from 64.5% (using SAP or partial AID) to 78.6% with AID ($p=0.002$) from 14-32 weeks until delivery with a reduction in hypoglycaemia.^{112–115} This system is not commercially available and the lack of a control group precludes conclusions on a causal effect. Data on unregulated, open-source artificial pancreas systems (OpenAPS) is limited to case reports of pregnant women with strong diabetes self-management skills, showing potential benefits in women with T1D, but again are limited by lack of control groups.^{110,116–119}

The consensus panel recommends the use of AID systems with demonstrated evidence of benefits from large RCTs (Box 1).^{61,62,97,120–122} AID systems with at least a 5% (72 minutes) increase in daily TIRp are

recommended to achieve clinically relevant benefits for obstetric and neonatal outcomes.¹²³ The lowest glucose targets and strictest AID settings should be used to achieve optimum glucose levels in most circumstances (Table 2). Insulin-to-carbohydrate ratios (ICR) need to be strengthened in pregnancy to accommodate increasing insulin resistance and delayed insulin absorption (Table 2). Boluses should initially be given 10-15 minutes before meals, but may need to be given up to 30 minutes before meals in late pregnancy, depending on the AID system used (Table 2). Educational resources to support women using AID systems during pregnancy and experienced healthcare staff must be accessible to optimise care.^{124,125} Support should be individualized and intensified as needed, to ensure the woman is able to operate these devices effectively. Due to delayed insulin absorption later in pregnancy, with increasing insulin doses and increased risk of blockage of infusion sets, it is often necessary (especially later in pregnancy) to change the infusion sets more frequently (at least every three days).²

Higher values for HbA1c, time above range in pregnancy (TARp), average glucose, glucose management indicator (GMI), glycaemic variability (GV) metrics, and lower TIRp (all reflecting maternal hyperglycaemia) are associated with increased pregnancy complications.^{56,123,126-140} An observational cohort study of 117 women with either T1D (58%) or T2D¹³⁹ described optimal pregnancy outcomes with 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).^{141,142} A target for mean glucose could also be useful,^{130,143} as mean glucose is highly correlated with overall glycaemia and a modifiable determinant of fetal hyperinsulinemia (Table 1).^{130,144} Some experts suggest tighter overnight TIRp targets but to date there is no evidence to support the use of different daytime versus nighttime targets (Table 1). It should be noted that studies other than those using AID systems used SMBG glucose targets to optimise therapy and the sole use of the CGM derived targets were not tested in RCT settings.

Intrapartum and immediate postpartum care in T1D

Guidelines recommend intrapartum glucose levels of 4.0-7.0 mmol/L (72-126 mg/dL) to reduce the risk for neonatal hypoglycaemia.¹⁴⁵⁻¹⁴⁷ However, recent studies suggest that persistent maternal hyperglycaemia during the second and third trimesters and LGA, indicative of sustained fetal hyperinsulinaemia, are more strongly associated with neonatal hypoglycaemia.^{146,148-150} Therefore, targeting intrapartum glycaemia might not reverse sustained fetal hyperinsulinaemia.¹⁵¹ A more pragmatic approach with intrapartum glycaemic targets of 5.0-8.0 mmol/L (90-144 mg/dL) has been suggested to minimise maternal hypoglycaemia.¹⁴⁶ For some, continuation of CSII (including full and/or partial AID) intrapartum can deliver in-target glycaemia during this period.¹⁵²⁻¹⁵⁵ Insulin sensitivity

increases immediately after delivery, so insulin doses should be reduced $\geq 50\%$ postpartum compared to late 3rd trimester doses, often 20% lower than before pregnancy, with further reductions in women who are breastfeeding.^{146,156,157}

Observational data from 27 women showed that use of the precursor of CamAPS® FX maintained tight glycaemia intrapartum and early postpartum.¹⁵⁸ Case series with the Tandem t:slim X2 pump with Control IQ® showed that target TIRp could be maintained intrapartum.^{100,107} Compared to routine care, MiniMed 780G® use was associated with higher TIRp intrapartum (71.5% vs 63.1%), without increased TBRp, and with >85% TIR 3.9-10.0 mmol/L (70-180 mg/dL) in the early postpartum period (Table 3).¹⁵⁹

Avoiding the need to switch mode of insulin therapy before delivery empowers women to manage their glucose levels, and reduces healthcare costs and staff burden.^{153,154} Antenatal counselling and training for HCPs and pregnant women are crucial (Box 1). Suggestions for implementing AID intrapartum are listed in Table 3.

