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Clinical Practice Guideline

Preexisting Diabetes and Pregnancy: An Endocrine Society and European Society of Endocrinology Joint Clinical Practice Guideline

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The above organizations endorse this clinical practice guideline.

Supporting Organization: Society for Maternal-Fetal Medicine (SMFM)

Participating Organization: American College of Obstetricians and Gynecologists (ACOG)

Abstract

Background: Preexisting diabetes (PDM) increases the risk of maternal and perinatal mortality and morbidity. Reduction of maternal hyperglycemia prior to and during pregnancy can reduce these risks. Despite compelling evidence that preconception care (PCC), which includes achieving strict glycemic goals, reduces the risk of congenital malformations and other adverse pregnancy outcomes, only a minority of individuals receive PCC. Suboptimal pregnancy outcomes demonstrated in real-world data highlight the need to further optimize prenatal glycemia. New evolving technology shows promise in helping to achieve that goal. Dysglycemia is not the only driver of poor pregnancy outcomes in PDM. The increasing impact of obesity on pregnancy outcomes underscores the importance of optimal nutrition and management of insulin sensitizing medications during prenatal care for PDM.

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Objective: To provide recommendations for the care of individuals with PDM that lead to a reduction in maternal and neonatal adverse outcomes.

Methods: The Guideline Development Panel (GDP) composed of a multidisciplinary panel of clinical experts, along with experts in guideline methodology and systematic literature review, identified and prioritized 10 clinically relevant questions related to the care of individuals with diabetes before, during and after pregnancy. The GDP prioritized randomized controlled trials (RCTs) evaluating the effects of different interventions (eg, PCC, nutrition, treatment options, delivery) during the reproductive life cycle of individuals with diabetes, including type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM). Systematic reviews queried electronic databases for publications related to these 10 clinical questions. The Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) methodology was used to assess the certainty of evidence and develop recommendations. The approach incorporated perspectives from 2 patient representatives and considered patient values, costs and resources required, acceptability and feasibility, and impact on health equity of the proposed recommendations.

Results: In individuals with diabetes mellitus who have the possibility of becoming pregnant, we suggest asking a screening question about pregnancy intention at every reproductive, diabetes, and primary care visit. Screening for pregnancy intent is also suggested at urgent care/emergency room visits when clinically appropriate (2 | ⊕OOO). This was suggested based on indirect evidence demonstrating a strong association between PCC and both reduced glycated hemoglobin (HbA1c) at the first prenatal visit and congenital malformations.

In individuals with diabetes mellitus who have the possibility of becoming pregnant, we suggest use of contraception when pregnancy is not desired (2 | ⊕⊕OO). This was suggested based on indirect evidence in women with diabetes, where PCC—including contraception as a key component—showed a clinically significant association with improvements in first-trimester HbA1c and the rate of congenital malformations, together with indirect evidence from the general population regarding the reduction of unplanned pregnancies and pregnancy terminations with the use of contraception.

In individuals with T2DM, we suggest discontinuation of glucagon-like peptide-1 receptor agonist (GLP-1RA) before conception rather than discontinuation between the start of pregnancy and the end of the first trimester (2 | ⊕OOO). This was suggested based on limited data on risk of exposure to GLP-1RA receptor agonists during pregnancy.

In pregnant individuals with T2DM already on insulin, we suggest against routine addition of metformin (2 | ⊕OOO). This was suggested based on the GDP judgment that the benefit of adding metformin to insulin to achieve decrease in rates of large for gestational age infants did not outweigh the potential harm of increasing the risk of small for gestational age infants or adverse childhood outcomes related to changes in body composition.

In individuals with PDM, we suggest either a carbohydrate-restricted diet (<175 g/day) or usual diet (>175 g/day) during pregnancy (2 | ⊕OOO). This was suggested based on the GDP judgment that the available evidence was limited and very indirect, resulting in significant uncertainty about the net benefits or harms. As such, the evidence was insufficient to support a recommendation either for or against a carbohydrate intake cutoff of 175 g/day.

In pregnant individuals with T2DM, we suggest either the use of a continuous glucose monitor (CGM) or self-monitoring of blood glucose (SMBG) (2 | ⊕OOO). There is lack of direct evidence supporting superiority of CGM use over SMBG for T2DM during pregnancy. There is indirect evidence supporting improved glucometrics with the use of CGM for individuals with T2DM outside of pregnancy, substantial improvements in neonatal outcomes for individuals with T1DM using CGM during pregnancy and the potential for decreasing adverse pregnancy outcomes with improved glucometrics in individuals with T2DM.

In individuals with PDM using a CGM, we suggest against the use of a single 24-hour CGM target <140 mg/dL (7.8 mmol/L) in place of standard-of-care pregnancy glucose targets of fasting <95 mg/dL (5.3 mmol/L), 1-hour postprandial <140 mg/dL (7.8 mmol/L), and 2-hour postprandial < 120 mg/dL (6.7 mmol/L) (2 | ⊕OOO). This was suggested based on indirect evidence that associated adverse pregnancy outcomes with a fasting glucose > 126 mg/dL (7 mmol/L).

In individuals with T1DM who are pregnant, we suggest the use of a hybrid closed-loop pump (pump adjusting automatically based on CGM) rather than an insulin pump with CGM (without an algorithm) or multiple daily insulin injections with CGM (2 | ⊕OOO). This was suggested based on a meta-analysis of RCTs which demonstrated improvement in glucometrics with increased time in range (MD +3.81%; CI −4.24 to 11.86) and reduced time below range (MD −0.85%; CI −1.98 to 0.28) with the use of hybrid closed-loop pump technology.

In individuals with PDM, we suggest early delivery based on risk assessment rather than expectant management (2 | ⊕OOO). This was suggested based on indirect evidence that risks may outweigh benefits of expectant management beyond 38 weeks gestation and that risk assessment criteria may be useful to inform ideal delivery timing.

In individuals with PDM (including those with pregnancy loss or termination), we suggest postpartum endocrine care (diabetes management), in addition to usual obstetric care (2 | ⊕OOO). As the postpartum period frequently overlaps with preconception, this was suggested based on indirect evidence demonstrating a strong association between PCC and both reduced HbA1c at the first prenatal visit and congenital malformations.

Conclusion: The data supporting these recommendations were of very low to low certainty, highlighting the urgent need for research designed to provide high certainty evidence to support the care of individuals with diabetes before, during, and after pregnancy. Investment in implementation science for PCC is crucial to prevent significant mortality and morbidity for individuals with PDM and their children. RCTs to further define glycemic targets in pregnancy and refinement of emerging technology to achieve those targets can lead to significant reduction of harm and in the burden of diabetes care. Data on optimal nutrition and obesity management in pregnancy are lacking. More research on timing of delivery in women with PDM is also needed.

Keywords: type 1 diabetes, type 2 diabetes, pregnancy, continuous glucose monitor (CGM), insulin pump, delivery timing, metformin, hybrid closed loop, automated insulin delivery, glucagon-like peptide -1 receptor agonist (GLP1-RA)

Abbreviations: AID, automated insulin delivery; BHG, basal hyperglycemia; BMI, body mass index; CGM, continuous glucose monitor; COC, combined oral contraceptive; DMPA, depot medroxyprogesterone acetate; ES, Endocrine Society; ESE, European Society of Endocrinology; EtD, Evidence to Decision; GDP, Guideline Development Panel; GDM, gestational diabetes mellitus; GLP-1RA, glucagon-like peptide-1 receptor agonist; GRADE, Grading of Recommendations, Assessment, Development, and Evaluation; GWG, gestational weight gain; HCL, hybrid closed-loop; IOM, Institute of Medicine; IUD, intrauterine device; LARC, long-acting reversible contraception; LGA, large for gestational age; MDI, multiple daily injections; MEC, Medical Eligibility Criteria; MiTY, Metformin in Women with Type 2 Diabetes in Pregnancy; MOMPOD, Metformin Plus Insulin for Preexisting Diabetes of Gestational Diabetes in Early Pregnancy; NICU, neonatal intensive care unit; NTD, neural tube defect; OR, odds ratio; PCC, preconception care; PCOS, polycystic ovarian syndrome; PDM, preexisting diabetes mellitus; RCT, randomized controlled trial; RDA, recommended dietary allowance; RR, risk ratio; rtCGM, real-time continuous glucose monitoring; SAPT, sensor-augmented pump therapy; SGA, small for gestational age; SMBG, self-monitoring of blood glucose; T1DM, type 1 diabetes mellitus; T2DM, type 2 diabetes mellitus; VTE, venous thromboembolism.

Preexisting diabetes (PDM) is defined as any type of diabetes diagnosed prior to the current pregnancy. The prevalence of PDM has doubled in the last 20 years and now complicates about 1% of pregnancies worldwide, ranging from 0.5% in Europe, to 2% in the United States, and up to 2.4% in Africa and the Middle East[1]. PDM significantly increases the risk of adverse pregnancy outcomes, as shown in Tables 1 and 2.

Specialized diabetes care throughout all stages of the reproductive cycle is needed to improve pregnancy outcomes (Fig. 1). Preconception care (PCC) is widely recommended to optimize glycemia, address treatment for obesity, manage the increasing

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Table 1. Rates of pregnancy complications in preexisting diabetes in a United States cohort, 2004-2011

Adverse event	No diabetes N = 773 751	Type 1 diabetes N = 1125	Type 2 diabetes N = 10 136
Miscarriage, %	19.7%	17.9%	25.2%[a]
RR [95% CI]		0.91 [0.80-1.67]	1.28 [1.24-1.32]
Any congenital malformation, %	13.4%	18.5%[a]	19.0%[a]
RR [95% CI]		1.38 [1.15, 1.67]	1.42 [1.33, 1.51]
Any congenital heart defect, %	3.2%	8.9%[a]	6.9%[a]
RR [95% CI]		2.80 [2.10, 3.73]	2.16 [1.92, 2.41
Intrauterine fetal demise, %	0.3%	0.4%	0.8%[a]
RR [95% CI]		1.47 [0.55, 3.92]	2.5 [1.94, 3.26]
Hypertensive disorders of pregnancy, %	28.2%	47.4%[a]	55.4%
RR [95% CI]		1.68 [1.56, 1.81]	1.97 [1.92, 2.01]
Macrosomia, %	4.6%	11.0%[a]	6.6%[a]
RR [95% CI]		2.38 [1.85, 3.07]	1.43 [1.27, 1.61]
Cesarean delivery, %	27.4%	52.5%[a]	48.5%
RR [95% CI]		1.92 [1.79, 1.82]	1.37 [1.35, 1.38]

Abbreviation: RR, risk ratio.
[a]Indicates statistical significance compared to no diabetes. (Modified from Jovanovič L et al. *Diabetes Metab Res Rev*. 2015;31(7):707-716. ©The Authors, published by John Wiley & Sons, Ltd.[2]).

Table 2. Rates of pregnancy complications in preexisting diabetes in a United Kingdom cohort, 2014-2018

Adverse event	Type 1 diabetes N = 8690	Type 2 diabetes N = 8685	*P* value
Congenital malformation	4.5%	4.0%	.17
Stillbirth	1%	1.3%	.072
LGA	52.5%	26.2%	<.0001[a]
SGA	5.4%	14.1%	<.0001[a]

Abbreviations: LGA, large for gestational age; SGA, small for gestational age.
[a]Indicates statistical significance between type 1 and type 2 diabetes. (Modified from Murphy HR et al. *Lancet Diabetes Endocrinol*. 2021;9(3):153-164. ©Elsevier Ltd.[3]).

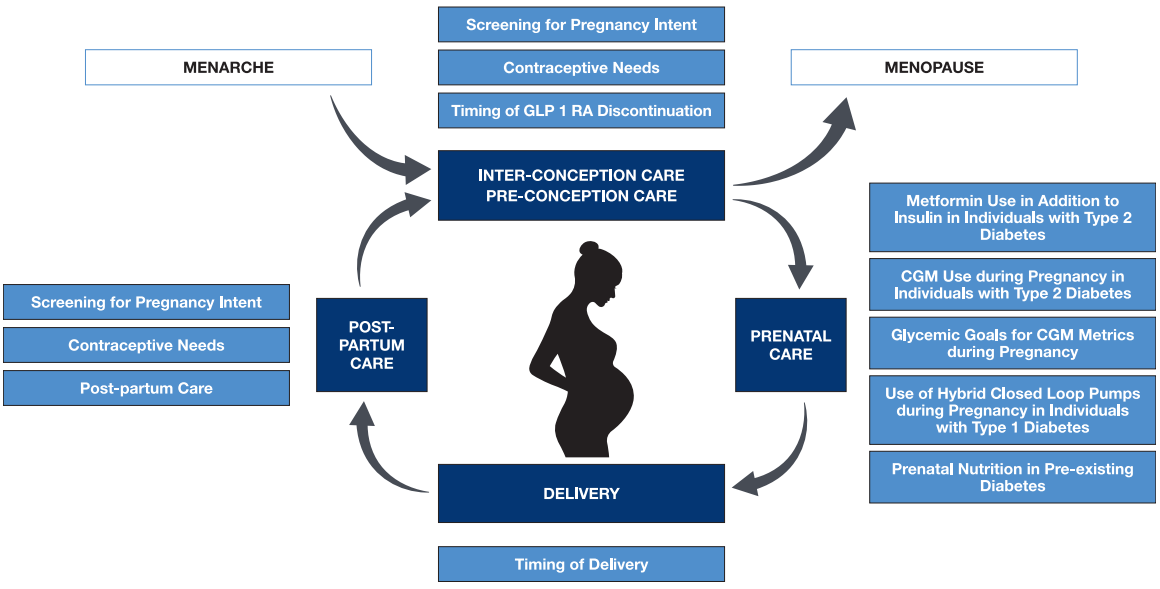

Figure 1. Clinical questions addressed at different stages of reproductive life for individuals with pre-existing diabetes.

complexity of new therapeutics and technologies, and screen for and treat diabetes complications as well as ensure initiation of folic acid supplementation[4]. Despite strong evidence that PCC, focused on achieving glycemic targets before conception, reduces the risk of miscarriage, congenital malformations, and other adverse outcomes, the large gaps in education, access, and care result in missed opportunities[5]. Improvements in glycemia during the prenatal period improve outcomes, but, even with expert care, both glycemia and outcomes remain suboptimal[6]. Supporting a healthy lifestyle, including nutrition, exercise, sleep, and mental health is important throughout the reproductive lifecycle of individuals with PDM[7,8]. Nutrition during pregnancy is especially important, as maternal nutrition has been shown to impact offspring health for generations through epigenetic changes[9].

With the rapid advancement of new diabetes technology promising improvement in glycemia to near-normal levels during pregnancy, there is an urgent need to optimize the use of these new technologies in this particularly at-risk population.

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Delivery is an especially critical point for both mothers and offspring. Understanding how to reduce maternal and neonatal risks during this vulnerable time is essential. The postpartum period is often when those with PDM need the most support. Their recovery is more likely to be complicated by surgical complications, postpartum hypertension, and increased glycemic variability, in addition to the physical and emotional demands of breastfeeding and neonatal care. Glycemic management during this time is essential for maintaining maternal health, reducing maternal hypoglycemia, supporting breastfeeding, and optimizing this new potential preconception period.

List of Recommendations

Question 1. *Should a screening question about pregnancy intention vs no screening question be used in every healthcare provider appointment for individuals with diabetes mellitus who have the possibility of becoming pregnant?*

Recommendation 1

In individuals with diabetes mellitus who have the possibility of becoming pregnant, we suggest asking a screening question about pregnancy intention at every reproductive, diabetes, and primary care visit. Screening for pregnancy intent should also be addressed at urgent care/emergency room visits when clinically appropriate (2 | ⊕OOO).

Technical remarks

- There are no data supporting a specific timing or frequency of screening.
- A critical component of preconception care (PCC) is optimization of glycemia to reduce adverse pregnancy outcomes, including congenital malformations. The Guideline Development Panel suggests that for screening for pregnancy intent to be effective, 3 actions are required:
  - Provision of basic counseling about the benefits of PCC
  - Evaluation of contraception needs and/or family planning referral
  - Referral for PCC to achieve goals of therapy
- This recommendation applies to individuals with all types of PDM, including type 1 and type 2 diabetes mellitus.

Question 2. *Should contraception vs no contraception be used in individuals with diabetes mellitus who have the possibility of becoming pregnant?*

Recommendation 2

In individuals with diabetes mellitus who have the possibility of becoming pregnant, we suggest use of contraception when pregnancy is not desired (2 | ⊕⊕OO).

Technical remark

- Clinician counseling about contraception should be noncoercive and patient centered. Shared decision making should prioritize an individual's autonomy and be informed by the clinician's expertise.

Question 3. *Should discontinuation of glucagon-like peptide-1 receptor agonist before pregnancy vs glucagon-like peptide-1 receptor agonist discontinuation between the start of pregnancy and the end of the first trimester be used in individuals with preexisting type 2 diabetes?*

Recommendation 3

In individuals with type 2 diabetes, we suggest discontinuation of glucagon-like peptide-1 receptor agonist (GLP-1RA) before conception rather than discontinuation between the start of pregnancy and the end of the first trimester (2 | ⊕OOO).

Technical remarks

- Sudden discontinuation of GLP-1RA may cause hyperglycemia and weight gain, which increases the risk for congenital malformations and spontaneous abortion. Timely transition and titration of alternative antihyperglycemic agents after discontinuing GLP-1RAs is necessary to minimize hyperglycemia.
- The timing of discontinuation prior to pregnancy is individualized based on the anticipated likelihood of conception after discontinuing contraception, type of GLP-1RA used, and risks of prolonged time off GLP-1RAs prior to pregnancy.
- Active management of glycemia is required after GLP-1RA discontinuation.

Question 4. *Should insulin vs insulin with the addition of metformin be used in pregnant individuals with preexisting diabetes type 2?*

Recommendation 4

In pregnant individuals with type 2 diabetes mellitus (T2DM) already on insulin, we suggest against routine addition of metformin (2 | ⊕OOO).

Question 5. *Should a carbohydrate-restricted (<175 g per day) diet vs usual diet (>175 g per day) during pregnancy be used in individuals with preexisting diabetes mellitus?*

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Recommendation 5

In individuals with preexisting diabetes mellitus (PDM), we suggest either a carbohydrate-restricted diet (<175 g per day) or usual diet (>175 g per day) during pregnancy (2 | ⊕OOO).

Technical remarks

- There is no clear evidence on the optimal amount of carbohydrate intake during pregnancy; however, lower and higher extremes are harmful based on indirect evidence.

Question 6. *Should a continuous glucose monitor vs no continuous glucose monitor (self-monitoring blood glucose as standard of care) be used in pregnant individuals with type 2 diabetes mellitus?*

Recommendation 6

In pregnant individuals with type 2 diabetes mellitus (T2DM), we suggest either continuous glucose monitor (CGM) or self-monitoring of blood glucose (SMBG) (2 | ⊕OOO).

Technical remarks

- Both CGM and SMBG are considered reasonable alternatives for monitoring glucose during pregnancy; however, in individuals with T2DM, there is limited direct evidence of superiority of CGM use. CGM may offer a potential advantage over SMBG in certain subgroups of preexisting T2DM.
- Ideal glycemic ranges, CGM metrics, and % time in range for individuals for T2DM may be different compared to those which have been demonstrated to improve clinical outcomes in type 1 diabetes mellitus.

Question 7. *Should a single continuous glucose monitoring target of <140 mg/dL (7.8 mmol/L) be used vs standard-of-care pregnancy glucose targets of fasting <95 mg/dL (5.3 mmol/L), 1-hour postprandial <140 mg/dL (7.8 mmol/L), and 2-hour postprandial <120 mg/dL (6.7 mmol/L) in individuals with preexisting diabetes mellitus using continuous glucose monitoring?*

Recommendation 7

In individuals with preexisting diabetes mellitus (PDM) using a continuous glucose monitor (CGM), we suggest against the use of single 24-hour CGM target <140 mg/dL (7.8 mmol/L) in place of standard-of-care pregnancy glucose targets of fasting <95 mg/dL (5.3 mmol/L), 1-hour postprandial <140 mg/dL (7.8 mmol/L), and 2-hour postprandial <120 mg/dL (6.7 mmol/L) (2 | ⊕OOO).

Technical remark

- When CGM is used in individuals with PDM, providers and patients should use fasting and postprandial glucose targets (whether measured by CGM or self-monitoring of blood glucose) as the basis for insulin adjustment and not a single glucose target of 63-140 mg/dL.
- When using CGM in conjunction with HCL, providers should be aware that not all HCL algorithms can meet these targets.
- This recommendation applies to all types of PDM, including type 1 and type 2 diabetes mellitus.
- There are limited data on the appropriate lower limit of the target for fasting or postprandial glucose in pregnancy.

Question 8. *Should a hybrid closed-loop pump (pump adjusting automatically based on continuous glucose monitor) vs insulin pump with continuous glucose monitor (without an algorithm) or multiple daily insulin injections with continuous glucose monitor be used in individuals with type 1 diabetes mellitus who are pregnant?*

Recommendation 8

In individuals with type 1 diabetes mellitus (T1DM) who are pregnant, we suggest the use of a hybrid closed-loop (HCL) pump (pump adjusting automatically based on continuous glucose monitor [CGM]) rather than an insulin pump with CGM (without an algorithm) or multiple daily insulin injections with CGM (2 | ⊕OOO).

Technical remark

- Not all HCL algorithms are appropriate for use in pregnancy. The individual algorithms used in HCL technology vary in their effects on glucometrics and, presumably, on clinical outcomes as well. The decision to use HCL technology—and which specific system to choose—should be made by the patient in collaboration with a clinician experienced in both diabetes management during pregnancy and diabetes technology.

Question 9. *Should early delivery based on risk assessment vs expectant management be used in individuals with preexisting diabetes mellitus?*

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Recommendation 9

In individuals with preexisting diabetes mellitus (PDM), we suggest early delivery based on risk assessment rather than expectant management (2 | ⊕OOO).

Technical remarks

- There are no validated obstetric risk assessment tools for individuals with PDM.
- Risk assessment criteria that may be useful to inform ideal delivery timing include the history of diabetes-related complications, measures of glycemia, ultrasound assessment of fetal growth and amniotic fluid volume, and presence of other comorbidities associated with adverse perinatal outcomes.
- Risks may outweigh any benefits of expectant management beyond 38 weeks gestation, even among those with ideal glycemic management.

Question 10. *In postpartum individuals with preexisting diabetes mellitus (including those with pregnancy loss or termination), should postpartum endocrine care (comprehensive diabetes management), in addition to usual obstetric care vs usual obstetric care be used?*

Recommendation 10

In individuals with preexisting diabetes mellitus (PDM) (including those with pregnancy loss or termination), we suggest postpartum endocrine care (diabetes management), in addition to usual obstetric care (2 | ⊕OOO).

Technical remark

- In addition to routine obstetric care, immediate postpartum care for individuals with PDM should prioritize glycemic management to support healing, promote lactation, and facilitate the transition to interpregnancy and long-term diabetes management.
- Ideally, postpartum diabetes care should be delivered by a multidisciplinary team that includes physicians specializing in diabetes and/or endocrinology, as well as nurses, dietitians, and certified diabetes care and education specialists. This team should also support ongoing, long-term established follow-up.
- In many cases, postpartum care also serves as preconception care (PCC) for a future pregnancy. Approximately half of all deliveries occur among individuals who already have at least one child, highlighting the opportunity for postpartum care to contribute meaningfully to PCC. There is strong evidence that preconception care improves several pregnancy outcomes in individuals with PDM.

Methods of Development of Evidence-Based Clinical Practice Guidelines

This guideline was developed jointly by the Endocrine Society and European Society of Endocrinology using the process detailed on the Endocrine Society website (https://www.endocrine.org/clinical-practice-guidelines/methodology) and summarized here. The primary goal of the Guideline Development Panel (GDP) was to provide recommendations for the care of individuals with preexisting diabetes (PDM). This focus arises from the increasing prevalence of PDM among pregnant individuals and the central role that endocrinologists play in their care. The panel identified many important clinical questions regarding the care of individuals with PDM during pregnancy. However, due to limited resources, we prioritized 10 of these questions and focused on 5 key clinical outcomes deemed critical for decision making for each. The GDP followed the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) methodology (Tables 3 and 4), which includes the Evidence to Decision (EtD) framework to ensure all important criteria are considered when making recommendations[12,13]. The process was facilitated by the GRADEpro Guideline Development Tool (GRADEpro GDT)[14]. The GDP included 2 co-chairs and 15 content experts representing the following specialties: adult endocrinology, general internal medicine, obstetrics and gynecology, maternal-fetal medicine, nutrition, diabetes education, and pharmacology. Two patient representatives with lived life experience of diabetes and pregnancy were also included on the panel. Members were identified by the Endocrine Society (ES) and European Society of Endocrinology (ESE) Boards of Directors and the ES Clinical Guidelines Committee and ESE Clinical Committee and were

Table 3. GRADE certainty of evidence classifications

Certainty of evidence	Interpretation
High ⊕⊕⊕⊕	There is high confidence that the true value of the estimate of interest is on one side of a threshold of interest or within a specific range.
Moderate ⊕⊕⊕O	There is moderately confidence that the true value of the estimate of interest is on one side of a threshold of interest or within a certain range. The true value of the estimate may deviate slightly from the target of the certainty rating (ie, may possibly fall in a different range).
Low ⊕⊕OO	There is low confidence that the true value of the estimate of interest is on one side of a threshold of interest or within a certain range. The true value of the estimate may deviate from the target of the certainty rating (ie, likely fall in a different range).
Very Low ⊕OOO	There is very-low confidence that the true value of the estimate of interest is on one side of a threshold of interest or within a certain range. The true value of the estimate may deviate significantly from target of the certainty rating (ie, probably fall in a different range).

