

SIGN Management of Diabetes in Pregnancy consultation

COMMENTS RECEIVED FROM EXTERNAL REFEREES AND OTHERS

All reviewers submitted declarations of interests which were viewed prior to the addressing of comments.

Invited reviewers			Type of response and declared interests
AB	Amy Brown	Advanced Pharmacist Diabetes and Endocrinology, Glasgow Royal Infirmary, Glasgow	<i>Individual response.</i> Nothing declared.
AI	Alison Irvine	Lead Diabetes Specialist Nurse, NHS Shetland	<i>Individual response.</i> Nothing declared.
CP	Caroline Page	Diabetes Specialist Nurse, NHS Orkney	<i>Individual response.</i> Nothing declared.
CPk	Christine Park	Consultant in Diabetes and Endocrinology, Aberdeen Royal Infirmary, NHS Grampian	<i>Individual response.</i> Nothing declared.
FS	Fiona Strachan	Consultant Diabetologist, NHS Grampian	<i>Individual response.</i> <u><i>Non-personal financial interests</i></u> Endowment grants for education to staff on team from NHSG <u><i>Non-financial personal interests</i></u> Currently working with Digital Health and Innovation team as part of Moray Growth Deal funding looking at development of app-based technologies to support personalised patient held data base with applicability to linking with primary/secondary care/third sector partners. Also allied to Right Decision Tool activity via to highlight opportunities in primary care for diabetes prevention.

HR	Hannah Robertson	Consultant Physician - Diabetes and General Internal Medicine, NHS Grampian	<p><i>Individual response.</i></p> <p><u>Personal financial</u> Speaker fee from Janssen (Johnston and Johnston) September 2015</p>
KM	Kenneth Muir	Consultant in Diabetes and Endocrinology, Raigmore Hospital, Inverness	<p><i>Individual response.</i></p> <p>Nothing declared.</p>
LE	Laurie Eyles	Professional Adviser, Framework for the Prevention, Early Detection and Early Intervention of Type 2 Diabetes, Scottish Government	<p><i>Individual response.</i></p> <p><u>Personal non-financial</u> Professional Adviser role involves speaking publicly on the national approach by Scot Gov to type 2 diabetes prevention and remission, including at conferences sponsored by patient advocacy groups i.e. Diabetes UK – Scottish Government – ongoing.</p> <p>Advising on website content/speaking at conference on diet, weight management and treatment - Talk Lipoedema – ceased April 2023.</p> <p><u>Non-personal, non-financial</u> Obesity – PhD researcher in my team conducted clinical research and published outcomes/speaks nationally and internationally about them - NHS Lothian Dietetics – ongoing – topic specific.</p>
MSJ	Mohammad Sadiq Jeeyavudeen	Consultant Diabetes and Endocrinology, Western General Hospital, Edinburgh	<p><i>Individual response.</i></p> <p>Nothing declared.</p>
SB	Sarah Bruce	Diabetes Specialist Nurse and Independent Nurse Prescriber, Aberdeen Royal Infirmary, Aberdeen	<p><i>Individual response.</i></p> <p>Nothing declared.</p>
SC	Sinead Currie	Lecturer in Health Psychology, University of Stirling	<p><i>Individual response.</i></p>

			Nothing declared.
SMcG	Siobhan McGuinness	Person with lived experience, Glasgow	<p><i>Individual response.</i></p> <p><u>Interest in topic</u> I have direct experience of the condition or the services under review (as either a service user/patient/carer of a person with a related condition). I am likely to be directly impacted by the topic under review.</p> <p><u>Paid employment</u> Employed within the General Pharmaceutical Council (the body for regulation of pharmacy professionals)</p>
UH	Una Hendry	Midwife, Aberdeen Maternity Hospital, Aberdeen	<p><i>Individual response.</i></p> <p>Nothing declared.</p>
Open consultation			Type of response and declared interests
AC	Angela Cartwright	Midwife, UKHSA	<p><i>Individual response.</i></p> <p>Nothing declared.</p>
CR	Colin Rae	Consultant Anaesthetist, Glasgow Royal Infirmary, Glasgow	<p><i>Individual response.</i></p> <p>Nothing declared.</p>
CS	Christopher Smith	Consultant Physician in Diabetes and Endocrinology, Royal Alexandra Hospital, Paisley	<p><i>Individual response.</i></p> <p>Nothing declared.</p>
CW	Counterweight	Anna Bell-Hicks commenting on behalf of Counterweight	<p><i>Group response.</i></p> <p><u>Nature and purpose of your group</u> Counterweight is a provider of evidence based weight management and diabetes remission programmes. We</p>

			<p>partner with the NHS / Research institutions and provide a service direct to consumers.</p> <p><u>How might the statements and recommendations in the draft SIGN guideline impact on your organisation's functions/status/productivity?</u></p> <p>Counterweight has a strong evidence base which favours the recommendation of significant weight loss approaches using a range of dietary approaches, particularly in the case of diabetes remission, the use of a total Diet Replacement plan. The programme is called Counterweight Plus, and is already part of the Scottish government guideline for diabetes remission in the prevention and treatment Framework for diabetes. Counterweight trains and supports workforce across all Scottish Health boards to deliver the Counterweight plus programme. Our organisation may be strengthened following a recommendation in favour of the use of a Total Diet Replacement weight loss programme. Patients would have potentially another route to access this intervention which is currently restricted to very tight entry criteria in NHS Scotland.</p>
DSim	David Simmons	Professor of Medicine and Director, Diabetes Obesity and Metabolism Translational Research Unit, Western Sydney University	<p><i>Individual response.</i></p> <p>Nothing declared.</p>
DS	Doug Stewart	Diabetes Prevention Specialist Dietitian, NHS Ayrshire and Arran	<p><i>Individual response.</i></p> <p>Nothing declared.</p>
LC	Luisa Crawford	Community Dietitian, Stirling Community Hospital, Stirling	<p><i>Individual response.</i></p> <p>Nothing declared.</p>
LW	Lesley White	Diabetes Dietitian, NHS Fife	<p><i>Individual response.</i></p> <p>Nothing declared.</p>

RCN		Caroline Rapu, Programme Manager, Quality Assurance of Resources/Callum Metcalfe-O'Shea, RCN Professional Lead for Long Term Conditions commenting on behalf of the Royal College of Nursing	<p><i>Group response.</i></p> <p><i>Nature of your group/organisation – professional body.</i></p> <p><i>How might the statements/recommendations in the draft impact on your organisation – the draft SIGN recommendations will have an impact on how nurses and midwives will care for and support pregnant women with diabetes</i></p>
SMc	Steve McCabe	Clinical Director of Primary Care, NHS Highland	<p><i>Individual response.</i></p> <p>Nothing declared.</p>
TL	Tara Lee	Clinical Research Fellow, Diabetes and SpR O&G, Norfolk and Norwich University Hospitals NHS Foundation Trust	<p><i>Individual response.</i></p> <p>Nothing declared.</p>

General: Have the epidemiology and the clinical context of the target condition been accurately described?			
<i>Section</i>	<i>Reviewers</i>	<i>Comment</i>	<i>Development group response</i>
	AB, AI, CP, CPK, DS, HR, KM, LW, MSJ, SC, SMc, TL, UH	Yes (all listed reviewers answered “yes” individually to this question)	Thank you
	AC	Yes Although there could have been more attention to the socio-economic disparities, particularly of T2DM and GDM, this would not have changed the recommended care.	Thank you. We acknowledge this fact and have added a sentence to section 1.1 to emphasise this, “The guideline development group notes that, as with type 2 diabetes, GDM is more prevalent in people from economically disadvantaged groups and ensuring that testing and treatment are made available to all women on an equitable basis is a key aim of service delivery.”
	CW	Yes/No. How many women with type 2 diabetes are overweight or obese? How many women with type 1 diabetes are overweight or obese? These are important statistics to help plan weight management services in the preconception stage.	Thank you. We have added the following statistics to section 1.1: In 2022, 67% of adults with type 1 diabetes and 89% of adults with type 2 diabetes were overweight or obese. (Scottish Diabetes Survey 2022)
	LE	Yes, I think the guideline is incredibly comprehensive in this respect, certainly from my perspective, however there will be experts better placed than me to comment on this question.	Thank you
	SMcG	Yes.	Thank you

		It is clear this guideline is for diabetes in pregnancy and it is concise in the statistics within the introduction of why the guideline is required.	
General: Please comment on the sections providing the perspective of people with lived experience we have engaged with. Does the guideline accurately reflect the views and experiences of people with lived experience?			
	AB, AC, AI, CP, CPK, DS, KM, MSJ, SC, SMc, SMcG, TL	Yes (all listed reviewers answered "yes" individually to this question)	Thank you
	CW	Preconception care. I apologise if I have missed this but I did not read of any involvement from people living with diabetes of reproductive age around the recommendations you have made in this guideline. I would highly recommend that diabetes remission interventions are discussed with people living with overweight or obesity with type 2 diabetes and for those who are type 1 the benefits of weight loss for both mother and future offspring. This is missing in the checklist for provision of information at section 7.	<p>The guideline development group has included two members with type 1 diabetes who have experienced pregnancies. The group also includes representation from Diabetes UK who engage with, represent and advocate for people living with diabetes.</p> <p>SIGN contacted organisations which represent women with diabetes, including Diabetes Scotland, The Alliance, IPAG Scotland, BHF, CHSS and Carers Trust, to identify issues of concern. We also asked members of the SIGN Patient and Public Involvement Network to highlight any relevant issues.</p> <p>Diabetes remission is not part of the scope of this guideline, however is being addressed in another SIGN guideline in development on prevention and early recognition and treatment of type 2 diabetes. This comment has been shared with that group.</p>
	HR	<p>Yes.</p> <p>I'm not sure how the patient perspective was achieved - was it part of the guideline group/surveys - how wide a reach was there? If only part of the guideline group, this may not be truly reflective of those who have struggled with diabetes or find accessing care more challenging and there are no references in this section which may have helped gain appreciation of this.</p>	Thank you. As above.

