WHO recommendations on care for women with diabetes during pregnancy

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Foreword

Noncommunicable diseases, including diabetes, are among the leading health challenges of our time. Their impact is especially profound during pregnancy, when the health of both mother and child is at stake. Each year, millions of women experience pregnancies complicated by diabetes, with consequences that extend far beyond the perinatal period – affecting lifelong health for mothers and their children.

This is an opportunity to change millions of lives for the better. Diagnosing and treating pre-existing conditions will result in better outcomes for women and their children. High quality care in pregnancy is a clinical imperative and should be treated as a public health priority. Diabetes in pregnancy increases the risk of life-threatening complications such as pre-eclampsia, stillbirth, birth injury, and long-term cardiometabolic disorders for both women and their children. The burden is greatest in low- and middle-income countries, where access to specialized care and resources may be limited, yet the need is most acute.

This guideline responds to the urgent need for evidence-based recommendations to improve care for women with diabetes during pregnancy. Developed through a rigorous process involving global experts, patient representatives, and key stakeholders, it provides practical guidance for healthcare providers, policy-makers, and programme managers across diverse settings.

By integrating diabetes management with broader maternal and child health strategies, these recommendations aim to:

- reduce preventable complications and deaths
- support individualized, respectful, and woman-centred care
- empower health systems to address the growing burden of NCDs in pregnancy
- promote health equity and improve outcomes for future generations.

We extend our deepest gratitude to all contributors whose expertise and dedication have shaped this guideline. Their commitment to advancing maternal and newborn health, and to tackling the challenges of NCDs in pregnancy, is reflected throughout this work.

It is our hope that this guideline will serve as a catalyst for action – supporting the implementation of best practices and fostering healthier futures for women, children, and communities worldwide.

Jeremy Farrar
Assistant Director General
Health Promotion Disease Prevention and Care

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Acronyms and abbreviations

AR	absolute risk
CERQual	Confidence in the Evidence from Reviews of Qualitative research
CGM	continuous glucose monitoring
CI	confidence interval
dL	decilitre
DOI	declaration of interest
eGFR	estimated glomerular filtration rate
ESG	Evidence Synthesis Group
EtD	evidence-to-decision
FPG	fasting plasma glucose
g	gram
GDG	Guideline Development Group
GDM	gestational diabetes mellitus
GLP-1RA	glucagon-like peptide-1 receptor agonists
GRADE	Grading of Recommendations, Assessment, Development, and Evaluation
HAPO	Hyperglycemia and Adverse Pregnancy Outcome study
HbA1c	glycated haemoglobin
HRP	United Nations Development Programme/United Nations Population Fund/UNICEF/ WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction Programme
kg	kilogram
L	litre
MD	mean difference
mg	milligram

mmHg	millimetres of mercury
mmol	millimole
mol	mole
NCDs	noncommunicable diseases
NPH	neutral protamine Hagedorn
PICO	Population (P), Intervention (I), Comparison (C), Outcome (O)
QES	qualitative evidence synthesis
RCT	randomized controlled trial
SGLT2	sodium-glucose transport protein 2
SMBG	self-monitoring of blood glucose
WHO	World Health Organization

Executive Summary

Introduction

Diabetes mellitus, commonly known as diabetes, is one of the most prevalent noncommunicable diseases (NCDs), with 830 million adults living with diabetes in 2022 (1). The prevalence is rising more rapidly in low- and middle-income countries than in high-income countries, with 85% of adults with diabetes living in low- and middle-income countries in 2022 (1). While more than 95% of people with diabetes have type 2 diabetes (2), in 2017, there were nine million people with type 1 diabetes (3), which is characterized by deficient insulin production and requires daily administration of insulin. It is estimated that around half of all people living with diabetes are undiagnosed (4).

About one in six live births (21 million per year) is affected by diabetes during pregnancy (5). Diabetes in pregnancy can be pre-existing (type 1 or type 2, also referred to as pre-gestational diabetes) or hyperglycaemia can be first detected during pregnancy, which is classified as either diabetes in pregnancy or gestational diabetes mellitus (GDM) (6). Women with a history of GDM have an increased risk of type 2 diabetes after childbirth (7). The risks increase throughout the life span, with a cumulative incidence of type 2 diabetes of up to 70 percent 28 years after a pregnancy complicated by GDM (8).

The management of type 1 and type 2 diabetes during pregnancy requires intensified treatment and monitoring. In addition, any type of diabetes during pregnancy has effects on the fetus, birth process and long-term cardiometabolic health outcomes across the lifespan for both the pregnant woman and the exposed child. Pregnancy-related complications of diabetes (including GDM), include pre-eclampsia and other hypertensive disorders of pregnancy for the woman; and stillbirth, macrosomia, hypoglycaemia, seizures, birth injury and congenital anomalies for the developing baby. Children born after pregnancies complicated by diabetes have increased risks of obesity, cardiovascular disease, metabolic syndrome, type 2 diabetes, hypertension, and fatty liver disease (9).

Clinical recommendations for the management of diabetes in pregnancy are essential to improve maternal and newborn health. In 2013, WHO published diagnostic criteria and classification of hyperglycaemia first detected in pregnancy, but did not provide recommendations on diabetes management (6). The WHO 2016 antenatal care guidelines identified this as a priority research area, particularly in low- and middle-income countries (10). In a review of pregnancy-specific guidelines, 25 guidelines relating to diabetes in pregnancy were found (25 addressed GDM and four addressed type 1 and/or type 2 diabetes), of which 18 were from upper middle- or high-income countries, two were from low- and middle-income countries, and five were from international societies (11). Given that the disease burden of diabetes is global, with most cases in low- and middle-income countries, guidelines applicable to these environments are needed.

Target audience

WHO maternal and perinatal health guidelines are relevant to those providing care and support during pregnancy, labour, childbirth and postnatal periods, in any health-care setting.

The primary audience for this guideline includes policy-makers or service providers who are responsible for developing national and local health-care protocols and policies, as well as managers of maternal and child health programmes. The guideline will also be useful to those directly providing care to women during pregnancy, such as obstetricians, midwives, endocrinologists, nurses, general practitioners, dietitians and diabetes educators. Finally, the information in this guideline will be useful for developing clinical tools for pre- and in-service training of health workers and health-system strengthening efforts to enhance their delivery of clinical care.

Guideline development methods

The development of this guideline was guided by the process described in the *WHO handbook for guideline development* (12). The guideline was developed using the following steps: (i) identification of priority questions and outcomes; (ii) retrieval of evidence; (iii) assessment and synthesis of evidence; (iv) formulation of the recommendations; and (v) planning for the dissemination, implementation, impact evaluation and future updating of the recommendations.

De novo systematic reviews were used to prepare evidence profiles for the prioritized questions. The quality of identified scientific evidence underpinning the recommendations was appraised using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) and the GRADE Confidence in the Evidence from Reviews of Qualitative research (GRADE-CERQual) approaches, for quantitative and qualitative evidence, respectively. The GRADE evidence-to-decision (EtD) framework – an evidence-to-decision tool that includes intervention effects, values, resource use, equity and human rights, acceptability and feasibility criteria – was used to guide the formulation of recommendations by the Guideline Development Group (GDG). The GDG comprised an international group of experts who convened on 12–15 May 2025 for consideration of the non-pharmacological management recommendations and on 29–31 July 2025 for consideration of the pharmacological management recommendations.

Principles underpinning the recommendations

- WHO envisions a world where every pregnant woman and baby receive quality care throughout pregnancy, childbirth and the postnatal period (10). *WHO recommendations on antenatal care for a positive pregnancy experience* highlight the importance of providing effective communication about physiological, biomedical, behavioural and sociocultural issues, as well as effective social, cultural, emotional and psychological support, to pregnant women in a respectful way (10).
- Although women with diabetes may have complex care needs during pregnancy, it is important to consider the individual woman's values and preferences and facilitate the most positive pregnancy experience that is possible while managing these needs effectively.

- There is potential to improve health outcomes for women and babies by taking a life-course approach that integrates prevention of, and care for, NCDs, such as diabetes, with care that addresses sexual, reproductive, maternal, newborn and child health needs (13).
- A critical aspect of optimal antenatal care is shared decision-making when pharmacological treatments are recommended. This involves a collaborative approach where health-care providers and pregnant women make medication-related decisions together, considering both the best available evidence on the benefits and harms to the woman and the developing baby, as well as the woman's preferences and values. It also respects the woman's right to make decisions about her care, including the right to decline or discontinue treatment.
- The aim of glucose-lowering treatment for pregnant women with diabetes is to achieve the best possible glycaemic control with the resources available when this cannot be achieved with diet and physical activity alone. Irrespective of the treatment or protocol used, high-quality care prioritizes the wellbeing and safety of the woman and baby, ensuring that the treatment provided is likely to be beneficial and achieve the desired outcomes, and minimizing risks of harm. Treatments are offered according to the woman's preferred approach, affordability, cost–effectiveness and other available resources.

Recommendations

The GDG issued 27 recommendations – four on core practices in caring for women with diabetes during pregnancy; six on glucose monitoring; two on pharmacological treatment for pregnant women with type 1 diabetes, four on pharmacological treatment for pregnant women with type 2 diabetes and two on pharmacological treatment for women with GDM; and nine on additional monitoring and assessments. The recommendations are intended for use in addition to routine antenatal care.

To ensure that the recommendations are correctly understood and applied in practice, the GDG provided additional remarks. Users of the recommendations should refer to these remarks, which are presented directly beneath the recommendations in Section 3.1. The recommendations are given below.

Topic		Recommendation
Core practices in caring for women with diabetes during pregnancy		
Advice on diet, physical activity and weight management	1	For pregnant women with type 1, type 2 or gestational diabetes, provide individualized advice on diet, physical activity and weight management based on existing WHO guidance, including: • dietary advice for the general adult population; • physical activity advice for the general pregnant population; • weight management advice based on the above dietary and physical activity advice, with a focus on appropriate gestational weight gain.

Topic		Recommendation
Antenatal education	2	For pregnant women with type 1, type 2 or gestational diabetes, provide education on: • the effects of diabetes in pregnancy on maternal, fetal, newborn and child health outcomes; • diet and physical activity; • appropriate gestational weight gain; • managing glycaemia; • the need for additional monitoring of fetal growth and wellbeing.
Specialized care	3	For pregnant women with type 1 or type 2 diabetes, deliver multidisciplinary and specialized care provided by health-care providers trained in maternal and diabetes care.
	4	For women with GDM, consider multidisciplinary and specialized care provided by health-care providers trained in maternal and diabetes care, depending on access and availability.
Glucose monitoring		
Mode of glucose monitoring	5	For pregnant women with type 1, type 2 or gestational diabetes, recommend self-monitoring of blood glucose (SMBG) in addition to routine care, where feasible.
	6	For pregnant women with type 1 diabetes, recommend the use of a continuous glucose monitoring (CGM) system, where feasible.
	7	For pregnant women with type 2 or gestational diabetes, do not routinely recommend use of a CGM system.
Glycated haemoglobin (HbA1c)	8	For pregnant women with type 1 or type 2 diabetes, measure HbA1c in the first trimester or as soon as antenatal care is initiated.
	9	For women with GDM, do not routinely measure HbA1c.
Glycaemic targets	10	For pregnant women with type 1, type 2 or gestational diabetes, individualize glycaemic targets to optimize glycaemic control and improve maternal and neonatal outcomes.
Pharmacological treatment for pregnant women with type 1, type 2 or GDM		
Type 1 diabetes	11	For pregnant women with type 1 diabetes, recommend continuation of the same type of insulin used before pregnancy unless a change is considered necessary to optimize blood glucose control and outcomes for the woman and baby.
	12	For pregnant women with type 1 diabetes, recommend continuation of the method of insulin delivery used before pregnancy unless a change is considered necessary to optimize blood glucose control and outcomes for the woman and baby.

Topic		Recommendation
Type 2 diabetes	13	For pregnant women with type 2 diabetes who are unable to maintain optimal blood glucose levels with diet and physical activity alone, recommend initiation of metformin or insulin to optimize blood glucose control and outcomes for the woman and baby.
	14	For pregnant women with type 2 diabetes who are receiving monotherapy with insulin or metformin and who are unable to achieve optimal blood glucose levels, consider initiation of a combination of metformin and insulin to optimize blood glucose control and outcomes for the woman and baby.
	15	For pregnant women with type 2 diabetes who are already receiving glucose-lowering medication, recommend that medications with safety concerns during pregnancy be replaced with insulin and/or metformin.
	16	For pregnant women with type 2 diabetes who required insulin to achieve optimal blood glucose levels before pregnancy, recommend continuation of the same type of insulin unless a change is considered necessary to optimize blood glucose control and outcomes for the woman and baby.
GDM	17	For women with GDM who are unable to achieve optimal blood glucose levels with diet and physical activity alone, recommend initiation of metformin or insulin to optimize blood glucose control and outcomes for the woman and baby.
	18	For women with GDM who are receiving monotherapy with metformin or insulin and are unable to achieve optimal blood glucose levels, consider initiation of a combination of metformin and insulin to optimize blood glucose control and outcomes for the woman and baby.
Additional monitoring and assessments		
Fetal monitoring	19	For pregnant women with type 1, type 2 or gestational diabetes, perform a routine ultrasound scan before 24 weeks.
	20	For pregnant women with type 1 or type 2 diabetes, consider performing the routine ultrasound scan as early as possible in pregnancy, with a follow-up ultrasound to assess fetal anatomy and growth in the second trimester.
	21	For pregnant women with type 1, type 2 or gestational diabetes, consider additional ultrasound growth scans after 24 weeks, as indicated.
	22	For pregnant women with type 1, type 2 or gestational diabetes requiring blood glucose-lowering medication, consider additional monitoring of fetal wellbeing, as indicated.
Retinopathy screening	23	For pregnant women with type 1 or type 2 diabetes, screen for retinopathy when antenatal care is initiated and provide follow-up based on the risk of retinopathy progressing.
	24	For women with GDM, do not routinely screen for retinopathy.