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Table 4. GRADE strength of recommendation classifications and interpretation

Strength of recommendation	Criteria	Interpretation by individuals	Interpretation by health care clinicians	Interpretation by policy makers
1: Strong recommendation for or against	Desirable consequences CLEARLY OUTWEIGH the undesirable consequences in most settings (or vice versa).	Most individuals in this situation would want the recommended course of action, and only a small proportion would not.	Most individuals should follow the recommended course of action. Formal decision aids are not likely to be needed to help individual individuals make decisions consistent with their values and preferences.	The recommendation can be adopted as policy in most situations. Adherence to this recommendation according to the guideline could be used as a quality criterion or performance indicator.
2: Conditional recommendation for or against[a]	Desirable consequences PROBABLY OUTWEIGH undesirable consequences in most settings (or vice versa).	The majority of individuals in this situation would want the suggested course of action, but many would not. Decision aids may be useful in helping individuals make decisions consistent with their individual risks, values and preferences.	Clinicians should recognize that different choices will be appropriate for each individual and that clinicians must help each individual arrive at a management decision consistent with the individual's values and preferences.	Policy-making will require substantial debate and involvement of various stakeholders. Performance measures should assess whether decision making is appropriate.

Reprinted from Schunemann HJ et al. *Blood Adv*. 2018;2(22):3198-3225. © The American Society of Hematology, published by Elsevier[11].
[a]In cases in which the EtD criteria did not favor one option over the other, both options would be appropriate, and the choice between them should follow a shared decision-making approach.

vetted according to the ES conflict-of-interest policy (Endocrine Society 2019), which was followed throughout the guideline process to manage and mitigate conflicts of interest. Detailed disclosures of GDP members and the management strategies implemented during the development process can be found in Appendix A. Overall, 36% of panel members reported potentially relevant conflict of interest. In addition, the group included a clinical practice guideline methodologist from the Mayo Evidence-Based Practice Center, who led the team that conducted the systematic reviews and meta-analyses, and a methodologist from the ES, who advised on methodology and moderated the application of the EtD framework and development of the recommendations.

To lead each guideline question, 2 to 3 GDP members were assigned. The 10 clinical questions addressed in this guideline were prioritized from an extensive list of potential questions through a survey of the GDP members and discussion. The Mayo Evidence-Based Practice Center conducted a systematic review for each question and produced GRADE evidence profiles that summarized the body of evidence for each question and the certainty of that evidence[15]. Systematic searches for evidence were conducted in February 2022 and updated in February 2025. In parallel with the development of the evidence summaries, the GDP members searched for and summarized research evidence for other EtD criteria, such as individuals' values and preferences, costs and resources required, cost-effectiveness, feasibility, acceptability, and the potential impact on health equity. Evidence from randomized controlled trials (RCTs) was prioritized for the systematic reviews. In the absence of primary RCTs, the GDP considered evidence from comparative observational studies and indirect evidence from alternative populations or interventions deemed to be clinically comparable. Evidence from RCTs supports 3 of the recommendations (Recommendations 4, 6, and 8), while the rest are based on observational data or indirect evidence from acceptable alternative populations and interventions, which limits the certainty of the supporting evidence[16]. For example, drawing conclusions from studies performed in nonpregnant populations is suboptimal, as it ignores both the unique physiology of pregnancy and the impact of an intervention on the fetus. Results from studies in individuals with gestational diabetes mellitus (GDM) may not be generalizable to those with PDM. Similarly, distinctions must be drawn for individuals with type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM) in pregnancy. For 2 recommendations, the panel considered both of the evaluated alternatives to be acceptable without suggesting one over the other due to the high level of uncertainty regarding the net benefits or harms of the evaluated alternatives and other EtD criteria[17].

Following the GRADE methodology, the panel considered all elements of the EtD framework, including stakeholder values and preferences (with input from clinical experts and 2 patient representatives), costs and resource requirements, cost-effectiveness, acceptability, feasibility, and potential impacts on health equity. However, the panel did not find robust evidence for most of these EtD factors in relation to the clinical questions, highlighting the need for research in these areas.

Research evidence summaries noted in the EtD frameworks were compiled using standardized terminology templates for clarity and consistency[18]. During an in-person GDP meeting and a series of video conferences, the GDP judged the balance of benefits and harms, in addition to the other EtD criteria, to determine the direction and strength of each recommendation[17–19] (see Tables 3 and 4).

The draft recommendations were posted publicly for review, and the draft guideline manuscript was reviewed by the ES Clinical Guidelines Committee and ESE Clinical Committee, representatives of any co-sponsoring organizations, representatives of the ES and ESE Boards of Directors, and an Expert Reviewer. Revisions to the guideline were made based on submitted comments and approved by the Clinical Guidelines Committee and Clinical Committee, the Expert Reviewer, and the Boards of Directors. Finally, the guideline manuscript was reviewed before publication by *The Journal of Clinical Endocrinology & Metabolism* and *European Journal of Endocrinology* publishers' reviewers.

This guideline will be reviewed annually to assess the state of the evidence and determine if any developments warrant an update to the guideline.

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Screening for Pregnancy Intention

Background

Unfavorable pregnancy outcomes are common in individuals with preexisting diabetes mellitus (PDM) and are related to modifiable factors such as maternal hyperglycemia and body mass index[20]. For outcomes such as congenital malformations[21] or miscarriage[22], the exposure period begins weeks before the pregnancy is recognized. The World Health Organization (WHO) defines preconception care (PCC) as "a set of interventions that are to be provided before pregnancy, to promote the health and well-being of women and couples, as well as to improve the pregnancy and child-health outcomes"[23]. The US Centers for Disease Control and Prevention (CDC) defines PCC as "a set of interventions that aim to identify and modify biomedical, behavioral, and social risks to a woman's health or pregnancy outcome through prevention and management"[24]. As pregnancies are often unplanned[25], PCC, including a focus on optimizing maternal glycemia, is necessary to improve maternal and fetal/neonatal outcomes[4,5,26]. Therefore, understanding the effect of screening for pregnancy intention was deemed a priority.

Screening for pregnancy intention in the general population includes initiatives such as the ONE KEY QUESTION® (OKQ), developed by the Oregon Foundation for Reproductive Health[27]. This initiative proposes that primary care clinicians ask individuals "Would you like to become pregnant in the next year?". For those who answer "yes," the clinician offers preconception counseling and screenings to ensure that modifiable risk factors are addressed before pregnancy. For those who answer "no," the clinician provides counseling on the full range of contraceptive options to ensure that the method they use is optimal for their circumstances. This approach is endorsed by the American College of Obstetricians and Gynecologists and the American Society for Reproductive Medicine[28].

Question 1. *Should a screening question about pregnancy intention vs no screening question be used in every healthcare provider appointment for individuals with diabetes mellitus who have the possibility of becoming pregnant?*

Recommendation 1

In individuals with diabetes mellitus who have the possibility of becoming pregnant, we suggest asking a screening question about pregnancy intention at every reproductive, diabetes, and primary care visit. Screening for pregnancy intent is also suggested at urgent care/emergency room visits when clinically appropriate (2 | ⊕OOO).

Technical remarks

- There are no data supporting a specific timing or frequency of screening.
- A critical component of preconception care (PCC) is optimization of glycemia to reduce adverse pregnancy outcomes, including congenital malformations. The Guideline Development Panel (GDP) suggests that for screening for pregnancy intent to be effective, 3 actions are required:
  - Provision of basic counseling about the benefits of PCC
  - Evaluation of contraception needs and/or family planning referral
  - Referral for PCC to achieve goals of therapy.
- This recommendation applies to individuals with all types of PDM, including type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM).

Summary of Evidence

The meta-analysis results, a detailed summary of the evidence, and Evidence to Decision (EtD) tables can be found online at: https://guidelines.gradepro.org/profile/1PAEgaVAt10.

Benefits and Harms

The systematic review did not identify any randomized controlled trial (RCT) examining the effects of a screening question about pregnancy intention in individuals with diabetes on the following outcomes:

- Contraception prescription
- Referral for PCC
- Unplanned pregnancy
- Glycated hemoglobin (HbA1c) at the first prenatal visit
- Congenital malformations

The GDP found indirect evidence for the effects of PCC on HbA1c at the first prenatal visit and congenital malformations. The GDP also found indirect evidence for the benefits of a screening question asking about pregnancy intention and contraceptive use on documentation of contraceptive use but not on contraception prescribing. The GDP found no indirect evidence for the outcomes of unplanned pregnancy or referral for PCC.

The indirect evidence supporting this recommendation includes multiple studies that demonstrate the association of PCC on HbA1c at the first prenatal visit and congenital malformation in individuals with diabetes. A systematic review and meta-analysis of 36 studies (34 cohort studies) with 8199 participants demonstrated that PCC was associated with a lower HbA1c in the first trimester by an average of −1.27% (mean difference, −1.27%; 95% CI: −1.33 to −1.22; 4927 participants; 24 studies; moderate certainty evidence) and with a lower rate of congenital malformations (risk ratio [RR], 0.29 [0.21-0.40]) with high certainty (25 studies; 5903 participants)[5].

The GDP identified further indirect evidence supporting this recommendation, as a previsit question was found to improve documentation of contraceptive use. In a cluster RCT, academic internists who were randomized to the intervention group ($n = 26$) were provided with information on their female individuals' pregnancy intentions and contraceptive use as a "vital sign" taken immediately before visits, while academic internists in the control group ($n = 27$) received only standard intake information. Data were abstracted for 5371 visits from 2304 individuals. Screening in the intervention group increased documentation of contraceptive use from a

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baseline of 23% to 57% in the intervention group but was unchanged at 28% in the control group ($P < .001$). Additionally, for visits involving teratogenic medications, documentation of contraceptive use increased from 14% to 48% in the intervention group compared with a decrease from 29% to 26% in the control group ($P < .001$) However, the intervention had minimal impact on documented provision of family planning services[29].

The GDP did not identify any indirect evidence of harm from the screening question on any of the 5 outcomes. One potentially undesirable effect of PCC is maternal hypoglycemia in the first trimester, which was evaluated in the meta-analysis of Wahabi et al[5]. There was very low certainty about the effect of PCC on maternal hypoglycemia during the first trimester (RR: 1.38; 95% CI: 1.07-1.79; 3 studies; 686 participants). The grade of evidence was downgraded from low to very low due to inconsistency of the direction of effect and high heterogeneity ($I^2 = 76\%$) in the included studies[5]. The GDP deemed the final goal of a screening question about pregnancy intention to be receipt of PCC and access to contraception.

Other Evidence to Decision Criteria and Considerations

Women with T1DM express concerns about the effect of high glucose on the health of their infant[30]. Although we did not find studies of the value placed on the respective outcomes prioritized, the GDP judged that reducing congenital malformations would be of very high importance for most individuals.

The resources needed depend on how screening is implemented and could be substantial. Medical record modifications and staff/clinician time are required. PCC increases use of services, including diabetes education, nutrition counseling, contraception, and medical care.

We did not identify any study directly evaluating cost-effectiveness of pregnancy intention screening. We did find cost-effectiveness data derived from estimates of PCC. The GDP judged that the indirect evidence for the cost-effectiveness of PCC favors screening those with diabetes for pregnancy intention. A US study estimated that the cost of PCC (20 preconception visits) was $3676 (1992 USD). However, the reduction in costs for maternal and neonatal length of hospital stay, neonatal intensive care unit (NICU) admission, and long-term costs related to congenital malformations resulted in cost savings of $1.86 for every dollar spent[31]. An Irish study in 2016 demonstrated that attendees of a PCC clinic had adjusted difference in complication costs €2578.00 lower than usual antenatal care[32]. A systematic review of 6 economic evaluation studies of PCC that included 1800 individuals with diabetes (among other clinical contexts), found that PCC was likely to be cost-effective regarding specific health outcomes[33]. A study that modeled the impact of PCC resulted in large societal and health care cost savings[34]. Estimating that 2.2% of US births are to individuals with known PDM, universal PCC might avert 8397 (90% prediction interval [PI], 5252–11 449) preterm deliveries, 3725 (90% PI, 3259-4126) birth defects, and 1872 (90% PI, 1239-2415) perinatal deaths annually in the United States. Associated discounted lifetime costs averted for the affected cohort of children could be as high as $4.3 billion (90% PI, $3.4-$5.1 billion in 2012 USD)[34].

We did not identify any studies that evaluated the effect of the intervention on health equity, nor did we find any studies that applied a reproductive justice framework to PCC for individuals with diabetes. It should be noted that the burden of unintended pregnancy is higher in minoritized populations[35]. This is of particular importance because the GDP identified disparities in access to PCC and in pregnancy outcomes for individuals with diabetes. Minoritized populations are also at risk for biased or coercive reproductive health counseling[36]. The intervention could have a positive impact on health equity if implemented with appropriate attention to addressing interpersonal and structural barriers, including local policies that restrict reproductive health care. However, inconsistent or biased implementation could worsen disparities in pregnancy outcomes.

The GDP evaluated reproductive intention screening to be acceptable to individuals with diabetes. A systematic review of screening for reproductive intention in a primary care setting identified 7 studies that measured acceptability and participant satisfaction, both of which were high in all 7 studies[37]. Another systematic review identified 53 US-based studies using 22 screening tools and standardized approaches to preconception, interconception, and reproductive health, evaluating a variety of outcomes[38]. Five studies included adolescents with either T1DM or T2DM. Adolescent participants in the Randomized Efficacy Trial of Early Preconception Counseling for Diabetic Teens (READY-Girls) study found the screening and educational tools to be acceptable. Findings included increased knowledge about reproductive health and the benefits of PCC as well as intentions to seek PCC before a future pregnancy[4,38,39]. It is important to note that none of these studies were conducted in the context of local policies that eliminate access to termination of pregnancy, which may impact the acceptability of screening for pregnancy intent.

The GDP determined that the feasibility of reproductive screening varied based on limitations on clinician time, clinician comfort discussing contraception, and varied resources for referrals for PCC/contraceptive counseling/prescribing. Lack of sufficient time, clinician self-efficacy, and resources to provide subsequent care are barriers to implementation[32,40–44]. A quality improvement intervention at a single US academic outpatient endocrinology practice was initiated to improve rates of PCC and contraception prescribing by endocrinologists to individuals with diabetes. The intervention included distribution of electronic education reminders about diabetes in pregnancy and contraceptive options to clinicians as well as teaching materials for individuals and simplified note templates for documentation. After the intervention, contraception discussion at the visit increased from 4% to 18% ($P = .03$), while the increases in contraception prescription (from 0% to 2%) and PCC (from 0% to 6%) were not significant[40].

Justification for the Recommendation

Given the high prevalence of maternal and fetal complications in individuals with PDM and indirect evidence of large beneficial effects on the risk for congenital malformations and moderate benefit for first-trimester HbA1c reduction with PCC, the GDP judged that screening individuals with diabetes for pregnancy intention is likely of benefit if it leads to increased uptake of PCC.

No studies were identified that compared a screening approach to a nonscreening approach for pregnancy intention in individuals with diabetes. Therefore, the GDP's approach to this question followed a framework proposed by Murad

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and colleagues[45]. This framework includes a series of factors that need to be considered to support screening:

- Importance: The condition is an important health problem in terms of prevalence and/or consequences.
  - The GDP noted that lack of pregnancy planning has been linked to important health problems in individuals with PDM.
- Natural history: The condition for which screening is being performed has a well-understood natural history that includes a latent (preclinical) phase.
  - The GDP agreed that the adverse effects of lack of pregnancy planning might manifest only after a latency period and that early intervention could improve these outcomes.
- Difference in management and treatment availability: Those with positive screening test results would be managed differently from those with negative screening test results.
  - The GDP agreed that the management will differ for individuals who screen positive (ie, pregnancy intention) vs negative and that resources and management strategies exist (PCC) and contraception, respectively for both groups.
- Test accuracy and safety: High or moderate certainty evidence supports acceptable accuracy of the screening test (eg, acceptable false-positive and false-negative rates).
  - The screening intervention in this situation (ie, pregnancy intent) is obtained directly from the individuals with diabetes who have the possibility of becoming pregnant.
- Available treatment: Effective management is available that improves patient-important outcomes when implemented in the latent (preclinical) phase.
  - PCC is available, and the identified systematic reviews showcase positive effects in the outcomes of interest.
- Difference in outcomes: The benefits of management according to screening results outweigh the harms of screening (eg, overdiagnosis, unnecessary treatment for false positives, anxiety, stigma, etc.).
  - The GDP did not identify any harms related to a screening question other than the financial costs associated with PCC according to the individual's response.
- Other considerations: The screening strategy should be cost-effective, acceptable to relevant stakeholders, and feasible to implement.
  - The provision of PCC to individuals with diabetes appeared to be cost-effective and acceptable to individuals and clinicians, with feasibility depending on system structures and support.

The justification for a screening question about the possibilities of pregnancy is based on the significant benefits for PCC, which are used as a surrogate, and lack of considerable harm.

Comments

Two subgroups need additional consideration: adolescent girls/young individuals with T1DM and women with T2DM. Serious adverse pregnancy outcomes can be especially high among adolescents and young women. The early and unpredictable timing of sexual debut, the high percentage of individuals who have at least one episode of unprotected sex[46], the higher occurrence of major malformations (20.5%), and the high prevalence of serious adverse pregnancy and neonatal outcomes support early intervention to reduce risks[47]. As is true for all individuals, contraceptive counseling for adolescents should be devoid of coercion, involve shared decision making, and respect individual autonomy. Access to contraception for adolescents should be available prior to sexual debut.

Women with T2DM may have lower awareness of pregnancy risks related to diabetes and reduced PCC attendance than do those with T1DM[48], as well as increased risk for certain adverse outcomes[2,3].

Research Considerations

Direct evidence from pragmatic RCTs is needed to evaluate the benefit of the intervention of a screening question in individuals with diabetes who could become pregnant. Implementation studies are also needed. Suggested studies include:

- Evaluating how a screening question about pregnancy intention changes rates of 1) contraception prescription or referral to a family planning clinic, 2) referral for PCC, 3) unplanned pregnancy, 4) HbA1c at first prenatal visit, and 5) congenital malformations.
- Evaluating whether pairing a screening question about pregnancy intention and a screening question about immediate contraceptive needs increases referrals for PCC or to a family planning clinic and contraceptive use and reduces unplanned pregnancies and congenital malformations as well as decreases HbA1c at the first prenatal visit.
- Comparing the outcomes of interest and associated costs/savings among various approaches to screening for pregnancy intention; these approaches could include automated direct communication to individuals, automated reminders to clinic staff to prescreen at visits, and automated reminders to clinicians to screen regarding pregnancy intention during visits with protocols streamlining referrals for PCC and/or contraception provision. Similarly, evaluating the effects of different intervals of screening (eg, annually) and ideal healthcare settings (eg, primary care, urgent care) can clarify the downstream effects of screening for pregnancy intent.
- Addressing the knowledge gap of endocrinologists and primary care clinicians regarding safe and effective contraceptive prescribing.

Contraception

Background

In women with diabetes, unplanned pregnancies or pregnancies occurring during periods of suboptimal maternal health can result in adverse outcomes for both the mother and fetus[5,20]. Contraception is key in preventing such situations, but there are a number of issues with contraception in this population, including a lower prevalence of use than that observed in the general population[49], factors potentially affecting contraception effectiveness such as obesity[50,51] and treatments for diabetes or obesity such as glucagon-like peptide-1 receptor agonists (GLP-1RAs) or malabsorptive bariatric surgery[51,52]. Also, both GLP-1RAs and bariatric surgery can increase fertility through weight loss[53]. Additionally, there are safety concerns specific to this population which likely contribute to health care practitioners' feeling of unease in prescribing contraception and which, in turn, may help explain the low use of

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contraception among women with diabetes[54]. The Guideline Development Panel (GDP) judged the problem to be a priority.

Question 2. *Should contraception vs no contraception be used in individuals with diabetes mellitus who have the possibility of becoming pregnant?*

Recommendation 2

In individuals with diabetes mellitus who have the possibility of becoming pregnant, we suggest use of contraception when pregnancy is not desired (2 | ⊕⊕OO).

Technical remarks

- Clinician counseling about contraception should be noncoercive and patient centered. Shared decision making should prioritize an individual's autonomy and be informed by the clinician's expertise.

Summary of Evidence

The meta-analysis results, a detailed summary of the evidence, and Evidence to Decision (EtD) tables can be found online at: https://guidelines.gradepro.org/profile/OmX-7fy37oQ.

Benefits and Harms

The systematic review did not identify any randomized controlled trials (RCTs) evaluating the effect of contraception use (all contraceptive methods) by individuals with diabetes who could become pregnant on:

- Preconception care (PCC)
- Unplanned pregnancies
- Glycated hemoglobin (HbA1c) at the time of the first prenatal visit
- Congenital malformations
- Miscarriages or terminations

The GDP put weight on indirect evidence in the general population, which suggested large effects of contraception in reducing unplanned pregnancies and terminations. Additionally, in women with diabetes, indirect evidence highlighted the role of PCC including contraception in improving first-trimester HbA1c and preventing congenital malformations. This judgment was supported by the plausibility of the associations, despite the bias inherent to observational studies, which constitute the vast majority of those addressing PCC in women with diabetes.

All contraceptive methods can be expected to reduce the risk of unwanted pregnancies. The CHOICE project involved a prospective cohort of more than 9000 women from the general population and showed how offering effective, no-cost, reversible contraception for 2 to 3 years had an impact on reducing unplanned pregnancies and terminations[55-59]. Using teen pregnancies as a surrogate of unplanned pregnancies, in the period from 2008 to 2013, the mean annual rates of unplanned pregnancies among CHOICE participants were much lower than the corresponding national rates given for comparison (34.0 and 158.5 per 1000 teens, respectively)[55,56]. Similarly, the abortion rate in CHOICE participants from 2008 to 2010 was less than half the regional and national rates (4.4 to 7.5 per thousand in CHOICE participants, 13.4 to 17.0 per thousand regional rates, 19.6 per thousand national rates, $P < .001$)[57]. The more frequent choice of long-acting reversible contraception (LARC) methods and its effectiveness were key for these outcomes[58]. This was especially true for adolescents and women younger than age 21 years who had significantly higher discontinuation rates of short-acting reversible contraception (SARC) methods (51%, ages 14-19 years vs 41%, ages 20-45 years)[59] and were twice as likely as older women using the same method to experience an unintended pregnancy (hazard rate 1.9; 95% CI: 1.2-2.8), while this was not the case in LARC users[60]. Similarly, a systematic review and meta-analysis published in 2020 reported that young women were less likely to choose LARC than SARC methods (risk ratio [RR], 0.37; 95% CI: 0.17-0.80), while continuation rates were higher in LARC users (RR, 1.60; 95% CI: 1.21-2.12)[61]. The effectiveness of contraception in reducing unintended pregnancies and terminations has also been shown in a recent RCT with a cluster design conducted in China. The intervention included face-to-face education, videos, and educational pamphlets delivered at 5 points during pregnancy and postpartum, aligned with usual care. Among 1279 participants with a 78% follow-up at 1 year, the intervention reduced unintended pregnancies and terminations to one-third (OR, 0.33; 95% CI: 0.16-0.70 for unintended pregnancies and OR, 0.30; 95% CI: 0.09-0.99 for terminations, respectively)[62].

Contraception is anticipated to facilitate the opportunity of PCC. Hormonal intrauterine devices (IUDs), combined oral contraceptives (COCs), and with limited evidence, progestin-only contraceptives, have minimal impact on glycemic regulation and lipid profile and, by allowing time to optimize diabetes management before pregnancy, contraception is expected to contribute to improved HbA1c levels at the first prenatal consultation[51,63]. A lower rate of congenital malformations and miscarriages due to a reduction in periconceptional hyperglycemia can also be anticipated. Further supporting evidence favoring contraception comes from its use being a component of the PCC intervention as defined in the systematic reviews of Wahabi et al that showed significant improvement in 2 outcomes of interest: HbA1c in the first trimester and congenital malformations, as previously described[5,64,65].