Late postpartum care in T1D

For breastfeeding women, insulin doses are approximately 20% lower compared to prepregnancy,¹⁶⁰⁻¹⁶³ and potentially increase risk for nighttime hypoglycaemia if insulin doses are not appropriately reduced.^{161,162,164} The CLIMB study in 18 women using MiniMed 670G/770G® with early (6 to 10 days postpartum) or delayed (12 weeks postpartum) AID use reported less maternal hypoglycaemia¹⁶⁵ and the small decrease in glucose after nighttime breastfeeding was lessened with AID versus SAP use.¹⁶⁵ In the PICLS study, involving 23 women with T1D, AID use was resumed 3-7 days postpartum, with similar postpartum TIR 3.9-10.0 mmol/L (70-180 mg/dL) between groups and a trend towards lower TBR <3.9 mmol/L (<70 mg/dL) with AID.⁹⁴ The AiDAPT extension trial continued CamAPS® FX use throughout pregnancy, labor, birth, and up to 6 months postpartum with significantly improved TIR compared to intensive insulin therapy with CGM (72% with AID vs. 54% with standard intensive therapy).⁸⁹ These studies support the continued use of AID postpartum (Box 1).⁸⁹ 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 T2D have 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 to women without diabetes.¹⁶⁶ Pregnant women with T2D also tend to be older, have higher body mass index (BMI) and receive less-frequent prepregnancy and antenatal care, than

women with pregestational T1D.³ Although women with T2D may more often achieve glycaemic targets compared to women with T1D during pregnancy,³ rates of stillbirth and perinatal mortality are higher in T2D, suggesting that lower glucose targets may be needed.³ Non-glycaemic determinants, such as socioeconomic deprivation, pre-pregnancy BMI, coexistent medical conditions and GWG should also be considered.

Prepregnancy care in T2D

For women with T2D, a preconception HbA1c target of <6.5% (<48 mmol/mol) is recommended to reduce congenital anomalies, but the pregnancy HbA1c target of <6.0% (<42 mmol/mol) may be more applicable to reduce rates of perinatal mortality as well as pre-eclampsia, preterm birth, LGA and NICU admissions.^{29,167} Therapies demonstrating safety in pregnancy should preferentially be used, which means insulin is often needed to achieve preconception glucose goals.²⁹ CGM can be a useful tool as it is associated with reduced HbA1c, increased TIR and less hypoglycaemia in non-pregnant adults with T2D.¹⁶⁸ In a pilot study,¹⁶⁹ preconception use of CGM in women with prediabetes or T2D was associated with positive changes in weight and fitness, and with increased time between 3.9-7.8 mmol/L (70-140 mg/dL), although adequately powered studies in prepregnancy and pregnancy are urgently needed.

Pregnancy care in T2D

The evidence for using CGM during T2D pregnancy is currently scarce, with no substantive RCT data. There are ongoing RCTs examining the efficacy of CGM in women with T2D.^{170,171} Three RCTs comparing CGM vs SMBG during pregnancy have included small numbers of women with T2D alongside those with T1D and GDM.¹⁷²⁻¹⁷⁴ All of the studies used older CGM systems episodically, and in one study participants were masked to CGM data. These studies lacked statistical power to evaluate the effectiveness of CGM in T2D pregnancy.