Topic		Recommendation
Renal assessment	25	For pregnant women with type 1 or type 2 diabetes, assess renal function when antenatal care is initiated and arrange specialist follow-up for women if impaired renal function is identified.
	26	For women with GDM, do not routinely assess renal function.
	27	For pregnant women with type 1 or type 2 diabetes with impaired renal function, emphasize the importance of maintaining blood pressure levels below 130/80 mmHg during pregnancy and offer antihypertensives known to be safe in pregnancy as indicated. Advise women to modify major risk factors for cardiovascular disease (e.g. smoking, unhealthy diet, sedentary behaviour) and to seek specialist postnatal follow-up.

1 Introduction

1.1 Background

Diabetes is one of the most prevalent NCDs, with 830 million adults living with diabetes in 2022 (1). The prevalence is rising more in low- and middle-income countries than in high-income countries, with 81% of adults with diabetes living in low- and middle-income countries in 2022 (1). While more than 95% of people with diabetes have type 2 diabetes (2), in 2017 there were nine million people with type 1 diabetes (3) which is characterized by deficient insulin production and requires daily administration of insulin. It is estimated that around half of all people living with diabetes are undiagnosed (4).

About one in six live births (21 million per year) is affected by diabetes during pregnancy (5). Diabetes in pregnancy can be pre-existing (type 1 or type 2, also referred to as pre-gestational diabetes) or hyperglycaemia can be first detected during pregnancy, which is classified as either diabetes in pregnancy or GDM (6). Women with a history of GDM have an increased risk of type 2 diabetes after childbirth (7). The risks increase throughout the life span, with a cumulative incidence of type 2 diabetes of up to 70 percent 28 years after a pregnancy (8).

The management of type 1 and type 2 diabetes during pregnancy requires intensified treatment and monitoring. In addition, any type of diabetes during pregnancy has effects on the fetus and birth process. Pregnancy-related complications of diabetes (including GDM), include pre-eclampsia and other hypertensive disorders of pregnancy for the woman; and stillbirth, macrosomia, hypoglycaemia, seizures, birth injury and congenital anomalies for the developing baby. Children born after pregnancies complicated by diabetes have increased risks of obesity, cardiovascular disease, metabolic syndrome, type 2 diabetes, hypertension, and fatty liver disease (9).

Clinical recommendations for management of diabetes in pregnancy are essential to improve maternal and newborn health. In 2013, WHO published diagnostic criteria and classification of hyperglycaemia in pregnancy, but did not provide recommendations on diabetes management (6). The WHO 2016 antenatal care guidelines identified this as a priority research area, particularly in low- and middle-income countries (10). In a review of pregnancy-specific guidelines, 25 guidelines relating to diabetes in pregnancy were found (25 addressed GDM and four addressed type 1 and/or type 2 diabetes) of which 18 were from upper middle- or high-income countries, two were from low- and middle-income countries, and five were from international societies (11). Given that the disease burden of diabetes is global, with most cases in low- and middle-income countries, guidelines applicable to these environments are needed.

1.2 Rationale and objectives

In July 2021, the WHO Steering Group convened a scoping meeting – comprising an independent panel of 15 external experts and relevant stakeholders from the six WHO regions – to explore the scope for a new guideline thematic area covering screening for and management of NCDs in pregnancy, childbirth, and the postnatal periods.

To inform the discussions, the WHO Steering Group developed two evidence syntheses. These described the existing definitions and concepts related to NCDs in pregnancy (14) and mapped the (then) current guidelines and recommendations related to maternal health and NCDs (11). The 'universe' of thematic areas/conditions to be considered for inclusion in guideline development was based upon a review of the indirect maternal conditions. In considering the breadth and depth of potential thematic areas, the scoping group were requested to assess the general prevalence of the conditions, the interaction between the condition and pregnancy, and the potential for intervention during maternal health contacts.

The following topic areas were considered the highest priorities:

- cardiovascular conditions
- diabetes
- respiratory conditions
- haemoglobinopathies (including sickle cell disease and thalassaemia)
- mental health disorders and substance use.

Guidelines on the management of sickle cell disease were published in June 2025. The management of diabetes is the second of these topics to be addressed. Guidelines on screening for diabetes during pregnancy are currently under development.

1.3 Target audience

WHO maternal and perinatal health guidelines are relevant to those providing care and support during pregnancy, labour, childbirth and postnatal periods, in any health-care setting.

The primary audience for this guideline includes policy-makers or service providers who are responsible for developing national and local health-care protocols and policies related to care during pregnancy, childbirth and the postnatal period, and those directly providing care to women during pregnancy, including obstetricians, midwives, endocrinologists, nurses, general practitioners, dietitians and diabetes educators, and managers of maternal and child health programmes, in all settings. The guideline will also be useful for developing clinical tools for pre- and in-service training of health workers and health-system strengthening efforts to enhance their delivery of clinical care.

It is expected that the guideline will be of interest to professional societies involved in the care of pregnant women; nongovernmental organizations concerned with the promotion of woman-centered maternal care; and implementers of maternal and child health programmes.

1.4 Scope of the recommendations

The recommendations provide guidance on both the pharmacological management and the non-pharmacological management of diabetes during pregnancy. The priority questions that guided evidence synthesis and decision making for these recommendations were developed using the Population (P), Intervention (I), Comparison (C), Outcome (O) (PICO) format and are presented in the web annex to this Guideline. The priority outcomes used in decision making are listed in Annex 2.

1.5 Persons affected by the recommendations

The population affected by the recommendations is women with type 1, type 2 or GDM who receive antenatal care and give birth in low-, middle- and high-resource settings.

2 Methods

The guideline was developed using the process described in the *WHO handbook for guideline development* (12). In summary, the process included: (i) identification of the priority questions and outcomes; (ii) retrieval of the evidence; (iii) assessment and synthesis of the evidence; (iv) formulation of the recommendations; and (v) planning for the dissemination, implementation, impact evaluation and updating of the recommendations. Six main groups participated in this process and their specific roles are described below.

2.1 Contributors to the guideline

2.1.1 WHO Steering Group

The WHO Steering Group, comprising WHO staff members from the Department of Sexual and Reproductive Health and Research, the Department of Maternal, Newborn, Child and Adolescent Health and Ageing, the Department of Nutrition and Food Safety, and the Department of Noncommunicable Diseases and Mental Health, Rehabilitation and Disability managed the process. The WHO Steering Group drafted the key research questions in PICO format, identified the systematic review teams and guideline methodologists, as well as members of the Guideline Development Group and the External Review Group. In addition, the WHO Steering Group supervised the retrieval and syntheses of evidence, organized the GDG meetings, finalized the guideline document, and managed its dissemination, implementation and impact assessment. The members of the WHO Steering Group are listed in Annex 1.

2.1.2 Guideline Development Group

For the development of this guideline, 16 external experts and relevant stakeholders were invited to participate as members of the GDG. These individuals were drawn from a pool of approximately 50 experts and relevant stakeholders that constitute the WHO Maternal and Perinatal Health GDG. Those selected were a diverse group with expertise in research, guideline development methods, and clinical policy and programmes relating to improving the quality of care and outcomes for women with diabetes during pregnancy, as well as a representative of the affected population.

The GDG members were selected in a way that, as far as possible, represented a geographic and gender balance and ensured that there were no important conflicts of interest. The GDG comprised 44% women and 56% men.

Based on the documents prepared by the Steering Group, the GDG appraised and interpreted the evidence, and formulated the final recommendations on non-pharmacological management at a meeting convened on 12–15 May 2025 and on pharmacological management at a meeting convened on 29–31 July 2025. The group also reviewed and approved the final guideline document. The members of this group are listed in Annex 1.

2.1.3 Evidence Synthesis Group

WHO convened an Evidence Synthesis Group (ESG) composed of guideline methodologists and systematic review teams for the conduct or updating of systematic reviews, appraisal of evidence, and development of the EtD frameworks.

Two technical consultants, Jen Ramson and Myfanwy Williams, served as the guideline methodologists. They oversaw the appraisal of evidence using the GRADE methodology (15).

To inform this guideline, systematic reviews of qualitative evidence on diabetes and maternity care from the perspectives of health-care providers (16) and women with type 1 or type 2 diabetes (17) were conducted. This work was led by experts from the University of Central Lancashire (United Kingdom of Great Britain and Northern Ireland) with extensive experience in qualitative evidence reviews. In addition, the ESG initiated a new systematic review of economic evaluations for screening and management of diabetes in pregnancy (18).

The guideline methodologists worked closely with the ESG to review the evidence and prepare the GRADE EtD frameworks. Members of the ESG attended the GDG meeting to respond to technical queries from the GDG. The members of the ESG are listed in Annex 1.

2.1.4 External partners and observers

Representatives of the International Confederation of Midwives, International Council of Nurses, International Diabetes Foundation, International Federation of Gynecology and Obstetrics, International Pediatric Association and the Noncommunicable Disease Alliance participated in the GDG meetings as observers. These organizations collaborate with WHO Departments in guideline dissemination and implementation and were identified as significant implementers of the guideline. The list of observers who participated in the GDG meetings is included in Annex 1.

2.1.5 External Review Group

An external review group comprised four technical experts with interest and expertise in the provision of evidence-based care to improve the quality of care and outcomes for women with diabetes during pregnancy. The members had no important conflicts of interest. The experts reviewed the final document to identify any factual errors and commented on the clarity of language, contextual issues and implications for implementation. They ensured that the decision-making processes had considered and incorporated contextual values and the preferences of persons affected by the recommendations, health-care providers and policy-makers. It was not within the remit of this group to change the recommendations that were formulated by the GDG. Members of the External Review Group are listed in Annex 1.

2.2 Evidence identification and retrieval

Evidence to support the development of the guideline recommendations was derived from several sources by the systematic review teams working in collaboration with the WHO Steering Group.

2.2.1 Evidence on effectiveness

To inform the development of the recommendations, WHO commissioned a set of three *de novo* systematic reviews on the management of diabetes during pregnancy, one of which covered nine priority questions.

External groups of systematic reviewers were asked to prepare review protocols with clear PICO questions and criteria for identification of studies, including search strategies for different bibliographic databases, methods for assessing risk of bias and a data analysis plan (19–21). The WHO Steering Group and the guideline methodologists reviewed and endorsed the protocols before the systematic reviews were conducted.

The search strategies employed to identify the studies and the specific criteria for inclusion and exclusion of studies are described in the individual systematic reviews. Studies from low-, middle- and high-income countries were considered and there were no language restrictions. The entire systematic review development process was iterative, with the systematic reviewers and guideline methodologists constantly communicating with the WHO Steering Group to discuss challenges and agree on solutions.

2.2.2 Evidence on values, resource use and cost–effectiveness, equity and human rights, acceptability and feasibility

Values, equity and human rights, acceptability and feasibility

Two qualitative evidence syntheses (QES) explored the views and experiences of women with type 1 or type 2 diabetes during their encounters with maternity services (17) and those of health-care providers caring for women with diabetes during the maternity phase (16).

Evidence on the views and experiences of women with GDM was obtained from previously published systematic reviews of qualitative evidence. Existing reviews identified by a systematic search were appraised using the Joanna Briggs Institute Checklist for Systematic Reviews, and 14 high-quality reviews were referenced.

These reviews were the primary source of evidence on values, equity and human rights, acceptability, and feasibility.

Resource use and cost–effectiveness

The evidence synthesis team initiated a new systematic review of economic evaluations for the screening, management and treatment for women with diabetes during pregnancy (18). The review aimed to:

- synthesize the available evidence from economic evaluations of interventions to screen/diagnose, treat and/or manage diabetes during pregnancy;
- assess the methodological quality of the economic evaluation studies;
- identify the gaps in the evidence from economic evaluations of interventions to manage diabetes during pregnancy.

2.3 Quality assessment and grading of the evidence

2.3.1 Quality assessment of primary studies included in the reviews

For the effectiveness reviews, all eligible randomized controlled trials were assessed using a research integrity assessment tool adapted from that described by Weibel et al 2022 (22). The tool aims to detect any potential issues related to study retraction, trial registration, ethics approval, author contributions, plausibility of methods (e.g. randomization), and plausibility of study results.

For all trials judged to be trustworthy, two reviewers independently assessed the risk of bias of randomized trials using the revised Cochrane risk-of-bias tool (RoB 2.0). For non-randomized trials, the ROBINS-I tool was used. Any disagreement was resolved by discussion or by involving a third assessor.

For each included randomized controlled trial (RCT) and each outcome, the domains of bias explored were: randomization process; identification or recruitment of individual participants within clusters; deviations from intended interventions; missing outcome data; measurement of the outcome; selection of the reported result; and overall bias.

For non-randomized studies, the domains of bias explored were: confounding; selection of participants into the study; classification of interventions; deviations from intended interventions; missing data; measurement of outcomes; selection of the reported result; and overall bias.

The quality of studies included in the QES was appraised using the GRADE-CERQual tool (23) as outlined below.

The cost–effectiveness systematic review used the extended Consensus on Health Economics Criteria list (24) for assessing the quality of studies.

2.3.2 Assessment of certainty of the effectiveness evidence

For the effectiveness evidence, the certainty of evidence for a given outcome was rated using the standard GRADE approach based on consideration of study design limitations (risk of bias), inconsistency (heterogeneity or variability in results), indirectness (differences in study populations), imprecision (small study populations and/or few events; wide confidence intervals) and publication bias (12).

Where possible, evidence profile tables were prepared using GRADEpro software (25). These included the effect estimates (expressed as relative and absolute risk), explanations of the certainty assessments, and an overall certainty rating for each outcome and are included in the web annex to this guideline.

GRADE certainty of the evidence

The certainty of evidence for each outcome was rated as 'high', 'moderate', 'low' or 'very low' as defined by the GRADE methodology.

- **High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect.
- **Moderate certainty:** We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

- **Low certainty:** Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect.
- **Very low certainty:** We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.

Sensitivity analyses

When the main analysis included trials for which the reviewer had identified research integrity concerns, and authors had been contacted for clarification but had not yet replied, sensitivity analyses were conducted with these trials removed. Other than a probable reduction in risk of neonatal hypoglycaemia with CGM compared to SMBG among women with type 1 diabetes, there were no substantial changes in conclusions (i.e. no clear shifts in suggestion of benefit / harm / no difference) or certainty.