Overall, the GDP deemed the undesirable anticipated effects of contraception in women with diabetes to be trivial in comparison with pregnancy. Several Medical Eligibility Criteria (MEC) for contraceptive use are available, including those from the World Health Organization[66], United Kingdom[67], and United States (US MEC, published in 2024). As the US MEC is the most recent, it has been used as the primary reference for this guideline. The recent US MEC and *U.S. Selected Practice Recommendations for Contraceptive Use, 2024* provide recommendations for women with diabetes based on the duration of the disease and the presence and severity of complications[50,51]. IUDs, progestin-only pills, and implants fall under categories US MEC 1 (no restriction of use) or US MEC 2 (may require closer monitoring). The MEC 2 classification for progestin-only contraceptives in this population is due to an increased risk of thrombosis, although the risk is substantially lower than for COCs. For women with diabetes and complications, depot medroxyprogesterone acetate (DMPA) falls under US MEC 3 (risks may outweigh the benefits), a higher category than for other progestin-only methods due to concerns about DMPA's

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hypoestrogenic effects and reduction of high-density lipoprotein (HDL)-cholesterol levels. For women with chronic kidney disease and hyperkalemia, drospirenone-only pills fall under US MEC 4 due to the anti-mineralocorticoid activity of drospirenone. Finally, COCs fall under US MEC 2 for women without complications; US MEC 3 for women with non-severe complications; and US MEC 4 (unacceptable health risk) for women with established vascular disease, nephropathy, retinopathy; or long duration of the disease, due to the estimated additive risk of thrombosis from both factors[51].

The risk of any thromboembolism, either venous or arterial, in women with type 1 diabetes (T1DM) or type 2 diabetes (T2DM) was assessed in a US report using data from contraception claims[68]. The absolute risk in women with diabetes using hormonal contraception was low, but it was higher than in nonusers and differed by age. Among women younger than age 35 years using estrogen-containing contraceptives, the absolute rate of thrombosis was 10.0 events per 1000 woman-years of use vs 3.4 in nonusers, while in women 35 years and older, the corresponding risks were 11.8 and 7.7. As venous events accounted for one-third of the total events, the risk of venous thromboembolism (VTE) would be 3-fold lower than the risk of VTE in an unintended pregnancy in women with preexisting diabetes mellitus (PDM), estimated to be about 7.3 per 1000 person-years considering both antepartum and postpartum events[69]. The risk of pregnancy-related VTE should be added to the overall risk of severe maternal morbidity in women with PDM[70]. Risk of thrombosis was also increased in users of transdermal patches and in women using progestin-only contraceptives (age <35 years)[68]. In a comment to the article, Braillon noted that the European Union proposes that adverse events occurring at a frequency of 1% to 10% be described as "common," rates that were met in some of the subgroups[71].

Regarding obesity, the aforementioned US MEC do not identify obesity itself as a contraindication for any contraceptive method[51], while it should be recognized that obesity alone is a leading cause of adverse pregnancy outcomes according to the American College of Obstetricians and Gynecologists (ACOG)[72]. Considerations include reports linking injectable DMPA with weight gain in adolescent girls with obesity[73,74]. Weight gain at 36 months can be particularly notable in those adolescent girls who experience early weight gain (defined as >5% baseline weight gain within 6 months of DMPA use) compared with those who do not (11.08 vs 2.49 kg)[74]. The use of COCs is an independent risk factor for VTE, with additive effects with high body mass index (BMI). The relative risk for COC users with obesity has consistently been estimated to be 5 to 8 times that of nonusers with obesity, with limited information for women with BMI above 35 kg/m^2. However, none of the individual risk factors for VTE in COC users, including high BMI, increases the risk more than pregnancy[75]: the absolute VTE risk in healthy women of reproductive age is described as small[51] but the crude risk for VTE according to BMI and COC use is not usually given in the literature because studies either use a case-control design or report relative values[76]. In a retrospective cohort study including 64 165 women ages 16 to 40 years after knee arthroscopy, the rate of VTE was 0.95% in women without obesity or contraceptive use, 1.62% in those with obesity, 1.72% in those with COC use, and 3.13% in those with both obesity and COC use[77]. However, these risks can be considered an overestimation due to the higher risk of VTE associated with surgical intervention. In comparison, the risk of first pregnancy-associated VTE including both the antepartum and postpartum periods was 3.1 per 1000 person-years in women of healthy weight and 10.4 per 1000 person-years in women with obesity, respectively[69]. These risks of VTE should be added to the increased risk of severe maternal morbidity associated with obesity in pregnancy[78]. As to contraceptive patch or ring use, comparative studies on the risk for VTE by weight or BMI were not identified[51]. The few studies that have addressed acute myocardial infarction or stroke among women with obesity who use COCs have not identified an increased risk[51].

Additional considerations may apply if other risk factors such as hypertension coexist[50,51]. Specifically, if multiple risk factors exist, risk for cardiovascular disease might increase substantially[51].

In the absence of direct evidence, but considering a large effect of contraception use on preventing unplanned pregnancies, the GDP assessed the certainty of evidence about the overall effects of using contraception vs no contraception in women with diabetes who could become pregnant to be low.

Other Evidence to Decision Criteria and Considerations

The GDP concluded that women consistently considered the selected outcomes of high value, without major variability. Women with diabetes express concerns about potential malformations and overall health of their infants[79,80] and, although they do not specifically refer to HbA1c, they are also concerned about their blood glucose and describe miscarriage as a devastating experience[81]. As to PCC, women with diabetes have acknowledged its importance and potential benefits in various studies[48,82]. In the general population, information on women's perceptions on unintended pregnancies is scarce, but they are described as negative in reports from different countries[83,84]. Similarly, feelings about terminations are frequently described as intense and negative[85].

Based on data from the general population, the GDP considered that moderate costs would be required for implementation, with moderate certainty of the evidence. Costs would include expenses related to contraceptive methods, health care clinician training, and initiatives to raise awareness among women[54]. Methods to achieve contraception are usually not expensive[86]; nevertheless, cost remains as a key barrier to access, influencing both the methods chosen and user adherence[87]. Thus, in a retrospective cohort study involving 39 142 women with a new prescription for contraceptive pill, patch, or ring, 75% of participants were nonadherent during the study period, with higher rates of non-adherence in those women who had copayment[88]. This is in contrast with the CHOICE project that provided contraception at no cost, and in which 75% of participants opted for LARC methods and displayed notably higher rates of adherence (77% for users of LARC vs 41% for users of non-LARC methods)[89]. Thus, the ideal scenario would involve offering a range of contraceptive methods, including LARC methods, at no cost to women with diabetes.

Although no studies were identified that evaluated the cost-effectiveness of contraception in this population, the GDP concluded that cost-effectiveness probably favors the intervention. For this judgment, the GDP first considered evidence from women with diabetes, in which PCC interventions that include contraception as a component have been reported to be highly cost-beneficial[32]. Second, the GDP

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weighed that different contraception strategies have proven to be cost-effective in preventing unintended pregnancies and abortions in women without diabetes across different scenarios[31,57,90]. The high costs associated with preterm deliveries, birth defects, and perinatal deaths in women with PDM have already been mentioned[34]; the preconception intervention to prevent them requires effective contraception when glucose regulation and other factors are not adequate for pregnancy.

No studies have directly evaluated the effects of contraception use on equity among women with diabetes. It has been reported that social determinants of health such as household income, education attainment, and access to counseling are among the factors that positively influence family planning behavior[49,91] If improved contraception uptake would favor highly resourced individuals, it could increase inequity, with those with fewer resources falling further behind. However, available data suggest that this may not be the case. In a study examining National Composite Index for Family Planning surveys in low- and middle-income countries, Ross et al observed that improving access for all to affordable contraception improved equity across wealth groups[91]. Similarly, after elimination of cost sharing for contraception in US women, the lowest-income group had the greatest reduction in births due to unintended pregnancies[92]. In addition, the availability of a low-cost over-the-counter (OTC) birth control pill may promote equity in contraception access[93] by favoring disadvantaged groups[94]. Thus, OTC COC availability improves access for racial and ethnic minorities[95] as well as for adolescents[96], segments that have reported barriers to contraception access and high rates of nonuse. Overall, the GDP assessed that the impact on health equity of routine use of contraception in women with diabetes could vary depending on the local context. Local policies that limit access to termination of pregnancy may increase the acceptability of contraception.

The acceptability of the proposed intervention to key stakeholders was assessed as potentially variable. A systematic review addressing contraception in the general population across different scenarios concluded that contraceptive values and preferences are dynamic throughout a woman's lifespan and that these values and preferences are key elements women consider, alongside perceived benefits and side effects[97]. Potential factors influencing contraception use include religious beliefs, opinions of significant others and other family members, and desired family size[49,54]. In an integrative review of 19 qualitative studies, women favored methods with natural preservation of menstruation and used negative language concerning daily hormonal and LARC methods. Regarding IUDs, there were issues regarding autonomy and power due to the need of a health care provider's involvement for insertion and removal. Power dynamics with partners also influenced contraception use and method. Similarly, women perceived an unequal power relationship with their health care providers, feeling that clinicians often tried to convince them to choose a preferred method. The study concluded that women's desire for contraceptive control and agency may be more important than the perceived effectiveness described by the health care provider[98]. Among adolescents and young women, privacy, autonomy, and safety of the contraceptive method were identified as the key issues in a systematic review including 9693 subjects from the general population[99].

The implementation of the intervention was judged as likely feasible but with some challenges. In recent reports, pregnancy planning is described as feasible by some women and as unrealistic by others[100], and it has already been mentioned that clinicians feel unease with contraception prescription in this population[39]. Similarly, a systematic review and meta-analysis of interventions aimed at improving postpartum contraception use in the general population reported limited success[101]. Additionally, there was no difference in repeat pregnancies or induced abortions during the year following childbirth, leading the authors to conclude that more feasible strategies are needed. On the other hand, with local policies such as the US Affordable Care Act's elimination of cost sharing for contraception[92], the availability of OTC COCs[94] and the expanded prescribing by pharmacists will likely improve the feasibility of the intervention in the United States[102,103]. A recent quality initiative to provide PCC for women with T1DM and T2DM observed no difference in contraception prescription despite contraception being discussed more often during the visit. Most (80%) of health care clinicians identified inadequate time during visits as the main reason for not providing this care[40].

Justification for the Recommendation

This recommendation is based on indirect evidence drawn from studies conducted in both the general population and in women with diabetes. In the general population, the availability of free contraception has been shown to effectively prevent unplanned pregnancies and terminations. Among women living with diabetes, observational data has shown that PCC, including contraception as a key component, has a clinically significant association with first-trimester HbA1c and with the rate of congenital malformations. A causal relation is accepted, supported by the plausibility of the observed associations.

To support the conditional recommendation, the GDP placed high importance on women's perspectives of the acceptability of the use and types of contraception, recognizing that this acceptability is variable, influenced by personal beliefs, perspectives of significant others, and dynamic throughout a woman's lifespan.

Comments

Among individuals with diabetes who could become pregnant, there are 3 important subgroups to consider: (i) adolescent girls/young women; (ii) women with T2DM, as previously discussed; and (iii) women with diabetes and obesity. Women with diabetes and accompanying obesity require special consideration, due to the high prevalence of the association and the potential impact of obesity on effectiveness and undesirable effects of contraceptive methods.

Universally, clinician counseling about contraception should be noncoercive and patient centered. Shared decision making should prioritize an individual's autonomy and be informed by the clinician's expertise[36,104].

Research Considerations

Among individuals with diabetes who could become pregnant, and considering specific subgroups such as adolescents, women with obesity, women with T2DM, and minorities, the following studies are suggested:

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- Evaluating the provision and uptake of contraception counseling, alongside failure rates and safety aspects to monitor real-world status of this matter
- Generating direct evidence from RCTs evaluating interventions to promote contraception advice, assess associated safety outcomes, and measure its effectiveness on increasing PCC and reducing unplanned pregnancies, congenital malformations, HbA1c at the time of the first prenatal visit, miscarriage, and planned terminations

Glucagon-Like Peptide-1 Receptor Agonists

Background

Rates of preconception use of glucagon-like peptide-1 receptor agonists (GLP-1RAs) in individuals with type 2 diabetes mellitus (T2DM) are increasing, due to their benefits in weight loss, atherosclerotic cardiovascular disease, and chronic kidney disease and their low risk for hypoglycemia, high efficacy, and potential to simplify treatment regimens[4,105]. GLP-1RAs are also being used for weight management before conception and improved fertility in individuals with polycystic ovarian syndrome (PCOS)[106,107].

Manufacturers have cited early pregnancy losses and fetal abnormalities in animal studies when exposed during organogenesis that coincided with marked maternal body weight loss, leading to a recommendation to stop using semaglutide 2 months before pregnancy and a recommendation against routine use of all GLP-1RAs during pregnancy. Before discontinuation, it is also recommended to evaluate the risks and benefits, incorporating the implications of hyperglycemia during pregnancy[108–110]. The risk of fetal exposure on discontinuation likely differs significantly among GLP-1RAs due to differences in structure, pharmacokinetics, and potency. Tirzepatide is a dual GLP-1RA and glucose-dependent insulinotropic polypeptide (GIP) agonist and so it must be evaluated for risk independently from GLP-1RAs.

Discontinuing GLP-1RAs has also been associated with rebound weight gain in nonpregnant adults[111,112] and weight gain is expected with transition to insulin. Excess gestational weight gain (GWG) has been observed in those exposed to GLP-1RAs before pregnancy compared with those who were not[113]. Another concern is the development of hyperglycemia without appropriate glycemic management and risk of teratogenicity if this occurs during the first trimester[114]. The impact of GLP-1RA discontinuation earlier in the preconception period compared with the start of pregnancy has an unknown impact on pregnancy outcomes.

Question 3. *Should discontinuation of glucagon-like peptide-1 receptor agonist before pregnancy vs glucagon-like peptide-1 receptor agonist discontinuation between the start of pregnancy and the end of the first trimester be used in individuals with preexisting type 2 diabetes?*

Recommendation 3

In individuals with type 2 diabetes mellitus (T2DM), we suggest discontinuation of glucagon-like peptide-1 receptor agonist (GLP-1RA) before conception rather than discontinuation between the start of pregnancy and the end of the first trimester (2 | ⊕OOO).

Technical remarks

- Sudden discontinuation of GLP-1RA may cause hyperglycemia and weight gain, which increases the risk for congenital malformations and spontaneous abortion. Timely transition and titration of alternative antihyperglycemic agents after discontinuing GLP-1RAs is necessary to minimize hyperglycemia.
- The timing of discontinuation prior to pregnancy should be individualized based on the likelihood of conception after discontinuing contraception, type of GLP-1RA used, and risks of prolonged time off GLP-1RAs prior to pregnancy.
- Active management of glycemia is required after GLP-1RA discontinuation.

Summary of Evidence

The meta-analysis results, a detailed summary of the evidence, and Evidence to Decision (EtD) tables can be found online at: https://guidelines.gradepro.org/profile/enkL3dLKogQ.

Benefits and Harms

The systematic review did not identify any randomized controlled trial (RCT) evaluating the effects of the timing of GLP-1RA discontinuation on the outcomes of interest for individuals with preexisting T2DM. The Guideline Development Panel (GDP) identified the following as important outcomes related to discontinuing GLP-1RA in early pregnancy:

- Congenital malformations
- Spontaneous abortion
- Large for gestational age (LGA) infants
- Small for gestational age (SGA) infants
- Maternal gestational weight gain

The only comparative study identified[115] provided indirect evidence comparing exposure to GLP-1RA vs insulin alone based on prescription fill history. The study population was limited to those with live births, and a minority had preexisting T2DM. The primary outcome was to compare the risk of congenital anomalies between those who stopped GLP-1RA in early pregnancy to the group with T2DM that received insulin only. There was no difference in the rate of congenital anomalies between groups. The rate of major congenital malformations in infants born to mothers with T2DM was 5.3% and 8.3% in infants exposed to GLP-1RA. Compared to insulin, the adjusted risk ratio for major congenital malformations with GLP-1RA was 0.95 (95% CI: 0.72-1.26). The study was limited by the retrospective nature of the analysis, lack of information regarding glycemia in study participants, unclear data as to whether the GLP-1RA was discontinued before or after organogenesis (5 weeks' gestation), maternal nutrition, GWG, and neonatal outcomes (including weight).

There are no direct data relating to the risk of spontaneous abortion, effect on fetal growth (LGA or SGA), or impact on GWG (either excessive or inadequate). A systematic review of indirect data on GLP-1RA exposure during pregnancy in

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animal offspring found an association with reduced fetal weight and/or growth and delayed ossification and skeletal variants[116], typically associated with marked maternal weight loss. Although GLP-1 receptors are expressed in the human placenta[117], available data show minimal placental transfer of exendin-4 in mouse models, ex vivo human placental experiments of liraglutide, and a case study of human umbilical vein blood after liraglutide use to term[116]. The impact of GLP-1RAs on placental GLP-1 receptor function is unknown. These data resulted in the U.S. Food and Drug Administration (FDA) not approving routine GLP-1RA use during pregnancy.

Another observational cohort study[118] providing indirect evidence evaluated exposure of GLP-1RAs for obesity and T2DM in early pregnancy (27.4% of the study population) and reported no difference in congenital anomalies, spontaneous abortions, or increased numbers of LGA or SGA neonates compared with reference groups with T2DM and obesity without GLP-1RA exposure. There was no information on GWG or glucose in this study.

Other indirect evidence examined the effect of shorter-acting GLP-1RAs in women with infertility in the preconception period[119] and[106]. The GLP-1RA groups generally had either greater or no difference in weight loss and a higher spontaneous pregnancy rate at 12 weeks after stopping GLP-1RAs alone or combined with metformin. There were no significant differences in maternal or neonatal outcomes between groups.

The FDA approval package for the weight loss formulation of liraglutide provided data from the manufacturer's pharmacovigilance database of 109 liraglutide-exposed pregnancies reporting an incidence of 29.4% spontaneous abortions and 8.3% incidence of congenital abnormalities, and 6 of the 9 cases could not rule out liraglutide exposure as a cause. The data from the manufacturer are difficult to interpret without background information, such as whether any of the individuals had preexisting diabetes mellitus (PDM), and, if so, what their degree of glycemia was; what the rates of obesity were in this population, as obesity is a risk factor for congenital anomalies; and whether any of the individuals were taking other medications associated with congenital anomalies.

Seven case reports described exposure during pregnancy to a variety of GLP-1RA. One reported mild bilateral pyelectasis[120]; another reported atrial septal defect[121]. Other case reports[122–126] did not report congenital anomalies. Two case reports described increased GWG when longer-acting GLP-1RAs were stopped in pregnancy[122,125] while others did not report on GWG. Of the case reports that reported fetal weight, 2 showed increased fetal weight[122,123,125], while one did not[122].

In summary, there is no direct evidence comparing the intervention to the control. All the reviewed studies addressing whether GLP-1RAs should be discontinued before pregnancy or between the start of pregnancy and the end of the first trimester in individuals with PDM have limitations. These limitations include various study designs, including individuals with and without preexisting T2DM, use of GLP-1RAs with differences in potency and half-lives, variable discontinuation times in gestation, and concomitant use with other medications, such as metformin. There were differences in baseline socioeconomic and ethnic study groups. The panel believed that the lack of information on level of glycemia when GLP-1RAs were stopped in early gestation was a significant limitation. The limited available evidence supports a likely low risk in humans of congenital anomalies, most likely due to GLP-1RAs being too large to cross the placenta. The indirect effects of GLP-1RAs affecting placental function are not known. The risk of spontaneous abortion does not appear to be increased in the infertility trials[106,119]. The case reports were not consistent on effects of GLP-1RAs on GWG or altered fetal growth. However, the animal and pharmacovigilance data are concerning.

Other Evidence to Decision Criteria and Considerations

The most common fear in individuals using medication during pregnancy is fetal harm[127]; therefore, the main outcomes of LGA and SGA infants, congenital malformations, spontaneous abortion, and GWG were judged to have no important uncertainty or variability in value for individuals.

The medication costs for the early switch to insulin from GLP-1RAs are variable and difficult to determine due to pricing differences in different countries. Additionally, costs will vary depending on the patient's dosing needs, whether both basal and bolus insulin are required, and type of health care coverage. The switch to insulin will require closer follow-up by a health care provider during the transition, closer glucose monitoring, and potentially more frequent injections requiring additional supplies. This transition will occur in both the intervention and comparator, but the higher treatment complexity may occur for a longer duration if GLP-1RAs are stopped before pregnancy rather than the first trimester. However, the risk of longer exposure to GLP-1RAs during pregnancy and the costs of potential adverse pregnancy outcomes need to be considered. No cost-effective studies were identified.

There is no direct evidence evaluating the impact of the intervention on health equity. The potential for higher treatment complexity for a longer duration and the need for more frequent follow-up when converting to insulin to provide adequate glycemic management may be a challenge for those with health disparities in the pre-pregnancy period, whereas they may qualify for additional resources once pregnant. Access to care and additional resources varies; therefore, the GDP judged that the impact of the intervention on health equity varies.

The GDP judged that the acceptability of the intervention varies. Discontinuation of GLP-1RAs before pregnancy is likely acceptable by individuals if evidence shows this would minimize fetal harm[127]. However, there is a lack of supporting data, and some may be hesitant to discontinue GLP-1RAs pre-pregnancy due to rebound effects if they were able to achieve significant weight loss and glycemic targets. Additionally, acceptability and feasibility may be less if more complex regimens are needed to replace GLP-1RAs.

The GDP acknowledged challenges to the feasibility of the intervention given low rates of pregnancy planning and preconception care (PCC) uptake. In addition, GLP-1RAs are associated with improved fertility, which can lead to unplanned pregnancies. Appropriate PCC and provider/patient education can significantly improve the feasibility of the intervention.

Justification for the Recommendation

The GDP did not find any direct evidence comparing GLP-1RA discontinuation between the start of pregnancy

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and the end of the first trimester in individuals with preexisting T2DM. The only comparative study identified[115] was indirect evidence restricted to pregnancies resulting from live births and exposure to GLP-1RAs based on filled prescription history. A minority of the study population had preexisting T2DM and had GLP-1RA exposure, which was discontinued in early pregnancy.

GLP-1 receptors are expressed in the human placenta[117]; therefore, although available data shows minimal placental transfer, the impact of GLP-1RAs on the GLP-1 receptors in the placenta are unknown. The GDP prioritized the uncertainty of the potential harms of the GLP-1RAs but acknowledged the risks of hyperglycemia and weight gain with discontinuation.

Other factors that may impact outcomes of exposure to GLP-1RA during pregnancy are the type of GLP-1RA used, trimester of exposure, maternal phenotype, amount of weight loss achieved prior to conception, and GWG.

The timing of GLP-1RA discontinuation should balance the limited data on risk of exposure to GLP-1RA during pregnancy and the potential for nutrient deficiency and worsened nausea and vomiting in pregnancy against the known risks of hyperglycemia and excessive weight gain which may continue in the first trimester and throughout pregnancy. GLP-1RA use is not recommended during pregnancy; however, many on therapy may be planning for pregnancy. Contraception should be used while on GLP-1RA rather than not using contraception and stopping GLP-1RA once pregnant. The resources required and acceptability to discontinue GLP-1RAs while minimizing hyperglycemia before pregnancy vary depending on maternal characteristics and access to care. Although the GDP acknowledged challenges to stopping GLP-1RAs before pregnancy, it is possible with use of effective contraception during the period when pregnancy is not desired and adequate preconception planning. A major consideration in the GDP's recommendation to stop GLP-1RAs before conception was to afford the time needed to transition the patient to insulin and achieve optimal glycemia before organogenesis rather than risk unknown consequences of GLP-1RA exposure and hyperglycemia in the transitionary period if stopped as soon as pregnancy is suspected. Ideally, stopping GLP-1RAs and using contraception should be a joint decision made by the patient and provider. When stopping GLP-1RA therapy, optimizing glycemia (eg, with insulin) and maintaining a healthy diet are necessary. Although the individual may desire pregnancy soon after stopping GLP-1RAs, achieving and sustaining optimal glycemia and nutrition before conception not only will decrease the risk of congenital anomalies but may help with healthy GWG in pregnancy. Priority should be placed on ensuring effective contraception or adequate preconception planning to effectively stop GLP-1RAs before pregnancy, since their effects in pregnancy are unknown.