	LE	<p>For me, I was surprised not to see more about how stigmatised women feel, particularly those with type 2 and GDM in pregnancy (this might be reflective of the lived experience panel on your guideline group – there is a big difference in my experience in how women with type 1 vs women with type 2/GDM experience their pregnancy journey. It is a very common theme in consultations and focus groups that women feel their body weight/BMI is the focus of clinical discussions, often feeling labelled, blamed and guilty that due to their diet and lifestyle they have placed their pregnancy and baby at risk. This study The WRISK project: Understanding and improving the way risk in pregnancy is communicated to women - SSA (addiction-ssa.org) did a huge amount of work speaking to women with lived experience and understanding how health professionals could better communicate pregnancy risk to women. Body weight and diabetes featured frequently. I understand that Big Births - BMI 30+? Pregnant? Trying to Conceive? Post Natal? UK Info & Support is supporting RCOG with their review of current clinical guideline on managing obesity in pregnancy? (Rebecca R will likely know more!) so if you wanted to try and get more balance (if needed!) then this might be a good source of feedback.</p>	<p>Thank you for this comment.</p> <p>Agree – we have added a point to section 1.1.1 acknowledging this issue and encouraging HCPs to use sensitive language and to avoid blame/guilt.</p> <p>We have added a bullet point containing a link to this resource in the Provision of information section:</p> <p>“Using person-centred communication skills, sensitively highlight risks relating to congenital malformation, miscarriage, stillbirth and abnormal growth of the baby (small or large for gestational age). Explain the evidence supporting these risks and help the woman to weigh up and evaluate her choices without implying blame or negatively impacting her experience of pregnancy.”</p>
1.1	DSim	<p>Para 1: Many of the 4-10% have IFG/IGT and lesser degrees of hyperglycaemia fulfilling the criteria for GDM when entering pregnancy so should not be called incident GDM. This will be confusing when we enter the discussions over early vs incident GDM. We had a discussion over this in Sydney 2022.</p> <p>Para 2: “neonatal admission” could better be termed “Neonatal intensive care unit admission (eg with neonatal respiratory distress)”.</p>	<p>Thank you. We have revised this to “up to 11% of pregnancies may be complicated by incident gestational diabetes (GDM) and early screening may detect up to 3% of women with likely undiagnosed diabetes in early pregnancy.”</p> <p>We have also added a new section (1.2.3) to the introduction with the definitions which we use throughout the guideline, including GDM which acknowledges that some women may have raised HbA1c levels in early pregnancy which do not meet diagnostic thresholds and who have not received an oral glucose tolerance test. Such women may be considered on the pathway for gestational diabetes.</p> <p>Thank you. We have made this change.</p>

1.1.1	DSim	Bullet point 2: Suggest add – “Avoiding negative comments and promoting the positives”.	Disagree. While we agree with the intention, these comments were derived from patient groups to represent the perspective of women with diabetes and we prefer the framing that emphasises this.
	SMcG	Section 1.1.1 defines the main concerns of people with lived experience.	Thank you
Section 3: Preconception care			
Are the summaries of benefits and harms, safety, and cost effectiveness evidence accurate and reasonable interpretations of the evidence?			
	AB, AC, DS, HR, SC, SMC, SMCg, TL, UH	Yes (all listed reviewers answered “yes” individually to this question)	Thank you
	AI	Yes. For Type 2 preconception planning it suggests intermittently-scanned glucose monitoring as a possibility for optimising glucose control. With the latest update of the Libre 2 and the availability of DEXCOM 1 on prescription is the description of intermittently-scanned (flash) glucose monitoring now obsolete. As described in Section 4.1.1	Thank you – we have added a new section on definitions to the introduction which includes CGM (now section 1.2.3, including material moved from 4.1.1). The description of isCGM is not obsolete when we are considering published evidence using it in that mode. We also acknowledge the functional update to Freestyle Libre 2 and we note that all current CGM systems can now function in real time.
	CP	Yes. Evidence base along with cost effectiveness really clear.	Thank you
	CW	No. There is omission of evidence for diabetes remission for those living with overweight or obesity and type 2 diabetes- The DiRECT Trial. Durability of a primary care-led weight-management intervention for remission of type 2 diabetes: 2-year results of the DiRECT open-label, cluster-randomised trial. The Lancet Diabetes and Endocrinology https://doi.org/10.1016/S2213-8587(19)30068-3 .	Thank you. This is not directly relevant to the scope of this guideline. Weight management is a routine aspect of pre-pregnancy counselling and we have added a new GPP to offer dietary advice to all women who are planning pregnancy. We note that this is one of several weight mgmt. programmes. This comment has been shared with the prevention and early recognition and treatment of type 2 diabetes group. The new GPP is “Women should be offered advice on weight management prior to pregnancy in line with guidance from the Royal College of Obstetricians and Gynaecologists and national programmes (for example, the Type 2 diabetes - Framework for prevention, early detection and

			intervention). This is likely to be of particular benefit to women with type 2 diabetes or prior GDM when planning pregnancy.”
	KM	Yes. I didn't see anything on cost effectiveness.	Thank you. No evidence on cost effectiveness of interventions was identified in this section.
	SB	Yes. High dose Folic acid 5 mg for a minimum 3 months prior to conception.	Thank you. We have included the sentence in para 1 “High-dose Folic Acid (5 mg) should be prescribed and taken for three months prior to stopping contraception to reduce the risk of congenital abnormalities.” We have reinforced this with a new GPP in this section “All medications should be reviewed prepregnancy for suitability in pregnancy and women should be advised to take 5 mg Folic acid for at least 3 months prior to conception.”
3.1.1	CPk	When talking of CGM and closed loop systems, there is no differentiation specified between type 1 diabetes and other forms of pre-existing diabetes.	Agreed – we have clarified this sentence by adding “...in women with T1DM”.
3.1.2	MSJ	Para 12: It reads "...tighter control will increase the incidence of hypoglycaemia"....It is not always that tighter control will increase the incidence of hypoglycaemia. If this can be modified to the frequency of hypoglycaemia is increased in compared to with the liberal target	Agreed – we have modified this to “carries a potential to increase....”
Section 3: Preconception care			
To what extent is the evidence presented generalisable to NHSScotland?			
	AB	The evidence considers both Scottish data as well as studies from similar populations.	Thank you
	AC	Is CGM available for women with T2DM in Scotland? Aware in England, there is a reluctance to provide these even to women using insulin.	Yes – based on individualised assessment for women with insulin-treated type 2 diabetes.
	CP	This is really important for our primary care teams as they may be the only contact for our Type 2 women.	Thank you
	CPk	I would mirror the concerns raised later that setting targets too tight may disengage those who feel this would be unattainable and don't feel they would try at all.	Thank you – Agreed. We have removed the word “target” from the GPP which already emphasises that any fixed level of HbA1c should not be used as a threshold for access to services. We have not set a numerical ‘target’. Agreed

		Ongoing education and support will be required to engage those with type 2 diabetes and their primary care teams.	
	HR	I think the evidence is reasonable to be generalised to preconception care.	Thank you
	KM	Not fully generalisable, but this is taken into account.	Thank you
	MSJ	The guidelines was written well and is generalisable to NHS Scotland.	Thank you
	SC	Yes, the evidence presented is generalisable to NHS Scotland.	Thank you
	SMcG	Preconception care as identified in the guideline is reasonable for NHS Scotland to manage with the exception of GDM. Individualised discussions with those planning pregnancy is key and this guideline highlights that.	Thank you

Section 3: Preconception care

Is there a clear link between evidence and recommendations that describes the volume, strength and consistency of the evidence? E.g. after reading the relevant section of the guideline, can you understand the basis for the suggested recommendations?

	AB, AC, AI, CP, CPk, DS, MSJ, SB, SMc, SMcG, TL, UH	Yes (all listed reviewers answered “yes” individually to this question)	Thank you
	CW	Yes. With the exception of omitting the evidence from the DiREct trial, this is well written. Durability of a primary care-led weight-management intervention for remission of type 2 diabetes: 2-year results of the DiRECT open-label, cluster-randomised trial. The Lancet Diabetes and Endocrinology	Thank you. This evidence is well known to us and implementation is being considered through the “Type 2 diabetes prevention programme”. The comment has also been shared with the SIGN prevention and early recognition and treatment of type 2 diabetes guideline group.

		https://doi.org/10.1016/S2213-8587(19)30068-3	
	HR	No. I don't think it is has been described in the evidence how the other risk factors influence an individualised target different to HbA1c of <48 mmol/mol. With retinopathy I would aim for a more gradual reduction. Sticking to tighter HbA1c of <48 would be more important if they are already at a higher risk of preeclampsia. I would also feel that relaxing of HbA1c for an individual target would be more important based on patients' capabilities which may be limited by social situation/mental health etc	Thank you. We have replaced the word “target” in the GPP with “level”. Glucose attainment will be individualised to align with personal preferences / capacity.
	KM	Yes the recommendations make sense in light of the presented evidence. The final recommendation on patients with T2DM is worth including. I would maybe go a step further and recommend that patients with T2DM are all referred to secondary care given the numbers are small, and risks are higher. In this final recommendation I would consider replacing intermittently-scanned flash glucose monitoring with continuous glucose monitoring, or include both given recent Libre 2 updates.	Thank you. This is a good practice point and we have not reviewed an evidence base that might support a universal recommendation for all patients. Thank you – agreed. We have made this change. We have added a new section on definitions to the introduction which includes CGM and have moved some information from section 4.1.1 to this new section. Section 4.1.1 acknowledges the functional update to Freestyle Libre 2 and we acknowledge that most current CGM systems transmit information in real time.
	SC	Yes. Section 3. Suggest inclusion of Wahabi et al (2020) https://doi.org/10.1371/journal.pone.0237571 as a comprehensive systematic review and meta-analysis of the effectiveness of prepregnancy care for women with diabetes for improving maternal and perinatal outcomes.	Thank you. We have added the results of this meta-analysis which relate to the HbA1c outcome.

Section 3: Preconception care

Do you have any other comments?

