NICE National Institute for Health and Care Excellence

Appendix B: Stakeholder consultation comments table

2018 surveillance of Diabetes in pregnancy: management from preconception to the postnatal period (2015)

Consultation dates: 17 to 31 May 2018

Do you agree with the proposal to not to update the guideline?			
Stakeholder	**Overall response**	**Comments**	**NICE response**
Royal College of Obstetricians and Gynaecologists (RCOG)	No	The CONCEPPT trial was a landmark study that should be reflected in current UK guidance for women with type I DM in pregnancy [Lancet 2017]. It represents a focus on how the glucose control information is collected, rather than on how the insulin is delivered. With an improvement in outcomes for the baby, particularly a *reduction* in the need for neonatal care unit admission, this information is highly relevant for the NHS.	Thank you for your comment. Given the stakeholder feedback disagreeing with NICE's proposal not to update the recommendations on continuous glucose monitoring, NICE have reflected on the current evidence underpinning these recommendations, and the value of the new evidence available. NICE agree that the CONCEPTT trial is an important study that showed improvements to outcomes in the infant. As such, NICE agree that this is an area that should be looked at by an expert committee with the skills to fully evaluate the merits of continuous glucose monitoring. NICE now proposes to update the recommendations on continuous glucose monitoring.

Leeds Teaching Hospitals NHS Trust	No	With respect I think NICE has been misled. It is completely incorrect to say that 'no impact on recommendations is expected due to heterogeneity across studies resulting in unclear benefits'. There have been **SIGNIFICANT** advances in relation to the use of Continuous Glucose Monitoring in diabetic pregnancy that urgently need addressing. 1) The landmark CONCEPTT trial (a multicentre, open-label, randomised controlled trial of 325 women with Type 1 diabetes) has **DEFINITIVELY established the effectiveness of continuous-wear, real-time continuous glucose monitoring (CGM) on maternal glucose control and obstetric and neonatal health outcomes.** *Lancet 2017 390(10110) 2347-2359*. The numbers of pregnant women with Type 1 diabetes needed to treat with CGM to prevent one newborn complication are six for both neonatal intensive care admission and large for gestational age, and eight for neonatal hypoglycaemia. **National guidelines need to be revised to recommend offering CGM to all pregnant women with type 1 diabetes.** 2) Flash continuous glucose monitoring using Freestyle Libre is now available on the NHS tariff, following NICE medtech briefing110. https://www.nice.org.uk/advice/mib110/chapter/Summary. And is being widely commissioned and used by people	Thank you for your detailed comments. With regards to continuous glucose monitoring, please note that NICE now proposes to update the guideline focussing on continuous glucose monitoring. Please see the response on page 1 for the rationale for this proposal.

		with diabetes, supported by Diabetes UK and NHS England. The recent Freestyle Libre in Pregnancy (FLIPS) study has demonstrated its accuracy and acceptability in pregnant women with Type 1, 2 and Gestational diabetes. *Diabetes Technol Ther. 2018 Mar;20(3):180-188.* It is the only CGM to be approved with CE Mark for use in pregnancy. This needs considering in the NICE pregnancy guidelines. 3) A recent RCT of 50 women with gestational diabetes has shown that CGM significantly improves glycaemic control. Diabetic Med. 2018 Apr 16. doi: 10.1111/dme.13649. [Epub ahead of print]. Given the now established efficacy of CGM in pregnancy, and the advances in CGM accessibility and accuracy, including for pregnancy, it is an urgent necessity that the NICE Diabetes in Pregnancy guidelines are reviewed as scheduled to enable more definitive guidance on CGM to be given nationally. Without this, it is likely that there will be an unacceptable delay to improving the care of women with diabetes in pregnancy nationally.	Thank you for providing these references. These were not part of our evidence summary as they have published after our search cut-off date of February 2018. We have considered both of these studies for inclusion and the decisions are below. Scott et al. Accuracy, User Acceptability, and Safety Evaluation for the FreeStyle Libre Flash Glucose Monitoring System When Used by Pregnant Women with Diabetes. *Diabetes Technol Ther. 2018 Mar;20(3):180-188.* Excluded as not an RCT (for surveillance reviews we generally limit to RCTs as it is a rapid process aimed at finding key triggers to guideline update) Parmasivan et al. Continuous glucose monitoring results in lower HbA1c in Malaysian women with insulin-treated gestational diabetes: a randomized controlled trial. Diabetic Med. 2018 Apr 16. doi: 10.1111/dme.13649. [Epub ahead of print]. Now included in evidence summary– thank you for highlighting this study
Novo Nordisk Ltd	No	Published evidence relating to best management of diabetes in pregnancy is available and not included in the current guideline. We believe that every opportunity	Thanks you for your comments. Please note that NICE now proposes to update the guideline on continuous glucose monitoring. Please see the response on page 1 for the rationale for this proposal.