Comments

In the absence of direct evidence supporting the safety of continued use during pregnancy, the GDP recommended discontinuing GLP-1RAs before pregnancy. The preconception use of GLP-1RAs in women with obesity to decrease excessive weight before pregnancy, for the reduction of adverse perinatal complications of pregnancy, such as hypertensive disorders of pregnancy and fetal overgrowth, serves important goals. Decreasing weight and improving the metabolic condition of women with obesity is being assessed currently, using the lifestyle interventions of healthy diet and increased physical activity[128].

The manufacturer prescribing recommendations for some GLP-1RAs suggest stopping therapy before conception due to early pregnancy losses and fetal abnormalities in animal studies, when exposed during organogenesis, that coincided with marked maternal body weight loss. Yet, this approach has risk for harm if no proactive attention to glycemic management is in place or discontinuation occurs in the absence of active pregnancy plans. Effective coordination of care in both the preconception period and early pregnancy is needed with discontinuation of GLP-1RAs, and glucose should be immediately and actively monitored.

Although the percentage of unintended pregnancies in the United States declined from 43.3% in 2010 to 41.6% in 2019, approximately 40% remain unintended[129]. Women of childbearing age on GLP-1RAs who are not planning pregnancy, even with a history of infertility, should use effective contraception to minimize unplanned pregnancies. A recent literature review addresses the variable impact of GLP-1RAs on the efficacy of oral contraceptives[52].

Requirements to improve implementation of the recommendation include effective education of clinicians, diligent counseling and surveillance of individuals of childbearing age, and access to PCC.

Research Considerations

The increasing use of GLP-1RAs in T2DM emphasizes the need for further research related to use in the preconception period and exposure during pregnancy, and close postmarketing surveillance and registry data collection for analysis is encouraged. Proposed areas for future research include:

- Evaluating the potential effects of GLP-1RA exposure and discontinuation in pregnancy on fetal development, teratogenicity, spontaneous abortion, fetal growth, maternal glycemic management, maternal GWG, preterm birth, placental drug passage, and lactation (for those who continue GLP-1RAs during pregnancy, consider establishing a registry of pregnancy outcomes)
- Evaluating weight maintenance after stopping GLP-1RAs in the preconception period
- Evaluating glycemic management after stopping GLP-1RAs in the preconception period
- Comparing use of short-acting vs long-acting GLP-1RAs in the preconception period and impact on pregnancy outcomes

Addition of Metformin for Patients on Insulin

Background

Although a number of evidence-based guidelines recommend insulin as the preferred antidiabetic medication in pregnancy[4,130], rates of metformin use in pregnancies complicated by type 2 diabetes mellitus (T2DM) have been steadily increasing[131]. Metformin may improve hepatic insulin resistance, decrease insulin requirements, reduce gestational weight gain (GWG), and decrease the risk of infants born large for gestational age (LGA). Results of systematic reviews in individuals with gestational diabetes mellitus (GDM) comparing metformin to insulin

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have been mixed, with some showing a lower risk of LGA, preeclampsia, neonatal hypoglycemia, and less GWG, while others do not[132,133]. Metformin in GDM also tends to be more acceptable for individuals and clinicians as an alternative to insulin due to its low cost, oral route, ease of administration, and low risk for hypoglycemia. However, individuals with T2DM in pregnancy have more severe insulin deficiency and more severe insulin resistance and typically require insulin to achieve optimal glycemia, so metformin is not a substitute for insulin in T2DM as it can be in GDM[134]. Concerns for metformin use in pregnancy are primarily due to the risk of fetal growth restriction in some individuals and long-term fetal programming potential for childhood obesity, with increased fat mass reported in some childhood cohorts but not others[135–139]. Unlike insulin, metformin has been found to exhibit marked maternal-to-fetal transfer, achieving fetal levels at least as high as maternal levels due to high expression of OCT3 cation transporters in the placenta in the second and third trimesters[140]. Metformin is concentrated in both fetal and placental mitochondria 1000-fold. Metformin has pleiotropic effects, including activating AMP kinase (AMPK) and inhibiting mitochondrial complex 1 respiration, and has antiproliferative and nutrient restriction properties through AMPK and decreased mTOR[134,141,142]. Notably, it crosses the placenta poorly in the first trimester and does not increase the risk of major malformations[134,143]. Pathophysiologic studies providing plausible mechanistic data as to how the properties of metformin might result in fetal effects have been recently published in monkeys who share similarities in placental structure with humans. Metformin given maternally at doses that achieve equivalent levels in humans resulted in decreased fetal weight and skeletal muscle mass and bioaccumulated in the fetal kidney and liver[141]. Considering the increasing prevalence of metformin use during pregnancy, the need for insulin therapy in most people with preexisting T2DM, and the concerns of intrauterine metformin exposure to the fetus, the Guideline Development Panel (GDP) prioritized evaluation of metformin added to insulin compared to insulin alone in preexisting T2DM.

Question 4. *Should insulin vs insulin with the addition of metformin be used in pregnant individuals with preexisting diabetes type 2?*

Recommendation 4

In pregnant individuals with type 2 diabetes mellitus (T2DM) already on insulin, we suggest against routine addition of metformin (2 | ⊕OOO).

Summary of Evidence

The meta-analysis results, a detailed summary of the evidence, and Evidence to Decision (EtD) tables can be found online at: https://guidelines.gradepro.org/profile/PvD5bujp9rM.

Benefits and Harms

The systematic review identified 2 randomized controlled trials (RCTs) addressing the effect of adding metformin to insulin therapy vs continuing insulin only during pregnancies complicated by T2DM[144,145]. The 5 important patient outcomes determined critical for decision making included:

- LGA infants
- Small for gestational age (SGA) infants
- Neonatal intensive care unit (NICU) admission
- Preeclampsia
- Offspring overweight (body mass index [BMI] ≥85th percentile; extracted estimate is for BMI Z score for risk of overweight [≥1 SD using World Health Organization reference] at 0-18 years)

The meta-analysis performed for this guideline included 2 RCTs: Metformin in Women with Type 2 Diabetes in Pregnancy (MiTY) and Metformin Plus Insulin for Preexisting Diabetes of Gestational Diabetes in Early Pregnancy (MOMPOD). It revealed a decreased risk of LGA in the group of insulin plus metformin (risk ratio [RR] 0.74 [0.62-0.89]); the effect for the other 4 short-term outcomes of interest did not reach statistical significance, including SGA (RR 1.43 [0.98-2.10]).

The rate of LGA was decreased in both the MiTY RCT (25 Centers in Canada and 4 in Australia) and the MOMPOD RCT (17 centers in the United States). However, in the MOMPOD RCT, it is unclear whether similar degrees of glycemia were achieved (the major driver of fetal overgrowth) because only 39% of participants had glycated hemoglobin (HbA1c) levels available at term to ascertain if glycemia was similar. Only the MiTY RCT (not the MOMPOD RCT) showed an increase in SGA (13% in the metformin group vs 7% in the placebo group; $r = 1.96$ [1.1-3.64]). Notably, the MOMPOD RCT was stopped at 75% for not yielding a difference in the composite outcome, so it was not powered to evaluate the rate of SGA alone. The primary composite outcomes were not statistically different in either of the RCTs, and the GDP's patient-important outcomes of NICU admissions and preeclampsia/hypertensive disorders in pregnancy were not different. Notably, the enrollment in MOMPOD in the United States included a population that was 80% Black or Hispanic compared to the population in the MiTY RCT, which was predominantly European, Non-European, and Asian with only 2.5% Hispanic and 15% African or Caribbean, which might affect baseline risk for outcomes and interpretation of results. Although not included in the GDP's 5 patient-important outcomes, GWG and insulin requirements were statistically significantly decreased in MiTY but not MOMPOD.

A reduction in the rate of LGA could be a benefit and possibly translate to a decreased risk of obesity in childhood and reduced cesarean deliveries, but there is no evidence that metformin decreased primary cesarean deliveries. Although a decrease in the rate of LGA is a favorable outcome, the effect of metformin on body composition (lean mass vs fat mass) is likely more important, which is unknown in the human offspring in T2DM. If metformin decreases skeletal muscle mass in humans, as was demonstrated in the monkey fetuses exposed to similar levels of metformin in utero as humans would be[141], this could result in a decrease in LGA through a decrease in lean mass, which is associated with the subsequent development of metabolic disease and obesity. An increase in SGA, seen in MiTY but not MOMPOD, would be undesirable given its association with more long-term adverse outcomes, especially if it is a result of reduced lean muscle mass, as in the data from monkeys. Having SGA status, like LGA status, is also a risk factor for childhood obesity,

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especially when the offspring is exposed later in life to an obesogenic postnatal environment[146].

The GDP strongly weighted RCTs, rather than observational trials or retrospective studies. A recently published retrospective study often cited using health care claims data, compared individuals with preexisting T2DM who continued metformin vs those who discontinued metformin during the second trimester[147]. It found no differences in the adjusted relative risk of perinatal outcomes including LGA, preeclampsia, and NICU admissions. Of note, SGA results were divided by cohort due to heterogeneity, and the commercially insured cohort found a higher risk for SGA infants in the metformin group (aRR 1.99; 95% CI: 1.1-3.62), while the publicly insured cohort did not (aRR 0.8; 95% CI: 0.48-1.33). Prescription bias and residual confounders affecting those who continued metformin vs those who did not may account for these inconsistent results[147].

The only follow-up trial of offspring overweight/obesity with maternal T2DM randomized to metformin plus insulin vs insulin alone is the MiTY Kids study, but it was limited to offspring growth at ages 6 to 24 months[148]. It found no difference in the BMI Z score at 24 months but an increase in the growth trajectory of males ages 6 to 24 months. Developmental programming of metabolic disease suggests that males may be more affected than females and that age 2 years is likely not long enough to see differences in offspring weight or body composition that predict future obesity risk[146].

The only RCTs that followed the offspring to evaluate the risk of childhood overweight/obesity at 5 to 10 years were conducted in pregnant women given metformin vs no treatment for GDM or polycystic ovarian syndrome (PCOS), not in pregnancies complicated by T2DM in which the mothers were also taking insulin. An increased tendency to overweight/obesity has been observed in children ages 5 to 10 years whose mothers were treated with metformin in 2 studies: the Metformin in Gestational Diabetes: the Offspring Follow-Up (MiG TOFU) and the Intrauterine Metformin Exposure and Offspring Cardiometabolic Risk factors (PedMet) study in women with PCOS[137,139]. In the MiG TOFU follow-up of the offspring in the MiG RCT[139], the Auckland cohort but not the Adelaide cohort demonstrated increased weight at ages 7 to 9 years. An increase in children overweight at 5 to 10 years was also seen in the PedMet study. No increase in overweight/obesity was demonstrated in a third study that followed two cohorts in Finland whose mothers were randomized to metformin vs insulin for GDM[138]. A recent meta-analysis of the Rowan and Paavilainen RCTs[138,139,149] concluded no difference in offspring weight at 9 years but excluded the PedMet RCT of pregnancies complicated by PCOS[137].

Although indirect in evidence and not established in human studies, a recent small RCT randomizing human dose equivalents of metformin to pregnant Rhesus monkeys (who share many anatomical, physiologic, placental, and genomic similarities to humans) vs control, assessed fetal organs and tissues by sacrificing the fetal monkeys at the equivalent gestation of the human third trimester[141]. The fetal monkeys demonstrated growth restriction primarily in skeletal muscle and exhibited renal dysmorphology[141]. Initiation of metformin in early pregnancy resulted in fetal bioaccumulation, growth restriction, and renal dysmorphology in this primate model. These findings of decreased lean mass in fetal monkeys could, in part, explain the SGA offspring exposed to metformin in utero as well as the increased risk of childhood overweight/obesity seen in some, but not all, follow-up offspring studies. Additionally, in animal models, untoward effects of metformin use during pregnancy were seen beyond early adulthood, underscoring the need for long-term follow-up studies in humans to be certain about potential programming effects[150].

Other Evidence to Decision Criteria and Considerations

The most common fear in individuals using medication during pregnancy is fetal harm[127]; therefore, the main outcomes of LGA and SGA, NICU admissions, preeclampsia, and offspring overweight were judged to have no important uncertainty or variability in value for individuals. Reduced GWG, also valued by individuals, occurred in the MiTY RCT but not in the MOMPOD RCT. Notably, the majority of patients enrolled in each trial were categorized as obese at randomization.

The resources required to add metformin to insulin are low, with modest wholesale prices in the United States and Europe. Most clinicians are comfortable prescribing metformin, and, if metformin could substantially decrease the amount of insulin required, including a decrease in injection frequency, it could decrease resource utilization. In the RCTs included in the systematic review, total insulin dose requirements were decreased in the metformin plus insulin group compared with the insulin alone group in the MiTY trial (1.1 ± 1.0 vs 1.5 ± 1.1 units/kg; $P < .0001$) but were similar in the MOMPOD trial (0.9 ± 0.61 vs 1.11 ± 3.1 units/kg). Based on the data available, the cost savings in the metformin plus insulin vs the insulin alone group were judged to be low by the GDP since metformin alone is rarely adequate to attain glycemic targets in T2DM, and, although it may reduce total insulin dose, it may not reduce the frequency and number of insulin injections. Formal cost-effectiveness studies in a population with T2DM were not found. In addition to the costs of therapy and follow-up in the intervention group, the long-term impact on the potential adverse outcomes in offspring, including epigenetic effects, and the associated costs are unclear[134,141,151].

No studies addressing the impact of the intervention on health equity were identified, but the lower cost and high accessibility of metformin could improve or worsen health equity, depending on the long-term outcomes in the offspring.

The addition of metformin to insulin is likely to be acceptable to most, if the patient does not have gastrointestinal adverse effects, when considering cost and the potential for less GWG. In a systematic review evaluating beliefs about medicines among pregnant women, it was found that women tend to be more reluctant to use medicines during pregnancy, which may limit the acceptability of the addition of metformin to insulin. In the same systematic review, the most common fear of medication use was the "risk of harm to the unborn child"[127]. Therefore, many mothers may have concern over the high concentration of metformin in fetal and placental tissues in the second and third trimesters as well as the unknown long-term metabolic health risk in the offspring.

Justification for the Recommendation

The GDP judged that the benefit of adding metformin to insulin to achieve a decrease in rates of LGA alone did not outweigh the potential harm of increasing the risk of SGA or adverse childhood outcomes related to changes in body composition, supported by indirect evidence. Although the meta-analysis demonstrated a modest decrease in LGA (RR 0.74 [0.62-0.89]), the GDP weighted the consideration of potential

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harm to the offspring more heavily given that it is a major concern for individuals and clinicians[127] and that metformin would not be able to replace insulin use in the vast majority of pregnant individuals with T2DM. These concerns for harm were based on the limited data that the rate of SGA was increased in the MiTY RCT, that metformin has high maternal-to-fetal placental transfer in the second and third trimesters, the indirect data suggesting the potential adverse impact on skeletal muscle and kidney development in a nonhuman primate model, and that some offspring exposed from GDM and PCOS pregnancies appeared to have an increased risk of overweight at ages 5 to 10 years[137,139,141,142,146].

Given these concerns and the absence of long-term offspring data in T2DM pregnancies, the GDP recommends against the routine addition of metformin to insulin treatment in individuals with preexisting T2DM. The small benefit of a decrease in rates of LGA in the meta-analysis did not result in a decrease in primary cesarean deliveries and was not considered to outweigh the potential long-term risks, especially given the lack of reduction in preeclampsia, SGA, or NICU admissions, which were the other major outcomes of interest. In addition, the intervention was judged to have limited impact on patient burden or cost for most individuals, as most individuals with T2DM, unlike GDM, would likely require similar insulin dosing frequency, with possibly some reduction in total insulin dosing, which was not consistent between the 2 RCTs.

Comments

The panel recognizes the potential for cost savings in adding metformin to insulin or in reducing the total insulin dose required or gestational weight gain (seen in the MiTY RCT but not the MOMPOD RCT), especially in resource-constrained settings, in subgroups in which effective basal/bolus therapy with insulin may be difficult to achieve using insulin alone, and those with extreme insulin resistance, at very high risk for LGA and excess GWG. Notably, some subgroups with mild T2DM may respond well to metformin and require little insulin, although most patients with T2DM also require insulin to attain glycemic targets. Additionally, those unwilling to inject multiple doses of insulin or who have psychosocial, financial, access, or other barriers that preclude the safe and effective use of insulin may benefit from metformin. In these individuals, metformin could be considered, especially if cost savings are appreciable and patient preference is strong, to minimize the frequency or dosing required of insulin injections. When discussing metformin with individuals in these subgroups, a comprehensive discussion of potential risks and benefits of metformin is necessary to allow the patient to make an informed decision.

In the MiTY RCT, the group for whom metformin exposure in pregnancy was most likely to result in SGA and should be avoided were pregnant individuals with chronic hypertension and/or nephropathy who are at risk for fetal growth restriction[152]. This group also has one of the highest risks of preeclampsia. Given that metformin was not shown to decrease preeclampsia but was associated with SGA in the MiTY RCT, especially in this subgroup, metformin in individuals with chronic hypertension or nephropathy is likely to pose higher risks than benefits.

The GDP prioritized the question of whether metformin should be added to insulin in patients with preexisting T2DM. However, metformin is commonly used in T2DM outside of pregnancy, so there are multiple clinical situations in which addition or discontinuation of metformin, either preconception or prenatally, might be relevant but that were not directly addressed by our literature review or GDP deliberations.

The large RCTs (MiTY and MOMPOD) did not address the question of continuing metformin in patients with T2DM already on it and adding insulin given that all patients in MiTY and MOMPOD were only on insulin at enrollment. The GDP did identify a RCT with a limited sample size which included patients who had T2DM for <5 years or who had a new diagnosis of T2DM and who were not on insulin. These patients with "mild" T2DM were randomized to metformin vs insulin. The majority (85%) failed metformin alone during pregnancy and insulin had to be added[153]. Therefore, the analysis focused on comparing those randomized to metformin in which insulin was added (n = 90) compared to randomized to insulin alone (n = 100). In this single RCT with a limited sample size, the group who failed metformin in which insulin was added compared to the group on insulin alone demonstrated less insulin requirements but no difference in GWG or LGA between groups. However, there was an increase in SGA in the metformin + insulin group (14.4%) vs insulin alone (2%) group ($P < .01$).

There are substantial safety data for metformin in the first trimester due to poor placental crossing from a lack of cation transporters in the first trimester. Therefore, for those already on metformin, it could be safely stopped at the end of the first trimester after organogenesis is completed to avoid sudden withdrawal and the risk of hyperglycemia-induced malformations.

Research Considerations

The increasing use of metformin warrants further research to define the risks and benefits of adding this therapy to insulin in individuals with preexisting T2DM. Proposed areas for future research include:

- Identifying subgroups that would particularly benefit from the use of metformin (eg, those at lower risk for fetal growth restriction, those who have low insulin requirements, etc.)
- Identifying the subgroups at the highest risk of fetal growth restriction from metformin (eg, those with chronic hypertension, nephropathy, a history of preeclampsia, obstructive sleep apnea [OSA], or evidence of microvascular or macrovascular disease, which increase the risk of placental insufficiency)
- Evaluating the effect of maternal metformin use on newborn subcutaneous and visceral fat and lean mass (eg, by dual-energy x-ray absorptiometry [DXA], air-displacement plethysmography, 3D ultrasound, or magnetic resonance imaging [MRI])
- Designing and executing rigorous long-term follow-up studies of offspring at 5 years to adulthood who were exposed to metformin in utero that include outcomes such as body composition; lean tissue and subcutaneous and visceral fat measures; renal, vascular, and cardiac function; indices of metabolic or mitochondrial dysfunction; and neurocognitive outcomes, considering duration and intensity of exposure
- As noted, metformin is commonly used in patients with T2DM outside of pregnancy. Its addition or discontinuation may be relevant in various clinical scenarios, and the

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potential harms and benefits of different approaches should be evaluated through formal RCTs and systematic literature reviews to inform clinical practice recommendations.

Carbohydrate-Restricted Diet

Background

Carbohydrates are the main macronutrient that determine postprandial hyperglycemia, and the amount as well as the type of carbohydrate in the meal plan influence the glycemic response in individuals with diabetes[154,155].

Systematic reviews and meta-analyses suggest that low-carbohydrate diets may improve glycemia (including time in range [TIR], time below range [TBR], and glycemic variability), reduce weight and insulin dose, and lower the risk of severe hypoglycemia in nonpregnant individuals with type 1 diabetes mellitus (T1DM)[156,157], while short-term benefits on glycemia and adiposity and long-term benefits on dyslipidemia were reported for nonpregnant individuals with type 2 diabetes mellitus (T2DM)[158,159].

In contrast, the Institute of Medicine's (IOM) nutrition guidelines recommend that pregnant women supplement their daily intake for at least a total of 175 grams of carbohydrates to promote fetal growth and brain development[160–162], and some experts suggest an even higher recommended dietary allowance (RDA) of 220 grams to account for the estimated 35 grams of carbohydrate required by the placenta in the third trimester[161].

It should be noted that the IOM RDA is an overestimation of the true requirement, as 97.5% of the population requires less[161], and it ignores the possibility that some glucose may come from gluconeogenesis (with a maximum capacity of 160-180 g during starvation)[161,163,164].

While insufficient calorie and carbohydrate intake leads to moderately increased levels of ketone bodies in nonpregnant and pregnant women without diabetes[165,166], as well as in women with preexisting diabetes mellitus (PDM)[130,160,167], these abnormalities are associated with acidosis only in extreme circumstances[168]. Furthermore, with adequate calorie intake, the amount of carbohydrate intake (in the range of 100-250 g) is unrelated to ketone levels in pregnant women with obesity[169], although calorie and carbohydrate requirements are not constant throughout pregnancy and are likely to reach the highest level in the last trimester of pregnancy, with fetal and placental energy demands[170]. However, a weak correlation ($r = 0.2$-0.3) between increased levels of maternal ketone bodies and the offspring's mental development at age 2 years have been described[154,171] and extreme carbohydrate restriction (<95 g/day) during pregnancy is associated with a 20% to 100% increased risk of neural tube defects (NTDs)[172–174].

Dieting has become more prevalent in the United States in the last 2 decades. Altogether, approximately 40% of the adult population is performing some weight loss effort (mostly dieting) according to National Health and Nutrition Examination Survey (NHANES) data, including 39% of women who are nonobese and 33% of women with obesity who restrict their carbohydrate intake[175].

According to a narrative review and observational data, pregnant women with PDM consume 200 to 250 grams of carbohydrate daily (~50 g more than controls), indicating that up to a third of women could consume less than the recommended 175 grams[155,176–179]. A Scandinavian study reported even lower intakes during pregnancy (159 g in T1DM and 167 g in T2DM), which translates to 40% to 50% of individuals with less carbohydrate intake than the IOM recommendation[180].

The increasing proportion of nonpregnant and pregnant women following carbohydrate-reduced diets and the theoretical considerations of the associated potential harms make it essential to clarify adequate carbohydrate intake in women with PDM. Thus, the Guideline Development Panel (GDP) judged this question to be a priority because medical nutrition therapy is one of the cornerstones of effective diabetes management.

Question 5. *Should a carbohydrate-restricted (<175 g per day) diet vs usual diet (>175 g per day) during pregnancy be used in individuals with preexisting diabetes mellitus?*

Recommendation 5

In individuals with preexisting diabetes mellitus (PDM), we suggest either a carbohydrate-restricted diet (<175 g per day) or usual diet (>175 g per day) during pregnancy (2 | ⊕OOO).

Technical remarks

- There is no clear evidence on the optimal amount of carbohydrate intake during pregnancy; however, lower and higher extremes are harmful based on indirect evidence.

Summary of Evidence

The meta-analysis results, a detailed summary of the evidence, and Evidence to Decision (EtD) tables can be found online at: https://guidelines.gradepro.org/profile/KJbcH53XFDI.

Benefits and Harms

The systematic review did not identify any randomized controlled trials (RCTs) evaluating the effect of carbohydrate-restricted (<175 g/day) vs usual (>175 g/day) diets during pregnancy in individuals with PDM on the risk of the selected outcomes:

- Large for gestational age (LGA) infants
- Small for gestational age (SGA) infants
- Neonatal hypoglycemia
- Developmental delay up to age 18 years
- Offspring overweight (body mass index [BMI] ≥85th percentile) up to age 18 years

The only indirect evidence on PDM came from a secondary analysis of the DAPIT RCT and suggested that a carbohydrate intake above 191 g/day was associated with doubling the risk of hyperglycemia (glycated hemoglobin [HbA1c] ≥ 6.5%) after adjustment for maternal age, diabetes duration, and BMI among women with T1DM[155].