2.3.3 Assessment of the certainty of (confidence in) the qualitative evidence

The findings of studies included in the QES were appraised using the GRADE-CERQual tool (23). The GRADE-CERQual tool, which uses a similar conceptual approach to other GRADE tools, provides a transparent method for assessing and assigning the level of confidence that can be placed in evidence from reviews of qualitative research. The systematic review team used the GRADE-CERQual tool to assign a level of confidence to each review finding according to four components: methodological limitations of the individual studies; adequacy of data; coherence; and relevance to the review question of the individual studies contributing to a review finding.

The confidence of evidence for each review finding is rated as 'high', 'moderate', 'low' or 'very low' (23).

- **High confidence:** It is highly likely that the review finding is a reasonable representation of the phenomenon of interest.
- **Moderate confidence:** It is likely that the review finding is a reasonable representation of the phenomenon of interest.
- **Low confidence:** It is possible that the review finding is a reasonable representation of the phenomenon of interest.
- **Very low confidence:** It is not clear whether the review finding is a reasonable representation of the phenomenon of interest.

2.4 Formulation of the recommendations

The WHO Steering Group supervised the preparation and finalization of summary of findings tables and narrative evidence summaries in collaboration with the guideline methodologists using the GRADE EtD framework (26). The EtD framework includes explicit and systematic consideration of evidence on the intervention in terms of specified domains: effectiveness, values, resources, equity and human rights, acceptability and feasibility. Using the EtD framework template, the Steering Group and guideline methodologists created summary documents for each priority question covering evidence on each domain. For each priority question, judgements were made on the impact of the intervention on each domain, to inform and guide the decision-making process.

The WHO Steering Group provided the EtD frameworks for discussion, including evidence summaries and summary of findings tables, to GDG members one week before the GDG meetings. The GDG members were asked to review and electronically provide comments on the documents before the GDG meeting. During the online meetings of the GDG (12–15 May 2025 and July 29–31 2025), under the leadership of the GDG chairpersons, the GDG members collectively reviewed and discussed the frameworks.

The purpose of the meetings was to formulate and reach consensus on recommendations, based on explicit consideration of the range of evidence presented in the EtD frameworks and the judgements of the GDG members.

In formulating the recommendations, the GDG used the GRADE EtD frameworks and considered separately the synthesized evidence on effectiveness of the intervention, values of stakeholders, resource use and cost–effectiveness of the intervention, acceptability and feasibility of the intervention, and the impact of the intervention on equity and human rights. For each of these domains, the certainty of evidence was evaluated using methods that were appropriate to the available supporting evidence synthesis (such as GRADE or GRADE CerQual) and the GDG made judgements on the effects of an intervention across these domains.

It was the view of the GDG that, as certainty of evidence was evaluated across several domains to arrive at the recommendation, and not just for evidence on effectiveness of the intervention, this cannot be captured within a single 'certainty' rating. Providing the certainty of evidence for effectiveness alone within the recommendation texts does not adequately demonstrate the consideration of all the types of evidence, and could potentially confuse the target audience.

A further step in the GRADE approach is to attribute one of two levels of strength (i.e. strong or weak, strong or conditional) to each recommendation. Since 2016, all consolidated WHO maternal and perinatal health guidelines and updates of recommendations have not taken this step based on feedback received from users about the challenges of interpreting recommendations coupled with specific evidence ratings. It was the view of the GDG that a change in the presentation approach of this set of recommendations could create confusion for the target audience.

2.5 Management of declaration of interests

All GDG members and other external contributors were required to complete a standard WHO declaration of interests (DOI) form before engaging in the guideline development process and taking part in any of the guideline development meetings. Before finalizing experts' invitations to participate in the development of the guideline, the WHO Steering Committee reviewed all the DOI forms using the criteria for assessing the severity of a conflict of interest in the *WHO handbook for guideline development* (12) to determine whether any identified conflict of interest warranted action. Each member was asked to update their DOI form prior to the each GDG meeting in case information had changed in the intervening period. None of the meeting participants declared a conflict of interest that was considered significant enough to pose any risk to the guideline development process or to reduce its credibility. A summary of the DOI statements and how conflicts of interest were managed is included in Annex 3.

2.6 Decision making during the GDG meetings

The GDG meetings were designed to allow participants to discuss the supporting evidence and to reach a consensus on the final wording of each recommendation. Consensus was defined as the agreement by three quarters or more of the GDG, provided that those who disagreed did not feel strongly about their position. No GDG member expressed opposition to the recommendations.

2.7 Document preparation and peer review

The WHO Steering Group made a draft version of the EtD frameworks available to the participants one week before the meeting for their comments. During the meeting, the frameworks were modified in line with the participants' deliberations and remarks. Following the meeting, the WHO Steering Group worked with the guideline methodologists to prepare a full guideline document to accurately reflect the deliberations and decisions of the participants. The draft document was sent electronically to GDG members for their final review and approval. The final document was also sent for peer review to four external independent experts who were not involved in the development of the guideline. The WHO Steering Group evaluated the advice of the peer reviewers for inclusion in this document. After the meetings and external peer reviews, the modifications made by the WHO Steering Group to the document consisted only of the correction of factual errors and edits to address any lack of clarity.

3 Recommendations and supporting evidence

The GDG issued 27 recommendations – four on care for all women with diabetes (type 1, type 2 or gestational) during pregnancy, six on glucose monitoring, two on pharmacological treatment for pregnant women with type 1 diabetes, four on pharmacological treatment for pregnant women with type 2 diabetes and two on pharmacological treatment for women with GDM, and nine on additional monitoring and assessments. This section outlines the recommendations corresponding to the priority questions.

To ensure that the recommendations are correctly understood and appropriately implemented in practice, additional 'remarks' reflecting the summary of the discussions by the GDG are included. The recommendations should be applied in conjunction with the implementation considerations.

The EtD frameworks – presenting the available effectiveness evidence, the balance between the desirable and undesirable effects, values of stakeholders, resource requirements, cost–effectiveness, acceptability, feasibility and equity, and human rights that were considered in formulating each recommendation – are presented separately in the web annexes to this guideline.

3.1 Recommendations

3.1.1 Core practices in caring for women with diabetes during pregnancy

Advice on diet, physical activity and weight management

Recommendation

1 For pregnant women with type 1, type 2 or gestational diabetes, provide individualized advice on diet, physical activity and weight management based on existing WHO guidance, including:

- dietary advice for the general adult population;
- physical activity advice for the general pregnant population;
- weight management advice based on the above dietary and physical activity advice, with a focus on appropriate gestational weight gain.

Rationale

- Counselling about healthy eating during pregnancy to prevent excessive gestational weight gain was recommended by the WHO antenatal care guidelines (10). Physical activity during pregnancy to improve maternal and fetal health outcomes was recommended by the WHO antenatal care guidelines (10) and the WHO 2020 guidelines on physical activity and sedentary behaviour (27). A healthy diet and regular physical activity are also integral to type 2 diabetes management (28).
- In the context of limited direct empirical evidence on advice on diet, physical activity and weight management advice for pregnant women with diabetes, the GDG developed this recommendation based on existing WHO guidance.
- The GDG chose to base its recommendation on dietary advice on WHO guidance for the general population (29–32), as WHO guidance on diet in the general pregnant population (10) and the general population with type 2 diabetes (28) is non-specific, recommending a 'healthy diet', while guidance for the general adult population provides details on how this might be achieved.
- The GDG chose to base its recommendation on physical activity advice on the WHO recommendation specific to the general pregnant population (27), noting that the risks for the amounts and types of physical activity recommended for pregnant and postnatal women are low and are outweighed by substantial health benefits.

Remarks

Specific dietary and physical activity advice

- Dietary advice following WHO recommendations for the general adult population (29–32):
  - carbohydrates primarily from wholegrains, vegetables, fruits and pulses (legumes);
  - at least 400 g vegetables daily; 25 g naturally occurring fibre daily;
  - limitation of total fat intake to 30% of total energy intake, with fat consumed primarily unsaturated fatty acids and no more than 10% of total energy from saturated fats and no more than 1% of total energy intake form trans-fatty acids; and
  - reduction of free sugars to less than 5–10% of daily intake.
- Physical activity advice following WHO recommendations for the general pregnant population (27):
  - regular physical activity throughout pregnancy;
  - 150 minutes per week of moderate-intensity aerobic activity;
  - incorporating resistance (muscle strengthening) exercise and stretching; and
  - continuation of pre-pregnancy physical activity habits for women who, before pregnancy, were habitually engaged in vigorous-intensity aerobic activity, or who were physically active.

Individualization of advice

- Individualizing advice on diet, physical activity and weight management, based on each woman's weight and/or glycaemic control, including specialized advice from a registered dietitian or exercise physiologist

with expertise in diabetes during pregnancy, may be beneficial. Cultural tailoring of both dietary and physical activity advice is likely to improve uptake.

- Weight management is defined as achieving appropriate gestational weight gain in relation to the mother's pre-pregnancy weight. WHO is developing gestational weight gain standards for the general pregnant population, which may also inform advice for women with diabetes on appropriate gestational weight gain during pregnancy.

Benefits and harms

- The limited evidence identified through the systematic review conducted to inform this guideline suggested a possible reduction in gestational weight gain in women with type 1 or type 2 diabetes with a diabetes-specific high carbohydrate, high fibre, low fat diet versus routine care (n=20 women) (*low certainty*). It also suggested a possible reduction in risk of preterm birth in women with GDM with individualized dietary advice compared to routine care (n=234 women) (*low certainty*). No harms were identified for any diet.
- The limited evidence identified in the review of physical activity versus routine care found only very low certainty evidence on the benefits or harms of physical activity advice for women with type 1 diabetes, and no evidence on women with type 2 diabetes.
- Among women with GDM, with any physical activity there was probably little to no difference in gestational weight gain (n=595 women) (*moderate certainty*) and possibly little to no difference in risk of caesarean birth (n=1014 women) and instrumental vaginal birth (n=375 women) (*low certainty*). There was possibly little to no difference in gestational weight gain with aerobic activity (n=263 women) or aerobic plus resistance activity (n=268 women) (*low certainty*).
- There was possibly little to no difference in effect on gestational age at birth with any maternal physical activity (n=301 babies), resistance exercise (n=64 babies), or combined aerobic and resistance activity (n=169 babies) (*low certainty*).There was possibly little to no difference in effect on birthweight with any physical activity (n=651 babies), resistance exercise (n=64 babies) or combined aerobic and resistance activity (n=276 babies) (*low certainty*).
- There was no evidence of other benefits or harms for women with GDM, although the lack of benefits or harms is not established as many outcomes were of very low certainty.

Equity and human rights

- Evidence from the QES suggests that for some women on low or limited incomes, the extra costs of finding or buying 'healthy food' may be prohibitive and lead to an inequitable service for these women (*moderate confidence*) (16).

Acceptability to women

- *Women with type 1 or type 2 diabetes:* The QES found that some women view pregnancy as an opportunity for behavioural change (*moderate confidence*) and welcome advice on diet and physical activity provided it is given in a clear, understandable and culturally appropriate format (including pictures and online resources) by health-care providers who are sensitive to their individual needs (*high confidence*) (17). Some women may struggle, however, to adapt to dietary changes (*low confidence*) or find some foods difficult

to tolerate because of digestive problems or morning sickness (*low confidence*) (17). In certain contexts, the additional cost of recommended 'healthy food' can lead to poor adherence by some women on low or limited incomes (*low confidence*) (17). In addition, some women may be confused by inconsistent or conflicting dietary advice from different health-care providers (*low confidence*) (17). In some contexts where weight gain during pregnancy is viewed as a cultural norm, women (and their families) may be resistant to weight management advice (*low confidence*). In addition, some women may feel guilty about their weight (*low confidence*) and find it difficult to discuss weight management concerns with health-care providers who lack empathy or sensitivity (*moderate confidence*).

- *Women with GDM:* The systematic reviews referenced in the QES found that some women felt that adapting to dietary changes was a steep learning curve, with very limited time to make the changes (33–35) (*high confidence*). Some also found it difficult to accept dietary advice, especially if it conflicted with their regular diet or their normative cultural diet (33, 35) (*moderate confidence*). Authors indicated there was a clear need for personalized dietary advice for women from different cultural population groups (35–38) (*high confidence*). For some women, the financial implications of healthy eating, or adapting to advised diets can be a barrier (38) (*moderate confidence*). Authors also stressed the importance of engaging family support (especially partners) in helping women adapt to dietary changes (35, 37) (*moderate confidence*). In addition, some women with GDM hold the belief that recommended dietary changes may not support the optimal wellbeing of the developing baby so may be reluctant to accept dietary advice (34, 37) (*low confidence*). In regard to physical activity advice, some women may be more likely to engage with the advice because of a desire to avoid pharmacotherapy (*low confidence*) (36).
- *Women with all types of diabetes:* Among women with all types of diabetes, some may struggle to incorporate additional physical activity into their routines because of family or work-related commitments (*high confidence*) (16, 33–35, 39). In addition, some women in specific contexts may be reluctant to exercise because of cultural beliefs around pregnancy or because they feel uncomfortable about exercising in public (*moderate confidence*) (16, 35, 37, 40).

Acceptability to implementers

- The QES found that, from the health-care provider perspective, women are generally receptive to dietary advice (*high confidence*) provided it is delivered in a clear, understandable format in a sensitive, empathic manner (*high confidence*) (16). Some providers, however, expressed a sense of frustration when they encountered women who appeared unwilling or unable to adhere to dietary advice (*moderate confidence*) (16).
- In some contexts, providers felt dietary information was predominantly focused on a 'western' diet and didn't address the needs of culturally diverse populations (*moderate confidence*) (16). This left some providers feeling poorly prepared and lacking the resources (including dietary information in different languages and/or translators) to offer appropriate advice to some minority population groups (*low confidence*) (16).
- Some health-care providers found conversations about weight to be challenging, especially with women who became defensive about their weight (*low confidence*) or with women from specific cultural backgrounds who held different beliefs about weight management during pregnancy (*low confidence*) (16).