In a retrospective observational study comparing 82 pregnant women with T2D who used CGM versus 278 who did not, CGM users had reduced odds of a composite neonatal adverse outcome, of preterm birth and NICU admissions.¹⁷⁵ A pilot study from Australia demonstrated that using intermittently scanned CGM (isCGM) is feasible among remote and diverse populations (75% Aboriginal or Torres Strait Islander) with T2D pregnancy (n=57), but with variable sensor usage.¹⁷⁶ Among persistent CGM users, maternal hyperglycaemia was associated with higher rates of neonatal complications.¹⁷⁷

There remains an unmet need for large scale, adequately powered trials of CGM use in pregnancy complicated by T2D, and for studies assessing the relationship between CGM metrics and T2D

pregnancy outcomes, including studies on the use of AID systems or connected insulin smart pens in T2D pregnancies. Women with T2D generally achieve lower HbA1c during pregnancy than women with T1D, yet rates of stillbirth and perinatal mortality are higher than in T1D.³ Glucose remains the single most important modifiable factor influencing this, suggesting that greater TIRp may be needed for women with T2D to improve these outcomes. As women with T2D are increasingly using CGM before pregnancy, and often become pregnant while using CGM, the expert consensus recommendation is that CGM may be offered to women with T2D during pregnancy (Box 2), based on available resources and individual preference. A higher TIRp (>80%, Box 2) is suggested to be used in pregnancy based on expert opinion, acknowledging the current lack of solid evidence (level E evidence).

Care during labor and delivery in T2D

Research is needed to identify target glucose ranges for use during labor in women with T2D, and to understand the impact of using diabetes technologies during labor in T2D. As in T1D, the decision to continue use of any technologies during childbirth should be individualized, discussed with the mother, and determined before labor begins, considering the prior experience of the healthcare team within the hospital setting and the knowledge and experience of the mother.¹⁵¹

Postpartum care in T2D

Data are especially needed to determine how diabetes technologies can help to avoid hypoglycaemia postpartum and can reduce the risk for neonatal hypoglycaemia. Despite the lack of data on optimizing technology use postpartum for women with T2D,¹⁷⁸ we suggest optimising TIR 3.9-10.0 mmol/L (70-180 mg/dL, as in other non-pregnant T1D women) in the immediate postnatal period, while establishing breastfeeding and adapting to new routines.¹⁴⁶ Using CGM could enhance glycaemia in this period by facilitating reaching TIR of >70%.¹⁷⁹

Diabetes Technology in Gestational Diabetes Mellitus

GDM is generally defined as hyperglycaemia, first detected during pregnancy, provided that overt diabetes has been excluded.¹⁸⁰ It is the most common medical complication of pregnancy, with a global prevalence of 14%.¹⁸¹ GDM is associated with increased risks for perinatal complications, compared to women without hyperglycaemia, including pre-eclampsia, LGA, and neonatal hypoglycaemia, as well as greater long-term maternal and offspring risks for diabetes and cardiovascular disease.¹⁸² GDM results from a chronic defect in β-cell compensation that is detected by routine glucose testing in pregnancy but the causes are varied, as they are for diabetes outside of pregnancy.¹⁸³

Management of GDM includes medical nutrition therapy, with pharmacotherapy (generally insulin or, in some cases, metformin) if required, and counseling on health-promoting behaviours, to achieve maternal glucose goals, alongside obstetric surveillance to monitor fetal growth.¹⁸² A 2021 systematic review and meta-analysis of 3982 women reported that treatment for GDM diagnosed at 24-28 weeks' gestation is associated with lower risk of primary caesarean deliveries, macrosomia, LGA births, shoulder dystocia, birth injury, and admission to NICU.¹⁸⁴ To date, there is a single treatment trial of early GDM, showing that early diagnosis and treatment in women prior to 20 weeks' gestation, modestly reduced the risk of a composite of serious perinatal complications (driven almost entirely by reduced neonatal respiratory distress) compared to deferred treatment.¹⁸⁵

Care during GDM

Evidence to support specific SMBG-derived glucose targets in GDM is limited. The TARGET trial involving 1100 women, showed a similar rate of LGA births for tighter targets, with FPG ≤ 5.0 mmol/L (≤ 90 mg/dL), 1-hour postprandial ≤ 7.4 mmol/L (≤ 133 mg/dL), 2-hour postprandial ≤ 6.7 mmol/L (≤ 120 mg/dL) versus less tight targets (FPG < 5.5 mmol/L [< 99 mg/dL], 1-h postprandial < 8.0 mmol/L [< 144 mg/dL]), 2-h postprandial < 7.0 mmol/L [< 126 mg/dL]).¹⁸⁶ 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. To be balanced against these benefits was an increase in maternal haemorrhage, coagulopathy, embolism and obstetric complications.¹⁸⁶