Most evidence on carbohydrate-reduced diets derives from studies performed among women with gestational diabetes (GDM) or obesity. The RECORD trial randomized women with obesity and less than 20 weeks' gestation to either a

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low-carbohydrate diet (130-150 g/day) or usual care. While no significant difference in SGA and LGA and neonatal hypoglycemia were found, the study was not powered for these outcomes. Potentially favorable effects were found on glycemia, gestational weight gain, and blood pressure, although the carbohydrate intake of the intervention arm remained far above the intended amount at about 190 g/day (95% CI: 163-216 g/day)[181]. Similarly, RCTs that compared modestly lower carbohydrate intake to usual care in GDM reported no difference in the outcomes (rate of LGA, SGA, neonatal hypoglycemia as well as birthweight, newborn fat mass and fat-free mass, maternal hypertension, cesarean delivery, percent fat mass, fat-free mass, and maternal ketone levels), suggesting no harmful effects, at least during pregnancy and delivery. The achieved carbohydrate intakes were higher than aimed for, but the mean intake still remained below or around the 175-gram cutoff (165-177 g)[182,183]. This is further supported by a systematic review and a meta-analysis including 2 studies that found no harmful effect of the low-carbohydrate diet (aiming for 40%-45% vs 55%-60% of energy intake from carbohydrates) on different pregnancy outcomes (LGA and SGA, glycemia, insulin requirement, birthweight, cesarean deliveries, perinatal mortality, and maternal hypertension) in GDM[184,185].

We identified indirect evidence from observational studies that severe carbohydrate restriction during pregnancy (lowest 5th percentile of carbohydrate intake corresponding to <95 g/day) is associated with a 20% to 100% increased risk of NTDs in the general population[172–174]. Furthermore, the popular high-fat, low-carbohydrate diet (<100 g) is nutritionally inadequate and required vitamin and other micronutrient supplementation according to a systematic review[186].

Altogether, indirect evidence coming from studies in women with obesity and GDM provided no evidence of any harmful effect of moderate restriction of carbohydrate intake (>130 g/day) on LGA, SGA, neonatal hypoglycemia, as well as birthweight and perinatal mortality and maternal glycemia, weight gain, hypertension, ketonuria, cesarean delivery, and insulin requirement[181–185].

Given that we found no direct evidence in PDM on our prespecified outcomes, the certainty of evidence is very low. The only indirect evidence in PDM is suggesting better glycemia with meal plans having fewer than 191 g/day of carbohydrates[155]. Given that maternal glycemia is the most important predictor of pregnancy outcomes in PDM, any beneficial effect of carbohydrate restriction on glycemia could be of utmost importance[160,187].

We found indirect evidence of a neutral effect of low-carbohydrate diets on SGA and LGA and neonatal hypoglycemia in GDM but no evidence (not even indirect) on the other selected outcomes[182–185].

Research findings suggest that severe restriction of carbohydrate intake (<100 g/day) during pregnancy is associated with adverse pregnancy outcomes[172–174,184].

Other Evidence to Decision Criteria and Considerations

The GDP judged that there was consistent high value of the selected outcomes to individuals.

According to a small observational study, the cost of the actual diet of pregnant women with diabetes (T1DM, T2DM, and GDM) was like that of a recommended diet based on computer simulation, suggesting that the quality of the diet can be improved without further financial strain on the pregnant women[176]. Therefore, the group judged that the cost of the intervention is negligible. Limited indirect data demonstrated variable acceptability and feasibility[7,181,182,184,186,188].

No formal evaluation of cost-effectiveness was identified.

In general, there is low adherence to dietary guidelines, but adherence is better in women with higher education, older age, and nonsmoking status[188]. Furthermore, obese women highlighted that competing priorities could be a significant barrier to following a low-carbohydrate diet that probably would increase inequities among pregnant women[181]. Thus, equity could be a problem with the proposed intervention, as not all people will have the same ability to implement the recommendation.

According to a randomized trial among obese pregnant women, an intervention aiming at a low carbohydrate intake (130-150 g/day) was well accepted by the mothers. However, some participants found the diet challenging, especially at later stages of pregnancy[181].

None of the articles reviewed investigated the actual feasibility of a low-carbohydrate diet during pregnancy in individuals with PDM. Adherence to low-carbohydrate diets was low in GDM[7]. According to randomized trials among obese pregnant and GDM women, the carbohydrate reduction achieved in the intervention group was limited and remained far below the intended aim (140 vs 190 g of carbohydrate/day) and only ~20% met their target intake that suggests a limited achievability of a diet with limited carbohydrate[181,182]. While participation may be high in dietary education, studies performed among GDM women suggest that adherence to low-carbohydrate diets are generally poor, and targeted intakes are rarely achieved and even the level of adherence varies by different patient characteristics, including socioeconomic status.

Justification for the Recommendation

The GDP did not identify any direct evidence evaluating the effects of a carbohydrate-restricted diet in people with PDM. Indirect evidence in women with PDM suggests some glycemic benefit with carbohydrate intake less than 191 g/day. All other indirect evidence focused on GDM and women with obesity. Additionally, these studies used different definitions of low-carbohydrate diets that either emphasized the proportion of energy from carbohydrates of the total energy intake or used different cutoff values of daily intake. There were mostly neutral findings on LGA and SGA and neonatal hypoglycemia as well as newborn fat mass and fat-free mass. Data on other outcomes (glucose, weight gain, and blood pressure) suggest some benefit of carbohydrate restriction in pregnant women with obesity, while most outcomes (including LGA and SGA) were similar in the intervention and control groups in GDM. In addition, there was some indirect evidence from the general population of an increased risk of NTDs among pregnant women in the lowest fifth percentile of carbohydrate intake (<100 g/day).

The GDP judged this evidence to be too indirect, leading to significant uncertainty regarding the net benefits or harms and limited to support a recommendation in favor of or against a cutoff of 175 g/day carbohydrate intake. The GDP felt that the optimal carbohydrate intake probably reflects a wider range that includes the current cutoff value, but the lower and upper limits are not clearly defined in existing studies. It

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seems clear that both the lower and upper extremes are harmful for both mother and child. Moreover, pregnancy carbohydrate requirements may be impacted by such individualized factors as maternal size, gestational weight gain, pre-pregnancy BMI, type of PDM, presence of coexisting health conditions, dietary patterns and food choices prior to conception, changing nutritional needs as the pregnancy progresses, and other factors.

Comments

Similarly to overall energy requirements, nutritional status (such as the presence or absence of obesity) may impact the total daily carbohydrate requirement of women with PDM[181]. Furthermore, the type of diabetes may require the modification of daily carbohydrate requirement when factoring in differences in insulin resistance and insulin secretion. Social factors (including socioeconomic status, level of education, and health literacy) may affect access to high-quality food sources and available carbohydrate sources[154,188]. These factors could modify both the required amount of carbohydrate as well as the acceptability of the recommended dietary intervention.

While participation may be high in dietary education, studies performed in women with GDM suggest that adherence to low-carbohydrate diets is generally poor, and targeted intake is rarely achieved; even the level of adherence varies by individual characteristics, including socioeconomic status and cultural beliefs[181,182]. Implementation should consider dietary patterns depending on geographical region, social attitudes, and migration status[154]. Additionally, food choices and maternal eating patterns are often influenced by food preferences of the whole family, and high-quality food is often more expensive than processed snack foods and fast food[189].

Research Considerations

Proposed areas for future research include answering the following questions:

- What is the lowest and highest daily amount of carbohydrate and energy intake that can be safely consumed to maintain optimal glycemia and pregnancy outcomes for women with PDM?
- Does the optimal daily amount of carbohydrate and energy intake differ based on the type of diabetes or BMI for women with PDM?
- What is the lowest and highest daily amount of carbohydrate and energy intake that can be safely consumed to optimize long-term outcomes of the offspring of women with PDM?
- What is the impact of the quality of carbohydrates in the meal plan on glucose management in women with PDM?
- What is the required daily intake of carbohydrates in the first, second, and third trimesters for women with PDM?

Continuous Glucose Monitoring vs Self-Monitoring of Blood Glucose in Individuals With Preexisting Type 2 Diabetes Mellitus

Background

The prevalence of type 2 diabetes mellitus (T2DM) is now higher than type 1 diabetes mellitus (T1DM) in many obstetric populations, continues to rise rapidly, and has more than tripled in the last 10 years in some populations[190]. Some adverse pregnancy outcomes, including stillbirths, cesarean deliveries, Infants large for gestational age (LGA), and neonatal intensive care unit (NICU) admissions, are higher in individuals with T2DM than in those with T1DM due to greater prevalence of comorbidities, including obesity, hypertension, renal disease, and obstructive sleep apnea. As a result, improving pregnancy outcomes in T2DM may require optimizing numerous factors in addition to improving the degree of glycemia and may require different targets for glycemia compared with T1DM[20,191–197].

Frequent glucose monitoring is critical in T2DM in pregnancy to appropriately modify treatment regimens with the increasing insulin resistance of pregnancy. Although continuous glucose monitor (CGM) use in T1DM is considered standard of care[4], the current standard in T2DM is self-monitoring of blood glucose (SMBG) (fasting and either 1 or 2 hours postprandial). Ease of use and increasing access to CGM technology means that more individuals with T2DM are interested in using CGM during pregnancy. The American Diabetes Association (ADA) recommends that CGM in pregnancy should be combined with SMBG to achieve optimal pre- and postprandial targets[4,198]. If CGM is not used, the standard of care is to continue SMBG 4 times daily.

Question 6. *Should a continuous glucose monitor vs no continuous glucose monitor (self-monitoring blood glucose as standard of care) be used in pregnant individuals with type 2 diabetes mellitus?*

Recommendation 6

In pregnant individuals with type 2 diabetes mellitus (T2DM), we suggest either continuous glucose monitor (CGM) or self-monitoring of blood glucose (SMBG) (2 | ⊕OOO).

Technical remarks

- Both CGM and SMBG are considered reasonable alternatives for monitoring glucose during pregnancy, however, in individuals with T2DM, there is limited direct evidence of superiority of CGM use. CGM may offer a potential advantage over SMBG in certain subgroups of individuals with preexisting T2DM.
- Ideal glycemic ranges, CGM metrics, and % time in range (TIR) for individuals for T2DM may be different compared to those which have demonstrated to improve clinical outcomes in T1DM.

Summary of Evidence

The meta-analysis results, a detailed summary of the evidence, and Evidence to Decision (EtD) tables can be found online at: https://guidelines.gradepro.org/profile/srCtCPBX3EQ.

Benefits and Harms

The 5 important patient outcomes determined to be critical for decision making included:

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- Large for gestational age (LGA) infants
- Small for gestational age (SGA) infants
- Neonatal hypoglycemia
- Admission to the NICU
- Glucometrics (TIR, time above range [TAR], and time below range [TBR])

The systematic review identified 3 randomized controlled trials (RCTs) in pregnant individuals with T2DM, T1DM, or GDM randomized to management with CGM or without CGM. The fewest number of individuals included had T2DM[199–201]. None of the identified studies enrolled only individuals with T2DM, and 1 of the 3 studies did not analyze individuals with T2DM separately[201]. Moreover, CGM was not used continuously in the trials that analyzed T2DM separately, one using real-time CGM (rtCGM) technology for only limited periods and the other using blinded CGM for only limited periods[200,202]. The current rtCGM technology commonly used on a continual basis was not used in any of the 3 RCTs.

Therefore, direct evidence is limited to 2 RCTs comparing limited CGM use in addition to SMBG vs SMBG that included a small number of individuals with T2DM in pregnancy that could be analyzed separately from individuals with T1DM or insulin-requiring gestational diabetes (GDM): the Copenhagen RCT[202] and the GlucoMOMS RCT[200]. The total number of individuals with T2DM in both studies was n = 109 (56 on CGM and 53 on standard therapy). The Copenhagen RCT included n = 123 individuals with T1DM and only 31 individuals with T2DM (16 with CGM and 15 controls), who were randomized to rtCGM for 6 days at 5 gestational periods during pregnancy. The GlucoMOMS study also included many more T1DM (n = 109) and GDM individuals on insulin (n = 108) than individuals with T2DM (n = 78), who were randomized to wear a CGM for about 6 days every 6 weeks but were blinded to the results. Our meta-analysis combining the T2DM individuals in these trials (n = 109) demonstrated no difference in LGA[15]. These results were consistent with another published meta-analysis. A third RCT randomized 71 pregnant individuals (n = 46 with T1DM, n = 25 with T2DM) to CGM vs standard medical care[201]. However, the 25 individuals with T2DM (10 on CGM and 15 on standard therapy) were not analyzed separately, so pregnancy outcomes could not be determined. When the analysis from the 3 RCTs was not restricted to only T2DM but also included T1DM and GDM, the results were also similar showing no significant difference in the outcomes of interest, LGA, SGA, neonatal hypoglycemia, or NICU admissions.

The certainty of the evidence for using CGM for T2DM in pregnancy was considered very low. Both the Copenhagen and GlucoMOMS trials used intermittent CGM, and it is not clear whether changes in insulin dose were primarily based on SMBG or CGM, but they were likely primarily based on SMBG. Given that results from only 56 individuals with T2DM and 53 controls are available from 2 RCTs for analysis, this small sample size could lead to imprecision when assessing outcomes.

Although the GlucoMOMS RCT did not have adequate sample size to determine the efficacy of CGM, Rademaker published a post hoc analysis to determine if CGM metrics correlated with pregnancy outcomes[203]. A major limitation of the GlucoMOMs trial was that offline glucose profiles were obtained by clinicians retrospectively after each week of blinded CGM, and the individuals could not see the data in real time. None of the measured glycemic metrics improved over trimesters in subjects with T2DM alone, including TIR, mean glucose, and glycated hemoglobin (HbA1c). These findings contrast with those from individuals with T1DM in whom TIR and mean glucose improved.

In the CONCEPTT RCT for T1DM, the benefits for neonatal outcomes were very large, with ORs about 0.50 for LGA (53% vs 69%), NICU stays more than 24 hours (27% vs 43%), and neonatal hypoglycemia (15% vs 28%), although the differences in glycemic measures were modest (~0.2% difference in HbA1c, 68% vs 61% in TIR, and no difference in severe hypoglycemia)[6]. The number needed to treat to improve these outcomes was only 6 to 8 for T1DM. Whether these same benefits or glucometric targets will prove beneficial in pregnant individuals with T2DM requires adequately powered RCTs using current rtCGM technologies[204].

Indirect evidence in an exclusively T2DM population in pregnancy includes a recent retrospective study of 360 individuals[205] who delivered singletons without anomalies at a single academic tertiary care center between 2019 and 2023[205]. The authors reported their findings in 82 (22.7%) of pregnant women with T2DM using rtCGM (Dexcom G6® or Freestyle Libre®) initiated at 21 weeks continuously to delivery compared with 278 women who used SMBG 4 times daily and glucose logs. CGM was associated with an approximately 50% lower odds of the primary composite neonatal morbidity (65.9% CGM vs 77% SMBG; aOR 0.48 95% CI [0.24-0.94]) and preterm birth (13.4% vs 25.2%; aOR 0.48, 95% CI [0.25-0.93]) and nearly a 70% reduction in NICU admissions (33.8% vs 47.6%; aOR 0.36 95% CI [0.16-0.8]). This study using current rtCGM technology included a diverse cohort, and more than half of individuals had government-assisted or no insurance. There were no differences in rates of LGA and SGA, neonatal hypoglycemia, and HbA1c before delivery, but the decrease was greater in the HbA1c from baseline to delivery in the individuals who used CGM. Gestational weight gain was higher in the CGM users. The individuals using CGM were more likely to identify as non-Hispanic Black compared with those using SMBG, and, although their baseline HbA1c levels were higher, they had lower body mass index (BMI) values and rates of hypertension and presented for prenatal care at earlier gestational ages. As a result, selection bias for the individuals who used CGM vs those who did not may have significantly influenced the outcome.

Another retrospective study in Alabama adds to indirect evidence and included 117 individuals, of whom 58% had T1DM and 42% had T2DM[206]. This study demonstrated that 83% of the cohort developed at least one of the composite adverse pregnancy outcomes (neonatal mortality, LGA or SGA infant, NICU admission, hypoglycemia, birth trauma, or hyperbilirubinemia)[206]. Different glucose metrics were related to outcomes: specifically, for each 5% increase in TIR, the odds of neonatal morbidity decreased by 28%; the associations appeared similar in T1DM and T2DM.

In T2DM outside of pregnancy, CGM was superior to SMBG for HbA1c reduction (weighted mean change difference −0.40; 95% CI −0.55 to 0.24)[207]. Data in T2DM outside of pregnancy, especially in individuals using insulin, demonstrate that rtCGM improves HbA1c and TIR (70-180 mg/dL) and may reduce all-cause hospitalizations[208,209], but these improvements have largely occurred without changes in insulin dose or medications. Difficulties in extrapolating data from T2DM outside of pregnancy to pregnancy include that there are different

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TIR targets in T2DM outside of pregnancy (70-180 mg/dL), that the 4 times a day fasting and postprandial SMBG was not the standard-of-care control group, and that the primary outcomes were very different than those in pregnancy (prevention of fetal overgrowth and adverse pregnancy outcomes).

Other Evidence to Decision Factors

We did not identify any studies evaluating patient's values regarding the prioritized outcomes, yet the Guideline Development Panel (GDP) considered the selected outcomes to be highly important to most individuals with T2DM.

We did not identify any study that summarized the required resources and associated costs for implementing CGM in pregnant individuals with T2DM. From a broader perspective, the resources required are likely to be much greater in T2DM compared with T1DM if CGM use were to be expanded, due to the rapidly increasing prevalence of T2DM. Furthermore, the population with T2DM has much less experience with CGM compared with the T1DM population, and this is often also the case for many obstetric (OB) clinicians who care for pregnant individuals with T2DM. Additional costs related to patient and clinician education and training might not be currently available. However, efforts to train OBs in CGM and CGM access are increasing, including nonprescription CGM, so CGM acceptability and use are likely to increase over time[210]. No formal cost-effectiveness analysis was identified.

Overall, the GDP judged that using CGM in individuals with T2DM during pregnancy was feasible and acceptable. A feasibility and acceptability study conducted in Northern Australia in 57 pregnant individuals with T2DM using intermittently scanned CGM (Free Style Libre)[211,212] reported a mean sensor use of about 12 weeks and mean sensor activity of 60%. Forty-one individuals used CGM for 15 weeks with some modest but limited change in the average glucometrics from early to late pregnancy. LGA infants were associated with hyperglycemic metrics early in pregnancy. Each 1% TIR was associated with a 4% to 5% reduction in neonatal complications. Most participants found CGM "worthwhile," and 94% would recommend its use to others. Reasons for discontinuing the sensor included skin irritations (25%), sensors falling off early, and distrust of CGM accuracy.

Justification for the Recommendation

Adequately powered RCTs comparing continual rtCGM with SMBG in pregnant individuals with T2DM that demonstrate improvements in any of the outcomes prioritized by the panel were not identified[200–202,213]. The panel evaluated the indirect evidence supporting 1) improved glucometrics using CGM in T2DM outside of pregnancy[208]; 2) substantial improvements in neonatal outcomes including LGA infants, NICU stays, and neonatal hypoglycemia in individuals using CGM in T1DM[6]; and 3) the potential for decreasing adverse pregnancy outcomes with improved glucometrics in individuals with[203,206,214]. A recent retrospective study using current CGM technology demonstrated an improvement in composite neonatal morbidity, NICU admissions, and preterm birth was also factored in improved glucometrics in individuals with T2DM[205].

The benefits of CGM in T2DM outside of pregnancy cannot be directly extrapolated to T2DM in pregnancy because, in the nonpregnant population, individuals infrequently use 4 times daily SMBG, the TIR target of 180 mg/dL is higher, and the major differences in primary outcomes measured are HbA1c and hospitalizations rather than adverse pregnancy outcomes.

It is also problematic to extrapolate the data from CGM in T1DM in pregnancy to T2DM in pregnancy given the multiple drivers of adverse outcomes and fetal overgrowth associated in T2DM compared with T1DM and a lower risk of maternal hypoglycemia in T2DM. Indirect evidence also suggests that in both T2DM and GDM, higher and tighter TIR and a lower mean glucose may be required to improve pregnancy outcomes[20,195–197,210,215,216].

Retrospective studies supporting use in T2DM were likely to suffer from selection bias, and it was not clear whether the standard of care (4 times daily SMBG) was being consistently used in the control groups.

The GDP considered that both CGM and SMBG could be used during pregnancy to support glucose monitoring and improve glycemia. This recommendation is derived from limited direct evidence evaluating the effect of CGM use in the outcomes of interest and from indirect evidence that supports potential benefits when compared with SMBG. This is an important consideration, as the GDP judged that glucose monitoring and achieving glycemic targets is important for the pregnant patient, but the available evidence of EtD factors does not demonstrate superiority of CGM vs no CGM (SMBG).

Comments

Because T2DM is a heterogenous disorder of variable insulin resistance and insulin deficiency, certain subgroups may benefit from CGM, including those using pumps, those with more severe insulin deficiency, and those with higher risk for maternal hypoglycemia. Certain individuals, especially those using CGM before pregnancy, may prefer CGM over SMBG given ease of use. Others are likely to value it less due to "sensor fatigue" from alarms, site irritation, and sensor failure. Quality of life and glycemia may improve with continuous rtCGM in some subgroups who use the data to change lifestyle and treatment practices based on real-time data and immediate feedback. Individuals and clinicians should collaborate when deciding if CGM or SMBG will best address the needs of each individual.

A glycemic range between 63-140 mg/dL (3.5-7.8 mmol/L) is currently recommended in pregnancy. The CGM metric for time in range (TIR) in pregnancy is >70% in T1DM and not defined but possibly >90% in T2DM[217]. Ideal glycemic range and TIR for pregnancies complicated by all types of diabetes need further study. The recommended TIR by CGM may need to be higher in T2DM than in T1DM, and tighter glycemic targets and a lower mean glucose may need to be achieved earlier in pregnancy in T2DM and in GDM to improve pregnancy outcomes[197,211,215–217]. The risk of hypoglycemia is much lower in T2DM, and other metabolic factors, apart from simply glucose, are likely to contribute to adverse pregnancy outcomes[20,195–197,218].

Research Considerations

Several RCTs evaluating T2DM in pregnancy comparing rtCGM to standard care are currently in progress in the United States and the United Kingdom and will be valuable in addressing this question but have yet to be completed[219,220]. Other suggested studies include the following:

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- Robust RCTs adequately powered for an improvement in pregnancy outcomes are greatly needed to determine if there are benefits of continuous rtCGM in pregnant individuals with T2DM compared with fasting and postprandial SMBG, what CGM metrics are predictive, the degree of improvement in glycemic metrics that are required to decrease neonatal morbidity, when in gestation improved glucose metrics are most important, and the potential of artificial intelligence to facilitate interpretation of these large data sets which can translate into improved clinical outcomes.
- Given the heterogeneity of individuals with T2DM, studies will be needed to determine if specific cohorts of individuals with more severe insulin deficiency or specific metabolic phenotypes, comorbidities, and cultural backgrounds may accept and benefit from CGM compared with others. Individuals with T2DM using insulin pumps attempting to achieve lower glycemia targets may experience more benefit and may need to be evaluated separately.
- Cost-effectiveness and feasibility trials are also a priority given the substantial resources that will be needed for both clinicians and individuals and the lower number of individuals with T2DM who are accustomed to using CGM.

Single Continuous Glucose Monitor Glycemic Target vs Standard-of-Care Pregnancy Fasting and Postprandial Targets

Background

Since the CONCEPTT randomized controlled trial (RCT) demonstrated a reduction in rates of large for gestational age (LGA) infants and neonatal hypoglycemia with the addition of continuous glucose monitoring (CGM) in pregnancies complicated by type 1 diabetes mellitus (T1DM), CGM is increasingly used in pregnancy[6,221]. Currently recommended, long-standing glycemic targets in pregnancy are:

- Fasting glucose 70-95 mg/dL (3.9-5.3 mmol/L)
- 1-hour postprandial glucose 110-140 mg/dL (6.1-7.8 mmol/L)
- 2-hour postprandial glucose 100-120 mg/dL (5.6-6.7 mmol/L)

In 2019, with the advent of CGM, the International Consensus on Time in Range recommended that the time in range (TIR) in pregnancy be defined as 63 to 140 mg/dL (3.5-7.8 mmol/L) using the definition chosen in previous studies in predominantly T1DM in pregnancy, which generally used traditional fasting and postprandial targets for insulin adjustment[217,222,223]. The International Consensus in Time in Range further suggested that the TIR metric for T1DM be more than 70% (63-140 mg/dL [3.5-7.8 mmol/L]) based on data from CONCEPTT. The metric was left undefined for type 2 diabetes mellitus (T2DM) due to lack of data, but > 90% (63-140 mg/dL [3.5-7.8 mmol/L]) is often suggested for T2DM[217].