- Indirect evidence suggests that some health-care providers found protocols and guidelines about the management of diabetes in pregnancy to be confusing and sometimes conflicting and wanted more clarity about the advice and guidance they should be giving to pregnant women (*moderate confidence*) (16).

Feasibility

- The QES found that some health-care providers lack the time to discuss dietary, physical activity and weight management advice with women (*high confidence*) (16). Furthermore, findings also indicate that a few health-care providers omit dietary advice completely and move straight to discussing insulin use because they don't feel they have the time to explain information about diet (*low confidence*). In addition, some health-care providers felt that they lacked knowledge and skills and wanted more training on a variety of issues related to lifestyle advice including nutrition, physical activity and cultural awareness (*moderate confidence*). In some contexts, providers also highlighted a shortage of dieticians as a potential barrier to the provision of appropriate dietary advice for women with diabetes (*low confidence*).

Antenatal education

Recommendation

2 For pregnant women with type 1, type 2 or gestational diabetes, provide education on:

- the effects of diabetes in pregnancy on maternal, fetal, newborn and child health outcomes;
- diet and physical activity;
- appropriate gestational weight gain;
- managing glycaemia;
- the need for additional monitoring of fetal growth and wellbeing.

Rationale

- Education and counselling in pregnancy to improve maternal health outcomes was recommended by the WHO 2016 antenatal care guidelines (10). The GDG noted the need for education specific to diabetes during pregnancy in addition to the education and counselling provided routinely as part of antenatal care.

Remarks

Benefits and harms

- The limited evidence identified through the systematic review conducted to inform this guideline suggested that education of women with GDM resulted in a possible increase in follow-up for assessment for development of type 2 diabetes in the long term, potentially due to increased understanding of the need for re-assessment (n=107 women) (*low certainty*). The GDG noted that this lack of evidence does not negate the known positive effects of engaging with women.

Potential approaches to diabetes-specific antenatal education

- Culturally relevant resources may be beneficial and promote women's empowerment, shared decision-making, and health literacy.

Equity and human rights

- Evidence from the QES suggests that additional educational sessions may have financial implications for some women which could limit engagement (*low confidence*) (16). Health-care providers highlighted the extra costs associated with attendance for additional clinic visits including transportation, childcare and time off work. They also mentioned the lack of translation services in several high-income settings, which could result in an inequitable service for some women from migrant and refugee communities (*low confidence*).

Acceptability

- *Women with type 1 or type 2 diabetes:* The QES found that some women view pregnancy as an opportunity for change and would welcome the opportunity to learn more about how to manage their condition (*moderate confidence*) (17). Women may also want more information about the effects of diabetes on pregnancy provided it is delivered in a clear, understandable and consistent format (*moderate confidence*) by health-care providers who are sensitive to their specific needs (*high confidence*). In addition, some women would like more peer support, so may benefit from antenatal education initiatives that provide this opportunity (*moderate confidence*).
- *Women with GDM:* The systematic reviews referenced in the QES found that women had varying experiences with regard to the quality and amount of information provided though there was a general desire for more information (including education), especially individualized information given by health-care providers with whom they had an existing relationship (*high confidence*) (35–38). Some women from different ethnic minority backgrounds living in high-income countries also found there was a lack of culturally appropriate information and/or access to translators (*moderate confidence*) (37). For some women, the lack of continuity (seeing different health-care providers at each clinic visit) resulted in inconsistent and/or conflicting information (*high confidence*) (33, 35, 36, 38) and the limited time spent with health-care providers at each visit sometimes led to women feeling unsatisfied because educational needs were overlooked (*moderate confidence*) (36, 38). Therefore, women with GDM often supplemented their educational needs by accessing online resources (of varying quality) or online support groups (*moderate confidence*) (36). While there were different views about the amount of education and information provided, some women with GDM felt that there was too much focus on diabetes and not enough on the actual pregnancy (*moderate confidence*) (41).
- *Health-care providers:* The QES of health-care providers' views on providing maternity care to women with diabetes found that providers recognized the need for more education, information and resources for pregnant women, particularly those with GDM who may not be familiar with the condition (*high confidence*) (16). Some health-care providers also highlighted the importance of using pictures, videos and interactive resources to make the information more understandable to a broad cross-section of women from different educational backgrounds and ethnicities (*low confidence*). However, some health-care providers also raised the possibility of 'information overload', especially for women with GDM, who may already be processing a significant amount of new information (*low confidence*).

Feasibility

- Evidence from the QES suggests that some health-care providers lacked the knowledge and skills (including sociocultural awareness) to support women with diabetes (type 1, type 2, GDM) and required

more training to improve relevant aspects of their practice (*high confidence*) (16). Indirect evidence indicated that diabetes services for pregnant women were often running at full capacity or overloaded (*high confidence*). Health-care providers highlighted a lack of time and the unavailability of resources (including health-care staff and translators) as key factors in their ability to provide 'additional' support and services to women with all types of diabetes (*high confidence*).

Specialized care

Recommendations

3	For pregnant women with type 1 or type 2 diabetes, deliver multidisciplinary and specialized care provided by health-care providers trained in maternal and diabetes care.
4	For women with gestational diabetes, consider multidisciplinary and specialized care provided by health-care providers trained in maternal and diabetes care, depending on access and availability.

Rationale

- In light of a lack of direct empirical evidence on specialized care for pregnant women with diabetes, the GDG developed this recommendation based on the complex care needs of women with diabetes during pregnancy, which warrant specialized care.

Remarks

What is specialized care?

- Specialized services aim to deliver timely, high-quality care that addresses pregnancy and diabetes care and their interrelated effects in pregnancy, over and above routine antenatal care. Specialized care may include a multidisciplinary team that integrates diabetes and antenatal care, with systems established to facilitate communication between team members.

Who provides specialized care?

- The team may comprise experts in different aspects of care that are known to be effective for pregnant women with diabetes (such as an obstetrician, endocrinologist/diabetologist, maternal fetal medicine specialist, pharmacist, midwives, specialist nurses, a nutritionist/dietician, exercise specialist, psychologist, counsellor, etc.), and may connect with other local services as needed (e.g. social work). Care may be coordinated through case conferences, digital care platforms or other available mechanisms.

Setting

- In some settings, specialized care may be provided at a local/regional centre that is not co-located with routine antenatal services. Some provision may be possible via telehealth. In some contexts, standard care for pregnant women with type 1, type 2 or GDM may already be somewhat specialized.

Aims of specialized care

- Although this list is non-exhaustive, specialized care may aim to:
  - provide education and psychological support to the pregnant woman to manage her diabetes during pregnancy;

- support the woman in monitoring blood glucose;
- support the woman in maintaining target glucose levels;
- effectively manage the use of insulin and/or oral glucose-lowering agents in pregnancy;
- provide individualized dietary and activity advice, education and support;
- undertake and respond to appropriate fetal surveillance.

Equity and human rights

- Indirect evidence from the QES (16) indicates that specialized services may not be available in all settings, particularly in low-income contexts (***l****ow confidence****).***
- In addition, where specialized services are available, the additional costs associated with attendance (transportation, childcare, time away from work) may be prohibitive for some women, especially those on low incomes and/or those requiring extra clinic visits to support other aspects of their antenatal care and/or diabetic management (*low confidence*).

Feasibility

- Indirect evidence from the QES (16) suggests that health-care providers recognize the importance of inter-professional collaboration and a multidisciplinary team approach to care (*moderate confidence****).***
- ***Indirect evidence from the same review*** (16) suggests that some health-care providers would like more specialized training to better understand diabetes management during pregnancy (*moderate confidence****).***

3.1.2 Glucose monitoring

Mode of glucose monitoring

Recommendations

5	For pregnant women with type 1, type 2 or gestational diabetes, recommend SMBG in addition to routine care, where feasible.
6	For pregnant women with type 1 diabetes, recommend the use of a CGM system, where feasible.
7	For pregnant women with type 2 or gestational diabetes, do not routinely recommend use of a CGM system.

Rationale

- Regular monitoring of blood glucose levels, and recognizing when they are low or high, is crucial to managing diabetes during pregnancy and preventing complications. Women using insulin or other glucose-lowering agents require more frequent monitoring.
- The GDG noted that SMBG has been standard care for people with type 1 diabetes since the mid- to late-1980s and it is unethical not to offer it in this population.
- In the context of potential harm to the developing baby from both hypoglycaemia and hyperglycaemia and limited empirical evidence on the harms and benefits of different modes of glucose monitoring during pregnancy, these recommendations provide guidance on the appropriate mode of monitoring for the different types of diabetes.

Remarks

These recommendations supersede and extend beyond the previous WHO self-care recommendations, which recommend SMBG for non-pregnant people with type 1 or type 2 diabetes using insulin based on individual need, and for women with GDM (42).

Benefits and harms

- *Self-monitoring of blood glucose (SMBG):* The systematic review conducted to inform this guideline found only very low certainty evidence for women with type 1 diabetes and no evidence for women with type 2 diabetes so conclusions about harms and benefits cannot be drawn. For women with GDM, compared to glucose monitoring at antenatal visits, there was evidence of a reduction in gestational weight gain, birthweight, large for gestational age, macrosomia, shoulder dystocia, and birth injury with SMBG (*high certainty*). No harms were identified for any group.
- *Continuous glucose monitoring:* For women with type 1 diabetes, there was a probable increase in third trimester time in target glucose range, and a probable reduction in neonatal intensive care unit admission with CGM compared to SMBG (*moderate certainty*). There was also a possible increase in wellbeing (patient satisfaction and perceived quality of life at 34 weeks) (*low certainty*). For women with GDM, there was a reduction in gestational weight gain (*high certainty*).

Frequency of monitoring

- There is insufficient evidence to support a recommendation on the frequency of monitoring in any type of diabetes during pregnancy. The frequency of monitoring will depend on the severity of the woman's diabetes, and availability of health-care services and other resources.

Routine use

- While Recommendation 7 advises against *routinely recommending* use of CGM in pregnant women with type 2 diabetes or GDM due to resource implications, this does not preclude its use for some pregnant women with diabetes (e.g. in women with GDM using insulin) where its use could potentially improve outcomes, where available.

Equity and human rights

- Evidence from the QES indicates that in some low-income contexts the availability of equipment/devices required to monitor glucose levels (glucometers, sensors, etc) may be limited or lacking (*low confidence*) (16). In settings where women (or their families) are expected to buy monitoring equipment/devices they may not have the resources to do so (*low confidence*) (16, 17).

Acceptability

- Evidence from the QES suggests that some women with type 1 or type 2 diabetes become more anxious about their blood glucose levels during pregnancy and tend to check/test their levels more frequently (sometimes multiple times a day), irrespective of the monitoring system used (*high confidence*) (17). Losing control of their diabetes management (due to pregnancy) can be disconcerting and worrying for women (*high confidence*), some of whom may require additional psychological or emotional support from health-care providers to address their concerns (moderate confidence).

- Although findings vary, some women with GDM find blood glucose monitoring to be a useful way of managing their condition without the use of insulin (*moderate confidence*) (37). However, some women with GDM find blood glucose monitoring to be time consuming and socially isolating (*moderate confidence*) (33), with some expressing concern about the associated pain and potential bleeding (*moderate confidence*) (33, 35). In addition, for women unused to the routine of blood glucose monitoring, there was a tendency to forget to test at regular intervals (*moderate confidence*) (38). The use of smartphone apps or health centre reminders sometimes negated this problem (*low confidence*) (38).

Feasibility

- While the QES found no direct evidence regarding the feasibility of different monitoring systems from the perspective of health-care providers (16), indirect evidence suggests that some may require additional training to better understand the management of diabetes during pregnancy (*moderate confidence*) and that some find guidelines and protocols for diabetes management (including monitoring) during pregnancy to be inconsistent, confusing and occasionally outdated (*moderate confidence*).

Glycated haemoglobin (HbA1c)

Recommendations

8	For pregnant women with type 1 or type 2 diabetes, measure HbA1c in the first trimester or as soon as antenatal care is initiated.
9	For women with gestational diabetes, do not routinely measure HbA1c.

Rationale

- HbA1c is used to reflect average plasma glucose over the last 8 to 12 weeks and is recommended by WHO to establish the diagnosis of type 2 diabetes and monitor glycaemic control in people with diabetes outside of pregnancy (28).
- In light of a lack of empirical evidence on health benefits of measuring HbA1c for pregnant women with diabetes, the GDG developed recommendations based on the capacity for testing of HbA1c early in pregnancy for women with type 1 or type 2 diabetes to act as an adjunct to risk stratification (e.g. in identifying risk for serious complications). The GDG acknowledged that HbA1c is not useful in caring for women with GDM.

Remarks

Availability

- The availability and affordability of HbA1c testing varies between countries and health-care settings (43).

Follow-up after testing

- Follow-up after HbA1c testing will depend on the individual woman's results and available resources.

Routine use

- While Recommendation 9 advises against *routinely recommending* HbA1c measurement in women with GDM, this does not preclude its use in clinical contexts where its use could potentially improve outcomes.

In some settings, HbA1c measurement may be used to identify type 1 or type 2 diabetes that was present before the pregnancy.

Equity and human rights

- Indirect evidence from the QES suggests that HbA1c monitoring may have financial implications for some women with low or limited incomes (*low confidence*) (16). Extra costs associated with attendance for additional clinic visits including transportation, childcare and time off work may be of particular concern for women on low incomes who may already require extra clinic visits to support their antenatal care and/or diabetes management (*low confidence*) (16).

Acceptability

- Evidence from the QES suggests that some women with type 1 or type 2 diabetes find HbA1c testing to be beneficial and reassuring (*low confidence*) (17). However, some women may feel guilty or anxious when their HbA1c levels do not fall within recommended or acceptable levels (*high confidence*), or frustrated or angry when their encounters with health professionals focus disproportionately on the HbA1c reading (and diabetes management) rather than on routine antenatal care (*low confidence*).

Feasibility

- Indirect evidence from the QES suggests that some health-care providers may require additional training to better understand the management of diabetes during pregnancy (*moderate confidence*) and find different guidelines and protocols for diabetes management (including screening and monitoring) during pregnancy to be inconsistent, confusing and occasionally outdated (*moderate confidence*) (16).
- The GDG noted that convenience and ability to self-monitor may be factors that influence the modes of testing that are implemented.