A recent Cochrane review reported with low-certainty evidence that tighter glycaemic management (FPG ≤ 5.0 or 5.1 mmol/L [≤ 90 or 92 mg/dL], PPG ≤ 6.7 or 7.4 mmol/L [≤ 120 and 133 mg/dL]) was potentially associated with reduced neonatal risk of death or severe infant morbidity, compared to less tight glycaemic management (FPG ≤ 5.3 or 5.8 mmol/L [≤ 95 or 104 mg/dL], PPG ≤ 7.8 or 8.0 mmol/L [≤ 140 or 144 mg/dL])¹⁸⁷ 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 < 5.0 mmol/L (< 90 mg/dL) was associated with less macrosomia, LGA births, neonatal hypoglycaemia, neonatal jaundice and pre-eclampsia for women with GDM, again with low certainty of evidence.¹⁸⁸ Although HbA1c is positively associated with perinatal complications in GDM,¹⁸⁹ the clinical utility of HbA1c in GDM is limited, since specific HbA1c thresholds lack sensitivity for predicting complications.¹⁹⁰⁻¹⁹²

CGM metrics for monitoring glycaemia during GDM

There is insufficient evidence for using CGM in the management of women with GDM, thus SMBG remains the standard of care for glucose management in GDM (Box 2). A 2017 Cochrane review

reported less GWG with CGM versus SMBG (mean difference -1.26kg), based on low-certainty evidence.¹⁹³ A 2022 review of 6 trials (482 women), found similar benefits of CGM on GWG, plus improvement in HbA1c and birthweight, based on low-certainty evidence.¹⁹⁴ A meta-analysis suggested that episodic use of CGM in GDM was associated with improved third trimester HbA1c and reduced LGA births.¹⁹⁵ The outcomes of the GRACE open-label RCT, presented at the European Association for the Study of diabetes (EASD) 61st Annual Meeting,¹⁹⁶ reported that 170 women diagnosed with GDM and assigned to use CGM had fewer LGA newborns compared to 175 women with GDM in the SMBG control group (3.5% vs 10.3%, p=0.014). The CGM group also had improved time in tight range. Further, adequately powered studies are needed to establish the clinical efficacy of CGM therapy in GDM (Box 3).

Recommended TIR targets for management of GDM still need to be determined. While women with GDM can achieve higher TIRp than women with T1D, this higher TIRp does not appear to translate into reduced LGA births,^{195,197–200} nor improvement in other perinatal outcomes.^{201–203} Mean sensor glucose (SG), a marker of average glucose levels, is associated with excess fetal growth in GDM.^{195,197–200,204} A cohort study of 1302 women in China with GDM found mean SG and TARp to be associated with a composite outcome of preterm birth, LGA births, fetal distress, premature rupture of membranes and NICU admission.¹⁹⁹ Additionally, TIRp, TARp, area under curve, mean amplitude of glycaemic excursion (MAGE) and mean SG were positively associated with LGA births, while TBRp was inversely associated with LGA births.¹⁹⁹ However, characteristics of these women (such as low BMI) are not representative of wider GDM cohorts, and mean SG levels were low even for women at the highest risk of complications.¹⁹⁹ In a secondary analysis of the DiGest RCT with a limited sample of 361 women with GDM,²⁰⁵ a mean glucose level < 6.1 mmol/L (110 mg/dl) was suggested as a therapeutic target for management of GDM. There is insufficient evidence at this point to suggest a mean glycaemia target for GDM.