In practice, the recommended TIR is being used as a target instead of a metric and thereby targeting higher nocturnal and premeal levels of glycemia, despite the American Diabetes Association (ADA) recommendation that CGM metrics should not be used as a substitute for fasting and postprandial glucose targets[4]. The effect of using different targets on pregnancy outcomes is unclear, and this is critical due to evidence that glucose targets are strongly associated with maternal and neonatal outcomes. In fact, the International Consensus on Time in Range noted in their recommendation that "Recent data suggest that even more stringent targets and greater attention to overnight glucose profiles may be required…"[217].

Even mild hyperglycemia in pregnancy is associated with adverse maternal and neonatal outcomes, including LGA and neonatal hypoglycemia[21,187,197,203,223–242]. Therefore, establishing ideal glycemic targets is critical.

Question 7. *Should a single continuous glucose monitor target < 140 mg/dL (7.8 mmol/L) be used vs standard-of-care pregnancy glucose targets of fasting <95 mg/dL (5.3 mmol/L), 1 hour postprandial <140 mg/dL (7.8 mmol/L), and 2-hour postprandial < 120 mg/dL (6.7 mmol/L) in individuals with preexisting diabetes mellitus using continuous glucose monitoring?*

Recommendation 7

In individuals with preexisting diabetes mellitus (PDM) using a continuous glucose monitor (CGM), we suggest against the use of a single 24-hour CGM target < 140 mg/dL (7.8 mmol/L) in place of standard-of-care pregnancy glucose targets of fasting <95 mg/dL (5.3 mmol/L), 1-hour postprandial <140 mg/dL (7.8 mmol/L), and 2-hour postprandial < 120 mg/dL (6.7 mmol/L) (2 | ⊕OOO).

Technical remarks

- When CGM is used in individuals with preexisting diabetes, providers and patients should use fasting and postprandial glucose targets (whether measured by CGM or SMBG) as the basis for insulin adjustment and not a single glucose target of 63-140 mg/dL.
- When using CGM in conjunction with HCL, providers should be aware that not all HCL algorithms can meet these targets.
- This recommendation applies to all types of PDM, including T1DM and T2DM.
- There are limited data on the appropriate lower limit of the target for fasting or postprandial glucose in pregnancy.

Summary of Evidence

The meta-analysis results, a detailed summary of the evidence, and Evidence to Decision (EtD) tables can be found online at: https://guidelines.gradepro.org/profile/ZkTiAkkxaZg.

Benefits and Harms

No RCTs were identified that compared the effects of using a 24-hour CGM target of 63 to 140 mg/dL (3.5-7.8 mmol/L) to using traditional pregnancy glucose targets (fasting 70-95 mg/dL [3.9-5.3 mmol/L]), 1-hour postprandial 110-140 mg/dL [6.1-7.8 mmol/L], 2-hour postprandial 100-120 mg/dL

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[5.6-6.7 mmol/L]) in individuals with PDM on the outcomes of interest:

- LGA
- Small for gestational age (SGA) infants
- Neonatal hypoglycemia
- Glucometrics (including TIR, time below range [TBR], and time above range [TAR])
- Glycemic emergencies

Indirect evidence supports using a 24-hour CGM TIR target of 63 to 140 mg/dL (3.5-7.8 mmol/L) in individuals with PDM by demonstrating association with maternal and neonatal outcomes (including LGA infants and neonatal hypoglycemia)[2,6,206,223,243–245]. However, other CGM metrics and measures of glycemia are also associated with these outcomes.

The 2017 CONCEPTT trial was a multicenter RCT including 215 pregnancies complicated by T1DM with suboptimal glycemia for pregnancy (glycated hemoglobin [HbA1c], 6.5%-10.0%) comparing standard of care to standard of care plus the addition of CGM[6]. CONCEPTT demonstrated that CGM use resulted in improved neonatal outcomes with reductions in LGA (53% vs 69%; $P = .0210$) and rates of neonatal hypoglycemia (15% vs 28%; $P = .0250$)[6,246]. There were no differences in SGA or rates of maternal hypoglycemia[6]. CONCEPTT provided no comparison of CGM TIR to traditional targets.

Meek concluded that TIR, TAR, and HbA1c were the most predictive of outcomes, including LGA and rates of neonatal hypoglycemia, although predictive ability varied by trimester[247]. Overnight and fasting glucose levels were not explored.

A 2023 retrospective cohort study of CGM use in 102 pregnancies complicated by T1DM explored the use of unique CGM parameters[244]. For LGA, second and third trimester HbA1c, mean glucose, TAR, and TIR were all predictors, with TAR in the third trimester being the strongest. Overnight and fasting glucose levels were not explored. The study provided no comparison of CGM TIR to traditional glucose targets, but, similar to the secondary analyses of CONCEPTT, it showed variation in the strength of association of various CGM metrics with selected outcomes across the timeline of pregnancy.

A 2024 retrospective cohort analysis of 117 individuals using CGM during pregnancy complicated by preexisting T1DM and T2DM found that TIR was again associated with LGA and neonatal hypoglycemia but not SGA[206]. Each 5-percentage point increase in TIR reduced odds of the neonatal composite outcome (LGA, SGA, neonatal intensive care unit [NICU] admission, neonatal hypoglycemia, birth trauma, and hyperbilirubinemia) by 28% (odds ratio [OR], 0.72; 95% CI: 0.58-0.89)[206]. No CGM metrics were predictive of SGA. Maternal glycemic emergencies were not reported. Overnight and fasting glucose levels were not explored. This study provided no comparison of CGM TIR to traditional glucose targets.

Evidence supporting using a traditional fasting glucose target lower than 95 mg/dL (<3.5 mmol/L) is indirect. A 2016 Cochrane review of 3 small RCTs comparing glycemic targets in pregnancies complicated with PDM concluded, despite low-quality evidence, that fasting glucose higher than 126 mg/dL (>7 mmol/L) compared to lower than 114 mg/dL (<6.38 mmol/L) increased risk of macrosomia, preeclampsia, and cesarean delivery[248]. This suggests against the current upper limit TIR recommended in pregnancy.

Several studies demonstrate an association between LGA infants and overnight glycemia[233,243]. These include a 2019 prospective observational study of 162 pregnancies complicated by gestational diabetes (GDM), which found that pregnancies with LGA had higher overnight glucose compared with those without (108.0 ± 18 mg/dL vs 99 ± 14.4 mg/dL [6.0 ± 1.0 mmol/L vs 5.5 ± 0.8 mmol/L]; $P = .005$)[233]. Also included is another analysis of the CONCEPTT data that showed that LGA was associated with mean glucose and mean glucose overnight in the second trimester, mean glucose and mean glucose overnight in the third trimester, and TIR and TAR in each trimester[2].

Finally, in a 2022 functional data analysis of more than 10.5 million CGM glucose measures in 386 pregnancies complicated by T1DM, the relationship between CGM metrics and LGA infants by time of day throughout gestation was studied[243]. This work highlights the importance of mean glucose, as it demonstrated a difference of 9 mg/dL (0.5 mmol/L) in mean glucose across the 24-hour day throughout pregnancy in pregnancies that resulted in LGA.

In a 2024 retrospective cohort analysis of CGM use in 177 pregnancies complicated by preexisting T1DM and T2DM, principal component analysis and k-means clustering was used to identify distinct 4 patterns of glycemia[210]:

- Well-controlled (mean glucose = 123 mg/dL [6.83 mmol/L])
- Suboptimal control with high variability (mean glucose = 154 mg/dL [8.6 mmol/L])
- Suboptimal control with minimal circadian variability (mean glucose = 148 mg/dL [8.3 mmol/L])
- Poorly controlled with peak overnight hyperglycemia (mean glucose = 166 mg/dL [9.2 mmol/L])

When compared with the well-controlled group, the group with high variability had higher rates of LGA infants (OR 3.34 [1.15-9.89]); the group with minimal circadian variability had higher rates of preterm birth (OR 2.59 [1.10-6.24]), cesarean delivery (OR 2.76 [1.09-7.46]), and NICU admission (OR, 4.08 [1.58-11.4]) but not LGA infants, neonatal hypoglycemia, or preeclampsia; and the poorly controlled group with peak overnight hyperglycemia had higher rates of LGA infants (OR 3.72 [1.37-10.4]), neonatal hypoglycemia (OR, 3.53 [1.37-9.71]), preeclampsia (OR, 2.54 [1.02-6.52]), and NICU admission (OR, 3.15 [1.2-9.09]). The study provided no comparison of CGM TIR to traditional targets but found that different patterns of glycemia during the day were associated with different adverse outcomes, calling into question whether a single 24-hour glucose target is ideal.

A 2024 observational study on 112 individuals using CGM intermittently during pregnancy complicated by T1DM explored the contribution of fasting/overnight glucose to TIR[249]. CGM was used for a 7-day period twice in the first trimester, once in the second, and twice in the third. Basal hyperglycemia (BHG) was defined as the area under the curve (AUC) where the glucose was at least 95 mg/dL (5.3 mmol/L) but less than the basal glucose threshold, defined as the average fasting glucose over that 3-day period for that individual subject. If a subject's basal glucose threshold was 95 mg/dL or lower, the BHG was 0. The contribution of BHG to high glucose in groups with TIR (63-140 mg/dL [3.5-7.8 mmol/L])

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lower than 60%, 60% to 78%, and at least 78% was 74.9% (range, 36.8%-100%), 69.2% (13.4%-100%), and 66.5% (10.0%-100%; $P < .001$), respectively, showing that BHG was increasingly a contributor to elevated glucose in those with the lowest TIR. Similarly, HbA1c was divided into 3 groups of less than 6.0%, 6.0% to 8.0%, and at least 8.0%, for which the contribution of BHG to HbA1c was 57.8% (0%-100%), 72.7% (36.8%-100%), and 80.7% (31.4%-100%); $P < .001$), respectively, showing that BHG was likewise increasingly a contributor to hyperglycemia in those with the highest HbA1c. The contribution rate of BHG to adverse outcomes was higher than that of postprandial hyperglycemia for most adverse outcomes, including LGA infants, preterm birth, and preeclampsia, but lower than that of postprandial hyperglycemia for neonatal hypoglycemia.

Use of an Alternative Single Glucose Target

In a 2023 multicenter RCT (AiDAPT study) in 124 pregnancies with T1DM suboptimal glycemia (HbA1c $\geq$ 6.5%) in early pregnancy[250] the standard care of insulin treatment with pump or multiple daily injections (MDI) guided by CGM using the usual targets of fasting glucose 63 to 100 mg/dL (3.5-5.3 mmol/L) and 1-hour postprandial glucose of lower than 140 mg/dL (7.8 mmol/L) was compared to use of an hybrid closed-loop (HCL) pump using an algorithm target of 100 mg/dL (5.5. mmol/L) in early pregnancy and 81 to 90 mg/dL (4.5-5.0 mmol/L) after 16 weeks. The intervention group had higher TIR (68.2% $\pm$ 10.5 vs 55.6% $\pm$ 12.5), lower mean glucose (125 mg/dL $\pm$ 14 mg/dL vs 136 mg/dL $\pm$ 16 mg/dL), lower HbA1c (6.0% $\pm$ 0.5 vs 6.4% $\pm$ 0.5), lower mean glucose overnight (125 mg/dL $\pm$ 14 mg/dL vs 135 mg/dL $\pm$ 17 mg/dL), and fewer mild (−1.7 [−3.0 to −0.5]) and moderate (−0.7 [−1.4 to 0.0]) hypoglycemic events with no difference in serious hypoglycemic events. Pregnancy outcomes were not analyzed statistically since the study had not been powered for this.

AiDAPT compared attainment of pregnancy-specific TIR (63-140 mg/dL) (3.5-7.8 mmol/L) while using HCL technology and adjusting the algorithm target throughout pregnancy with traditional insulin delivery without HCL technology (MDI or pump). So, while it demonstrated the feasibility of tighter targets in PDM when using HCL technology, it did not directly compare the current recommended TIR targets to traditional targets.

Other Evidence to Decision Criteria and Considerations

The Guideline Development Panel (GDP) determined that the 5 selected outcomes were important to most individuals, although no primary study directly assessed patient's values. Additional resources for education and CGM/pump reporting would be needed to change glycemic targets in pregnancy, but the cost would not be large. We identified no cost-effectiveness studies comparing specific targets in pregnancies complicated by PDM. CGM use in pregnancy has already been shown to be cost-effective[251–254], as well as acceptable and feasible[6,255]. Aligning TIR recommendations with existing fasting and postprandial targets is unlikely to significantly impact acceptability or feasibility. Studies of HCL pump technology have demonstrated the feasibility of achieving lower overnight TIR[250].

Justification for the Recommendation

There is no RCT comparing a single 24-hour CGM target of 63 to 140 mg/dL (3.5-7.8 mmol/L) with traditional pregnancy glucose targets (fasting 70-95 mg/dL [3.9-5.3 mmol/L], 1-hour postprandial 110-140 mg/dL [6.1-7.8 mmol/L], and 2-hour postprandial 100-120 mg/dL [5.6-6.7 mmol/L]) in pregnancy complicated by PDM. In the absence of direct evidence, the certainty of the evidence is considered to be very low.

Adopting a single TIR target in the absence of evidence is a concern, as outcomes in individuals who achieve the recommended TIR remain suboptimal[256,257]. The GDP identified indirect evidence that supports using traditional fasting targets to improve rates of LGA[2,206,243,249] and neonatal hypoglycemia[2,206,243]. The GDP placed high value on the evidence supporting the need to achieve overnight/fasting glucose values as required in the traditional targets; therefore, in the absence of comparative studies, the GDP recommended against using a single target of < 140 mg/dL (<7.8 mmol/L).

Ideal glucose targets in PDM are not known. Improving outcomes may require a lower peak postprandial target. There is indirect evidence in a GDM population that a lower postprandial target of less than 120 mg/dL would be beneficial[242], and 120 mg/dL (6.6 mmol/L) is closer to euglycemia[2,210,243,258].

Another possible reason for suboptimal outcomes is that using a single TIR target does not account for the contribution to poor outcomes of fasting/overnight hyperglycemia. There is indirect evidence for this as studies have shown associations between the relationship of fasting/overnight glycemia and adverse maternal and neonatal outcomes[2,210,243,249,258].

There is concern that the predictive value of fasting glucose on negative outcomes, including LGA infants, might be ignored if the focus is on a single 24-hour target. So, given the lack of direct evidence supporting using TIR as the target in PDM in pregnancy, we suggest against the routine use of a single target.

Research Considerations

Ideal fasting and postprandial targets need to be determined for PDM. Suggested studies include the following:

- RCTs comparing currently recommended TIR metrics to traditional fasting and postprandial glucose targets and to lower glycemic targets in PDM are a practical and immediate need. Nocturnal and daytime targets may need differentiation, and targets may need to differ between T1DM and T2DM.
- Additional studies are needed on glycemia by both time of day and by gestational age and their relationships to maternal and neonatal outcomes in both normal pregnancy and PDM.

These are important, as in practice, more and more individuals and providers are focusing on achieving TIR rather than fasting and postprandial targets. It is also a practical and immediate need as advancing pump technology is now reducing the barriers to achieving targets even in the euglycemic range, and there are data suggesting that too-tight control of glycemia in pregnancy can increase the risk of SGA in GDM[259] and of miscarriage in T1DM[260].

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Hybrid Closed-Loop Pump (Pump Adjusting Automatically Based on Continuous Glucose Monitor) vs Insulin Pump With Continuous Glucose Monitor (Without an Algorithm) or Multiple Daily Insulin Injections With Continuous Glucose Monitor

Background

Preexisting diabetes (PDM) in pregnancy presents formidable challenges to maintaining the optimal glycemia necessary to prevent poor maternal and fetal outcomes[250]. Glycemic metrics in pregnancy, including glycated hemoglobin (HbA1c), pre- and postprandial glucose, and time in range (TIR), are strongly associated with pregnancy outcomes[261–264]. The physical and psychological burden of diabetes self-management outside of pregnancy is well-documented. Coupling that burden with the tight glycemic targets and other demands of pregnancy adds additional stress and anxiety during pregnancy.

The use of hybrid closed-loop (HCL) pumps outside of pregnancy has shown improvements in HbA1c, TIR, rates of hypoglycemia, and quality of life[4]. There are few studies regarding the use of HCL pumps in pregnancy, but these limited studies have shown promise for individuals with T1DM[250,261–265]. The use of HCL pumps has been reported to improve both glycemia and quality of life[250,261,263,264]. HCL pumps have the potential to improve outcomes and reduce the unrelenting burden of diabetes self-management in pregnancy. Therefore, the Guideline Development Panel (GDP) prioritized this question.

Question 8. *Should a hybrid closed-loop pump (pump adjusting automatically based on continuous glucose monitor) vs insulin pump with continuous glucose monitor (without an algorithm) or multiple daily insulin injections with continuous glucose monitor be used in individuals with type 1 diabetes mellitus who are pregnant?*

Recommendation 8

In individuals with type 1 diabetes mellitus (T1DM) who are pregnant, we suggest the use of a hybrid closed-loop (HCL) pump (pump adjusting automatically based on continuous glucose monitor [CGM]) rather than an insulin pump with CGM (without an algorithm) or multiple daily insulin injections with CGM (2 | ⊕OOO).

Technical remark

- Not all HCL algorithms are appropriate for use in pregnancy. The individual algorithms used by HCL technology vary in their impact on glucometrics and therefore presumably also on outcomes. The decision on whether or not to use HCL technology and which technology to use should be made by the patient with expert advice from someone adept at the management of diabetes in pregnancy and insulin pump technology.

Summary of Evidence

The meta-analysis results, a detailed summary of the evidence, and Evidence to Decision (EtD) tables can be found online at: https://guidelines.gradepro.org/profile/QL50063lPEA.

Benefits and Harms

The systematic review identified 5 randomized controlled trials (RCTs)[250,261,263–265] and 1 prospective cohort study[262] evaluating the effect of a HCL pump (pump adjusting automatically based on CGM) for individuals with preexisting T1DM who are pregnant when compared to insulin pump with CGM (without an algorithm) or multiple daily insulin injections (MDI) with CGM on the prioritized outcomes:

- Large for gestational age (LGA) infant
- Small for gestational age (SGA) infant
- Neonatal hypoglycemia
- Glucometrics (time in range [TIR], time above range [TAR], time below range [TBR])
- Severe maternal hyper- or hypoglycemia

The results of the meta-analysis showed that TIR, and TBR were non-significantly improved in pregnant women using HCL pumps compared with standard care (TIR: MD, +3.81%; CI: −4.24 to 11.86; and TBR: MD, −0.88%; CI: −2.04 to 0.27). In addition, overnight glucometrics were significantly improved (TIR: MD +10.18%, 95% CI: 7.42 to 12.94; and TBR: −0.67%, 95% CI: −0.91 to −0.43). In terms of TIR, the only RCT displaying a worse outcome with HCL was that of Polsky 2024 that used a 670G system, which is no longer marketed due to the availability of upgraded models[265]. TAR and TIR did not differ when analyzed based on trimester. Finally, no significant differences were found in rates of LGA (risk ratio [RR] 0.95; CI: 0.66 to 1.37), SGA (RR 4.06; CI: 0.46 to 35.60), or neonatal hypoglycemia (RR 1.19; CI: 0.23 to 6.20). The reported studies provided direct evidence of the effects of HCL pump use in women with preexisting T1DM in pregnancy. Limitations of the primary evidence included small sample size (from 10 to 124 women evaluated, and mostly White) leading to imprecision, evaluation of different pump technologies, sensors and algorithms, initiation of the intervention at different time points during pregnancy with different glucose targets and variability in diet composition and carbohydrate intake of participants. These factors should be considered when evaluating study results.

Glucometrics

Stewart et al conducted a randomized crossover study comparing overnight HCL therapy with the control group using sensor-augmented pump therapy (SAPT) in 16 pregnant individuals with T1DM[264], to examine the safety, efficacy, and long-term feasibility of the 2 systems. Pregnant women randomized between 8 and 20 gestational weeks of pregnancy, were aged 18 to 45 years, with a level of HbA1c between 6.5% and 10%. The primary end point was a TIR of 63 to 140 mg/dL (3.5-7.8 mmol/L), and a secondary outcome was an TBR lower than 63 mg/dL (3.5 mmol/L). During the overnight phase, the overnight TIR was 74.7% vs 59.5%, absolute difference 15.2%, (95% CI: 6.1-24.2, $P = .002$) higher for the HCL group, with no statistical difference in time below range (TBR <63 mg/dL/3.5 mmol/L) (1.3

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vs 1.9; mean adjusted difference between groups 0.6, 95% CI −1.7 to 0.6).

During the continuation phase, 14 women used HCL for the entire 24-hour period until the time of delivery, and 12 continued use up to 6 weeks postpartum[266]. During the continuation phase, HCL therapy was associated with comparable levels of glycemia and significantly less nocturnal hypoglycemia than SAPT (1.6% vs 2.7%; mean adjusted difference between groups −1.1, 95% CI −0.2 to −2.1, $P = .06$).

This study went on to evaluate the feasibility and safety of using HCL for glucose management during labor, delivery, and postpartum. Users of HCL during these critical times spent 82% of their time in TIR during labor and delivery with a mean ± SD glucose level of 124 ± 36 mg/dL (6.9 ± 2.1 mmol/L). Individuals in the HCL group maintained this level of glycemia regardless of the delivery method including vaginal, elective cesarean, and emergency cesarean delivery.

In a 2023 multicenter RCT, Lee et al assessed the efficacy of HCL therapy, randomized 124 women with T1DM, 18 to 45 years old, before 14 weeks gestation with HbA1c levels from 6% to 11%, to either standard insulin therapy using MDI with CGM or SAPT vs HCL[250]. The primary outcome was the percentage of TIR time in the pregnancy-specific target glucose range (glucose targets 63-140 mg/dL [3.5-7.8 mmol/L]). Individuals using HCL spent more time in pregnancy-specific TIR during the treatment period (from 47.8% ± 16.4% at baseline to 68.2% ± 10.5% during the treatment period in the closed-loop group and from 44.5% ± 14.4% at baseline to 55.6% ± 12.5% during the treatment period in the standard group [mean adjusted difference between groups 10.5% points, 95% CI 7.0 to 14.0, $P < .001$]), less time in pregnancy-specific TAR (>140 mg/dL/7.8 mmol/L) (from 48.7% ± 18% at baseline to 29.2% ± 10.6% during the treatment period in the closed-loop group and from 51.8% ± 16.2% at baseline to 41.4% ± 13.2% during the treatment period in the standard group [mean adjusted difference between groups −10.2% points, 95% CI −13.8 to −6.6, $P < .001$]), and less pregnancy-specific TBR (< 63 mg/dL/3.5 mmol/L) (from 2.75% at baseline to 2.26% during the treatment period in the closed-loop group and from 2.26% at baseline to 2.02% during the treatment period in the standard group [mean adjusted difference between groups −0.43% points, 95% CI −1.04 to 0.19]) compared to controls.

A multicenter prospective real-world cohort study in Spain compared glucometrics and maternal-fetal outcomes of 112 women with preexisting T1DM using HCL with a median glucose target at 99 mg/dL (5.5 mmol/L) vs MDI with CGM[262]. The mean age of participants was 34.8 years, with HbA1c levels from 6.3% to 7.7%. Both groups had increased TIR (63-140 mg/dL/3.5-7.8 mmol/L) and decreased TAR (>140 mg/dL/7.8 mmol/L) at the second and third trimester with respect to first trimester. The HCL group spent less TBR (<63 mg/dL/3.5 mmol/L) compared to MDI group (HCL 3% vs 2% vs 1% from first to second and third trimester; MDI 4% vs 3% vs 2% from first to second and third trimester, $P < .05$). The HCL group gained more weight and had a higher prevalence of fetal macrosomia.

A European RCT evaluated an HCL system that uses an algorithm that automatically adapts the basal insulin rate and provides automated insulin bolus to correct for hyperglycemia and has a glucose concentration target of 5.5 mmol/L (100 mg/dL) ability to improve glycemic control with less hypoglycemia in 95 women with preexisting type 1 diabetes in pregnancy, aged 18 to 45 years, median start of therapy 10 gestational weeks, and with baseline HbA1c 6.5% in both groups 9%[261]. Of note, even though this was a HCL pump, it did not accommodate pregnancy-specific glucose targets in its algorithm. This study demonstrated a nonsignificant 3.3% overall improvement for mean TIR for women using HCL vs standard therapy (MDI/SAPT), (66.5% ± 10% vs 63.2% ± 12.4%, adjusted mean difference of 1.88, 95% CI −0.82 to 4.68, $P = .17$).