<p>CW</p>	<p>There should be more emphasis provided on the best way to achieve diabetes remission through dietary means.</p> <p>Suggest you include this systematic review: Churuangsuk C, et al. Diets for weight management in adults with type 2 diabetes: an umbrella review of published meta-analyses and systematic review of trials of diets for diabetes remission. Diabetologia. 2022 Jan;65(1):14-36. Conclusions/interpretation: Published meta-analyses of hypocaloric diets for weight management in people with type 2 diabetes do not support any particular macronutrient profile or style over others. Very low energy diets and formula meal replacement appear the most effective approaches, generally providing less energy than self-administered food-based diets. Programmes including a hypocaloric formula 'total diet replacement' induction phase were most effective for type 2 diabetes remission.</p> <p>An additional benefit of following a Total Diet Replacement weight loss programme with formula food can also lead to improved nutritional status prior to pregnancy.</p> <p>Early life impacts of maternal obesity: a window of opportunity to improve the health of two generations Laura Dearden and Susan E. Ozanne Published: 24 July 2023 https://doi.org/10.1098/rstb.2022.0222</p> <p>Environmental factors are modifiable across the life course and should therefore be a focus for interventions aimed at reducing cardio-metabolic disease incidence.</p> <p>Neonatal offspring exposed to maternal obesity or GDM during pregnancy are more likely to be born with a high or low birth weight and/or increased adiposity, predisposing them to obesity later in life.</p>	<p>See above</p> <p>Thank you. This is not relevant to the scope of this guideline, however the guideline development group fully endorses the goals of the Diabetes Prevention Programme. This comment has been shared with the SIGN prevention and early recognition and treatment of type 2 diabetes guideline group.</p> <p>Thank you. We acknowledge the importance of maternal obesity to immediate maternal health and associations with later childhood obesity and its complications. We have strongly endorsed the position of trying to offer people support with achieving an optimal weight prior to pregnancy via prepregnancy counselling for women with diabetes and the type 2 prevention pathways for women with previous GDM. However, we note that the relationship of maternal obesity to later childhood disease is likely complex with shared genetic as well as early and late environmental aspects. We have not reviewed evidence in this area as it was outwith the</p>
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			remit of this guideline but have referred readers to the appropriate RCOG guidance and the Scottish Government framework for prevention, early detection and intervention for type 2 diabetes
	DSims	<p>Suggest title of section could be “Preconception care among women with known pre-existing diabetes”.</p> <p>Para 1: The word “control” is now frowned upon by diabetes language groups.</p> <p>Para 1: “Other medications such as antihypertensives, statins, and glucose lowering treatments should be reviewed and, where required, switched to alternative medication which is more suitable for pregnancy” - What about population-based intervention approaches eg Dunne-JCEM (cost effective) and EASIPOD Murphy</p> <p>Para 2: “Blood glucose levels” or concentrations?</p>	<p>Agree – change has been made.</p> <p>Agree – we have changed this to “optimising diabetes management, including glycaemia...” Throughout the guideline, we have replaced the word “control” where possible with alternative wording, where it applies to management of blood glucose levels.</p> <p>Noted. We agree, however have not reviewed these. No change required.</p> <p>No change required.</p>
	HR	Minimal mention of psychological wellbeing/mental health needing considered/addressed.	<p>Noted. This was not the focus of the key questions in this section and no relevant evidence was identified.</p> <p>In section 3.1.2 we comment “The use of rtCGM makes these levels more attainable than in the past, however, reducing glucose levels towards normal carries a potential to increase the incidence of hypoglycaemia. The effect of this and the pressures of striving for normal glucose levels on time and mental health should not be ignored. An individualised balance must be sought.</p> <p>This individualised balance is also referenced in a GPP at the end of this section.</p>
	MSJ	In this section, 7 th line reads -"other medications such as....". It would read better "All medications needs reviewed"	Agreed – this has been reworded to “All medications, including antihypertensives, statins, and glucose-lowering treatments, should be reviewed and, where required, switched to alternative medication which is more suitable for pregnancy.”
	SB	At diabetes clinic we are looking more at GMI (Glucose Management Indicator) time in range rather than HbA1c is this something that can be considered?	We agree that this is good practice, however our key question was based on HbA1c targets and the evidence we have reviewed only includes this metric. We note that there is correlation between HbA1c and metrics derived

			from CGM, such as GMI, ambulatory glucose profiles and time in/above/below range.
	SC	<p>Section 3. It is wonderful to see a section included on preconception. This is an extremely important group who are often not targeted or provided for. Behaviour change in this group is paramount as their health and behaviours prior to conception and prior to first maternity booking appointment can have irreversible influence on the growing baby.</p> <p>However I feel there is some lack of focus on this group/ time period given the emerging literature in the area of preconception health and behaviour. For example, Why are these guidelines only aimed at those actively planning a pregnancy? Given a significant proportion of pregnancies are unplanned or women were ambivalent to becoming pregnant, it seems important that these guidelines are also applicable to who women who may become pregnant in the short-mid term, regardless of pregnancy intention/ planning status.</p> <p>Furthermore, how is pregnancy planning measured e.g. London Measure of Unplanned Pregnancy, one key question (Bellanca and Hunter, 2013), or through general discussion/ consultation? Are health professionals trained or aware of how best to ask this question/ make the decision about whether someone is in the planning stage or not. It is very important that women of reproductive age who have a diagnosis of diabetes (type 1 or 2 or previous GDM diagnosis), regardless of pregnancy intent, are informed of the pathway for pregnancy planning and preparation for pregnancy. This ensures they are aware, informed and know the steps to take/ resources available to actively plan a pregnancy, when they are ready.</p> <p>Literature shows that women with type 1 diabetes often do not attend pre-pregnancy clinics due to poor knowledge and awareness, negative perceptions of</p>	<p>Thank you.</p> <p>We acknowledge that not all pregnancies are planned, however in order to deliver recommendations to known population of women with diabetes who are, or become pregnant, we have identified several stages of planned services across the individual's journey of care.</p> <p>Training of healthcare professionals is not considered in the scope of this guideline, but may be addressed by Royal Colleges, GMC and other health regulatory bodies.</p> <p>Agreed. We have included that "Blood glucose levels should be optimised when women with diabetes are planning pregnancy. To facilitate this,</p>

		healthcare and communication issues, unclear attendance pathways and logistical issues (Ferry et al., 2022). Hence it is important to ensure that usual care for women of reproductive age with a diabetes diagnosis includes preconception pathways. This guidance, specifically the preconception guidance is also relevant for those not actively planning a pregnancy.	opportunistic conversation should be initiated during every annual review with women of childbearing age, including consideration of use of insulin pumps and CGM to optimise individual glucose levels Body mass index (BMI) should be reviewed and weight management advice offered if appropriate.”
	SMcG	While it is acknowledged that not everyone seeks preconception care for varying reasons there does not appear to be any comment around "booking" appointments being a number of weeks into gestation. Experience suggests booking appointments are done after at least 8 weeks of gestation but the evidence here suggests that optimising glycaemic control as early as possible is key. For those who have not had preconception care or discussion this could be significant in terms of increased risk.	Thank you. Agreed – We have added a GPP about encouraging diabetes teams to engage with women who have pre-existing diabetes early in pregnancy, preferably before the formal booking appointment. We have also added a bullet point to the Provision of information section to reassure women who have an unplanned pregnancy that the multidisciplinary diabetes team is always available to provide support and advises contact with them as soon as possible.
3.1.1	DSims	Para 1: "...maintained as close to the non-diabetic range..." The word 'diabetic' is now frowned upon by diabetes language groups Para 5: "...poor blood glucose control." The word 'poor' is now frowned upon by diabetes language groups. Para 6: "...the pregnancy not being fully planned." Access to effective contraception?	Agreed – we have changed this to "reference range in the general population." Agreed – we have changed this to "variable blood glucose levels" Noted, however we have reported these statistics directly from the paper.
3.1.2	DSims	Para 14: "...even without specific pregnancy planning they have a lower HbA1c". What about population-based intervention approaches eg Dunne-JCEM (cost effective) and EASIPOD Murphy? And increasing access to effective contraception Eg DCAPP https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6190660/ We've not got good effectiveness data yet though!	Thank you - we have removed the phrase "so that even without specific pregnancy planning they have a lower HbA1c" to clarify this section. No other specific population-based interventions were reviewed in the evidence for this question.

	KM	Paragraph starting 'A Scottish population' Sentence 2: remove "rate of". Would be useful to include stillbirth rate in patients without diabetes.	Agreed – we have corrected this typo. Noted, the paper does not include this information, but the Scottish Public Health Observatory reports this to be 3.8/1000 births in 2021. We have added this information.
Section 4: Antenatal care			
Are the summaries of benefits and harms, safety, and cost effectiveness evidence accurate and reasonable interpretations of the evidence?			
	AB, AC, CP, CPk, DS, HR, KM, MSJ, SB, SC, SMc, SMcG, TL, UH	Yes (all listed reviewers answered "yes" individually to this question)	Thank you
	AI	Yes. The benefits of remote monitoring of glucose levels for those using CGM in remote area should not be underestimated.	We acknowledge that there are additional benefits of remote monitoring of glucose levels for those living in remote and rural areas. This aspect was not assessed by our evidence base so we cannot make a direct recommendation but have acknowledged this in the text (see section 4.1.1).
Section 4: Antenatal care			
To what extent is the evidence presented generalisable to NHSScotland?			
	AB	As previous, selection of study data is from comparable populations therefore can be applied to NHS Scotland.	Noted. Thank you.
	CPk	It is acknowledged within the guidance that many of the studies have populations that vary from the NHSScotland populations.	Thank you.
	HR	Reasonable to generalise for NHS Scotland.	Noted. Thank you.
	KM	Yes	Thank you.
	MSJ	The guidelines was written well and is generalisable to NHS Scotland	Noted. Thank you.

	SC	Yes, the evidence presented is generalisable to NHS Scotland.	Noted. Thank you.
	SMcG	This seems reasonable provided monitoring is done adequately. Individualised care plans should be in place as far as possible and consideration of the impact of sticking within targets should be forefront to ensure best possible outcomes.	Noted. Thank you. We acknowledge the need for care to be tailored to individuals and believe we have emphasised the need for individualised care plans within the guideline.

Section 4: Antenatal care

Is there a clear link between evidence and recommendations that describes the volume, strength and consistency of the evidence? E.g. after reading the relevant section of the guideline, can you understand the basis for the suggested recommendations?

	AB, AC, AI, CP, DS, HR, KM, MSJ, SB, SC, SMc, TL	Yes (all listed reviewers answered "yes" individually to this question)	Thank you
	CPk	Yes. I'm unsure about the recommendation 'consider CGM in pregnant women with GDM' Could we differentiate isCGM and rtCGM?	The evidence of benefit to women with GDM using CGM, in particular for perinatal outcomes, was not conclusive enough to support a recommendation, however the guideline group had originally developed a good practice point suggesting that it could be considered, reflecting some evidence of improvement in glycaemic control and the guideline group's opinion that some women will benefit from this. On further reflection and consideration of feedback reflecting confusion among reviewers, the guideline development group has chosen to remove this good practice point. Evidence on CGM reflects the historical context in which studies were conducted, and the lack of comparative designs comparing isCGM versus rtCGM render it impossible to make recommendations between these subtypes of technology. Furthermore, as discussed in section 4.1.1, with recent changes in technology (specifically regarding Freestyle Libre 2), the most widely used type of isCGM now also provides rtCGM data, therefore the guideline group anticipates that this distinction will be become irrelevant as almost all people using CGM in Scotland will be using rtCGM devices.