Several large RCTs powered on pregnancy outcomes comparing CGM with SMBG in GDM are ongoing or recently completed.⁵ The first large RCT powered on pregnancy outcomes, the DipGluMo trial,²⁰⁶ did not show an improvement in maternal complications or perinatal outcomes in 156 women with CGM compared to use of SMBG in 143 women with GDM. TIRp was slightly higher with SMBG compared with CGM (96.9 vs 92.2%) later in pregnancy, although women preferred using CGM.^{206,207} A recent single-center RCT in 111 participants with GDM, which was not powered on pregnancy outcomes, reported higher TIRp in CGM group compared to SMBG (93% \pm 6 vs. 88% \pm 14), taking into account that there was a low compliance with SMBG in the control group.²⁰⁸

As there is lack of clear evidence, SMBG remains the standard of care for the management of GDM. However, based on expert opinion, CGM can be offered to women with GDM based on available resources and individual preferences, although evidence for improved perinatal outcomes is lacking. Acknowledging the lack of strong evidence, a suggestion based on expert opinion is made, in line with international consensus targets,³⁷ that if CGM is used in GDM, a target for TIRp >90% and TARp <10% could be used (level E)(Box 2). There is urgent need for RCTs evaluating the use of CGM in women with GDM, including CGM treatment targets and associations with perinatal outcomes.

CGM in the diagnosis of GDM

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.²⁰⁹ GDM was diagnosed using an oral glucose tolerance test (OGTT) at 24-28 weeks' gestation. CGM-measured glucose values were slightly higher than OGTT-based glucose levels.²¹⁰ The GLAM study showed increased mean SG (6.4 vs 5.8 mmol/L [115 vs 104 mg/dL]), standard deviation (SD) (1.2 vs 1.0 mmol/L [22 vs 18 mg/dL]) and decreased TIRp (84% vs 94%) from 13-14 weeks' gestation in women subsequently diagnosed with GDM at 24-28 weeks' gestation.²¹¹ Second trimester TARp >7.8 mmol/L (>140 mg/dL) best predicted GDM at 24-28 weeks' gestation, with an area under the receiver-operating characteristic (AUROC) curve of 0.81.^{211,212} The ongoing Glycaemic Observation and Metabolic Outcomes in Mothers and Offspring study (GO MOMs) observational study will provide further insights into early pregnancy glycaemia, and the comparisons between CGM and OGTT data.²¹³

CGM-derived thresholds for identifying GDM based on outcome associations

The GLAM study also demonstrated positive associations between CGM glucose metrics and pregnancy complications.²⁰⁹ LGA births and hypertensive disorders of pregnancy were associated with slightly higher mean SG (5.7 mmol/L [102 mg/dL] vs 5.6 mmol/L [100 mg/dL] for LGA [$p=0.01$] and 5.7 mmol/L [102 mg/dL] vs 5.5 mmol/L [99 mg/dL] for hypertensive disorders [$p<0.001$]). Percentage time >6.7 mmol/L (>120 mg/dL) and >7.8 mmol/L (>140 mg/dL) were also positively associated with LGA births and hypertensive disorders of pregnancy.^{201,211} However, the absolute difference in mean SG in women with and without perinatal complications was very small, highlighting the difficulty of defining clinical treatment thresholds.

Intrapartum care in GDM

There are no studies evaluating CGM targets during labor and delivery in women with GDM. 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 GDM.²¹⁴ Most of the data to support these targets are derived from studies on women with pre-existing diabetes rather than GDM.^{145–147}

Women with GDM on high doses of insulin may require increased glucose monitoring and active insulin dose titration. However, an RCT on intrapartum management in 76 women with GDM,²¹⁵ comparing tight (hourly glucose testing and treatment if glucose <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 <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.²¹⁵

Postpartum glucose in GDM

Most women can stop pharmacotherapy after delivery. Checking postpartum blood glucose concentrations before discharge from hospital is useful to identify women with persisting diabetes in need of pharmacological management at discharge. However, there is no clear consensus on what test to perform in the immediate postpartum period. An OGTT is ideally undertaken 6–12 weeks postpartum to assess glycaemic status²⁹ but is often not performed. Data is lacking 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.²¹⁶

Strengths and limitations

The consensus process and methodology that was undertaken has strengths and limitations. Strengths include the international composition of the consensus panel, and the considerable expertise reflected across 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 NGT methodology 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 are that the selection of the consensus panel was not systematized or in any way randomized, rather it was founded in their clinical experience in the application of diabetes technology in pregnancy complicated by diabetes. This may have introduced bias. A further limitation is that the literature databases searched were largely based in English language publications and relied on published studies, rather than a wider investigation of case-based and non-English language resources.