In one RCT, the authors compared HCL therapy to SAPT without specific glucose targets in 23 women with preexisting T1DM to evaluate safety, glucometrics, and health outcomes. Participants were enrolled in the first trimester, randomized at 14 to 18 weeks of gestation, mean age 31 years, mean HbA1c value 6.8%[265]. This study used an HCL pump, with participants randomized to using its activated HCL algorithm or the HCL algorithm. The HCL glucose target was 120 mg/dL (6.7 mmol/L), but lower targets could be used by deactivating the HCL algorithm (SAPT). Time spent below 63 mg/dL/3.5 mmol/L (TBR) decreased in both groups, significantly in the HCL group (3.5% ± 1.3% second trimester and 2.8% ± 1.3% third trimester vs 7.9% ± 1.3% run-in phase, $P < .05$ for both). However, those using SAPT had a 3.9% improvement in TIR (63–140 mg/dL) in the third trimester with respect to run-in phase (68.2% ± 3.1% vs 64.3% ± 3.1, $P < .05$), while this was non-significant in the HCL group (61.9 ± 3.2 vs 62.3 ± 3.2%). There was no difference in adverse safety or pregnancy outcomes between HCL and SAPT. The improved 3rd trimester A1C and average glucose noted in the SAPT group suggests the importance of which glycemic targets are used by HCL systems in pregnancy.

The studies that analyzed the use of HCL in pregnancy have demonstrated safe use of this system, along with some benefits. Women with preexisting T1DM spent either more time in pregnancy-specific TIR[250,264], or less time in TBR[261,263,265] Furthermore, many women with lower TIR in early pregnancy increased their TIR with the use of HCL technology, although using lower pregnancy targets in the AiDAPT study may have contributed to the favorable findings in the HCL technology arm[250]. Finally, pregnant women who had higher TIR in early pregnancy maintained or increased their TIR in later pregnancy and reported a decrease in their overall diabetes burden, worry about the health of their unborn child, along with improved sleep. As a result, the GDP discerned that the evaluated evidence probably favors the intervention.

Harms

The GDP also considered the undesirable effects from the intervention to be to be trivial.

Stewart et al reported 95 device failures, 18 during SAPT, 21 during closed-loop therapy and 56 during run-in and continuation phase, but none resulted in maternal severe hypoglycemia or hyperglycemia[263,264]. Lee et al reported no differences in device-related adverse events in the 2 groups of individuals evaluated[250]. Benhalima et al reported no differences in the device failures in the 2 groups (40 vs 39) with no related adverse events[261]. No adverse events related to device defects were reported by Polsky and Quiros[262,265].

In the RCT study by Lee et al, differences in pregnancy were not evaluated[250].

Quiros et al reported that newborns of HCL users were more likely to have higher birthweight (β-adjusted 279.0 g, 95% CI 39.5-518.5) and macrosomia (adjusted odds ratio

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3.18, 95% CI 1.05-9.67) compared to MDI users. However, these associations disappeared when maternal weight gain or third trimester HbA1c were included in the models[262].

In the RCT by Polksy et al, no differences in pregnancy outcomes of preterm birth, birth weight, neonatal complications, or admission to the neonatal intensive care unit are reported[265].

Other Evidence to Decision Criteria and Considerations

Resources needed for implementation include access to HCL technology and training for clinicians and increased diabetes self-management education and support (DSMES) for individuals. Rankin et al interviewed 19 health care professionals about their views on the training and support needed to roll out HCL technology to pregnant women with T1DM[267]. Interviewees identified challenges and opportunities to this rollout and provided practical suggestions to upskill inexperienced staff who would be supporting individuals using the technology. A key priority will be to determine how best to develop such services.

The GDP also considered the potentially higher cost of more advanced technologies, such as HCL pumps compared with insulin pumps with CGM and MDI with CGM, due to differences in cost and reimbursement of medication and diabetes supplies in different countries. Clinicians and health care systems also require training and available experts to support high-quality implementation of these technologies. From the clinician's perspective, the costs of technical training of device insertion, reading reports, and interpreting data may be cost-prohibitive.

None of the reviewed articles evaluated the costs of implementing HCL pumps or provided sufficient data on the main outcomes to determine cost-effectiveness[4,152,250,261,262,264–266]. CGM alone has been shown to be cost-effective in pregnancies in women with T1DM. Feig et al reports that if the National Health Service (NHS) in the United Kingdom paid for CGM for all women with T1DM during pregnancy, this would save £9.6 million per year, a cost reduction of 40% compared with self-monitoring of blood glucose[222]. The infants of women with T1DM using CGM in pregnancy had shorter neonatal intensive care unit (NICU) stays.

Ozaslan et al evaluated the feasibility of using closed-loop insulin delivery with a zone model predictive control (MPC) algorithm designed to be used by women with PDM in pregnancy[268]. Eleven pregnant women already using SAPT were enrolled in and completed this 2-day study, which demonstrated that a customized closed-loop control system tailored to pregnancy glucose targets is feasible for women previously using SAPT. The panel judged that the feasibility of the intervention will vary. These technologies are not available in all countries, and which technologies are available varies from country to country. Costs may be prohibitive to individuals and health care systems may not have the resources necessary to support their use. The intervention may be feasible if individualized management is performed, taking into consideration factors such as patients' preferences, accessibility, costs and access to careful clinical monitoring.

There was some evidence for acceptability. Wang et al took a qualitative study approach by interviewing 4 Canadian women with preexisting T1DM in pregnancy using a HCL system, who reported a reduction in the burden of diabetes management and improved sleep[269]. Lawton et al also took a qualitative approach to study the lived experiences of 23 women with preexisting T1DM in pregnancy using HCL technology, with the aim of informing health care clinicians on best practices for antenatal rollout and guidance and support for future users. These interviews revealed that HCL users experienced less diabetes self-management burden and worried less about diabetes-related pregnancy complications and being judged negatively by health care clinicians[4,79,270]. Additionally, they reported that having intensive input into their care and the support of health care professionals in early pregnancy contributed to successful adjustment to using HCL technology. Participants emphasized the importance of education in helping them make daily care decisions using HCL technology. These results suggest reducing the burden of diabetes with HCL technology and the need for adequate education to support effective use.

Data are scarce on the impact of the intervention on health equity. Additionally, mostly White women have been included in the studies[222]. Participants in the studies include in our meta-analysis reports were highly educated (many with a bachelor's degree or higher) White women, who were able to maintain contact with their diabetes health care team for frequent insulin adjustments and were able to attend diabetes self-management education. These attributes may not be generalizable to other women with PDM using advanced diabetes technologies.

Justification for the Recommendation

Identified studies show that HCL systems improve overnight time in, below and above range in patients with type 1 diabetes who are pregnant. Although the 24-hour outcomes are not statistically significant, the direction of effect remains consistent and favorable. The only RCT discordant in terms of TIR (Polsky 2024) used a HCL system that is no longer marketed. Finally, two meta-analysis have been recently published with different approaches which included observational studies and have reported potential benefits of HCL therapy[271,272]. No significant differences were found in maternal and neonatal outcomes in pregnant women treated with HCL compared with control groups. There was no identified harm for using HCL technology, in terms of maternal severe hypoglycemia or hyperglycemia, preterm birth, birth weight, neonatal complications, or admission to the NICU. The GDP judged that the intervention was acceptable to patients. This intervention may be feasible if the user can afford the technology, has a desire to use the technology, can maintain contact with their diabetes care team, and can attend diabetes self-management education visits with educators who are knowledgeable and experienced in using diabetes technology.

Comments

Implementation of HCL pump therapy requires expert advice from someone adept in the use of insulin pumps in pregnancy. The individual algorithms used by HCL technology use different glycemic targets and different algorithms and so vary in their impact on glucometrics and presumably pregnancy outcomes. The decision on whether or not to use HCL technology and which technology to use should be made with shared decision making by the patient and the clinician.

The GDP's primary objective was to assess the risks and benefits of HCL in individuals with preexisting T1DM. Yet, women with T2DM have a higher rate of stillbirths and perinatal mortality than women with T1DM, so it is also very important that they have good glycemic management during pregnancy. Further research in this area to better understand the implications of HCL in T2DM is needed.

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Recently, in a 13-week, multicenter trial, adults with insulin-treated T2DM were randomly assigned in a 2:1 ratio to receive insulin delivery with an HCL device or to continue their pretrial insulin delivery method (control group); both groups received CGM. A total of 319 patients underwent randomization. HbA1c levels decreased by 0.9% points (from 8.2% ± 1.4% at baseline to 7.3% ± 0.9% at week 13) in the HCL group and by 0.3% points (from 8.1% ± 1.2% to 7.7% ± 1.1%) in the control group (mean adjusted difference, −0.6% points; 95% CI −0.8 to −0.4; $P < .001$). The mean percentage of TIR (70-180 mg/dL) increased from 48% ± 24% to 64% ± 16% in the HCL group and from 51% ± 21% to 52 % ± 21% in the control group (mean difference, 14% points; 95% CI, 11 to 17; $P < .001$). In T2DM patients, HCL was associated with a greater reduction in HbA1c levels than CGM alone[20].

Finally, in order to achieve optimal use of these new technologies, specific training and support for users and health care providers are important.

Research Considerations

The GDP acknowledges that there are differences between HCL systems during pregnancy especially in terms of adequate glycemic targets, but data are not sufficient to suggest a preferential use of one technology. HCL use during pregnancy must be able to demonstrate a reduction of adverse maternal and fetal outcomes, yet most of the studies performed until now have not been powered for these outcomes. Furthermore, for optimal use of these new technologies, specific training and support for users and health care providers are important to maximize the clinical benefit of these technologies. An evaluation of how to properly implement these technologies in practice is also required.

Proposed future research questions include:

- Should HCL pumps vs MDI plus CGM be used to manage glycemic control in preexisting T2DM in pregnancy?
- For both T1DM and T2DM
  - What glycemic targets should HCL pumps use in pregnancy?
  - Should HCL glycemic targets vary based on time of day or trimester of pregnancy?
  - Which HCL algorithms are best in pregnancy?
  - Should HCL pumps be started before conception or after pregnancy confirmation in those with PDM?

Early Delivery Based on Risk Assessment

Background

Individuals with preexisting diabetes (PDM) are at higher risk for adverse perinatal outcomes; glycemia and comorbidities modify these risks. Some adverse outcomes, including maternal hypertensive disorders of pregnancy, delivery-related morbidity, and stillbirth, may be prevented by delivery before 39 weeks[130]. However, this is associated with an increased likelihood of neonatal intensive care unit (NICU) admission and other neonatal morbidities. Optimal delivery timing balances the known morbidity associated with preterm delivery with the risks for stillbirth and maternal complications in ongoing pregnancy. In women with PDM and ideal glycemia and without maternal hypertension or fetal growth abnormalities, the American College of Obstetricians and Gynecologists (ACOG) recommends delivery at 39 0/7 to 39 6/7 weeks[130,273,274]. In contrast, in the presence of vascular complications, hyperglycemia, or prior stillbirth, ACOG guidelines recommend considering delivery at 36 0/7 to 38 6/7 weeks; the existing guidelines do not comment on other common comorbidities, particularly obesity and other cardiometabolic abnormalities, that are independently associated with perinatal morbidity. The GDP prioritized this question because optimizing timing of delivery will improve outcomes in pregnancies complicated by PDM.

Question 9. *Should early delivery based on risk assessment vs expectant management be used in individuals with preexisting diabetes mellitus?*

Recommendation 9

In individuals with preexisting diabetes mellitus (PDM), we suggest early delivery based on risk assessment rather than expectant management (2 | ⊕OOO).

Technical remarks

- There are no validated obstetric risk assessment tools for individuals with PDM.
- Risk assessment criteria that may be useful to inform ideal delivery timing include the history of diabetes-related complications, measures of glycemia, ultrasound assessment of fetal growth and amniotic fluid volume, and presence of other comorbidities associated with adverse perinatal outcomes.
- Risks may outweigh any benefits of expectant management beyond 38 weeks gestation, even among those with ideal glycemic management.

Summary of Evidence

The meta-analysis results, a detailed summary of the evidence, and Evidence to Decision (EtD) tables can be found online at: https://guidelines.gradepro.org/profile/VGvoz_mXCdA.

Benefits and Harms

The systematic review did not identify any randomized controlled trial (RCT) evaluating the impact of delivery before 39 weeks based on risk assessment for the outcomes of interest:

- Perinatal mortality
- NICU admission
- Birth trauma
- Hypertensive disorders of pregnancy
- Maternal mortality

The Guideline Development Panel (GDP) weighted the indirect evidence demonstrating the risk of perinatal mortality, particularly stillbirth, at term in PDM. Additionally, the GDP gave weight to the indirect evidence in the general population demonstrating the lack of harm and potential benefits of labor induction at term.

The systematic review identified several retrospective cohort studies that compared neonatal and maternal outcomes based on timing of delivery at or beyond 36 weeks' gestation.

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Although many of these studies demonstrated an association of early delivery with adverse outcomes, particularly before 38 weeks, the GDP considered this indirect evidence to be of limited utility. Specifically, the GDP was concerned about the residual confounding inherent in any retrospective study of delivery timing, as, in clinical practice, individuals who deliver early are not the same (likely perceived by clinicians to be at higher risk for morbidity) as those whose pregnancies are managed expectantly. Other study limitations were the inclusion of individuals with GDM in addition to those with PDM and lack of standard reporting of confounders such as measures of glycemia or other measures by which clinical risk assessment could be performed. Finally, most studies reported composite neonatal morbidity and mortality; this complicated our assessment of whether early delivery might be beneficial for the neonate, as delivery decreases risks for some neonatal complications (such as stillbirth, macrosomia, and birth trauma) while increasing others, particularly respiratory morbidity. While there are several RCTs of labor induction at term, we identified only one that included any individuals with diabetes; most (94%) of the participants in that study had GDM, and those with diabetes-related complications were excluded, thus limiting the generalizability of the findings to pregnancies complicated by PDM[275].

Based on indirect evidence, the GDP concluded that there were some neonatal benefits of early delivery (37 0/7 to 38 6/7 weeks) based on risk assessment. Though the magnitude of these effects is unclear, the neonatal benefits of delivery before 39 weeks include prevention of macrosomia, birth trauma, and stillbirth. The incidence of birth trauma is associated with fetal size, which increases with increasing gestational age. In a meta-analysis of studies that excluded individuals with PDM, labor induction for suspected fetal macrosomia was associated with a reduced risk for shoulder dystocia (risk ratio [RR], 0.60; 95% CI: 0.37-0.98) and fracture (RR, 0.20; 95% CI: 0.05-0.79) compared with expectant management. PDM is consistently associated with stillbirth: a 2024 meta-analysis of 37 studies concluded that PDM was associated with a more than 3-fold increased risk for stillbirth (pooled odds ratio [OR] 3.74; 95% CI: 3.17-4.41; $I^2 = 82.5$). The risk for stillbirth is higher among individuals with type 2 diabetes mellitus (T2DM), who are more likely to have cardiometabolic risk factors for stillbirth and to be part of a minoritized community that experiences inequities in pregnancy outcomes and less likely to be cared for by dedicated multidisciplinary pregnancy teams than those with type 1 diabetes mellitus (T1DM)[273,276]. Class 3 obesity may confer additional risk for stillbirth that should be incorporated into decisions regarding delivery timing. In a retrospective analysis of more than 3 million births, while PDM was associated with a more than 9-fold increase in the risk for stillbirth, the adjusted hazard ratio for stillbirth at 37 to 39 weeks was 25.34 (95% CI: 15.58-41.22) in those with both PDM and class 3 obesity[277]. Retrospective studies that stratify outcomes by delivery timing in people with diabetes have not been sufficiently powered to identify a difference in stillbirth and birth trauma by gestational week. Based on data suggesting that the population-level risk for stillbirth increases by week at term, the GDP concluded that early-term delivery based on risk factors would reduce the incidence of stillbirth among people with diabetes.

Based on indirect evidence, the GDP also concluded there were likely maternal benefits of early delivery using risk stratification. These include reduced incidence of hypertensive disorders of pregnancy, cesarean delivery, and severe maternal morbidity. Retrospective studies among individuals with PDM have not found an association between week of delivery and risk for hypertensive disorders or severe maternal morbidity, in part because hypertensive disorders are an indication for delivery. However, as the prevalence of hypertension increases at term, delivery is protective; in a trial of labor induction vs expectant management in low-risk pregnancies at 39 weeks, labor induction was associated with a significant decrease in the risk for hypertensive complications (RR 0.6; 95% CI: 0.6-0.7)[278]. While the overall risk for cesarean delivery is high among people with diabetes, delivery at early term is not associated with significant differences in the risk for cesarean delivery in retrospective data. Early labor induction may even be protective against cesarean delivery; in low-risk individuals at term, induction was associated with decreased risk for cesarean delivery (RR 0.84; 95% CI: 0.76-0.93). Both hypertension and cesarean delivery are independently associated with severe maternal morbidity; however, no studies have demonstrated an association of early delivery with lower risk for severe maternal morbidity.

Based on indirect evidence, the GDP concluded that the harms of early delivery based on risk assessment are variable based on gestational age but trivial after 38 weeks. Potential harms include neonatal morbidity, such as NICU admission, respiratory distress syndrome, hypoglycemia, hyperbilirubinemia, and other diagnoses that could be related to prematurity. The GDP did not identify evidence suggesting maternal harm with early delivery based on risk assessment. Elective early-term (37 to 38 6/7 weeks) delivery is associated with neonatal morbidity in people without diabetes[279]. Among people with diabetes, delivery at 36 and 37 weeks is consistently associated with neonatal morbidity in retrospective studies. The harm of delivery is less clear at 38 weeks, with conflicting data. One large study using administrative data found an association of iatrogenic delivery, defined as pre-labor cesarean delivery or labor induction, with neonatal morbidity at 36 and 37 weeks, but not 38 weeks[280]. Similar results were seen in a single-center study that included 4750 participants with either PDM or gestational diabetes (GDM). A subsequent Canadian population–based study demonstrated a modest association of delivery at 38 weeks with NICU admission (adjusted [a]RR, 1.61; 95% CI: 1.36-1.90) compared with delivery after 39 weeks[281]. Meanwhile, in an analysis of US natality data, planned delivery at 38 to 39 weeks was associated with lower odds of neonatal morbidity than expectant management among people with diabetes (aRR, 0.88; 95% CI: 0.77-0.99). The GDP concluded that, in aggregate, the indirect evidence suggests minimal harm of delivery after 38 weeks[282].

Evidence to Decision Factors

The GDP felt there was little variability in the high value of the selected outcomes to individuals.

There are no cost-effectiveness analyses of risk-based delivery at term for people with PDM; we considered costs associated with labor induction and excess NICU admission to be most relevant; early delivery based on risk assessment might lead to excess NICU admissions, which are a driver of health care costs. The GDP estimated that the resources required for implementation would be moderate, but whether additional resources would be needed to proceed with early delivery is unclear; any resources beyond those required for birth after expectant management would be attributable to prolonged labor and delivery stay. Elective labor induction may be

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associated with additional cost among low-risk, nulliparous individuals at 39 weeks; however, the resources required depend on the baseline risks for hypertensive disorders and cesarean delivery, both of which are more common in people with diabetes[4,283,284]. Shared decision making about delivery timing is part of routine obstetric care; therefore, risk-based delivery before 39 weeks was judged to be feasible and acceptable and unlikely to require additional resources. Although there are no validated risk assessment tools, a standardized approach to delivery in pregnancies complicated by diabetes may improve equitable care delivery and decrease disparities in perinatal outcomes.

Justification for the Recommendation

This recommendation is based on indirect evidence drawn from retrospective cohort studies of individuals with PDM as well as RCTs in individuals with either GDM or normal glucose. In all populations including individuals with diabetes, delivery prior to 39 weeks is associated with neonatal morbidity related to prematurity, primarily respiratory; however expectant management at term is associated with maternal morbidity and other neonatal morbidities, including birth trauma and stillbirth. Observational data suggests glycemia and other comorbidities are important modifiers of the risk for adverse neonatal and maternal outcomes. The GDP placed high value on the outcome of stillbirth to support the conditional recommendation for delivery prior to 39 weeks among individuals assessed to have multiple risk factors for adverse outcomes.

Comments

Based on the available evidence, the panel concluded that in individuals with PDM, early delivery rather than expectant management should be considered. The recommendation is based in part on the lack of any validated obstetric risk assessment tools to address the question. The panel considered expectant management, defined as when intervention is delayed in favor of close monitoring of the mother and fetus with the goal of prolonging pregnancy to achieve an optimal perinatal outcome. The panel fully endorsed the judgment of the health care providers, in conjunction with joint decision making with the patient, to determine the optimal timing of delivery. The decisions are based on diabetes-related complications, obstetrical considerations such as hypertensive disorders of pregnancy and fetal growth and risk of stillbirth. Based on the evidence presented in this summary, the panel considered delivery no later than 38 6/7 weeks, even in those with ideal glycemic control, as a timepoint when maternal and fetal risk of morbidity begin to outweigh the benefits of expectant management.

Research Considerations

We suggest research addressing the following questions:

- What is the role of social determinants of health in addition to medical factors for predicting adverse perinatal outcomes, particularly stillbirth?
- Does the use of a risk assessment tool that incorporates the clinically evident risk factors associated with maternal morbidity and perinatal mortality to determine delivery timing reduce maternal morbidity and perinatal mortality?

Postpartum Endocrine Care

Background

The postpartum period, the time between delivery and 12 weeks postpartum, is a critical time for maternal and neonatal health. The interpartum period is also critical for preparing for the next pregnancy, as postpartum care is often also preconception care (PCC)[285]. Some components of postpartum care include contraceptive and pregnancy planning, care for diabetes and its complications, obesity care, lactation support, management of postpartum hypertension, screening for depression, and management of thyroid disorders[4,28,286–289]. Special attention is needed for diabetes complications, such as nephropathy[290].

Unfortunately, many people with diabetes experience lapses in care in both the immediate postpartum period and even during the first year postpartum[291,292]. Two common reasons for urgent visits and readmission postpartum are hypertension and infection[293]. Women with preexisting diabetes mellitus (PDM) have increased risk of severe maternal morbidity (and mortality) postpartum (adjusted odds ratio [aOR], 1.25 [1.13-1.37])[78]. PDM especially raises the risk for de novo postpartum hypertension (13% vs 3%; $P = < .001$) and persistent postpartum hypertension (21.5% vs 5.6%; $P < .001$)[294]. It is also a known risk factor for postpartum sepsis (OR, 3.46; 95% CI: 3.014-3.83)[295] and wound infection[296]. Therefore, lapses in postpartum care are especially concerning in this high-risk population.

Rates of breastfeeding are much lower in women with PDM for various reasons, including a higher rate of postpartum complications, fear of hypoglycemia, lapses in postpartum diabetes care with resultant variability in maternal glycemia, and lapses in lactation support[297–302]. Additionally, lapses in care resulting in hyperglycemia and decreased uptake of contraception and pregnancy planning could lead to increased risk of congenital malformations and miscarriage in a future pregnancy[4,5].

Management of maternal glycemia postpartum is challenging, as this period is characterized by dramatic changes in insulin requirements, increasing the risk of both hypo- and hyperglycemia. Insulin demand decreases dramatically with delivery of the placenta[4,303], followed by a gradual increase in insulin resistance in the weeks following delivery. Hypoglycemia, especially nocturnal, is recognized as a problem in lactating women, and this is cited as a reason some chose not to breastfeed[297,303,304]. Advances in diabetes technology may help reduce hyper- and hypoglycemia[167]; diabetes care increasingly relies on advanced technology (continuous glucose monitors [CGMs] and hybrid closed-loop [HCL] pumps) as well as a rapidly evolving array of oral and injectable pharmaceuticals. This complexity highlights the importance of expert diabetes care in the postpartum period[4,5]

Question 10. *In postpartum individuals with preexisting diabetes mellitus (including those with pregnancy loss or termination), should postpartum endocrine care (comprehensive diabetes management) in addition to usual obstetric care vs usual obstetric care be used?*

Recommendation 10

In individuals with preexisting diabetes mellitus (PDM) (including those with pregnancy loss or termination),

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we suggest postpartum endocrine care (diabetes management), in addition to usual obstetric care (2 | ⊕OOO).

Technical remarks

- In addition to routine obstetric care, immediate postpartum care for individuals with PDM should prioritize glycemic management to support healing, promote lactation, and facilitate the transition to interpregnancy and long-term diabetes management.
- Ideally, postpartum diabetes care should be delivered by a multidisciplinary team that includes physicians specializing in diabetes and/or endocrinology, as well as nurses, dietitians, and certified diabetes care and education specialists. This team should also support ongoing, long-term established follow-up.
- In many cases, postpartum care also serves as preconception care (PCC) for a future pregnancy. Approximately half of all deliveries occur among individuals who already have at least one child, highlighting the opportunity for postpartum care to contribute meaningfully to PCC. There is strong evidence that preconception care improves several pregnancy outcomes in individuals with PDM.

Summary of Evidence

The meta-analysis results, a detailed summary of the evidence, and Evidence to Decision (EtD) tables can be found online at: https://guidelines.gradepro.org/profile/b0DXzdWOGRA.