Glycaemic targets

Recommendation

10 For pregnant women with type 1, type 2 or gestational diabetes, individualize glycaemic targets to optimize glycaemic control and improve maternal and neonatal outcomes.

Rationale

- Glycaemic targets during pregnancy are usually lower than outside of pregnancy due to underlying pathophysiology and treatment risks (44). In type 1 diabetes, the absolute deficiency of insulin predisposes women to frequent glycaemic variability and a higher risk of severe hypoglycaemia, necessitating a careful balance between tight glucose control and safety. Therefore, glycaemic targets are often individualized based on hypoglycaemic risk. In contrast, individuals with type 2 diabetes typically retain some endogenous insulin secretion, leading to more stable glycaemic profiles and enabling more aggressive early control, although targets must be moderated in the presence of cardiovascular comorbidities or advanced age.
- The WHO PEN (Package of Essential Noncommunicable Disease Interventions) protocol recommends that most people with diabetes aim for an HbA1c of 7.0% (53 mmol/mol). If HbA1c measurement is not

available, a target fasting blood glucose of ≤7 mmol/L (126 mg/dl) and a postprandial plasma glucose of ≤9 mmol/L (45) can serve as surrogates. However, an individualized approach is encouraged in setting the patient's target level for glycaemic control, taking into account their comorbidities, risks from medication side-effects and likely benefit from tight glycaemic control in view of life expectancy (46).

- In the context of limited empirical evidence, the GDG developed this recommendation based on the potential harm to the developing baby from hypoglycaemia and hyperglycaemia and the importance of glucose monitoring as noted in Recommendation 5.

Remarks

Benefits and harms

- The systematic review conducted to inform this guideline found that for women with type 1 diabetes:
  - for *very tight* glycaemic targets (fasting plasma glucose [FPG] 3.33 to 5.00 mmol/L [60 to 90 mg/dL]) versus *moderately tight* glycaemic targets (FPG 5.27 to 6.38 mmol/L [95 to 115 mg/dL]), there was no evidence of benefit and possible increases in the percentage of days with maternal hypoglycaemia (n=22 women) and increased length of postnatal hospitalization (n=137 women) (*low certainty*);
  - for *tight* glycaemic targets (FPG <5.6 mmol/L [<101 mg/dL]) versus *moderate* (FPG 5.6 to 6.7 mmol/L glycaemic targets [101 to 121 mg/dL]) there was no evidence of benefit or harm;
  - for *moderate* glycaemic targets (FPG target 5.6 to 6.7 mmol/L [101 to 121 mg/dL]) versus *loose* glycaemic targets (FPG 6.7 to 8.9 mmol/L [121 mg/dL to 160 mg/dL]), there were possible reductions in caesarean birth (n=44 women), large-for-gestational age (n=44 babies) and respiratory distress syndrome (n=44 babies) (*low certainty*) and no certain evidence of harm.
- For *tight versus moderate* glycaemic targets or *moderate versus loose* glycaemic targets, the lack of harm is not established as many outcomes were of very low certainty.
- For women with GDM, with *tight versus moderate* glycaemic targets there was little to no difference in effect on induction of labour (n=1097 women), mean birthweight (n=1202 babies), large-for-gestational age (n=1202 babies), length of maternal antenatal hospitalization (n=1097 women), length of neonatal hospitalization (n=1097 babies), and length of postnatal hospitalization (n=1097 women) (*high certainty*), suggesting a lack of harm.

Individualized care

- The low certainty evidence identified through the review challenges the assumption that stricter glycaemic control always leads to better outcomes. In type 1 diabetes, tight control may increase harm (hypoglycaemia), highlighting the need for individualized targets that balance safety, benefits and resource use. In addition, the use of an individualized target allows for consistency in approach and ease of use in clinical practice. Other considerations include the woman's values and preferences, her ability to manage a hypoglycaemic event, and her access to health care.

New technologies

- Available technologies for glucose monitoring and control differ between high-income and low-income settings. In all contexts, the training that health-care providers can access will influence the technologies they are able to recommend.

Equity and human rights

- While the QES found no direct evidence, indirect evidence suggests that if women are required to attend a clinic to monitor glycaemic targets there may be financial implications that could be challenging for women with low or limited incomes (*low confidence*) (16). Health-care providers highlighted the extra costs associated with attendance for additional clinic visits including transportation, childcare and time off work. This was of particular concern for women on low incomes who already required extra clinic visits to support their pregnancy care and/or diabetes management (*low confidence*).

Acceptability

- Evidence from the QES indicates that some women find staying within specific glycaemic targets difficult to achieve (hard work) (*high confidence*) (16). Findings also suggest that some women feel under pressure to remain within glycaemic targets and feel criticized or judged by health-care providers when they fail to do so (*high confidence*). Findings from the same review (16) also show that losing control of their diabetes management (as a consequence of pregnancy) can be disconcerting and worrying for women, some of whom may require additional psychological or emotional support from health-care providers to address their concerns (*high confidence*). Evidence also shows that, while some women with type 1 or type 2 diabetes feel reassured by visiting clinics for regular monitoring, others wish to continue to self-manage to retain a sense of autonomy (*moderate confidence*) (16).
- Women with GDM felt they needed time to adjust to the new routine in order to achieve glycaemic targets and often felt there was insufficient time to do so (33, 36) (*high confidence*). Findings also show that concerns about the wellbeing of their baby was a major stimulus for achieving glycaemic targets and resulted in feelings of satisfaction and control when they were able to do so (33, 36, 41) (*high confidence*).
- The QES found no direct evidence regarding the acceptability of glycaemic targets from the perspective of health-care providers.

Feasibility

- While the QES found no direct evidence, indirect evidence suggests that some health-care providers may require additional training to better understand the management of diabetes during pregnancy (*moderate confidence*) (16). Indirect evidence from the same review also suggests that some health-care providers found different guidelines and protocols for diabetes management (including screening and monitoring) during pregnancy to be inconsistent, confusing and occasionally outdated (*moderate confidence*).

3.1.3 Pharmacological treatment

Type 1 diabetes

Recommendations

11	For pregnant women with type 1 diabetes, recommend continuation of the same type of insulin used before pregnancy unless a change is considered necessary to optimize blood glucose control and outcomes for the woman and baby.
12	For pregnant women with type 1 diabetes, recommend continuation of the method of insulin delivery used before pregnancy unless a change is considered necessary to optimize blood glucose control and outcomes for the woman and baby.

Rationale

- The GDG acknowledged that women with type 1 diabetes will likely be using insulin before becoming pregnant and considered the optimal approach to optimize blood glucose control and outcomes for the woman and baby.

Remarks

Choice of insulin

- The GDG acknowledged that the systematic review of evidence from randomized trials did not identify a clear difference in benefits and harms between different types of insulin during pregnancy (see *Desirable* and *undesirable effects* below). The choice of insulin for pregnant women with type 1 diabetes will be based on the woman's experiences of insulin before becoming pregnant, her glycaemic control during pregnancy, and local availability and expertise. When treatments previously used are continued into pregnancy, it is important to monitor glycaemic control and modify the regimen promptly when it is not achieving optimal blood glucose control.

Method of insulin delivery

- The GDG acknowledged that the availability of different methods for insulin delivery varies across countries and in various contexts and settings (e.g. twice daily injections, multiple daily injections, continuous subcutaneous insulin infusion, automated insulin delivery systems).

Frequency of insulin injections

- Based on physiological evidence, insulin resistance increases during the second and third trimesters of pregnancy (47). The GDG acknowledged that, although the evidence on the frequency of insulin injections in pregnant women with type 1 diabetes is limited, increased frequency of insulin injections or continuous subcutaneous insulin infusion may be required. Indirect evidence from the systematic review of evidence conducted to inform this guideline suggests improved glycaemic control with four times compared to twice daily injections in women with GDM. Automated insulin delivery systems and/or hybrid closed loop therapy may also be a consideration, as available.

Timing of insulin

- The GDG acknowledged that the study included in the systematic review that addressed this question did not provide evidence of a clear difference in benefits and harms between different timings of insulin during pregnancy (e.g. before or after meals). Indirect evidence (in non-pregnant type 1 diabetes populations) suggests that insulin before meals is advisable (48).

Adjunctive metformin

- Although the GDG prioritized this question, the systematic review identified no randomized trials investigating the use of adjunctive metformin for women with type 1 diabetes in pregnancy.

Desirable and undesirable effects of insulin types

- The systematic review conducted to inform this guideline identified the following comparisons and findings. The GDG acknowledged that changes in the market mean that some medications may become unavailable and that new products may become available and trigger review of the guidelines as evidence emerges.

- Compared to regular human insulin, treatment with rapid-acting insulin analogues may reduce the risk of preterm birth (<37 weeks) (absolute risk [AR] 110 fewer per 1000, 95% confidence interval [CI] from 178 fewer to 3 fewer; one trial, 268 babies; *low certainty*) and there is no clear indication of other desirable or undesirable effects.
- Compared to neutral protamine Hagedorn (NPH) insulin, treatment with insulin detemir may increase the risk of pre-eclampsia (AR 46 more per 1000, 95% CI from 0 more to 409 more; one trial, 310 women; *low certainty*) but there is no clear indication of other desirable or undesirable effects.
- For insulin degludec compared to insulin detemir, there is no clear evidence of desirable or undesirable effects (one trial, 188 women).

Desirable and undesirable effects of methods of insulin delivery

- There is no clear evidence of desirable or undesirable effects for continuous subcutaneous insulin infusion compared to conventional insulin delivery (multiple daily injections) (five trials, 169 women); insulin before compared to after meals (one crossover trial, nine women); or different settings for sensor-augmented pumps (one crossover trial, 11 women).

Resources

- The review of economic evaluations (18) identified a 2009 economic evaluation of an RCT included in the systematic review of effectiveness evidence. The evaluation compared regular human insulin with insulin aspart in 302 pregnant women with type 1 diabetes and reported that insulin aspart resulted in more live births ≥37 weeks without increasing total costs of treatment (49). However, the live birth endpoint was retrospectively applied and the treatment costs of human and insulin aspart were found to be identical because it had been assumed that both preparations were administered via cartridge whereas administration via cartridge for human insulin was not available at the time in the National Health Service of the United Kingdom of Great Britain and Northern Ireland.
- Evidence from surveys suggests that human insulins are more affordable than insulin analogues, with prices sourced from the public and private sectors in surveyed countries typically showing a 3- to 5-fold difference between the lowest and highest reported prices per 1000 international units (50).

Acceptability

- Evidence from surveys of women participating in an RCT suggests that insulin aspart is acceptable and may lead to slightly higher treatment satisfaction than regular human insulin because of flexibility with timing of injection before a meal (51).
- Evidence from the QES suggests that some women find it difficult when health-care providers change their medications (as a consequence of pregnancy) (17).

Type 2 diabetes

Recommendations

13	For pregnant women with type 2 diabetes who are unable to maintain optimal blood glucose levels with diet and physical activity alone, recommend initiation of metformin or insulin to optimize blood glucose control and outcomes for the woman and baby.
14	For pregnant women with type 2 diabetes who are receiving monotherapy with insulin or metformin and who are unable to achieve optimal blood glucose levels, consider initiation of a combination of metformin and insulin to optimize blood glucose control and outcomes for the woman and baby.
15	For pregnant women with type 2 diabetes who are already receiving glucose-lowering medication, recommend that medications with safety concerns during pregnancy be replaced with insulin and/or metformin.
16	For pregnant women with type 2 diabetes who required insulin to achieve optimal blood glucose levels before pregnancy, recommend continuation of the same type of insulin unless a change is considered necessary to optimize blood glucose control and outcomes for the woman and baby.

Rationale

- The GDG acknowledged that, while some women with type 2 diabetes may maintain optimal blood glucose levels with diet and physical activity alone before becoming pregnant, a woman's insulin requirement increases during the second and third trimesters of pregnancy (47). In this context, some women may need to initiate a glucose-lowering agent to optimize blood glucose control and outcomes for the woman and baby.

Remarks

Choice of glucose-lowering agent

- The GDG acknowledged that there is no clear difference in benefits and harms between metformin and insulin during pregnancy (see below), and clinical practices and availability of medications are highly variable. The choice of glucose-lowering agent for pregnant women with type 2 diabetes will be based on the woman's experiences of medication before becoming pregnant, her glycaemic control during pregnancy, local availability and expertise, and her values and preferences.
- The GDG noted that many blood-glucose lowering agents are either not recommended for use in pregnancy or do not have adequate safety data in pregnancy (e.g. glucagon-like peptide-1 receptor agonists [GLP-1RA] and sodium-glucose transport protein 2 [SGLT2] Inhibitors).

Dose of glucose-lowering agent

- The GDG acknowledged that, although the evidence on type 2 diabetes during pregnancy is limited, increased monitoring and/or intensity of glycaemic management may be required. Continuous subcutaneous insulin infusion may also be a consideration, as available.

Desirable and undesirable effects

- The systematic review conducted to inform this guideline identified the following comparisons and findings. The GDG acknowledged that changes in the market mean that some medications may become unavailable and new products may become available and trigger review of the guidelines as evidence emerges.

- For metformin compared to insulin, there is no evidence of desirable or undesirable effects as all outcomes were of very low certainty (one trial, 25 women). It should be noted that a significant proportion of women initially treated only with metformin will require the addition of insulin later in the pregnancy to achieve optimal glycaemic control
- Among women already receiving insulin, there is evidence of probable moderate desirable effects with metformin plus insulin compared to placebo plus insulin – reduced risk of caesarean birth (AR 94 fewer per 1000, 95% CI from 169 fewer to 6 fewer; one trial, 470 women; *moderate certainty*) and macrosomia (AR 71 fewer per 1000, 95% CI from 113 fewer to 6 fewer; one trial, 461 babies; *moderate certainty*) and a reduction in gestational weight gain (mean difference [MD] 1.8 kg lower, 95% CI 2.7 kg lower to 0.9 kg lower; one trial 482 women; *moderate certainty*) with adjunctive metformin. However, there is also evidence of probable moderate undesirable effects – small-for-gestational age (AR 64 more per 1000, 95% CI from 6 more to 168 more; one trial, 460 babies; *moderate certainty*).
- There may be small differences in the effects of insulin detemir compared with NPH – a possible desirable effect on reduced gestational weight gain (MD 3.62 kg lower, 95% CI 3.99 kg lower to 3.25 kg lower; one trial, 103 women; *low certainty*) but possible small undesirable effects – lower birthweight (MD 450.30 g higher, 95% CI 163.63 g higher to 736.97 g higher; one trial, 103 babies; *low certainty*).