Conclusion

There is strong evidence that CGM and AID can help women with T1D to meet glycaemic goals during pregnancy and in the postpartum period. More evidence is needed to determine whether AID can also improve pregnancy outcomes. The evidence on CGM use in pregnant women with T2D or GDM 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 T2D and GDM. An extended summary of gaps in evidence and priorities for future research is provided in Box 3. Manufacturers of diabetes technologies must also address their reporting systems to accommodate pregnancy-specific targets. Despite the evidence supporting application of diabetes technology in pregnancy with diabetes, inequity in provision of CGM and AID systems during pregnancy persists, and there remains an unmet need for intervention to improve access and health literacy in the employment of diabetes technologies for healthier maternal and neonatal outcomes.

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Box 1: Consensus recommendations for use of 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 (i.e., A, B, C, or E), that adheres to the evidence-grading system of the American Diabetes Association (ADA) Standards of Medical Care in Diabetes (see Appendix P5).²⁹

- Glycaemia should be optimised when planning pregnancy to reduce the risk for pregnancy complications.(A)²¹⁷⁻²¹⁹ Using CGM is recommended for all women with T1D* to optimise glycaemia prior to pregnancy to reduce pregnancy complications,(A)¹ such as fewer neonatal admissions to ICU, reduced incidence of LGA infants and lower occurrence of neonatal hypoglycaemia. CGM should be used to achieve and maintain a TIR 3.9–10.0 mmol/L (70–180 mg/dL) >70% per day prior to pregnancy, targeting an HbA1c <7.0% (<53 mmol/mol) or <6.5% (48 mmol/mol) if feasible.(A)^{1,220}
- CGM use during pregnancy results in important cost savings, or is cost neutral, compared to self-monitored blood glucose (SMBG) testing, with improved neonatal health outcomes.(A)⁶⁷⁻⁷⁰
- AID systems with RCT evidence for use in pregnancy, demonstrating clinically relevant benefits in glycaemia, are recommended for use by women with T1D intending to conceive, starting preconception[†].(A)^{61,62,97}
- AID systems with evidence from RCTs in pregnancy, showing clinically relevant benefits compared to standard insulin therapy and CGM, are recommended for women with T1D during pregnancy,[†] preferably those demonstrating clinically relevant improvements (5% TIRp increase daily), with pregnancy-specific glucose target settings, with systems that can adapt to changes in insulin sensitivity and/or a pregnancy-specific algorithm.(A)^{61,62,97} These can support improvements in TIRp 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 demonstrating clinically relevant benefits in glycaemia outside pregnancy, but with limited or no evidence of benefit in pregnancy, may be considered preconception,(B) and potentially continued in selected women with T1D during pregnancy, when used with assistive techniques and by experienced healthcare teams[†].(B) Systems with an appropriately low glucose target settings and clinically relevant benefits in glycaemia (at least 5% TIRp improvement) should preferably be used.(E)²⁹

- Continued use of AID systems during delivery and immediately postpartum can allow the user and an experienced healthcare team to maintain tight glycaemia without increased risk for TBR, and has the advantage that therapy does not need to be switched to manual insulin delivery or intravenous insulin infusion intrapartum.(B)^{158,159}
- AID can be safely used in early and late postpartum, with improved glycaemia compared to standard insulin therapy[†].(A)^{94,165,221}
- It is recommended to provide pregnant women with T1D using AID systems and their healthcare team with instructions for AID system management during labor and delivery and postpartum in the third trimester.(E)

* People using CGM devices must also have access to blood glucose meters (BGM) at all times. People who are taking insulin and using BGM should be encouraged to check their blood glucose levels when appropriate based on their insulin therapy.

† As for all insulin pump users, pregnant women using AID should be extremely vigilant regarding the risks of DKA, during times of hyperglycaemia, sickness, vomiting or diarrhea. They should be provided with ketone monitoring equipment and be reminded to carry spare insulin pump supplies, and insulin pens at all times.

AID, automated insulin delivery; CGM, continuous glucose monitoring; GDM, gestational diabetes mellitus; T1D, type 1 diabetes; T2D, type 2 diabetes.