Benefits and Harms

The systematic review identified no randomized controlled trial (RCT) comparing postpartum endocrine care (comprehensive diabetes management) plus usual obstetric care vs usual care in individuals with PDM on the prespecified outcomes of interest:

- Maternal severe hyperglycemia or hypoglycemia requiring medical attention
- Glucometrics (time in range [TIR], time above range [TAR], and time below range [TBR])
- Maternal hypoglycemia
- Use of contraception
- Glycated hemoglobin (HbA1c) within the first year postpartum

Indirect evidence from a previously described meta-analysis, demonstrating that PCC reduces HbA1c and congenital malformation, supports this recommendation[5]. This meta-analysis found that PCC (generally delivered by a multidisciplinary team that included endocrinologists and certified diabetes care and education specialists) resulted in not only a lower HbA1c in the first trimester and a reduction in congenital malformations but also a reduction in preterm delivery by 15% (risk ratio [RR] 0.85; 95% CI: 0.73-0.99), perinatal mortality (RR 0.46; 95% CI: 0.30-0.73), and neonatal intensive care unit (NICU) admissions (RR 0.75; 95% CI: 0.67-0.84).

Further indirect evidence to support this recommendation comes from retrospective analysis of the Atlantic-Diabetes in Pregnancy (Atlantic-DIP) program, a multidisciplinary intervention including preconception, pregnancy, and postpartum endocrine care for individuals with diabetes. In a retrospective chart review comparing 217 pregnancies before the initiation of the Atlantic-DIP program with 228 after the intervention was initiated[305], there was a significant reduction in first-trimester HbA1c (7.8% to 7.1%; $P < .001$) following the intervention, increased uptake of PCC (49% vs 23%; $P < .001$), and an important reduction in congenital malformations (5% to 1.8%; $P = .04$). Contraception uptake was not reported. Further indirect evidence supports the need for increased postpartum support in high-risk groups that included PDM. In a RCT comparing a single 6-week with 2-week and 6-week postpartum obstetric visits, the rate of urgent care visits decreased from 30% to 16% ($P = .01$)[293]. Diabetes care was not specified, and diabetes complications were not reported. A retrospective cohort study of individuals at high risk for maternal morbidity (38.6% with diabetes) compared 2590 enrolled in a postpartum program (which included endocrine follow-up for diabetes) with 3229 not enrolled[306]. While measures of glycemia and uptake of contraception were not reported, the adjusted incidence of all-cause hospitalizations within 30 days postpartum was 20% lower among enrollees (incident RR 0.80; 95% CI: 0.67-0.95). These studies suggest that more frequent postpartum care is beneficial in high-risk groups.

Indirect evidence from a RCT demonstrating that HCL technology vs sensor-augmented pump therapy (SAPT) in the postpartum period reduces maternal hypoglycemia supports this recommendation[307]. Participants ($n = 18$) in the closed-loop arm had less TBR (defined as <70 mg/dL/3.9 nmol/L [1.7% vs 5.5%; $P < .001$] and defined as <54 mg/dL/3 nmol/L [0.3 vs 1.1%; $P = .008$]). There were no episodes of severe hyper- or hypoglycemia reported, and no difference in TAR or TIR. HbA1c and contraceptive uptake were not reported. This study was designed to—and successfully did—demonstrate the value of a technological intervention; this would have been less feasible without the support of a team with specific diabetes expertise.

Other Evidence to Decision Criteria and Considerations

Hypoglycemia and fear of hypoglycemia in the postpartum period, at times leading to cessation of breastfeeding, emerged as an overriding concern among individuals in several studies[298,308,309]. Furthermore, studies suggest that individuals with diabetes would prefer more support, including from diabetes specialists, in the postpartum period[293,298,308–312].

There are no publications on the cost or cost-effectiveness of additional endocrine-focused postpartum care. Postpartum care could potentially be cost saving if it reduced rates of readmissions, increased rates of breastfeeding, and reduced rates of congenital malformations in future pregnancies. The cost-effectiveness of PCC is supported by a systematic review[33].

Factors associated with nonattendance of postpartum visits include younger age, Black race, Hispanic ethnicity, Medicaid insurance, mental health disorders, lower socioeconomic

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status, decreased access to prenatal care, adverse pregnancy outcomes, limited resources (eg, lack of access to care, limited childcare), and low health literacy[291,292,313], suggesting significant inequity in postpartum care. Higher rates of follow-up were associated with specialist (including endocrinologist) provider vs primary care[314] suggesting that if postpartum specialist visits were widely available to all individuals, postpartum endocrine care might reduce inequities among individuals with diabetes. Offering 2 postpartum visits (at 2 and 6 weeks) instead of only one at 6 weeks improved overall attendance at one visit for minority individuals in a RCT[293].

Justification for the Recommendation

The GDP based its recommendation on very low certainty indirect evidence suggesting that postpartum endocrine care could result in reductions in maternal hypoglycemia as well as in urgent visits and readmissions in the immediate postpartum period and moderate to high certainty evidence that PCC can reduce HbA1c and congenital malformations in subsequent pregnancies. Additionally, evidence suggests concerns about diabetes management and desire for support from individuals. The GDP judged that the risk of undesirable effects is low. Therefore, the GDP concluded that the balance of effects probably favors the intervention and that the evidence suggested it would be acceptable to individuals. Costs would be moderate, but, based on the indirect evidence of a preconception meta-analysis, it might be cost-effective. Feasibility and equity would vary.

Comments

Individuals who experience a pregnancy loss are even less likely to receive postpartum care, despite being at increased risk for adverse outcomes in the acute period (such as depression) and in future pregnancies. Ditosto et al provides a useful review of implementation strategies (such as virtual reminders, mHealth applications, medical home model, patient navigation, and postpartum transition clinics) for postpartum care in this especially vulnerable population[313].

Implementation Considerations

The feasibility of implementing postpartum endocrine care varies across health care settings and may be particularly difficult in the United States, where there is a shortage of physicians, including both endocrinologists and obstetricians[315,316]. Disadvantaged and minority populations must be considered. Endocrine care should be provided by health care specialists who have expertise in the care of diabetes and pregnancy. Strategies to improve uptake include (but are not limited to) scheduling postpartum care before delivery, flexibility in scheduling, consideration of childcare needs, and use of telehealth. Saldanha et al conducted a systematic review of strategies for the delivery of postpartum care[317] and concluded that providing contraceptive care early in the postpartum period was associated with greater uptake of contraceptive use and that both peer support and support from a lactation consultant increased rates of breastfeeding.

Research Considerations

RCTs comparing usual obstetric care with usual care plus endocrinologic/diabetes-focused care from hospital discharge to 12 months postpartum in individuals with diabetes are needed. Studies of cost-effectiveness, equity, implementation, and feasibility are also required. Specific questions to be answered include:

- Does diabetes-focused care and reduction in maternal hyperglycemia during the immediate postpartum period reduce the risk of postpartum complications and costs, including hypertension, infections, and emergency department/hospital admission rates?
- Does expert glycemic management in the immediate postpartum period reduce episodes of severe maternal hypoglycemia and improve lactation rates and duration?
- In individuals with overweight/obesity, does early obesity intervention in the postpartum period reduce body mass index and cardiovascular risk factors?
- Does the inclusion of diabetes-focused care in the postpartum period increase rates of PCC and contraceptive use, reduce unplanned pregnancies and rates of congenital malformation, and improve HbA1c level at 1 year and glucometrics?
- Does screening and interventions for diabetes distress reduce the risk of postpartum depression?

Summary

Using an evidence-based approach, *Diabetes in Pregnancy: An Endocrine Society Clinical Practice Guideline* addresses important clinical issues in the management of type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM) preconceptionally, during pregnancy, and in the postpartum period.

The prevalence of preexisting diabetes mellitus (PDM) has grown exponentially in the last 2 decades, primarily due to a marked increase in the prevalence of T2DM. PDM carries increased risk for adverse maternal and neonatal outcomes, including preeclampsia, cesarean delivery, preterm delivery, macrosomia, and congenital defects. Preconception care (PCC) is very important to minimize the risk of congenital defects as well as to maintain good glycemia in the preconception phase and during pregnancy. PDM requires pregnancy-specific diabetes care to reduce negative outcomes. In the last few years, technology has progressed to address the unique challenges individuals face in managing diabetes in pregnancy. Continuous glucose monitoring (CGM) and insulin pump technology have shown benefit by simplifying glycemic monitoring and insulin administration. Improvements in glycemia and perinatal outcomes have been reported with CGM use when compared with self-monitoring of blood glucose (SMBG). Hybrid closed-loop (HCL) pump systems combine CGM and insulin pump technologies with increasingly sophisticated algorithms. As technology becomes more integrated into the routine management of diabetes in pregnancy, practitioners need to provide individualized device selection, counseling, education and self-management support to ensure patient autonomy and safety. Optimization of glycemia, correct dietary advice, safe medication regimens, and careful attention to comorbid conditions can help mitigate these risks and ensure quality diabetes care before, during, and after pregnancy.

Research and investment in implementation and delivery of PCC are crucial to prevent significant mortality and

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morbidity now. Randomized controlled trials (RCTs) to further define glycemic targets in pregnancy and refinement of emerging technology to achieve those targets can lead to significant reduction of harm and in the burden of diabetes care. Data on optimal nutrition and obesity management in pregnancy are lacking, so clinical studies in this context are necessary.

Acknowledgments

The Endocrine Society and the Guideline Development Panel (GDP) thank Marie McDonnell, MD, and Roma Gianchandani, MD, who served as Clinical Guidelines Committee chairs during the development of this clinical practice guideline (CPG). The GDP thanks Endocrine Society staff members Maureen Corrigan, MA, Elizabeth York, MPH, Laura Mitchell, and Emma Goldberg, PhD for their expert guidance and assistance with all aspects of guideline development. We also thank the numerous contributors from the Mayo Evidence-Based Practice Center, especially Alaa Al Nofal, MD, MBA, for their contribution in conducting the evidence reviews for the guideline.

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Disclaimer

The Endocrine Society's clinical practice guidelines are developed to be of assistance to endocrinologists by providing guidance and recommendations for particular areas of practice. The guidelines should not be considered as an all-encompassing approach to individual care and not inclusive of all proper approaches or methods, or exclusive of others. The guidelines cannot guarantee any specific outcome or successful treatment, nor do they establish a standard of care. The guidelines are educational tools, not medical advice, and are not intended to dictate the treatment of a particular individual. Treatment decisions must be made based on the independent judgment of health care clinicians and each person's individual circumstances. The Endocrine Society makes every effort to present accurate and reliable information, and this guideline reflects the best available data and understanding of the science of medicine at the time the guideline was prepared. The results of future studies may require revisions to the recommendations in this guideline to reflect new data. This publication is provided "as is" and the Society makes no warranty, express or implied, regarding the accuracy and reliability of these guidelines and specifically excludes any warranties of merchantability and fitness for a particular use or purpose, title, or non-infringement of third-party rights. The Society, its officers, directors, members, employees, and agents (including the members of the Guideline Development Panel) shall not be liable for direct, indirect, special, incidental, or consequential damages, including the interruption of business, loss of profits, or other monetary damages, regardless of whether such damages could have been foreseen or prevented, related to this publication or the use of, inability to use, results of use of, or reliance on the information contained herein, based on any legal theory whatsoever and whether or not there was advice on the possibility of such damages.

Summary

- Total number of Guideline Development Panel (GDP) members = 14
- Percentage of total GDP members with relevant (or potentially relevant) conflict of interest (COI) for this Clinical Practice Guideline (CPG) = 36%

Individual Disclosures, Conflicts, and Management Strategies

Chair: Jennifer Wyckoff, MD
University of Michigan
Expertise: Adult Endocrinology

Disclosures (years): 2021-2025

- No disclosures

Open Payments Database: https://openpaymentsdata.cms.gov/physician/403735

Assessment and Management:

- No COI relevant to this CPG.
- No management required.

Co-Chair: Annunziata Lapolla, MD
University Studi di Padova
Expertise: Adult Endocrinology

Disclosures (years): 2021-2025

- No disclosures

Open Payments Database: N/A

Assessment and Management:

- No COI relevant to this CPG.
- No management required.

Bernadette Asias-Dinh, PharmD
University of Houston
Expertise: Pharmacy

Disclosures (years):

- American Pharmacist Association, Leadership Role
- Vecino Health Centers, Denver Harbor Family Health Center

Open Payments Database: N/A

Assessment and Management:

- No COI relevant to this CPG.
- No management required.

Linda Barbour, MD, MSPH
University of Colorado
Expertise: Adult Endocrinology

Disclosures (years): 2021-2025

- National Institutes of Health, Research Funding
- American Association of Clinical Endocrinology, Speaker
- Philadelphia Endocrine Society, Speaker

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- JAEB Center for Health Research, Data Safety Monitoring Boards
- UptoDate, Editor/Board Member
- Harold Hamm Diabetes Center/Presbyterian Health Foundation, Research Funding
- Helmsley Charitable Trust, Research Funding

Open Payments Database: https://openpaymentsdata.cms.gov/physician/974703

Assessment and Management:

- No COI relevant to this CPG.
- No management required.

Florence Brown, MD
Joslin Diabetes Center
Expertise: Adult Endocrinology

Disclosures (years): 2021-2025

- Dexcom (Dexcom manufactures and markets continuous glucose sensors), Research Funding
- UpToDate, Author

Open Payments Database: https://openpaymentsdata.cms.gov/physician/607275

Assessment and Management:

- Dr. Brown has an industry relationship relevant to this CPG.
- Dr. Brown was allowed to participate on the GDP because she is a renowned expert in the area of diabetes and pregnancy, and since she was nominated by the American Diabetes Association.
- Divestment: None required.
- COI management: Dr. Brown's relationship with Dexcom was deemed potentially relevant to questions related to continuous glucose monitoring. Dr. Brown was not involved in systematic reviews for PICO questions directly related to the above considerations. Dr. Brown did not vote on matters directly related to the above considerations. Dr. Brown did not draft guideline sections directly related to the above considerations. All GDP participants were made aware of Dr. Brown's potentially relevant industry relationship.

Patrick Catalano, MD
Massachusetts General Hospital
Expertise: Obstetrics, Gynecology, and Maternal Fetal Medicine

Disclosures (years):2021-2025

- National Institute of Child Health and Human Development, National Institute of Diabetes and Digestive and Kidney Diseases, Research Funding

Open Payments Database: https://openpaymentsdata.cms.gov/physician/488673

Assessment and Management:

- No COI relevant to this CPG.
- No management required.

Rosa Corcoy, MD, PhD
Hospital de la Santa Creu i Sant Pau
Expertise: Adult Endocrinology

Disclosures (years):2021-2025

- Ministerio de Ciencia e Innovacion, Research Funding
- Novo Nordisk (Novo Nordisk manufactures and markets insulin and GLP-1RA products.), Consulting
- Eli Lilly (Eli Lilly manufactures and markets insulin and GLP-1RA products, as well as smart pens and digital diabetes management tools.), Speaker, Research Funding
- Diabeloop (Diabeloop manufactures and markets hybrid closed-loop systems, as well as other technological diabetes solutions.), Speaker
- Ascensia (Acesncia manufacture and markets blood glucose monitoring systems, continuous glucose monitoring systems, and test strips.), Speaker
- Sanofi (Sanofi manufactures and markets insulin products, oral diabetes medications (glimepiride and lixisenatide), blood glucose monitoring systems, and insulin pens.), Speaker
- Merck (Merck manufactures and markets DPP-4 inhibitors.), Speaker
- ONALABS (ONALABS manufactures and markets continuous glucose monitors.), Consultant
- Generalitat de Catalunya, Research Funding
- Sociedad Espanola de Diabetes, Speaker, Editorial Board
- Sociedad Espanola de Endocrinología y Nutrición, Editorial Board
- The Diabetic Pregnancy Study Group – European Association for the Study of Diabetes, Treasurer

Open Payments Database: N/A

Assessment and Management:

- Dr. Corcoy has an industry relationship relevant to this CPG.
- Dr. Corcoy was allowed to participate on the GDP because she is a renowned expert in the area of diabetes in pregnancy.
- Divestment: None required.
- COI management: Dr. Corcoy's relationship with Novo Nordisk, Eli Lilly, Diabeloop, Ascencia, Sanofi, Merck and ONALABS were deemed potentially relevant to questions related to continuous glucose monitoring, closed-loop systems, insulin, and GLP-1RAs. Dr. Corcoy was not involved in systematic reviews for PICO questions directly related to the above considerations. Dr. Corcoy did not vote on matters directly related to the above considerations. Dr. Corcoy did not draft guideline sections directly related to the above considerations. All GDP participants were made aware of Dr. Corcoy's potentially relevant industry relationship.

Gian Carlo Di Renzo, MD, PhD
PREIS International School
Meyer Children's University Hospital
Firenze, Italy
Expertise: Obstetrics, Gynecology, and Maternal Fetal Medicine

Disclosures (years):2021-2025

- National Institutes of Health, Research Funding
- Organon, Consulting

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- Nestle (Nestle manufactures and markets nutritional supplements for pregnant women, for individuals with diabetes, and for pregnancy women at risk for gestational diabetes.), Advisory Board
- New European Surgical Academy, Secretary
- Italian Law Court

Open Payments Database: N/A

Assessment and Management:
- Dr. Di Renzo has an industry relationship relevant to this CPG.
- Dr. Di Renzo was allowed to participate on the GDP because he is a renowned expert in the area of diabetes in pregnancy.
- Divestment: Dr. Di Renzo divested from advisory board participation with Nestle prior to initiation of the guideline.
- COI management: Dr. Di Renzo's relationship with Nestle were deemed potentially relevant to questions related to nutrition. Dr. Di Renzo was not involved in systematic reviews for PICO questions directly related to the above considerations. Dr. Di Renzo did not vote on matters directly related to the above considerations. Dr. Di Renzo did not draft guideline sections directly related to the above considerations. All GDP participants were made aware of Dr. Di Renzo's potentially relevant industry relationship.

Nancy Drobycki, MSN, RN, CDCES
UT Southwestern Medical Center
Expertise: Nursing and Diabetes Education

Disclosures (years):2021-2025
- Association of Diabetes Care and Education Specialists, Education Leader for the State of Texas

Open Payments Database: N/A

Assessment and Management:
- No COI relevant to this CPG.
- No management required.

Alexandra Kautzky-Willer, MD
Medical University of Vienna
Expertise: Adult Endocrinology

Disclosures (years):2021–2025
- Bohringer Ingelheim (Bohringer Ingelheim manufactures GLP-1RAs.), Consulting, Advisory Board
- AstraZeneca (AstraZeneca manufactures and markets GLP-1RAs.), Consulting
- Sanofi (Sanofi manufactures and markets insulin products, oral diabetes medications (glimepiride and lixisenatide), blood glucose monitoring systems, and insulin pens.), Consulting
- Novo Nordisk (Novo Nordisk manufactures and markets insulin and GLP-1RA products.), Consulting, Research Funding
- Novartis (Novartis manufactures and markets GLP-1RAs and other pipeline treatments for diabetes.), Consulting
- Eli Lilly (Eli Lilly manufactures and markets insulin and GLP-1RA products, as well as smart pens and digital diabetes management tools.), Consulting, Advisory Board
- Amgen, Consulting

Open Payments Database: N/A

Assessment and Management:
- Dr. Kautzky-Willer has an industry relationship relevant to this CPG.
- Dr. Kautzky-Willer was allowed to participate on the GDP because she is a renowned expert in the area of diabetes in pregnancy.
- Divestment: Dr. Kautzky-Willer divested from advisory board participation prior to initiating the guideline.
- COI management: Dr. Kautzky-Willer's relationship with Böhringer Ingelheim, AstraZeneca, Novo Nordisk, Eli Lilly, Sanofi, and Novartis were deemed potentially relevant to questions related to glucose monitoring, insulin, SGLT2 inhibitors, DPP-4 inhibitors, and GLP-1RAs. Dr. Kautzky-Willer was not involved in systematic reviews for PICO questions directly related to the above considerations. Dr. Kautzky-Willer did not vote on matters directly related to the above considerations. Dr. Kautzky-Willer did not draft guideline sections directly related to the above considerations. All GDP participants were made aware of Dr. Kautzky-Willer's potentially relevant industry relationship.

Melanie Stephenson-Gray
Expertise: Patient Representative

Disclosures (years): 2021-2025
- Diabetes UK, Board Member

Open Payments Database: N/A

Assessment and Management:
- No COI relevant to this CPG.
- No management required.

Adam Tabák, MD, PhD
Semmelweis University of Medicine, University College London
Expertise: Adult Endocrinology

Disclosures (years):2021-2025
- Hungarian Diabetes Association, Research Funding, Board Member
- Ministry of Innovation and Technologies, Research Funding
- Bohringer Ingelheim (Bohringer Ingelheim manufactures GLP-1RAs.), Consulting
- 77 Elektronika Kft (77 Elektronika Kft manufactures and markets blood glucose meters, continuous glucose monitoring systems, diabetes data management systems, urine analyzers and test strips.), Speaker
- AstraZeneca (AstraZeneca manufactures and markets GLP-1RAs.), Speaker
- Sanofi-Aventis (Sanofi-Aventis manufacturers and markets insulin, glargine, insulin pens, and injections.), Consulting
- Diabetes Pregnancy Study Group of the EASD, Board Member

Open Payments Database: N/A

Assessment and Management:
- Dr. Tabák has an industry relationship relevant to this CPG.

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- Dr. Tabák was allowed to participate on the GDP because he is a renowned expert in the area of diabetes in pregnancy and he was nominated by the European Association for the Study of Diabetes.
- Divestment: None required.
- COI management: Dr. Tabák's relationship with Böhringer Ingelheim, AstraZeneca, and 77 Elektronika were deemed potentially relevant to questions related to glucose monitoring, insulin, SGLT2 inhibitors, DPP-4 inhibitors, and GLP-1RAs. Dr. Tabák was not involved in systematic reviews for PICO questions directly related to the above considerations. Dr. Tabák did not vote on matters directly related to the above considerations. Dr. Tabák did not draft guideline sections directly related to the above considerations. All GDP participants were made aware of Dr. Tabák's potentially relevant industry relationship.

Emily Weatherup, MS, RDN, CDCES
University of Michigan
Expertise: Patient Representative

Disclosures (years):2021-2025

- Association of Diabetes Care and Education Specialists, Conference Review Committee

Open Payments Database: N/A

Assessment and Management:

- No COI relevant to this CPG.
- No management required.

Chloe Zera, MD, MPH
Beth Israel Deaconess Medical Center
Harvard Medical School
Expertise: Obstetrics, Gynecology, and Maternal Fetal Medicine

Disclosures (years): 2021-2025

- Adriadne Labs, Research Funding
- Massachusetts Perinatal Neonatal Quality Improvement Network, Advisory Board
- American College of Obstetrics and Gynecology, Leadership Roles
- Society for Maternal Fetal Medicine, Leadership Role

Assessment and Management:

- No COI relevant to this CPG.
- No management required.

M. Hassan Murad, MD, MPH
Mayo Clinic
Expertise: Epidemiology, guideline methodology

Disclosures (2021-2025):

- Society for Vascular Surgery, methodologist
- American Society of Hematology, methodologist
- CHEST, methodologist
- World Health Organization, methodologist
- Evidence Foundation, methodologist

Open Payments Database: No entries.

Assessment and Management:

- No COI relevant to this CPG.
- No management required.

Naykky Singh Ospina, MD
University of Florida
Expertise: Adult Endocrinology

Disclosures (years):2021-2025

- No disclosures

Open Payments Database: No entries

Assessment and Management:

- No COI relevant to this CPG.
- No management required.

Appendix A. Guideline Development Panel makeup, roles, and management plans

Role	Name	Relevant COI?	Representative
Chair	Jennifer Wyckoff	No	
Co-Chair	Annunziata Lapolla	No	
Members	Bernadette Asias-Dinh	No	APhA
	Linda Barbour	No	
	Florence Brown	Yes	
	Patrick Catalano	No	ACOG
	Rosa Corcoy	Yes	
	Gian Carlo Di Renzo	Yes	
	Nancy Drobycki	No	ADCES
	Alexandra Kautzky-Willer	Yes	
	Melanie Stephenson-Gray	No	
	Adam Tabák	Yes	EASD
	Emily Weatherup	No	
	Chloe Zera	No	SMFM
Methodologists	M. Hassan Murad	No	
	Naykky Singh Ospina	No	

Abbreviations: ACOG, American College of Obstetricians and Gynecologists; ADCES, Association of Diabetes Care and Education Specialists; APhA, American Pharmacists Association; COI, conflict of interest; EASD, European Association for the Study of Diabetes; SMFM, Society for Maternal-Fetal Medicine.

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