			We have summarised this point in a new paragraph in section 4.1.1 (see response to KM comment below).
	SMcG	Yes. It is clear the evidence is limited and the authors are using both the evidence, practice and best educated considerations to formulate the guideline in the best interest of those affected.	Thank you. Noted
4.1.1	KM	Yes. CGM You have presented good evidence for use of CGM in T2DM/GDM and pleased to see this recommendation. Hopefully implementing this will lead to funding availability in pregnancy.	Thank you. As noted above, the good practice point on consideration of CGM in women with GDM has been removed. We have added a paragraph to explain that there may be circumstances where this technology may still represent the best option for individual patients, as determined on an individual basis and joint discussion between person with diabetes and healthcare team, but which cannot be supported by an evidence-based recommendation. “There are instances where women with GDM and clinical teams may jointly consider use of CGM, for example in those who are unable to undertake home blood glucose monitoring, or where remote monitoring would be advantageous. Compared with T1DM and T2DM there is a smaller body of evidence examining the use of CGM in GDM, and the majority of studies do not differentiate between the type of CGM, nor between those who manage glucose levels with insulin, metformin or diet. Furthermore, while the evidence is mixed, most studies do not report benefits in perinatal outcomes associated with CGM use in women with GDM. There is therefore insufficient evidence to support a recommendation for the overall use of CGM in GDM.” We have also added a research recommendation for further studies using modern versions of CGM in GDM.
Section 4: Antenatal care			
Do you have any other comments?			
	CPk	While the studies specify either isCGM or rtCGM, the discussion and recommendations are more generalised. There may be expectations that rtCGM with predictive low would be available to all with pre-existing diabetes.	Thank you. As noted above, the good practice point on consideration of CGM in women with GDM has been removed. We have added a paragraph to explain that there may be circumstances where this technology may still represent the best option for individual patients, as determined on an individual basis and joint discussion between person with diabetes and healthcare team, but which cannot be supported by an evidence-based recommendation.

		<p>The suggestion of early pregnancy HbA1c of 42-48 would be even lower than being aimed for in pre-pregnancy recommendation.</p> <p>I like the recommendation of maintaining individualised targets rather than adopting a target which in the discussion was only achieved in a minority.</p>	<p>The guideline does not recommend early pregnancy HbA1c targets of 42–48 mmol/mol.</p> <p>Noted. Thank you.</p>
	LC	<p>Page 9 suggests use of a CGM - clarity around diet, diet and metformin or diet and insulin</p> <p>Page 14 under Summary and Conclusions, it suggests that although tighter glycaemic control results in lower rates of LGA infants, there are greater obstetric harms for those achieving tighter glucose targets.</p> <p>Then further down, says that still we are aiming for tight control.</p>	<p>Thank you for your comment, the evidence around diet and pharmacological treatments is discussed in section 5.4.</p> <p>Thank you for your comment. We have explained the data regarding benefit versus harm of differing levels of glucose management. Based on this, we have recommended levels that the guideline group agreed balanced the benefits of tight control (lower glucose levels) with the potential harms of very tight control, i.e. we agreed levels that are above the lowest target levels discussed in the literature.</p> <p>Agreed. We have revised this to “In pregnant women with pre-existing diabetes, glucose levels closer to those in people without diabetes should be encouraged...”</p>
	LW	<p>It would be helpful to have some evidence-based dietary advice included for women with Type 1 and 2 diabetes and GDM, and who should deliver that advice eg dietitians working in secondary care specialist teams.</p>	<p>The relevant section of the guideline was not included in this first draft of the guideline. Your comments on the updated draft, specifically regarding the section discussing diet, exercise and other management options, will be appreciated in due course.</p>
	SB	<p>Currently using CGM in Type 1 and Flash monitoring in Type 2 diabetes, Gestational don't currently have access to CGM. Will funding cover GDM?</p>	<p>Thank you. As noted above, the good practice point on consideration of CGM in women with GDM has been removed. We have added a paragraph to explain that there may be circumstances where this technology may still represent the best option for individual patients, as determined on an individual basis and joint discussion between person with diabetes and healthcare team, but which cannot be supported by an evidence-based recommendation.</p>
4.2	DSims	<p>I found mixing GDM with T2DM with T1DM very confusing--they are all so different (yes-same in some ways)</p>	<p>Noted, however we have attempted to clearly state the available evidence in this section. The guideline states that “NICE guideline NG3 on diabetes in pregnancy: management from preconception to the postnatal period reviewed evidence on target ranges for blood glucose in women with T1DM, T2DM or GDM during pregnancy published up to 2014. This guideline identified six relevant studies (five studies in women with pre-existing</p>

			<p>diabetes and one in women with GDM)... The current (ie SIGN) guideline has identified a further four relevant studies published since the NICE guideline of which one is a systematic review which includes only women with pre-existing diabetes and also includes the primary studies included in the NICE guideline. Two studies include only women with GDM, while a further study focuses on the continuum of risk of glucose levels in women either meeting or just below the diagnostic threshold for GDM.”</p> <p>The wording of separate recommendations for pregnant women with pre-existing diabetes and pregnant women with GDM reflects the associations between different clinical outcomes and benefits and harms interpreted from this evidence base.</p>
4.2.1	AI	Recommendation of a fasting glucose of <5.5 mmol/L but does not suggest a pre-prandial level.	Thank you. Preprandial glucose targets were not included in the questions for this guideline. We did not identify specific evidence on this issue, however the guideline development group supports that preprandial glucose levels for women with GDM who are using insulin should be similar to fasting glucose levels, ie <5.5 mmol/L. We have added a GPP to explain this.
4.4	SMcG	The first recommendation is to discuss timing and mode of birth particularly during third trimester. Experience would suggest that the earlier this can be considered the more informed the choice is. In practice, although it suggests particularly, there is a risk that it is not discussed prior to third trimester which causes anxiety within the group. Perhaps this recommendation should be amended to highlight that mode of delivery and timing should be considered as early as possible with decisions being made in the third trimester.	Thank you for your comment. We have adapted this recommendation to encourage early discussion about birth timing, with confirmation by the third trimester.

Section 5: Gestational diabetes

Are the summaries of benefits and harms, safety, and cost effectiveness evidence accurate and reasonable interpretations of the evidence?

	AB, AC, AI, CP, CPK, DS, HR, KM,	Yes (all listed reviewers answered “yes” individually to this question)	Thank you
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LC, MSJ, SB, SC, SMc, SMcG, TL		
CS	Yes. Not only have the authors explored the evidence as highlighted in the relevant NICE document they've updated with the most up to date data.	Thank you.
FS	Yes - well written overview which highlights the limitations of trials to date. Interpretation and subsequent recommendations reasonable and pragmatic suggestions.	Thank you.

Section 5.4: Non-pharmacological management of women with gestational diabetes

Are the summaries of benefits and harms, safety, and cost effectiveness evidence accurate and reasonable interpretations of the evidence?

LE	Yes, the summaries are relevant and appropriate to the evidence reviewed, however it was surprising that there was no reference to the possible harms of providing dietary advice to women in pregnancy. There is published evidence available that references unintended harms, eg increased hypervigilance around food, disordered eating patterns - particularly in women with previous eating disorders. Women of higher body weight, a risk for GDM, have much higher risk of binge eating disorder and negative body image. This is highly relevant in a guideline advising on dietary management especially where the history of the women's relationship with food has not been assessed.	<p>Thank you. Noted. The key question (copied from NICE NG3) did not identify these potential effects as outcomes for analysis. Maternal harm outcomes analysed were "treatment failure", ie the need for escalation of treatment to pharmacological therapy and mode of delivery (vaginal or Caesarean birth).</p> <p>The group acknowledges that this comment addresses the importance of both how advice is given and the identification of disordered eating during and after pregnancy. The group believes that this emphasises the importance of dietary advice being given by suitably trained professionals which we have embedded within the recommendation in this section. We have added a paragraph to clarify this:</p> <p>"The NICE guideline identified no consistent evidence of harms associated with the provision of dietary advice beyond the increased risk of need for further treatment noted above. While taking account of the evidence described by NICE, the SIGN guideline development group was also aware of the potential for any dietary intervention to influence stress, anxiety, depression and disordered eating patterns and endorses the role of suitably trained individuals in the design of such programmes."</p>
RCN	Agree with recommendations that all patients should have access to registered nutritionist or provided with	Thank you.

		appropriate dietary advice to support improvement of abnormal glucose levels during pregnancy. Recommends either individually or in group sessions – need to understand feasibility and roles of who would undertake this i.e. midwife, practice nurse, specialist nurses etc. however in relation to workforce. NICE has provided thorough review of evidence demonstrating some of low quality but have highlighted importance of nutritional education during gestational diabetes. Section 5.4.2 explains how exercise is recommended irrespective of gestational diabetes, but more studies may be more applicable to help provide stronger recommendations for this patient cohort. However, all evidence has been reviewed accurately but could identify how further studies in this patient cohort may be needed for future improvements.	Agreed. We have added this to the research recommendation section.
	UH	Yes it would seem that combined lifestyle, dietary and exercise interventions are not harmful though the evidence to support the benefits is limited. It does report lower chance of large for gestational age babies with intervention.	Thank you.

Section 5.5: Pharmacological management of women with gestational diabetes

Are the summaries of benefits and harms, safety, and cost effectiveness evidence accurate and reasonable interpretations of the evidence?

	AB, CR KM, LC, LE, SMc	Yes (all listed reviewers answered “yes” individually to this question)	Thank you
	CS	Again, an excellent summary of the evidence building on the latest NICE document. Cost effectiveness not directly addressed but the therapies being offered are relatively cheap and used for short periods of time. and it is known using them (when needed over diet/lifestyle) to improve glycaemia will improve obstetric outcomes at a population level.	Thank you

FS	I would agree with conclusions drawn from evidence to date and ensuring patient informed choice guiding treatment pathway.	Thank you
RCN	The summaries do provide the relevant information as mentioned but do demonstrate that further studies/research into this area may be required for future recommendations. NICE again has provided thorough review of the evidence and limitations of the studies have been mentioned to highlight areas of improvement. However, the use of Glibenclamide is very limited now and use of Sulphonylureas in pregnancy is mainly contraindicated due to risk of neonatal hypoglycaemia. Additionally, no mention of the specific types of insulin profiles in terms of basal or bolus regimes which could impact on the readers' understanding of the recommendations (but may be outside the scope of document). However, it is clear to see that the recommendations do mention Metformin and Insulin outside of Sulphonylureas, which is clear from the evidence review.	Thank you This level of detail was not included in the key question that supported this section (derived from NICE NG3). Women with GDM may require rapid-acting and/or longer acting insulins.
UH	Not sure there is much said about cost-effectiveness though those on insulin would need more input from HCP ie education, reviews for titration, potentially treatment for hypoglycaemia. Otherwise this section looks ok.	Thank you. No further evidence was identified on cost effectiveness of these interventions.