Acceptability

- Evidence from studies included in the systematic review of effectiveness evidence comparing metformin with insulin for the treatment of GDM suggests that treatment satisfaction is higher with metformin than with insulin (52–54), which may be extrapolated to women with type 2 diabetes.

Availability

- The WHO 2021 report on access to insulin suggests that there are a significant number of markets in lower-income countries and in the WHO African Region, WHO South-East Asia Region and WHO Eastern Mediterranean Region where the availability of insulin does not meet demand (50).

Gestational diabetes

Recommendations

17	For women with GDM who are unable to achieve optimal blood glucose levels with diet and physical activity alone, recommend initiation of metformin or insulin to optimize blood glucose control and outcomes for the woman and baby.
18	For women with GDM who are receiving monotherapy with metformin or insulin and are unable to achieve optimal blood glucose levels, consider initiation of a combination of metformin and insulin to optimize blood glucose control and outcomes for the woman and baby.

Rationale

- The GDG acknowledged that, while some women with GDM may maintain optimal blood glucose levels with diet and physical activity alone, other women may need to initiate a glucose-lowering agent to optimize blood glucose control and outcomes for the woman and baby.

Remarks

Commencement of pharmacotherapy

- The GDG acknowledged that a two-week trial of diet and physical activity to achieve glycaemic control is typically conducted before considering commencement of blood glucose-lowering medication for GDM. The trials comparing different pharmacological agents included in the systematic review used a range of lengths of diet/activity (when described this ranged from 3 to 28 days, most commonly seven days). However, in some settings and for some clinical presentations (e.g. based on level of glycaemic control or maternal/fetal concerns), medication may be commenced without a trial of diet/activity.

Trigger for treatment initiation or change

- In the trials comparing different pharmacological agents included in the systematic review, thresholds used for insulin initiation, treatment agent switch and dose escalation were poorly and inconsistently reported. In most studies, the trigger for FPG was 5.0 to 5.5 mmol/L (90 to 100 mg/dL), with some using stricter (3.4 to 5.0 mmol/L [60 to 90 mg/dL]) or looser (<6.1 mmol/L [<110 mg/dL]) targets. One-hour postprandial targets ranged from <6.5 to <9.0 mmol/L (<117 to <162 mg/dL) and most studies used a two-hour postprandial target of <6.7 mmol/L (120 mg/dL), ranging between <5.6 and <7.8 mmol/L (<100 mg/dL and <140 mg/dL).
- In clinical practice, a flexible approach may be appropriate and triggers for treatment initiation or change will likely be based on a woman's blood glucose control and clinical criteria that reflect local realities (e.g. food insecurity, challenges in monitoring or follow-up), aiming to balance safety and feasibility.

Choice of glucose-lowering agent

- The GDG acknowledged that although there is some indication of possible benefits of commencing with metformin, overall the evidence does not strongly support metformin over insulin as a first-line medicine. Many women who begin pharmacotherapy with metformin will go on to need insulin. Clinical practices and the availability of medications are highly variable. The choice of glucose-lowering agent for women with GDM will be based on the woman's glycaemic control, local availability and expertise, and her values and preferences.
- Many blood-glucose lowering agents are either not recommended for use in pregnancy or do not have adequate safety data in pregnancy (e.g. GLP-1Ras and SGLT2 inhibitors). However, the GDG acknowledged that there may be situations where a blood-glucose lowering agent other than insulin or metformin needs to be considered (e.g. when a woman refuses insulin and metformin is not tolerated or is ineffective in achieving the woman's glycaemic control). In these circumstances other agents, such as a sulfonylurea, may be considered after discussion of potential benefits and harms.

Dosage of glucose-lowering agent

- Titration of medications for glycaemic control is individualized and guided by regular blood glucose monitoring.

Stopping treatment with glucose-lowering agents

- The GDG acknowledged that usual clinical practice is to stop treatment with glucose-lowering agents soon after the birth of the baby. Due to the increased risk of type 2 diabetes in women who have experienced GDM (7), follow-up assessment of glucose tolerance is essential 6 to 12 weeks postnatally.

Desirable and undesirable effects

- The systematic review conducted to inform this guideline identified the following comparisons and findings. The GDG acknowledged that changes in the market mean that some medications may become unavailable and new products may become available and trigger review of the guidelines as evidence emerges.

  Comparisons with placebo or no agent

  – When metformin is compared to placebo, there is evidence of moderate desirable effects – lower rates of need for initiation of insulin (AR 108 fewer per 1000, 95% CI from 164 fewer to 39 fewer; two trials, 622 women; *high certainty*) and large-for-gestational age (AR 84 fewer, 95% CI from 112 fewer to 37 fewer; one trial, 522 babies; *high certainty*) and a slight reduction in gestational weight gain (MD 1.13 kg lower, 95% CI 1.63 kg lower to 0.64 kg lower; three trials, 705 women; *high certainty*) and birthweight (MD 137.58 g lower, 95% CI 207.23 g lower to 67.92 lower; three trials, 705 babies; *high certainty*). There is also evidence of small undesirable effects – an increase in low birthweight (AR 42 more per 1000, 95% CI from 2 more to 115 more; two trials, 628 babies; *high certainty*) – affecting a small proportion of those exposed (<5%).

  – When other glucose-lowering agents are compared to placebo, there is no clear indication of desirable or undesirable effects for glibenclamide (one trial, 395 women), and effects were not estimable or were assessed to be of very low certainty for sitagliptin (one trial, 263 women). Three small trials (151 women), all of which took place before 1991, compared treatment with insulin versus no insulin among women with GDM. Diet and exercise interventions varied between groups. The trials did not provide a clear indication of desirable or undesirable effects for insulin versus no insulin. Most reported outcomes were not estimable or were assessed to be very low certainty.

  Comparisons of oral glucose-lowering agents and insulin

  – When metformin is compared to insulin as a first-line medication, there is evidence of probable or possible moderate desirable effects – induction of labour (AR 78 fewer per 1000, 95% CI from 131 fewer to 10 fewer; seven trials, 1703 women; *moderate certainty*); maternal hypoglycaemia (AR 147 fewer per 1000, 95% CI from 191 fewer to 75 fewer; four trials, 702 women; *low certainty*); admission to neonatal intensive care (AR 50 fewer per 1000, 95% CI from 80 fewer to 14 fewer; 16 trials, 3184 babies; *moderate certainty*); macrosomia (AR 44 fewer per 1000, 95% CI from 65 fewer to 17 fewer; 14 trials, 2728 babies; *low certainty*), shoulder dystocia (AR 16 fewer per 1000, 95% CI from 23 fewer to 0 fewer; five trials, 1290 babies; *low certainty*), neonatal hypoglycaemia (AR 97 fewer per 1000, 95% CI from 121 fewer to 69 fewer; 19 trials, 4104 babies; *low certainty*) and respiratory distress syndrome (AR 19 fewer per 1000, 95% CI from 32 fewer to 1 fewer; 10 trials, 2288 babies; *low certainty*). There is no clear indication of undesirable effects. The GDG acknowledged, however, that many women on metformin will progress to requiring insulin to maintain or achieve glycaemic control.

  – For glibenclamide compared to insulin, there is no clear indication of desirable effects, and evidence of probable moderate undesirable effects – maternal hypoglycaemia (AR 24 more per 1000, 95% CI from 3 more to 88 more; three trials, 988 women; *moderate certainty*) and neonatal hypoglycaemia (AR 28 more per 1000, 95% CI from 4 more to 62 more; nine trials, 1967 babies; *moderate certainty*) affecting a small proportion of those exposed (<3% for both outcomes).

  – There is no clear indication of desirable or undesirable effects for acarbose versus insulin (most outcomes very *low certainty*) (two trials, 150 women).

Comparisons of one oral glucose-lowering agent with another

– For metformin versus glibenclamide, there is evidence of possible moderate desirable effects – lower gestational weight gain (mean 7.78 kg versus 9.84 kg; MD 2.06 kg lower, 95% CI 3.98 kg lower to 0.14 kg lower; one trial, 200 women; *low certainty*) and reduced risk of large-for-gestational age (AR 111 fewer per 1000, 95% CI from 156 fewer to 16 fewer; one trial, 200 babies; *low certainty*) for >10% of exposed population, and no clear indication of undesirable effects. There is no clear indication of desirable or undesirable effects for glibenclamide versus acarbose (one trial, 43 women).

Comparisons of protocols

– When glibenclamide is compared to insulin as a second-line treatment to metformin, there is no clear indication of desirable effects and evidence of possible moderate undesirable effects – increase in birthweight (mean 3706 g versus 3262 g; MD 444 g higher, 95% CI 16.62 higher to 871.38 higher; one trial, 23 babies; *low certainty*). There is no clear indication of desirable or undesirable effects when glibenclamide (first line), metformin (second line), insulin (third line) is compared to metformin (first line), glibenclamide (second line), insulin (third line) (one trial, 108 women).

Comparisons of types of insulin

– There is no clear indication of desirable or undesirable effects for premixed insulin analogue versus premixed human insulin (one trial, 323 women), rapid-acting insulin analogue versus regular human insulin (five trials, 330 women), or intermediate-acting human insulin versus regular human insulin (one trial, 23 women).

Comparison of frequency of insulin

– When twice daily insulin is compared with insulin four times daily, there is evidence of possible moderate undesirable effects – neonatal hypoglycaemia (AR 500 more per 1000, 95% CI from 282 more to 855 more; one trial, 480 babies; *low certainty*) and hyperbilirubinaemia (AR 400 more per 1000, 95% CI from 252 more to 602 more; one trial 480 babies; *low certainty*). The systematic review analysis found a possible reduction in maternal hypoglycaemia in the twice daily compared to the four times daily group (AR 296 fewer per 1000, 95% CI from 332 fewer to 250 fewer; two trials, 754 women; *low certainty*). However, when the GDG requested further information, the systematic review team provided data that showed that 'glycaemic control' (an outcome not prioritized for the review) was improved in the four times daily group in both trials reporting the comparison.

Acceptability

- Evidence from studies included in the systematic review of effectiveness evidence comparing metformin with insulin for the treatment of GDM suggests that treatment satisfaction is higher with metformin than with insulin (52–54).

Limitations of the evidence

- The GDG acknowledged that the available evidence on pharmacotherapy for women with GDM is highly heterogeneous. Gestational age at trial commencement and the length of any initial trial of diet and/or exercise is variable, it is often unclear how many women received insulin in addition to the agent being trialled, and reporting of outcomes for women receiving 'rescue' insulin is poor.

3.1.4 Additional monitoring

Additional fetal monitoring

Recommendations

19	For pregnant women with type 1, type 2 or gestational diabetes, perform a routine ultrasound scan before 24 weeks.
20	For pregnant women with type 1 or type 2 diabetes, consider performing the routine ultrasound scan as early as possible in pregnancy with a follow-up ultrasound to assess fetal anatomy and growth in the second trimester.
21	For pregnant women with type 1, type 2 or gestational diabetes, consider additional ultrasound growth scans after 24 weeks, as indicated.
22	For pregnant women with type 1, type 2 or gestational diabetes requiring blood glucose-lowering medication, consider additional monitoring of fetal wellbeing, as indicated.

Rationale

- Monitoring to assess growth and wellbeing of the developing baby is a routine part of antenatal care, particularly in high-income countries. WHO recommends ultrasound before 24 weeks to estimate gestational age, improve detection of fetal anomalies and multiple pregnancies, reduce induction of labour for post-term pregnancy, and improve a woman's pregnancy experience (10). It also recommends that healthy pregnant women be made aware of the importance of fetal movements in the third trimester and of reporting reduced fetal movements, and that clinical enquiry about maternal perception of fetal movements occur at each antenatal care visit as part of good clinical practice (10).
- Given the potential for congenital anomalies and other adverse perinatal outcomes among women with diabetes of any type during pregnancy, the GDG considered that earlier and additional fetal monitoring is optimal.

Remarks

- There is little empirical evidence on fetal monitoring for pregnant women with type 1, type 2, or GDM. The GDG considered an approach that is woman-centred, based on the ethical principle of autonomy including the importance of informed decision making, and physiological evidence on how diabetes might impact pregnancy outcomes. In pregnant women with diabetes, the GDG acknowledged that antenatal fetal monitoring may help to inform the timing of childbirth.

Benefits and harms

- Based on limited evidence identified through the systematic review conducted to inform this guideline, there was no suggestion of benefits or harms with increased frequency of ultrasound scans (scans at 28 and 32 weeks compared to at 32 weeks only) in women with GDM (n=154 women). There was also no evidence of benefit or harm with computerized compared to visual interpretation of the nonstress test in women with unspecified diabetes and an indication for fetal heart assessment (n=85 women), although the lack of benefit or harm is not established as the limited outcomes reported were of very low certainty. For ultrasound growth scan compared to no ultrasound growth scan among women with 'pregestational and gestational diabetes', there was a probable reduction in small-for-gestational age (n=304 babies)

(*moderate certainty*), a probable increase in risk of caesarean section (n=3994 women) (*moderate certainty*) and a possible increase in risk of induction of labour (n=304 women) (*low certainty*).

Indications for additional ultrasound scans after 24 weeks

- Additional ultrasound scans after 24 weeks aim to identify growth restriction and accelerated growth and help in planning for the birth. Their use may be indicated when restricted or accelerated growth is suggested by fundal height measurement or in the context of complicated diabetes (i.e. insulin treated or when glycaemic control is poor) and will likely be based on availability of resources.
- Modelling to estimate the effect of the interval between examinations on fetal growth in the general pregnant population suggests that taking measurements at least three weeks apart may minimize false positive rates (55). False positive rates were higher when the first scan was performed at 36 weeks (compared to first scan at 32 weeks) (55).