		should be taken to ensure the latest evidence is included in national clinical guidelines.	We did not find evidence for other areas of the guideline that would change recommendations.
Royal College of Paediatrics and Child Health	Yes	We are happy with NICE decision not to review N3 guidance for now	Thank you for your comments and support. Please note that NICE now proposes to update the guideline focussing on continuous glucose monitoring. Please see the response on page 1 for the rationale for this proposal.
Royal College of Physicians and Surgeons of Glasgow	No	Both reviewers draw attention to the Concept study which they consider important for the management of diabetes and has been associated with better neonatal outcomes. The College considers this decision should be reviewed. One of our reviewers states that it is surprising that the topic experts have chosen not to update the guideline based on evidence from the Concept study (ref 47). This study, published in the Lancet, demonstrated clear benefit for CGMS users both in terms of target range BGs and HbA1c, and also low NNTs for important neonatal outcomes such as hypoglycaemia and admission to neonatal intensive care. The reason for 'sitting on the fence' appears to be that two other studies did not show benefit, but the quality of these studies (refs 45 and 46) is much lower. Our other reviewer states in light of the CONCEPT trial, the cost effectiveness of using DGM routinely for type 1 pregnancies needs to be evaluated. This should not be delayed as neonatal outcomes would improve with this treatment/monitoring modality.	Thank you for your reviewers' comments. Please note that NICE now proposes to update the guideline focussing on continuous glucose monitoring. Please see the response on page 1 for the rationale for this proposal

		The Royal College of Physicians and Surgeons of Glasgow although based in Glasgow represents Fellows and Members throughout the United Kingdom. While NICE has a remit for England, many of the recommendations are applicable to all devolved nations including Scotland. They should be considered by the relevant Ministers of the devolved governments. The College welcomes this Quality Standard in an important area for both the public and the Health professions.	
Association of British Clinical Diabetologists	No	There have been significant advances in relation to the use of Continuous Glucose Monitoring in pregnancy. The current status of CGM in pregnancy in NICE NG3,as follows, therefore needs updating: 1.3.17/18 Do not offer continuous glucose monitoring routinely to pregnant women with diabetes. Consider continuous glucose monitoring for pregnant women on insulin therapy: • who have problematic severe hypoglycaemia (with or without impaired awareness of hypoglycaemia) or • who have unstable blood glucose levels (to minimise variability) or • to gain information about variability in blood glucose levels This recommendation was based on the evidence available at the time from two randomised controlled trials: One had demonstrated benefit from intermittent retrospective CGM	Thank you for your detailed comments and references. Please note that NICE now proposes to update the guideline focussing on continuous glucose monitoring. Please see the response on page 1 for the rationale for this proposal.

		(1) and the other failed to demonstrate benefit from intermittent real-time CGM (2). These two studies used CGM in different ways, and a key point is that both used it ***only intermittently***. A definitive trial was awaited before stronger recommendations could be given. This has now come in the form of CONCEPTT, an international multicentre (33 centres) open-label, randomised controlled trial of 325 women with Type 1 diabetes (3). It has definitively established the effectiveness of ***continuous-wear real-time*** continuous glucose monitoring (CGM) on maternal glucose control and obstetric and neonatal health outcomes. The numbers of pregnant women with Type 1 diabetes needed to treat with CGM to prevent one newborn complication are six for both neonatal intensive care admission and large for gestational age, and eight for neonatal hypoglycaemia. To put this into context, in the UK 59% of women with T1DM are currently failing to achieve the pregnancy target for glucose control by the third trimester. 48% of babies are being born large for gestational age. 40% of babies born to mothers with T1DM need neonatal intensive care admission (NPID 2016 data (4)). NICE guidelines need to be revised to recommend offering real-time continuous-wear CGM to all pregnant women with type 1 diabetes, as per CONCEPTT, to improve these poor pregnancy outcomes.	