Section 5: Gestational diabetes

To what extent is the evidence presented generalisable to NHSScotland?

AB	Data appears to correlate well with NHS Scotland as described.	Thank you
CP	This needs to be incorporated into primary care systems for patients with Type 2	Noted. Thank you
CPk	Varied populations studied, not all directly applicable to NHSScotland, but acknowledged in discussion.	Noted. Thank you
HR	Very mixed groups and different cut off.	Noted. Thank you

	MSJ	The guidelines was written well and is generalisable to NHS Scotland.	Noted. Thank you
	SC	Yes, the evidence presented is generalisable to NHS Scotland.	Noted. Thank you
	SMcG	The recommendation made by the group is not to test everyone despite some evidence suggesting long term cost benefit analysis would be worthwhile. Risk factors in particular BMI would indicate a significant proportion of pregnant women will be tested. The authors acknowledge the limitations to some of the previous research in comparing to the population of Scotland.	Noted. Thank you
Section 5.4: Non-pharmacological management of women with gestational diabetes			
To what extent is the evidence presented generalisable to NHSScotland?			
	CR	I see no reason why the evidence would not apply throughout NHS Scotland	Thank you.
	CS	I think it applies equally to every Health Board (who will in general follow the same treatment principles in terms of supporting this obstetric cohort) and every HB will have systems in place to help these patients, and should be able to apply this evidence and guidance.	Thank you.
	FS	Recommendations leave sufficient interpretation to allow individual boards to work within this guidance according to available resource. Will work within the framework of Healthier Futures Diabetes strategies already being developed.	Thank you.
	KM	Adequately. I note this has been highlighted where there is concern	Thank you.
	LE	In general, yes, however the recommendation about dietetic referral should be strengthened. The NICE guidelines (NG3) and the Scottish Government type 2 diabetes prevention framework (which references the NICE guidance both recommend that 'all women with gestational diabetes should be referred to a dietitian'. In Scotland, this is best, and safest practice. Registered dietitians are the only regulated clinical nutritional	The group notes that while registered dietitians offer comprehensive and expert dietetic advice, routine care of women with gestational diabetes will involve contact with a range of professionals during pregnancy who may be able to engage at different times and in different ways which can all emphasise and reinforce the focused advice offered by dietitians. The group felt that, as long as healthcare staff were suitably trained, it would be appropriate for this information to be provided as widely as possible. The group believes that the combination of the recommendation for lifestyle

		professionals in the NHS and as such, it would be inappropriate for other professionals to provide specialist dietary advice for a clinical condition such as GDM. I would strongly advice adopting the NICE guideline on dietetic referral.	advice and support from a suitably trained professional and the good practice point for specific access to a registered dietitian is appropriate and covers both the general and specific aspects of service delivery.
	RCN	Unable to provide full comment in terms of application to NHS Scotland statistics as not made available during guidance. However, the four UK Chief Medical Officers have agreed on the recommendation of 150 minutes of exercise in pregnancy, irrespective of gestational diabetes as an example. More local based studies would need to be conducted within Scotland to ascertain the data accordingly. This applies to all the relevant sections in the guidance as this data is considering national statistics. However, this will be relevant for patients within Scotland and therefore the recommendations should be considered.	Thank you. Agreed. We have added this to the research recommendation section.
	SMc	The evidence presented is reasonable although it is noted that the studies are of mainly low quality making it difficult to make recommendations. It therefore means recommendations for women with gestational diabetes is very generic and in line with national recommendations for the population with regard to exercise. Access to dietary advice is helpful	Thank you.
	UH	I think that as these interventions are low cost and may have some benefit ie achieving post partum weight loss goals, they can be used in Scotland populations. Any intervention that promotes healthier lifestyles can only be good.	Thank you.
Section 5.5: Pharmacological management of women with gestational diabetes			
To what extent is the evidence presented generalisable to NHSScotland?			
	CS	Clearly applicable across Scotland, again all HBs will have processes and clinics in place to support this cohort.	Thank you
	CR	It is	Thank you

	FS	Evidence presented reflecting routine care in NHSScotland - supports current care practices with additional insight into discussions round metformin	Thank you
	KM	Adequate	Thank you
	LE	This reflects current practice already.	Thank you
	RCN	Unable to provide full comment in terms of application to NHS Scotland statistics as not made available during guidance. However, national evidence base has been used for the reviews and this will be applicable to the patient cohort within Scotland accordingly. More local based studies would need to be conducted within Scotland to ascertain the data accordingly. This applies to all the relevant sections in the guidance as this data is considering national statistics. However, this will be relevant for patients within Scotland and therefore, the recommendations should be considered.	Thank you
	SMc	I think it can be used generally for Scotland.	Thank you
	UH	Yes, I think it can be used in Scotland.	Thank you

Section 5: Gestational diabetes

Is there a clear link between evidence and recommendations that describes the volume, strength and consistency of the evidence? E.g. after reading the relevant section of the guideline, can you understand the basis for the suggested recommendations?

	AB, AC, AI, CW, DS, HR, KM, MSJ, SB, SC, SMC, SMCg, TL	Yes (all listed reviewers answered "yes" individually to this question)	Thank you
5.2	TL	Regarding recommendations for the diagnosis of GDM: we support your recommendation of ≥ 9.0 mmol/L as the diagnostic threshold of two-hour post 75g oral glucose level.	Thank you

5.2.2	KM	Diagnostic criteria. Really detailed summary of evidence and leads to a balanced recommendation.	Thank you
5.3	UH	<p>No.</p> <p>Detecting glucose intolerance. This section I found very difficult to interpret, the recommendation is to have women with HbA1c >42 doing glucose monitoring up until OGTT at 24-26 week in order to confirm or exclude a diagnosis of GDM? Having women doing BG monitoring will require resources and maybe treatment. At what stage are we saying they have GDM if no OGTT being done until 24 weeks?</p> <p>The next section then goes on to suggest treatment quite quickly for those above target. The swift pharmacological intervention perhaps will not help women to focus long term on lifestyle changes that may help reduce risk of developing Type 2 diabetes. We see a lot of women with GDM (IADPSG) criteria who have higher fasting levels but normal post prandial levels. The decision to treat often is made as to whether they have LGA babies on scan.</p>	<p>Thank you. The evidence reviewed suggested that raised HbA1c which is below the diagnostic threshold for overt diabetes is a specific, but not sensitive, test for later GDM. The proposal is that such women would begin glucose monitoring and receive dietary management and progress to more intensive treatment as required using usual criteria. The proposal is not to have all women having an OGTT at 24–26 weeks but to allow for this if clinical teams wish. Clinical experience shows that the majority of women undergoing monitoring will exceed treatment thresholds and do not require an OGTT. Where glucose levels are normal, an OGTT may be used to confirm that GDM was not present.</p> <p>We have acknowledged the observation that some women will have raised HbA1c and glucose levels in early pregnancy before an OGTT may be carried out in the definitions section (1.2.3). While it would not possible to formally confirm a diagnosis of GDM to such women, they would be managed on a GDM pathway and considered as having GDM.</p> <p>We agree that long-term lifestyle changes are key to prevention of later type 2 diabetes. At the same time in pregnancy it is important to try to offer control of blood sugar as early as possible – hence the progression to pharmacological therapy after trial of dietary management. This is consistent with current practice in most or all units. We do not think that this will discourage lifestyle intervention after pregnancy as pharmacological therapies will almost always be withdrawn after delivery for women with GDM, while most will be offered to join the type 2 diabetes prevention pathway in Scotland which includes lifestyle interventions.</p>
	CPk	<p>Yes.</p> <p>I do have concerns that changing the target for detection of GDM would be on the basis of cost more than health benefit.</p> <p>We already struggle to provide assessment for all those who would be eligible on the basis of BMI, but this remains a real risk factor. I can appreciate the suggestion of the raising of the fasting glucose level to 5.3 as this is then the target for fasting values suggested</p>	<p>We appreciate this comment. As detailed, the group felt that in the light of the TOBOGM trial there was good evidence in earlier pregnancy not to use the HAPO 1.75 (ie IADPSG) criteria both on the grounds of lack of utility in women with fasting glucose 5.1–5.2 mmol/L and potential for overtreatment. This criterion was not changed on a cost basis.</p> <p>We agree that dichotomising women into GDM and not-GDM always leads to concern for those close to the borderline criteria. Our approach to this is to:</p> <ul style="list-style-type: none"> • support promotion of healthy eating advice for all women in pregnancy, and

		for monitoring, but worry about those that we would miss with the higher 2-hour value proposed.	<ul style="list-style-type: none"> try to set the criteria at a level that will be clear and consistent for clinical teams (between early and later pregnancy) and where evidence of benefit seems clearest.
5.3.1	CPk	The last recommendation refers to women already monitoring glucose levels. We haven't discussed monitoring prior to diagnosis as a strategy within this document.	Thank you. The final good practice point refers to monitoring for women with HbA1c 42–47 mmol/mol. We know that these women are at high risk of GDM and rather than waiting until diagnosis can be confirmed in later pregnancy, pragmatically we have suggested monitoring. In our experience, such women often have monitoring fasting glucose above 5.3 mmol/L and can reasonably be given diagnosis of GDM for this and later pregnancy. The comment on OGTT is only to suggest to healthcare teams that, on an individual basis, if all monitoring is normal it would be reasonable to then have OGTT if the women wished and revise the diagnosis if the OGTT were normal.

Section 5.4: Non-pharmacological management of women with gestational diabetes

Is there a clear link between evidence and recommendations that describes the volume, strength and consistency of the evidence? eg after reading the relevant section of the guideline, can you understand the basis for the suggested recommendations?