Box 2: Consensus recommendations for use of diabetes technology in pregnant women with type 2 diabetes and those planning pregnancy or women with gestational diabetes mellitus

Each of the recommendations in this consensus have been assigned a level of supporting evidence (i.e., A, B, C, or E), that adheres to the evidence-grading system of the American Diabetes Association (ADA) Standards of Medical Care in Diabetes (see Appendix P5).²⁹

Pregnancy in type 2 diabetes

- Use of capillary-blood glucose testing is recommended for all women with T2D before and during pregnancy, along with education to reinforce consistent use.(A)
- Based on the evidence of CGM use in non-pregnant T2D populations, CGM may be used in preparation for pregnancy to help women with T2D achieve glycaemic targets.(B)^{168,220,222}
- CGM may be offered to women with T2D during pregnancy, based on available resources and individual preferences, but there is a lack of evidence of improved outcomes with CGM during T2D pregnancy.(E) There is also insufficient evidence to determine CGM metrics associated with optimal pregnancy outcomes for women with T2D. When CGM is used during T2D pregnancy, a target of >80% TIRp 3.5-7.8 mmol/L (63-140 mg/dL) may be applicable, with <4% below 3.5 mmol/L (63 mg/dL) and <15% above 7.8 mmol/L (140 mg/dL), but the most appropriate targets are currently unknown.(E)

Gestational diabetes mellitus

- Use of capillary-blood glucose testing is recommended for all women with GDM, along with education to reinforce consistent use.(A)
- CGM can be offered to women with GDM* based on available resources and individual preferences, although evidence for improved outcomes is lacking.(E)
- There is insufficient evidence to determine CGM metrics associated with optimal pregnancy outcomes for women with GDM. When using CGM in GDM, a target of >90% TIRp 3.5-7.8 mmol/L (63-140 mg/dL) may be suggested (E) but the most appropriate targets are currently unknown.(E)

* People using CGM devices must also have access to blood glucose meters (BGM) at all times. People who are taking insulin and using BGM should be encouraged to check their blood glucose levels when appropriate based on their insulin therapy.

AID, automated insulin delivery; CGM, continuous glucose monitoring; GDM, gestational diabetes mellitus; T1D, type 1 diabetes; T2D, type 2 diabetes.

Box 3: Priorities for future research

Type 1 diabetes

- More evidence is needed on whether AID systems can improve maternal and neonatal pregnancy outcomes. Data from large national audits, registries and/or meta-analyses could provide more information on pregnancy complications since the introduction of AID systems.
- More research is needed to determine whether the current proposed consensus glucose targets for pregnancy are adequate, should differ according to the trimester, and should be lower overnight compared to the daytime.
- More data are needed to determine the most appropriate 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 using AID in pregnancy.

Type 2 diabetes

- Data are needed on which glycaemic targets should be used at preconception and during pregnancy to optimize pregnancy outcomes in women with T2D.
- Large studies adequately powered on pregnancy outcomes are needed to determine whether use of CGM can reduce the risk for pregnancy complications in women with T2D.
- There is an unmet need for studies that investigate the relationship between CGM metrics and T2D pregnancy outcomes.
- Research is needed to identify target glucose ranges for use during labor in women with T2D, and to understand the impact of using diabetes technologies during labor in T2D.
- Data are needed on how to optimize diabetes technology use postpartum for women with T2D.
- Large studies are needed to assess the use of AID systems or connected insulin pens in T2D pregnancies.

Gestational diabetes mellitus

- There are unmet needs for understanding the value of CGM in the screening, diagnosis and management of GDM.
- Recommended CGM treatment targets for routine management of GDM, need to be determined.

- There is need for adequately powered studies on pregnancy outcomes to determine whether use of CGM can reduce the risk for pregnancy complications in women with GDM, including in early GDM.
- Research is needed to identify target glucose ranges for use during labor in women with GDM.
- More data are needed to determine whether CGM can be useful postpartum to screen for glucose intolerance (and whether it can replace the burden of OGTT) and to identify who is at the highest risk to develop an adverse metabolic profile on the long-term.

AID, automated insulin delivery; CGM, continuous glucose monitoring; OGTT, oral glucose tolerance test; GDM, gestational diabetes mellitus; T1D, type 1 diabetes; T2D, type 2 diabetes.