Women's values

- Evidence from the 2016 *WHO recommendations on antenatal care for a positive pregnancy experience* (10) showed that within the context of maternal and fetal assessment, women valued the opportunity to receive screening and tests to optimize their health and that of their developing baby as long as individual procedures were explained to them clearly and administered by knowledgeable, supportive and respectful health-care providers (*high confidence*).

Equity and human rights

- Indirect evidence from the QES suggests that additional fetal monitoring may have financial implications for some women with low or limited incomes (*low confidence*) (16). Health-care providers highlighted the extra costs associated with attendance for additional clinic visits including transportation, childcare and time off work. This was of particular concern for women on low incomes who may already require extra clinic visits to support their antenatal care and/or diabetic management (*low confidence*).

Acceptability

- Evidence from the QES suggests that some women with type 1 and type 2 diabetes found additional fetal monitoring to be beneficial and reassuring (*low confidence*) (17). Some women also indicated they would like more ultrasounds during the antenatal phase to curb feelings of anxiety (*low confidence*). However, evidence also suggests that some women may find it difficult to attend extra clinic visits because of work, family or financial considerations (*low confidence*) (17).
- For women with GDM, indirect evidence suggests that women with GDM may struggle to attend extra clinic visits because of work, family or financial considerations (40).

Feasibility

- Indirect evidence from the QES suggests that some health systems may struggle to cope with enhanced services for pregnant women with diabetes given the extra demands (staff and equipment) required to support these services in already overstretched health systems (*high confidence*) (16).

Retinopathy screening and care

Recommendations

23	For pregnant women with type 1 or type 2 diabetes, screen for retinopathy when antenatal care is initiated and provide follow-up based on the risk of retinopathy progressing.
24	For women with gestational diabetes, do not routinely screen for retinopathy.

Rationale

- Maintaining strict glycaemic control plays a vital role in reducing the risk of developing and worsening diabetic retinopathy. Persistent hyperglycaemia damages the small blood vessels of the retina, contributing to both non-proliferative and proliferative stages of diabetic retinopathy. Research indicates that not only average glucose levels but also fluctuations in blood glucose significantly influence the progression of diabetic retinopathy (56). Additionally, higher HbA1c levels correlate with increased retinopathy severity, although differences in disease progression are observed even among individuals with similar HbA1c readings (57). Recent studies further emphasize that initiating and maintaining good glycaemic control early can effectively delay the onset of diabetic macular oedema and the transition to proliferative disease stages (58).
- In the light of a lack of empirical evidence on screening for retinopathy, the GDG based its recommendations on the increased risk of retinopathy and its consequences associated with type 1 or type 2 diabetes (59), and a lack of risk for retinopathy in women with GDM.

Remarks

Follow-up after screening

- The GDG acknowledged that in some settings, it is common to re-screen pregnant women with type 1 or type 2 diabetes later in pregnancy but there is no standard timeframe for repeat screening. The GDG also acknowledged, that this practice may not be feasible or available in all settings.

Routine screening

- While Recommendation 24 advises against *routinely recommending* retinopathy screening for women with GDM, this does not preclude its use in clinical contexts where its use would potentially improve outcomes for the individual woman.

Equity and human rights

- Indirect evidence from the QES suggests that enhanced retinopathy care may have financial implications for some women with low or limited incomes (*low confidence*) (16). Health-care providers highlighted the extra costs associated with attendance for additional clinic visits including transportation, childcare and time off work. This was of particular concern for women on low incomes who already required extra clinic visits to support their antenatal care and/or diabetes management (*low confidence*).

Acceptability

- Indirect evidence from the QES suggests that some women find additional diabetes screening and monitoring services to be beneficial and reassuring (*low confidence*) (17). However, some women may find it difficult to attend extra clinic visits because of work, family or financial considerations (*low confidence*).

- Indirect evidence highlights the importance of teamwork, especially for women receiving additional (or enhanced) services (16). Some health-care providers felt there were gaps in the system caused by poor communication between different disciplines and/or departments and stressed the importance of 'joined up' care and efficient, multidisciplinary teamworking (*moderate confidence*).

Feasibility

- Indirect evidence from the QES suggests that some health systems may struggle to cope with enhanced services for pregnant diabetic women given the extra demands (in terms of resources, staff training and equipment) required to support these services in already overstretched health systems (*high confidence*) (16).

Renal assessment

Recommendations

25	For pregnant women with type 1 or type 2 diabetes, assess renal function when antenatal care is initiated and arrange specialist follow-up for women if impaired renal function is identified.
26	For women with GDM, do not routinely assess renal function.
27	For pregnant women with type 1 or type 2 diabetes with impaired renal function, emphasize the importance of maintaining blood pressure levels below 130/80 mmHg during pregnancy and offer antihypertensives known to be safe in pregnancy as indicated. Advise women to modify major risk factors for cardiovascular disease (e.g. smoking, unhealthy diet, sedentary behaviour) and to seek specialist postnatal follow-up.

Rationale

- Diabetic nephropathy is the most common cause of chronic kidney disease and end-stage renal disease worldwide. It arises as a microvascular complication of chronic hyperglycaemia, leading to structural damage within the glomeruli and progressive loss of kidney function (60). The early stages of diabetic nephropathy, characterized by microalbuminuria, signal systemic endothelial dysfunction and serve as a critical marker of poor metabolic control. Importantly, the progression of renal disease often mirrors the overall status of diabetes management – individuals with worsening nephropathy typically exhibit persistent hyperglycaemia, hypertension and dyslipidaemia (61).
- Laboratory assessment for renal function during pregnancy includes measurement of serum creatinine and protein in urine. Tests for proteinuria include spot albumin, protein/creatinine ratio, and 24-hour urine collection for albumin/protein. While estimated glomerular filtration rate (eGFR) is used in assessing renal function outside of pregnancy, its accuracy is reduced during pregnancy (62, 63). The GDG acknowledged that the different tests may not be available in all settings.
- Early and aggressive interventions targeting hyperglycaemia, blood pressure control, and renin-angiotensin-aldosterone system inhibition are now the foundation of management (64).
- In the light of a lack of empirical evidence on renal assessment for women with diabetes, the GDG based its recommendations on the increased risk of impaired renal function associated with type 1 and type 2 diabetes, and a lack of risk for impaired renal function in women with GDM.

Remarks

Assessing pre-eclampsia risk

- The urinary albumin/creatinine ratio or protein/creatinine ratio early in pregnancy may be used as a baseline when evaluating the risk of pre-eclampsia later in pregnancy.

Routine assessment

- While Recommendation 26 advises against *routine* renal assessment for women with GDM, this does not preclude its use in clinical contexts where its use would potentially improve outcomes, such as providing a baseline for comparison later in pregnancy during an evaluation for pre-eclampsia.

Blood pressure management

- Recommendation 27 has been adapted from advice for the management of type 2 diabetes, using medications that are used for blood pressure management during pregnancy. The WHO guideline on the treatment of non-severe hypertension in pregnancy suggests consideration of oral alpha-agonist (methyldopa) and beta-blockers as effective treatment options (65).

Equity and human rights

- Indirect evidence from the QES suggests that renal assessment at initiation of antenatal care may have financial implications for some women with low or limited incomes (l*ow confidence*) (16). Health-care providers highlighted the extra costs associated with attendance for additional clinic visits including transportation, childcare and time off work. This was of particular concern for women on low incomes who already required extra clinic visits to support their antenatal care and/or diabetes management (l*ow confidence*).

Acceptability

- Indirect evidence from the QES suggests that some women with type 1 or type 2 diabetes find additional assessment and monitoring services to be beneficial and reassuring (*low confidence*) (17). However, indirect evidence from this review also suggests that some women find it difficult to attend extra clinic visits because of work, family or financial considerations (*low confidence*)
- Indirect evidence highlights the importance of teamwork, especially for women receiving additional (or enhanced) services (16). Some health-care providers felt there were gaps in the system caused by poor communication between different disciplines and/or departments and stressed the importance of 'joined up' care and efficient, multidisciplinary teamworking (*moderate confidence*).

Feasibility

- Indirect evidence from the QES suggests that some health systems may struggle to cope with enhanced services for pregnant women with diabetes given the extra demands (in terms of resources, staff training and equipment) required to support these services in already overstretched health systems (*high confidence*) (16).

4 Dissemination and implementation of the guideline

The dissemination and implementation of this guideline is to be considered by all stakeholders involved in the provision of care for pregnant women at the international, national and local levels. There is a vital need to increase women's access to maternal health care and strengthen the capacity at health-care facilities of all levels to ensure they can provide high-quality services to all women giving birth. It is therefore crucial that the guideline recommendations be translated into care packages and programmes at country and health-care facility levels, where appropriate. In particular, the recommendations will need to be incorporated into existing programmes and policies on the management of diabetes in pregnancy and childbirth. The guideline may also inform the care of women with diabetes who are planning a pregnancy.

4.1 Dissemination and evaluation

Dissemination of an executive summary containing the recommendations, remarks, implementation considerations and research priorities will increase public awareness of the recommendations. Derivative tools developed by the WHO Steering Group will also aid understanding and adaptation of these recommendations to local contexts.

The recommendations and derivative tools will be disseminated through WHO regional and country offices, ministries of health, professional organizations, WHO collaborating centres, other United Nations agencies and nongovernmental organizations, among others. The recommendations will be published on the WHO website and promoted in the quarterly HRP News disseminated to over 8000 subscribers, including clinicians, health programme managers, policy-makers, researchers and service users working in sexual and reproductive health from all around the world. The recommendations will also be promoted in the monthly global diabetes compact newsletter disseminated to 3000 stakeholders, shared with the Global Diabetes Compact Forum, established by WHO to foster advocacy, collaboration, and the sharing of ideas to reduce diabetes risk and improve care for people with the condition (150 stakeholders) and be highlighted on World Diabetes Day.

The executive summary and recommendations from this publication will be translated into the six official United Nations languages for dissemination through the WHO regional and country offices and during meetings and scientific conferences organized by, or attended by, staff of the WHO Department of Sexual and

Reproductive Health and Research, the Department of Maternal, Newborn, Child and Adolescent Health and the Department of Noncommunicable Diseases and Mental Health. Technical assistance will be provided to any WHO regional office willing to translate these recommendations into any language used in that region. In addition, the publication of journal articles presenting the recommendations and key implementation considerations will be considered in compliance with WHO's open access and copyright policies. Relevant WHO clusters, departments and partnerships, such as the Partnership for Maternal, Newborn and Child Health, the Global Diabetes Compact Forum, and the Technical Advisory Group for Diabetes will also be part of this dissemination process.

To ensure that these recommendations have a positive impact on maternal and perinatal health at the country level, coordinated action between international agencies, national departments of health and key maternal and perinatal health stakeholders is needed. National and subnational working groups should assess current national guidelines and protocols and determine whether development of new guidelines or updating of existing guidelines is required in line with these new WHO recommendations. WHO staff at the headquarters, regional and country levels, as well as international agency partners and international professional societies (such as the International Federation of Gynaecology and Obstetrics and the International Confederation of Midwives), and national professional associations, can support national stakeholders in developing or revising existing national guidelines or protocols, and optimizing their implementation.

In the context of humanitarian emergencies, the adaptation of the current recommendations should consider their integration and alignment with other response strategies. Additional consideration of the unique needs of women in emergency settings, including women's values and preferences, should be made. Context-specific tools and toolkits may be required in addition to standard tools to support the implementation of the recommendation in humanitarian emergencies.

4.2 Implementation considerations

As part of the recommendation development process, implementation considerations were developed. These may assist policy-makers, clinicians and other stakeholders to better prepare for implementation.

- The successful introduction of evidence-based policies related to the management of chronic medical conditions such as diabetes into the antenatal care model will depend on well-planned, participatory and consensus-driven processes of integration and implementation. These processes may include the development or revision of national guidelines or protocols based on these recommendations, and engagement with all relevant stakeholder groups, including skilled health-care providers. Modifications to the recommendations, if necessary, should be made with justification and documented in an explicit and transparent manner. The WHO Department of Sexual and Reproductive Health and Research and the WHO Department of Maternal, Newborn, Child and Adolescent Health and Ageing will support national and subnational groups to adapt and implement the recommendations based on existing strategies.
- Implementation of the recommendations for managing diabetes in pregnancy must be considered within the broader context of ensuring that all women have access to respectful, woman-centred care throughout their life course.

- National health systems must support an enabling environment for the implementation of these recommendations, including education to support behaviour change among skilled health personnel teams to facilitate the use of evidence-based practices. Clear and up-to-date clinical protocols should be available to skilled health-care providers regarding the care of medical conditions in pregnancy.
- Local professional societies and training institutions can have an important role in implementation. An all-inclusive and participatory process should be encouraged.
- National health systems must ensure that supplies of medicines and commodities are available in health-care facilities where antenatal care services are provided. These resources must be safe, legitimate and manufactured according to good manufacturing practices. To ensure that the resources are of high quality, robust and sustainable regulatory, procurement and logistics processes must be established, ensuring that good-quality products are obtained, transported and stored correctly.
- Skilled health-care providers working in settings where women receive antenatal care will require training and supportive supervision on how to integrate the care of chronic medical conditions into routine antenatal care, and how to inform and counsel women, as appropriate. In settings where a new practice is introduced (or where recommended practices are changed), additional training and monitoring may be required. In contexts with high rates of personnel turnover, pre-service training and regular opportunities for ongoing training and competency assessment are particularly important.

4.3 Anticipated impact on the organization of care and resources

Effective implementation of the recommendations in this guideline may require reorganization of care and redistribution of health-care resources, particularly in low- and middle-income countries. The GDG noted that updating training curricula and providing training on the recommendations would increase their impact and facilitate their implementation.