	CR	Yes	Thank you.
	CS	Yes, the recommendations are clearly based on the quality of the evidence available (often lacking in this area).	Thank you.
	FS	Yes - recommendations do not over reach available evidence in their interpretation but give pragmatic and applicable clinical guidance.	Thank you.
	KM	Yes, and the recommendations look sensible.	Thank you.
	LE	Yes, it is clear from the evidence that there is no specific diet that is recommended for GDM for optimal outcome therefore this is understandable. It would however, be advisable to be more explicit in the recommendation about the meaning of the term 'lifestyle'. This is widely open to interpretation and further, without clear definition, it leaves the recommendation unclear for the clinician. There is no balancing recommendation e.g. advising what lifestyle advice to avoid (calorie deficit for example). This recommendation is too broad as it is currently worded so I am concerned that advice on diet	<p>Thank you.</p> <p>We have added a new paragraph to clarify the intention of lifestyle advice in pregnancy and moved this to the start of the section:</p> <p>“Lifestyle advice is general information about healthy living, including eating a balanced diet, healthy weight, exercise, quitting smoking and drinking less alcohol. In the context of pregnancy weight reduction alone is not a specific aim but lifestyle advice based on reduction of refined carbohydrates, avoidance of excessive weight gain and physical activity sensitive to the individual’s culture and existing eating habits is appropriate.”</p>

		and physical activity to women with GDM risks being highly variable and without any clear structure - potentially unsafe.	
	RCN	Yes, having read the relevant sections, it is clear there is a link between the quality of the evidence base and the recommendations made, with consideration of a four-country approach. NICE appraisals have reviewed expertly the research available to ensure accurate recommendations have been demonstrated. However, as mentioned, for section 5.4.2 more application to patients with gestational diabetes may improve the strength of the recommendation. However, overall the evidence is displayed clearly with sound reasoning for the recommendation.	Thank you. Agreed. We have added this to the research recommendation section.
	SMc	Yes, as above the evidence is low quality meaning any recommendations are required to be generic based on best knowledge and not specific to pregnancy.	Thank you.
	UH	My interpretation is that the evidence is mostly low quality. That said those that have dietary advice show better outcomes in reduced risk of LGA babies, shoulder dystocia, stillbirth, neonatal death and need for further treatment. On this basis the recommendation is understandable.	Thank you.

Section 5.5: Pharmacological management of women with gestational diabetes

Is there a clear link between evidence and recommendations that describes the volume, strength and consistency of the evidence? eg after reading the relevant section of the guideline, can you understand the basis for the suggested recommendations?

	AB	Yes, evidence base is clear and demonstrates reason for recommendations.	Thank you
	CS	The recommendations are clearly derived from the evidence base, which is well described, and the strength and consistency of evidence is well summarised.	Thank you
	CR	Yes	Thank you
	FS	Yes - clear link and offers option of two first-line agents while reflecting that patient preference will guide treatment pathway.	Thank you
	KM	Yes	Thank you

	LE	Yes	Thank you
	RCN	Yes, having read the relevant sections, it is clear there is a link between the quality of the evidence base and the recommendations made, with consideration of a four-country approach. NICE appraisals have reviewed expertly the research available to ensure accurate recommendations have been demonstrated. The only areas to highlight are that no specific insulins have been mentioned or alongside what dose of Metformin is required in gestational diabetes – in terms of once daily or twice daily dosing, that may improve outcomes. However, the basis for recommendations clearly utilises the evidence base to provide the recommendations that is understandable for the reader.	Thank you The guideline development group acknowledges that it has concentrated on the broader issues of which glucose-lowering agent to use in women diagnosed with gestational diabetes in line with the questions included in the NICE guideline and updated in this guideline. We have not reviewed evidence comparing specific insulins in GDM (but believe this will be limited) and expect healthcare professionals to follow advice on dosing and titration included in the BNF.
	SMc	The recommendations seem reasonable based on the evidence although it could be argued that rather than "Diabetes teams should explain to women with gestational diabetes that metformin crosses the placenta." it should be "Diabetes teams must explain to women with gestational diabetes that metformin crosses the placenta." Many women will not know this and with limited information for longer term effects this is vital in allowing women to have full information in their management.	Thank you. This is a strong recommendation and the guideline development group is satisfied that the wording reflects the intention of the need to provide appropriate advice.
	UH	I can understand the recommendations.	Thank you
Section 5: Gestational diabetes			
Do you have any other comments?			
	CW	Risks are BMI >30 Higher levels of GDM in studies looking at ethnicity, eg. higher rates seen in South Asian women versus those of Caucasian origin. TDR approach prepregnancy - targeted populations as mentioned above, for weight management such as TDR for >10% weight loss and Diabetes remission.	Thank you. This reflects the guideline contents. We fully agree that weight management should be promoted for those at risk of GDM and indeed for those with type 2 diabetes prior to pregnancy. Our comments on this relate to promotion of the Framework for the Prevention, Early Detection and Intervention of Type 2 Diabetes

			(https://www.gov.scot/publications/evaluation-implementation-framework-prevention-early-detection-intervention-type-2-diabetes/) .
	DSims	<p>Para 1: Need to clarify definition to exclude overt diabetes.</p> <p>Para 3: "...intolerance where HbA1c results are above normal for the non-pregnant state" Why HbA1c? Often do not reflect OGTT.</p>	<p>Thank you for this comment. We are aware of the debates regarding the importance of identifying women with overt diabetes in pregnancy.</p> <p>We have added a sentence "Women with overt diabetes detected in pregnancy (HbA1c \geq48 mmol/mol, fasting glucose \geq7.0 mmol/L, 2-hour or random glucose \geq11.1 mmol/L) represent a higher risk group for poor outcomes and will be detected clinically by glucose screening during pregnancy."</p> <p>HbA1c was identified as the glucose parameter most often measured routinely as standard care in early pregnancy and because of the association between HbA1c and later GDM. As noted in the guideline, this paragraph refers to testing in the first trimester.</p>
	SMc	<p>Yes.</p> <p>I welcome the guidance on the immediate follow up of gestational diabetes in the first few months post-delivery.</p> <p>However, I would welcome guidance on the longer term follow up of women with a history of gestational diabetes, especially those who choose not to get pregnant again.</p> <p>We know they have a 50% risk of developing type 2 diabetes within the next 10 years. I have for many years put recalls on these women for annual blood glucose checks.</p> <p>But I could not see such follow up recommended here.</p>	<p>Thank you. In section 6.2 we have included recommendations for annual testing by fasting plasma glucose or HbA1c and advice about the risk of developing type 2 diabetes. Throughout the guideline we have promoted diabetes prevention strategies and provided cross references to the national Framework for the Prevention, Early Detection and Intervention of Type 2 Diabetes.</p>
	SMcG	<p>Throughout the section one of the risk factors identified is previous GDM. If a woman does not meet any of the other risk factors in first pregnancy then it is in practice difficult to determine GDM as no testing is available unless something is amiss later in pregnancy. This would suggest a large population may have GDM without knowing and potentially causing harm to either mother, baby or both.</p>	<p>It is appropriate to consider previous GDM as a risk factor in subsequent pregnancies as we know these women are at risk of recurrence. Other comments relate to whether a universal testing strategy is taken or targeted to women with risk factors. We have continued the current policy which is also used in NICE. We agree that more women would be detected by testing with OGTT</p>

5.1.3	KM	<p>“Consider screening in women 35-40 years.” This is likely to lead to quite a lot more testing if implemented. When you say 'consider' is that a decision each health board has to make or is it a case of offering as optional to patients in that age bracket?</p>	<p>This would be implemented on a health board basis. We note that while the recommendation to test women at BMI ≥ 30 kg/m² has been in place for some years this has sometimes been slow to be implemented.</p>
5.2.2	DSims	<p>Para 16: Suggest “a further large <i>high-quality</i> multinational RCT...” (ie TOBOGM)</p> <p>Para 18: “Significantly fewer women in the early treatment group...lean body mass”</p> <p>Other Secondary outcomes (lean body mass was a secondary) include:</p> <ul style="list-style-type: none"> • time in neonatal nursery reduced by 0.78 days • 3rd and 4th degree perineal tears reduced by over 2% absolute, 77% relative <p>These are materially important</p> <p>Health economics section para 4: This was all before TOBOGM</p> <p>Summary and Interpretation section: 2nd bullet point - Include the one-hour criterion of 10.6 mmol/L even if not going to recommend its use because you’re not using it currently</p> <p>Recommendation: Incorrect one-hour criterion specified. OR 2.0 is ≥ 10.6 mmol/L</p> <p>Good Practice Point: Better at 10–14 weeks with other early tests.</p>	<p>Noted and agreed. We have incorporated these changes.</p> <p>We agree with this point and await publication of further health economic analyses following the TOBOGM trial.</p> <p>1-hour value – we have added this (corrected) value.</p> <p>Thank you – we have revised the GPP to:</p> <p>“In light of developing evidence that earlier treatment of GDM may be beneficial, amendment of the current testing windows to the earlier points of 10–14 weeks (for women with prior GDM) and the earlier part of the current testing window (24–26 weeks rather than 24-28 weeks) is suggested.”</p>

5.3.1	DSims	Para 4: HbA1c is not really a level. Why not just say HbA1c?	Thank you. Reworded to “HbA1c values...”
	HR	I am slightly confused about those found to have high risk of GDM based on HbA1c in early pregnancy. It isn't clear what would be expected re monitoring and if BG were above target would they need an earlier OGTT to confirm diagnosis or would treatment start and they would be diagnosed based on being a high risk, eg HbA1c 41 mmol/mol and BG monitoring consistent with GDM. I think it would be helpful to be clearer about expectations or if expectations not clear then clearer about uncertainty.	Thank you. We have clarified this recommendation that women with HbA1c 42–47 mmol/mol are at high risk of GDM and we suggest starting monitoring and dietary management. Such women with glucose levels above treatment thresholds may be considered as having GDM.
	KM	Second recommendation doesn't make sense to me. Would this be better ... 'HbA1c is not a sufficiently sensitive test to detect GDM, although higher levels in early pregnancy are associated with increased risk of GDM. Glucose monitoring is recommended in those with HbA1c ≥42' ?	Thank you – we have revised the wording in line with this suggestion.

Section 5.4: Non-pharmacological management of women with gestational diabetes

Do you have any other comments?

	CS	<p>Clear summary of and logical recommendations from the evidence.</p> <p>I was surprised to see the section on myo-inositol and probiotics as I'm not aware of anyone recommending it routinely/ However, I note as the evidence is poor and inconclusive no recommendations were made to use these treatments.</p>	<p>Thank you.</p> <p>We identified this literature as part of our broader searches on dietary interventions and it was felt appropriate to address this for this reason.</p>
	CR	No	Thank you.
	FS	With regard to exercise section recommendations, I would suggest that midwives are also mentioned in having a role to play in educating those women with identified higher risk of GDM in screening pathway from booking re value of exercise - diabetes team will meet these women relatively later	Thank you. We have added “multidisciplinary” into the good practice point to emphasise that physical activity / exercise advice can be shared with women by all suitably trained members of diabetes teams.
	KM	I have never been asked about myo-inositol but interesting to read the findings	As above

	LE	There is excellent dietary advice available through the British Dietetic Association, NDRUK and Diabetes UK that is evidence based and reliable. Is it possible to provide signposting or links to these resources within the guideline (is the guideline going on RDS as this would work well?)	Thank you. We have added links to My Diabetes My Way and Diabetes UK in the Sources of Further Information section (section 7.2.1) which include further dietary advice.
	RCN	Believe may be important to consider the psychological aspect of management for this patient cohort, as the process of pregnancy itself can produce many different emotions and feelings that can impact on the wellbeing of both the patient and the unborn baby. This may include regular need for conversations and midwifery input into explaining the long-term complications related to gestational diabetes. Additionally, appropriate information needs to be provided after birth around HbA1c annual screening and lifestyle/diet considerations to reduce risk of developing type 2 diabetes post birth.	Thank you. The guideline development group acknowledges that these are important points but notes that appropriately trained healthcare staff will engage with women sensitively regarding all aspects of their pregnancy. Midwifery input during and after pregnancy is routine care. Postpartum advice and interventions are predominantly supported via the diabetes prevention programme. We already include recommendations on the postnatal testing and advice for women who were diagnosed with gestational diabetes.
	SMc	It is unfortunate that evidence is limited and of low quality for non-pharmacological management of gestational diabetes although not surprising. It perhaps could be clearer what outcomes are being sought through non-pharmacological management - is it to maintain a healthy lifestyle or to improve birth rates in one way or another. It is unclear what the goal is for those women who are coping with a GD diagnosis which is often unexpected and how dietary input is beneficial	Thank you. The goal of all treatment approaches for women with gestational diabetes is the maintenance of blood glucose levels as close to those of women without diabetes as possible which, in turn, will minimise risk of pregnancy complications. We acknowledge the limitations of the evidence base however the guideline development group is aware that some form of healthy eating and lifestyle advice is usually also built into to all limbs of RCTs for pharmacological management, implying that the benefits of this intervention are often considered in tandem with pharmacological approaches as 'usual care'. Non-pharmacological management has always been first-line treatment with intensification of treatment to pharmacological agents for those who are unable to maintain agreed glucose levels (or, targets) via non-pharmacological approaches alone. It is also clear that many women will note a relationship of certain foods to increases in blood glucose post prandially and see an immediate benefit of such advice on their glucose levels.
	UH	No further comment	Thank you
5.4.1	HR	<i>This comment was made on the original version of the draft guideline before the full sections on management of gestational diabetes were added.</i>	

		I feel like this is too sparse and specific. Barriers to health-related behaviour change should be explored, psychological consideration re motivation and mental health considered. Clearly advice should be dietetic led but this may take the form of group education, psychology led services, online support as well as physical activity in addition to dietetic advice. Stating they should be referred to a dietician doesn't replicate a 'menu' of options.	Thank you. While these aspects were not included in the key questions adopted from the NICE NG3 guideline, we have added a new section on non-pharmacological interventions.
	LW	<i>This comment was made on the original version of the draft guideline before the full sections on management of gestational diabetes were added.</i> In section 5.4.1 it mentions that women should be offered "healthy eating" advice by dietitians - this is not current practice according to evidence - much more detailed advice is given regarding the role of carbohydrates and glycaemic load, as well as weight management	Thank you. This section was developed at a later date to the remainder of the draft guideline and circulated to all reviewers from the first consultation and additional invited reviewers. New recommendations on dietary strategies and advice have been added (see section 5.4.1).
5.4.2	HR	<i>This comment was made on the original version of the draft guideline before the full sections on management of gestational diabetes were added.</i> Would it be possible to state the proportion of reading above target eg 25%, 33%, 50 % of the time above target. This would help standardise care and decrease variation in practice.	See recommendation in section 4.2.1 "...CGM should be used to assess overall glycaemic levels and women should aim to spend at least 70% time in range (3.5–7.8 mmol/L)."
Section 5.5: Pharmacological management of women with gestational diabetes			
Do you have any other comments?			
	AB	"Insulin" treatment is recommended but with no comment on preferred regimes. Evidence base for specific regimes probably lacking to an extent that specific insulins types/regimes cannot be recommended and therefore any can be utilised to achieve blood glucose targets? Should there be a statement to make this clear?	Thank you. This level of detail was not included in the key question that supported this section (derived from NICE NG3).
	CR	No	Thank you

CS	<p>Arguably the sections on glibenclamide could be reduced/removed as the formulation has been withdrawn.</p> <p>May be worth commenting on evidence or lack thereof in relation to different types of insulin (human v analog in particular).</p>	<p>Thank you. This was included as it reflected treatment choices at the time the guideline was started, and the information from the NICE guideline. Recommendations on glibenclamide have been removed.</p> <p>We are unable to comment on the availability of evidence on different insulin regimens.</p>
FS	<p>Given volume of women presenting with GDM, would benefit from comment from the reviewers on use of CGM when insulin is being used as first line/adjunct option - will have a bearing on cost effectiveness.</p>	<p>Thank you. The guideline notes that “There is ... insufficient evidence to support a recommendation for the routine use of CGM in women with GDM.” The absence of such evidence prevents any analysis of cost effectiveness of CGM in this group.</p>
KM	<p>There is quite a bit of information on glibenclamide which is withdrawn. I suppose reasonable to keep in the guidance in case things change, or to support reintroduction if necessary. I have never prescribed it for GDM.</p>	<p>Thank you. This was included as it reflected treatment choices at the time the guideline was started, and the information from the NICE guideline. Recommendations on glibenclamide have been removed.</p>
LE	<p>There is recent evidence (Jan/Feb 2024) published on the safety of GLP1s in the preconception stage - is this relevant given the wish to establish good glycaemic control and weight management pre-pregnancy and post-partum?</p>	<p>Thank you. The choice of glucose-lowering agent in women with pre-existing diabetes before conception was not included within the remit of this guideline. The guideline development group acknowledges that this is a developing area with new evidence continuing to emerge over time.</p>
RCN	<p>No other inputs – could suggest stronger wording to recommend NOT using Sulphonylureas in GDM due to risk of neonatal hypoglycaemia in the recommendations section.</p>	<p>Thank you. The guideline notes this risk associated with sulphonylureas, and that the BNF indicates that they should be avoided in pregnancy, however we have not reviewed evidence to support a recommendation to not use them.</p>
UH	<p>What would be useful is clearer guidance on when to start treatment. Often it is 2 readings above target in 2 weeks, which is quite tight when dietary changes can still be made. We don't want to use a pill as the answer when education re diet could have longer term benefits. Difficult line sometimes.</p> <p>Also guidance on whether Metformin should not be used as 1st line, ie in women with SGA babies or abnormal LFT's. A decision tool would be really useful but I realise it's quite a difficult thing to develop as reviews of women with GDM are so individualised with many factors to be considered.</p> <p>For example sometimes difficult to know whether to treat</p>	<p>Thank you. The guideline includes a recommendation “Women with gestational diabetes who require pharmacological therapy to achieve glycaemic targets should be offered either metformin or insulin as first line.” The guideline development group notes that decisions on intensification of therapy are judged on a case-by-case basis depending on how well dietary changes have been made, their effect, whether more can be made and the individualised assessment of risk for the women and fetus.</p> <p>We agree with these comments - guidelines provide evidence for best practice for the most common circumstances within the confines of available literature. We acknowledge that some situations (for example advice to women with GDM but an SGA baby) require more individual assessment and advice and evidence for management of this specific situation was not included within the remit of the guideline.</p>

		higher fasting glucose when all other daytime readings are within target and the baby is normally grown. The guidance doesn't really help in this very common situation. I think some areas would treat and some would not.	
Section 6: Intrapartum and postnatal care			
Are the summaries of benefits and harms, safety, and cost effectiveness evidence accurate and reasonable interpretations of the evidence?			
	AB, AI, CP, CPk, DS, KM, MSJ, SB, SC, SMc, SMcG, TL	Yes (all listed reviewers answered "yes" individually to this question)	Thank you
	AC	Yes. Would be useful to include guidance regarding intrapartum management as this varies between maternity units.	Thank you. Clinical guidance around intrapartum glucose management and delivery was not included in the scope of the guideline. In section 1.2.1 we have include a statement to explain this and a reference to a guideline published by the Joint British Diabetes Societies for Inpatient Care where this is covered in detail.
	HR	No. To me this is all about postnatal detection of impaired glucose tolerance. Intrapartum care to me relates to the planning and run up of delivery and would include the impact steroids may have on glucose levels, expectations of glucose levels during delivery and immediately postnatally and doesn't seem to have been included. If the heading was called 'Detecting glucose intolerance after pregnancy' then I think it has been summarised and concluded well.	Thank you. Agreed. We have changed the title of this section to 'Detecting glucose intolerance after pregnancy'.
Section 6: Intrapartum and postnatal care			
To what extent is the evidence presented generalisable to NHSScotland?			
	AB	Very applicable and generalisable to NHS Scotland.	Thank you

	HR	It seems to have recommended a practical approach	Thank you
	KM	Satisfactory given that it is in line with NICE.	Thank you
	MSJ	The guidelines was written well and is generalisable to NHS Scotland.	Thank you
	SC	Yes, the evidence presented is generalisable to NHS Scotland.	Thank you
	SMcG	The evidence presented is completely generalisable to NHS Scotland.	Thank you

Section 6: Intrapartum and postnatal care

Is there a clear link between evidence and recommendations that describes the volume, strength and consistency of the evidence? E.g. after reading the relevant section of the guideline, can you understand the basis for the suggested recommendations?

	AB, AC, CP, DS, HR, KM, MSJ, SB, SC, SMc, TL, UH	Yes (all listed reviewers answered "yes" individually to this question)	
	SMcG	Yes. The recommendations are clear and consider the realistic options for further testing for GDM postpartum.	Thank you

Section 6: Intrapartum and postnatal care

Do you have any other comments?