As part of efforts to implement these recommendations, health-system stakeholders may wish to consider the following potential barriers to their application:

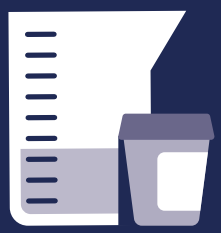
- feasibility of components of the recommendations, barriers and facilitators to their implementation;
- lack of human resources with the requisite expertise and skills to implement, supervise and support recommended practices;
- lack of infrastructure and multidisciplinary teams to support interventions;
- lack of resources for active implementation strategies;
- lack of essential equipment, supplies (e.g. insulin) and consumables (e.g. syringes for injection of insulin);
- lack of health information management systems designed to document and monitor recommended practices (e.g. patient records, registers);

- lack of consistent staffing from high provider turnover impacting the sustainability and scalability of interventions; and
- limited access to health services during emergencies and crises.

4.4 Monitoring and evaluating guideline implementation

The implementation and impact of these recommendations will be monitored at the health service, country and regional levels, as part of broader efforts to monitor and improve the quality of maternal and newborn care. The WHO document *Standards for improving quality of maternal and newborn care in health facilities* (66) provides a list of prioritized input, output and outcome measures that can be used to define quality of care criteria and indicators and that should be aligned with locally agreed targets. In collaboration with the monitoring and evaluation teams of the WHO Department of Sexual and Reproductive Health and Research and the WHO Department of Maternal, Newborn, Child, Adolescent Health and Ageing, data on country- and regional-level implementation of the recommendations will be collected and evaluated in the short to medium term to assess their impact on national policies of individual WHO Member States. Interrupted time series could be used to obtain the relevant data on the use of interventions contained in this guideline.

5 Research implications



The GDG identified important knowledge gaps directly related to the PICO questions, or which may have a direct impact on the implementation of these recommendations. The following areas were identified as priority questions for high-quality evidence generation.

5.1 Core practices in caring for women with diabetes during pregnancy

- What are women's preferences and values regarding diabetes education during pregnancy, and how do these affect engagement and outcomes?
- What is the effectiveness of culturally sensitive, woman-centred education interventions in improving maternal and neonatal outcomes in women with diabetes?
- What is the appropriate gestational weight gain range for women with diabetes, and how does it differ from general pregnancy recommendations?
- What training or task-sharing models effectively support non-specialist providers to deliver diabetes care and education during pregnancy in low-resource settings?
- How can self-care be supported and which services and support can be provided via telehealth (e.g. antenatal education, check-ins to assess glycaemic control)?
- Can a risk prediction tool or scoring system be developed and validated to identify pregnant women with diabetes at higher risk of adverse outcomes?
- What is the availability and utility of epidemiological outcome data disaggregated by diabetes status (type 1, type 2, GDM) versus general 'high-risk pregnancy' categories?

5.2 Glucose monitoring

- What are the optimal glycaemic targets in pregnancy for women with type 1, type 2 diabetes, or GDM to balance maternal and neonatal outcomes while minimizing hypoglycaemia?

- How should HbA1c and CGM targets be defined and used for different types of diabetes during pregnancy, especially in type 2 diabetes and GDM?
- What is the effectiveness and cost-effectiveness of CGM in pregnant women with type 2 or GDM, particularly women on insulin?
- How do serial HbA1c measurements and their trajectory across pregnancy relate to maternal and neonatal outcomes in women with type 1 or type 2 diabetes?
- What maternal and neonatal outcomes are associated with different glycaemic thresholds (e.g. fasting, 1 hour, 2 hour) based on Hyperglycemia and Adverse Pregnancy Outcome study (HAPO)-derived odds ratios, and how should they inform diagnostic criteria?

5.3 Pharmacotherapy

5.3.1 Type 1 diabetes in pregnancy

- What is the effectiveness of different insulin types (short- and long-acting human and analogue, and premixed), regimens (twice daily and basal-bolus) and delivery methods (syringe and vials, pens, insulin pumps, automated insulin delivery systems) on glycaemic control and maternal and neonatal outcomes for women with type 1 diabetes?
- Does the addition of metformin to insulin improve glycaemic control and maternal and neonatal outcomes compared to insulin alone?
- Can automated insulin delivery systems, with algorithms tailored to the physiological needs of pregnancy, be safely, effectively, and equitably implemented in low- and middle-income countries?
- What is the cost-effectiveness, and what are the barriers to, and facilitators of, implementing advanced insulin technologies (pumps, automated insulin delivery systems) in low-resource settings?
- How does the availability of insulin and monitoring resources and the quality and accessibility of the care in low- and middle-income countries influence maternal and neonatal outcomes?

5.3.2 Type 2 diabetes in pregnancy

- How do metformin and insulin compare as first-line treatment for type 2 diabetes in terms of glycaemic control and maternal and neonatal outcomes?
- What is the effect of continuing metformin alone versus switching to insulin during pregnancy on glycaemic control and maternal and neonatal outcomes?
- What is the effectiveness and safety of oral glucose-lowering agents during pregnancy in terms of glycaemic control and maternal and neonatal outcomes?
- How does combining metformin and insulin compare to monotherapy with either agent alone for women with type 2 diabetes?
- What are the impacts of *in utero* exposure to metformin on child growth, adiposity, and metabolic outcomes compared with children of women with type 2 diabetes in pregnancy not exposed to metformin?

- How do twice-daily, basal bolus and premixed insulin regimens compare in terms of efficacy, safety, and feasibility in low-resource settings?
- What are the barriers, facilitators, and cost-effectiveness implications of scaling up insulin and metformin access, including advanced insulin delivery methods, in low- and middle-income countries?

5.3.3 Gestational diabetes mellitus

- How do metformin and insulin compare as first-line treatment for GDM in terms of glycaemic control and maternal and neonatal outcomes?
- How does combining metformin and insulin compare to monotherapy with either agent alone for women with GDM?
- Which women with GDM require escalation to insulin, and what criteria best predict treatment failure with metformin or diet alone?
- What are the impacts of *in utero* exposure to metformin on child growth, adiposity, and metabolic outcomes compared with children of women with GDM in pregnancy not exposed to metformin?
- What are the short-term and long-term maternal and neonatal outcomes, acceptability, adherence, and cost-effectiveness of GDM treatments (metformin, insulin, combination) in low- and middle-income countries?

5.4 Additional monitoring and assessments

- For which subgroups of women with GDM is multidisciplinary or intensified care beneficial, and how should 'specialized care' be defined?
- What is the comparative effectiveness of different fetal monitoring strategies (e.g. ultrasound, Doppler, cardiotocography, fundal height) in improving outcomes among pregnant women with diabetes?
- How acceptable and feasible are various fetal monitoring strategies for women with diabetes across different health system settings?
- What is the optimal timing and frequency of retinopathy screening during pregnancy for women with pre-existing diabetes?
- Is serum creatinine or eGFR a more accurate marker for assessing renal function during pregnancy in women with diabetes?

6 Updating the recommendations

The Maternal and Perinatal Health Guideline Technical Advisory Group convenes regularly to review WHO's current portfolio of maternal and perinatal health recommendations and to help WHO prioritize new and existing questions for recommendation development and updating. These recommendations will be included in those reviews. In the event that new evidence that could potentially impact the current evidence base is identified, these recommendations may be updated. If no new reports or information is identified, the recommendations may be revalidated.

WHO welcomes suggestions regarding additional questions for inclusion in the updated recommendations. Please email your suggestions to srhmph@who.int.

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Annex 1.
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Annex 2.
Priority outcomes used in decision making

Priority outcomes included for all PICOs

Critical maternal outcomes

- Maternal death
- Maternal functioning and well-being
- Women's views and experiences

Important maternal outcomes

- Antenatal hospitalization
- Admission to intensive care
- Mode of birth

Critical newborn outcomes

- Stillbirth/fetal death
- Neonatal death
- Perinatal death

Important newborn outcomes

- Admission to neonatal intensive care
- Gestational age at birth
- Preterm birth (<32 weeks; <37 weeks)
- Birthweight
- Intrauterine growth restriction
- Low birthweight (<2500 g)
- Small-for-gestational age (<10th centile for gestational age)
- Apgar score of less than seven at five minutes
- Neurodevelopmental outcomes (into infancy and childhood)

Health service outcomes

- Antenatal admissions to hospital for the woman and length of stay
- Emergency department visits for the woman
- Admission to intensive care unit for the woman
- Length of postnatal hospitalization for the woman
- Length of neonatal hospitalization
- Costs of care for the woman or baby or both

Priority outcomes for individual PICOs

Maternal outcomes

- Early pregnancy loss (spontaneous or elective)
- Induction of labour
- Gestational weight change
- Glycaemia (time in range, hypoglycaemia)
- Hypertensive disorders of pregnancy (pre-eclampsia; any hypertensive disorder of pregnancy)
- Postpartum haemorrhage
- Childbirth-related injuries (e.g. perineal injuries etc)
- Diabetes later in life (maternal)
- Diabetes in the longer term (for GDM population)
- Diabetes-specific patient-reported outcomes
- Chronic kidney disease
- Long-term cardiometabolic outcomes
- Obesity in the longer term
- Visual loss or blindness
- Worsening retinopathy

Newborn outcomes

- Amniotic fluid abnormalities (polyhydramnios and oligohydramnios)
- Macrosomia
- Large-for-gestational age
- Birth injury
- Shoulder dystocia
- Neonatal hypoglycaemia
- Hyperbilirubinaemia
- Respiratory distress syndrome
- Transient tachypnoea of the newborn
- Neonatal seizures
- Congenital anomalies (among women who may have had poor glycaemic control prior to pregnancy)
- Breastfeeding
- Long term cardiometabolic outcomes

Annex 3.
Summary and management of declared interests from GDG members

Name and title	Expertise contributed to guideline development	Declared Interest	Management of declared interest
Guideline development group			
Sumaiya ADAMS	Obstetrics, gynaecology, content expert, and end-user	Vice chair of the Committee on the Impact of Pregnancy on Long-Term Health.	This declared conflict of interest was not considered significant enough to pose any risk to the guideline development process or to reduce its credibility. The conflict constitutes intellectual bias that does not pose major risk.
Amanda ADLER	Endocrinology, content expert, and end-user	Research funding from National Institute for Health and Care Research (NIHR) for clinical trial on diabetes in pregnancy (£4000 per year).	This declared conflict of interest was not considered significant enough to pose any risk to the guideline development process or to reduce its credibility. The conflict constitutes intellectual bias that does not pose major risk.
Fatima AL-SLAIL	Cardiology, content expert, and end-user	None declared	Not applicable
Emmanuel AMEH	Obstetrics, gynaecology, content expert, and end-user	None declared	Not applicable
Shabina ARIFF	Neonatology, content expert, end-user	None declared	Not applicable

Name and title	Expertise contributed to guideline development	Declared Interest	Management of declared interest
Stephen COLAGIURI	Endocrinology, content expert, and end-user	None declared	Not applicable
Margie DAVENPORT	Exercise physiology, content expert, and end-user	Consultant (e.g. regarding policies on exercise for pregnant athletes) to Fédération Internationale de Football Association (FIFA) and Women's Tennis Association (~20 000 CAD). Chair of the 2025 Canadian Guideline for Physical Activity, Sedentary Behaviour and Sleep throughout the First Year Postpartum. Co-Chair of the upcoming 2026 International Olympic Committee (IOC) Guideline on Recreational and Elite Athletes during and following pregnancy.	This declared conflict of interest was not considered significant enough to pose any risk to the guideline development process or to reduce its credibility. The GDG member participated in discussions but recused during development of recommendations related to exercise.
Mohamed HASSANEIN	Endocrinology, content expert, and end-user	None declared	Not applicable
Shane A NORRIS	Paediatrics, content expert, and end-user	Research grant from Canadian Institutes of Health to explore the impact of preconception health intervention of gestational diabetes incidence in women living in South Africa (CAD$ 500 000).	This declared conflict of interest was not considered significant enough to pose any risk to the guideline development process or to reduce its credibility. The conflict constitutes intellectual bias that does not pose major risk.
Rajalakshmi RAM PRAKASH	Gender and Rights Expert	None declared	Not applicable

Name and title	Expertise contributed to guideline development	Declared Interest	Management of declared interest
João Filipe RAPOSO	Endocrinology, content expert, and end-user	None declared	Not applicable
Sofia SACCONE	Endocrinology, content expert, and end-user	None declared	Not applicable
Placxedes SOSA	Patient representative	None declared	Not applicable
Nikhil TANDON	Endocrinology content expert, and end-user	Research grant from Indian Council of Medical Research (ICMR) for €657 200.	This declared conflict of interest was not considered significant enough to pose any risk to the guideline development process or to reduce its credibility. The conflict constitutes intellectual bias that does not pose major risk.
Hoang TRAN	Neonatology, content expert, and end-user	None declared	Not applicable
Kartik VENKATESH	Obstetrics, gynaecology, epidemiology, content expert, and end-user	Grant funding for diabetes research from the government of the United States of America for the following studies: ACHIEVE: Successfully achieving and Maintaining Euglycemia During Pregnancy for Type 2 Diabetes Through Technology and Coaching $1.5m DECIDE trial, $12.4m from Patient-Centred Outcomes Research Institute (PCORI)	This declared conflict of interest was not considered significant enough to pose any risk to the guideline development process or to reduce its credibility. The GDG member participated in discussions but recused during development of recommendations related to glucose monitoring. The DECIDE trial is ongoing, this was acknowledged during discussions. The participant's contributions to the discussions on the options of pharmacotherapy were restricted to published evidence as presented in the ETDs.

Name and title	Expertise contributed to guideline development	Declared Interest	Management of declared interest
External Review group			
Bosede AFOLABI	Obstetrics, gynaecology, epidemiology, content expert, and end-user	None declared	Not applicable
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Jeremy OATS	Obstetrics, gynaecology, content expert, and end-user	None declared	Not applicable

Web annex A. Evidence-to-decision frameworks for non-pharmacological care

WHO recommendations on care for women with diabetes during pregnancy: Evidence-to-decision frameworks on non-pharmacological care https://doi.org/10.2471/B09615

Web annex B. Evidence-to-decision frameworks for pharmacological care

WHO recommendations on care for women with diabetes during pregnancy: Evidence-to-decision framework on pharmacological care https://doi.org/10.2471/B09616

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