6.1.2	CP	This is an area that needs highlighting as even in a small board is complex and difficult to implement.	Noted. Thank you.
	CPk	Recommendation 3 (for those whose blood glucose levels returned to normal) - could 'OR' be added between 2 nd and 3 rd points as it seems that HbA1c test is less than best practice.	Disagree. The option and advice to test between 6–13 weeks and >13 weeks is already given so both time options are already covered.
	DSims	Recommendation 3	We are unclear what the reviewer is recommending. Is it to offer all women OGTT 1st and only do FBG/HbA1c if OGTT not possible? NICE address

		<p>Should this not be an 'opt-out' approach? Prior GDM is the most serious risk factor for T2DM. Women may go onto undiagnosed T2DM in the next pregnancy. Offer and opt out normalises the OGTT and makes declining less likely.</p> <p>However the discussion needs to use motivational interviewing and other person-centred language to ensure that if the woman is not going to do the OGTT its identified and the lesser test is available.</p>	<p>balance between uptake of prenatal screening and barriers to this for women. Data also suggest that FBG most reliable test up to 13 weeks.</p>
	KM	<p>There are some patients with GDM that are highly likely not to be at early risk of T2DM post delivery. Could GDM patients that are adequately controlled by diet alone and didn't meet any of the standard non-pregnancy diagnostic thresholds (7,11.1) on their OGTT simply just be offered an HbA1c after 13 weeks?</p>	<p>Both options are given for clinical teams to adapt to their own practice. Data suggests that FBG is more reliable as a diagnostic test between 6–13 weeks and NICE and SIGN have endorsed this option.</p>
	SMcG	<p>The only consideration would be around some form of optional psychological input postpartum particularly for those with GDM. It can be a considerable adjustment to be temporarily on medications including insulin to then suddenly cease.</p>	<p>Thank you. While this was not included within the scope of this guideline. This may be a reasonable option, where available locally. The GDG is aware of challenges accessing clinical psychology services</p>

Section 7

The Provision of Information section describes knowledge and material which may be useful in shared decision making between patients and professionals. It also contains sources of further information. Do you consider that the relevant information has been included?

	<p>AB, AC, AI, CP, CPk, DS, HR, MSJ, SB, SC, SMc, SMcG, TL, UH</p>	<p>Yes (all listed reviewers answered "yes" individually to this question)</p>	<p>Thank you</p>
	CW	<p>No.</p>	<p>Thank you. Diabetes remission is not part of the scope of this guideline, however is being addressed in another SIGN guideline in development on</p>

		I do think most relevant information has been included but nothing about diabetes remission for people living with type 2 diabetes with a significant weight loss programme underpinned by long term habit change. Counterweight Plus was the intervention used in the DiREct trial and is offered as a Diabetes remission programme across Scotland as part of the Diabetes prevention and treatment framework.	prevention and early recognition and treatment of type 2 diabetes. This comment has been shared with that group.
	KM	No. What about ABCD.care? https://abcd.care/dtn/education - lots of useful resources especially the diabetes tech in pregnancy section. https://abcd.care/dtn/diabetes-tech-pregnancy	Thank you – we have added this link to section 7.2.1
7.2.2	AI	DVLA states that they only need informed if people are using insulin for >3 months and in section.	Thank you. This is already included in this section
7.3	AI	It asked for women to inform the DVLA (this will depend on how long they will be on insulin as for many it will be less than 3 months. Needs clarification in the advice section) Retinal screening for should be offered for women diagnosed with diabetes prior to 14 weeks in pregnancy. Advice section needs to be clear that women diagnosed with gestational diabetes later in pregnancy are not offered retinal screening.	Thank you. We have reinforced the earlier comment describing the role of DVLA with additional points, as follows, on driving in the checklist for Provision of Information. “Signpost the guidance from the DVLA for people with diabetes . Ensure that women with diabetes who use insulin for over 3 months inform DVLA.” Thank you. We have added a subsection in the checklist for Provision of Information on retinal screening. This states that women diagnosed with GDM do not routinely require retinal screening but that they may be reviewed by local retinal screening service if they have a high HbA1c level measured at the booking appointment or in early pregnancy.
	DSim	Checklist contains mixture of GDM and others which is confusing. For women who already have diabetes before pregnancy: the tone and content of communication are really important. For women who are being tested for, or are diagnosed with diabetes or GDM:	Thank you. We have revised this section to more clearly separate advice for women with diabetes before pregnancy and those diagnosed during pregnancy.

		<p>Bullet point 2 – this is not appropriate for women with diet-managed GDM.</p> <p>For ‘All women with diabetes during pregnancy’</p> <p>First bullet point – does this apply to those with GDM?</p>	
Applies to whole guideline: Is the language and tone of the document appropriate?			
	<p>AB, AC, AI, CP, CPK, DS, HR, MSJ, SB, SC, SMc, SMcG, TL, UH</p>	<p>Yes (all listed reviewers answered “yes” individually to this question)</p>	<p>Thank you</p>
	<p>HR</p>	<p>Yes.</p> <p>Paragraph 1 on page 30 would be easier to read if stats and HbA1c cut off were in a table form.</p>	<p>Thank you. We have formatted this as a table.</p>
	<p>LE</p>	<p>The first thing I wanted to say was advice around language and obesity. This may all be adjusted now in the second draft anyway but for info - PHS published guidance for Scotland about the use of non-stigmatising and person-first language in their weight stigma hub for obesity Course: Challenging weight stigma learning hub PHS Learning (publichealthscotland.scot) so this would be a good information source to reference in the guideline as it covers important points like how to talk about body weight in relation to health risk. We know that women in pregnancy are particularly vulnerable to negative comments about weight and body image so for all professionals working with pregnant women, especially in the cohort of women with GDM, this learning resource is a crucial tool.</p> <p>This guidance –</p>	<p>Thank you, we have added this to the Sources of Further Information section.</p>

		<p>MAC01741_NN_UK_HCP_Obesity_Guidelines_FA1a (easo.org) is simple for policy makers and clinicians and sets out the simple way of saying 'living with obesity' rather than 'obese women' for example. In the same way we no longer say 'diabetic' or pre-diabetic' but 'with diabetes' etc. Happy to discuss this further, and Suze Connolly in PHS is the lead for weight stigma so I know would be happy to speak to the wider SIGN team if this would be helpful across all guidelines (acknowledging that weight and obesity appear in almost all health contexts now).</p> <p>I would perhaps reconsider the use of the word 'lifestyle' in terms of advice for women with moderate or high risk of type 2 post partum. Lifestyle is a term that is non-medical/clinical and is open widely to interpretation. I prefer to state exactly what we mean – whether that be balanced healthy diet, weight management, physical activity, smoking cessation, good sleep hygiene, alcohol, drugs, optimising mental health etc. I think in a clinical guideline the detail of this is important.</p>	<p>Thank you. We were unable to determine the original publisher of this resource and note that it repeats the same messages described above therefore we have not included this resource.</p> <p>Thank you. We have elaborated our use of the term lifestyle in section 5.4.1</p>
Applies to whole guideline: Do you have any other comments?			
	DS	<p>Please move the recommendations to the beginning of each section. Where the R is currently, it makes it more difficult to get an at a glance summary of what clinicians are meant to do as it is a large document. If the R parts are moved to the top of each section, this will make it more practical for clinical use and make it more likely that the recommendations will be enacted.</p>	<p>Thank you. The guideline is formatted to SIGN house style. Recommendations are presented at the end of sections following the evidence and rationale which underpin and support these. Key recommendations are presented at the beginning of the document for an 'at a glance' overview, and a quick reference guide which summarises only the recommendations is also available.</p> <p>We have also provided this guideline in a dynamic format on the Right Decision Service platform which allows users to view the recommendations at a glance.</p>
	HR	<p>Seems practical approach to a complicated situation and a basis for improving services and outcomes.</p>	<p>Thank you</p>
	KM	<p>Very good. Lots of detail.</p>	<p>Thank you</p>
	LE	<p>One point I may have missed is about long term follow up and HbA1c check; my understanding was that the evidence supported annual HbA1c check for life for</p>	<p>Thank you. The long-term follow up of women with diabetes during pregnancy was not included in the remit of this guideline.</p>

		women with previous GDM - is this not NICE guidance? I may have missed this part in the guidelines. This is what we encourage via the framework delivery.	Based on the clinical experience of the guideline development group, NICE recommended that women who have been diagnosed with gestational diabetes who became euglycaemic before discharge from hospital remain at high risk of diabetes and should be tested annually after their first postnatal test.
	LW	Requires further information about dietary advice and guidance about weight gain/control during pregnancy.	Thank you. The section on treatment, including recommendations on dietary interventions has now been developed and included.
	MSJ	Guidelines committee can consider following scenario as below as more and more we encounter in the clinical setting: The diagnosis of diabetes in pregnancy for mothers who are already on metformin before the pregnancy for some other indications like PCOS, etc. In those situation, what is the guidelines advice... whether to stop the metformin and test in first trimester or at 24-28 weeks?	Thank you. Management of women with conditions other than diabetes is outside the remit of this guideline. We cannot make further comment on this issue as we have not assessed the evidence base in order to do so.
	SB	Resources are very helpful.	Thank you
	SC	This is a well written guideline which summarises the literature comprehensively and systematically.	Thank you
	UH	A huge amount of data to get through and a lot of studies are conflicting. I appreciate that the evidence needs to be included to understand why the recommendations are being made. Thanks to all those involved. In the completed guideline if there was a way of presenting the data to make it an easier read that would be helpful eg flow chart?	Thank you. Key recommendations are presented at the beginning of the document for an 'at a glance' overview, and a quick reference guide which summarises only the recommendations is also available. The guideline will be formatted as an RDS toolkit to facilitate digital access at point of care and in app format.
1.2.4	AB	Target users of the guideline - Could "community pharmacists" be changed to "pharmacists". Reasoning - pharmacists work in a variety of roles including secondary care and GP practice and are likely to also benefit from the guideline.	Thank you. Agreed. We have made this change.
8.3	DSims	2 nd bullet point: And one hour of performed	Thank you. Agreed. We have made this change.
10.2	CW	Guideline Development Group	Thank you. Weight management and diabetes remission were not included in the remit of this guideline. We were unable to recruit a dietitian to this development group despite circulating requests to several sources. Input and feedback has been provided by a range of individuals and groups. A

		No expert in weight management / diabetes remission seems to have been involved. I am also not seeing any involvement from a specialist diabetes dietitian.	dietitian attended the final guideline development group meeting to offer feedback on revisions to the draft and to ensure that points raised by reviewers had been addressed.
10.3.2	AI	Dr Pauline Strachan should read Dr Pauline Wilson.	Thank you. This individual did not provide consultation feedback and has been removed from the published version of the guideline.
Annex 1	DSims	KQ S1 - Having a higher HbA1c as a group does not mean that treating individuals will make a difference.	Thank you.