		Two additional relevant papers that need considering are: 1) Flash continuous glucose monitoring using Freestyle Libre is now available on the NHS tariff, following NICE medtech briefing 110. It is being widely commissioned and used by people with diabetes, supported by Diabetes UK and NHS England. The recent Freestyle Libre in Pregnancy (FLIPS) study has demonstrated the accuracy and acceptability of flash glucose monitoring in pregnant women with Type 1, 2 and Gestational diabetes (5). It is currently the only CGM to be approved with CE mark for use in pregnancy. 2) A recent randomised controlled trial of 50 women with gestational diabetes has shown that CGM significantly improves glycaemic control (6) ***References*** 1) Effectiveness of continuous glucose monitoring in pregnant women with diabetes: randomised clinical trial. *Murphy HR et al. BMJ 2008;337:907-910.* *2)* The effect of real-time continuous glucose monitoring in pregnant women with diabetes: a randomized controlled trial. *Secher AL et al. Diabetes Care 2013;36:1877-1883* *3)* Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial. *Feig DS et al Lancet 2017 390(10110) 2347-2359.* *4)https://digital.nhs.uk/data-and-information/publications/statistical/national-pregnancy-in-*	Thank you for providing these references. Some of these were not part of our evidence summary as they have published after our search cut-off date of February 2018, or before our search start date of June 2014. Please note that studies published prior to June 2014 will automatically be excluded as they have been considered previously in surveillance or during guideline development. We have considered these studies for inclusion and the decisions are below. *Murphy HR et al. BMJ 2008;337:907-910.* Excluded as before our search cut-off point *Secher AL et al. Diabetes Care 2013;36:1877-1883* Already included in our surveillance review but the reference was wrong, apologies – reference has now been updated, thank you for highlighting this *Feig DS et al Lancet 2017 390(10110) 2347-2359.* Already included in review, thank you *https://digital.nhs.uk/data-and-information/publications/statistical/national-pregnancy-in-diabetes-audit/national-pregnancy-in-diabetes-annual-report-2016* Excluded as not an RCT (we don't generally consider audit data at surveillance as this a is a rapid review process looking at key triggers for review update)

		diabetes-audit/national-pregnancy-in-diabetes-annual-report-2016 *5)* Accuracy, User Acceptability and Safety Evaluation for the FreeStyle Libre Flash Glucose Monitoring System when Used by Pregnant Women with Diabetes. *Scott EM et al Diabetes Technol Ther. 2018 Mar;20(3):180-188.* *6)* Continuous glucose monitoring results in lower HbA_{1c} in Malaysian women with insulin-treated gestational diabetes: a randomized controlled trial. *Paramasivam SS et al. Diabetic Med. 2018 Apr 16. doi: 10.1111/dme.13649. [Epub ahead of print]*	*Scott EM et al Diabetes Technol Ther. 2018 Mar;20(3):180-188.* Excluded as not an RCT (for surveillance reviews we generally limit to RCTs as it is a rapid process aimed at finding key triggers to guideline update) Paramasivam et al. Continuous glucose monitoring results in lower HbA1c in Malaysian women with insulin-treated gestational diabetes: a randomized controlled trial. Diabetic Med. 2018 Apr 16. doi: 10.1111/dme.13649. [Epub ahead of print]. Now included in evidence summary – thank you for highlighting this study
Cambridge Universities NHS Foundation Trust	No	We would be very cautious about determining the need for a review based on incapacity in a struggling NHS. Given the challenges faced by the NHS at present, the concern would be that standards are considered malleable depending upon the available funding. The role of NICE is surely to recommend cost effective endeavours and advocate for high quality, evidence-based standards, rather than to support lower standards of care in financially constrained times. Good use of evidence also has the opportunity to improve the use of resources in the NHS. 2: The use of CGM in women with type 1 diabetes in pregnancy. The CONCEPTt study was recently completed, and as you mention, not included in previous Cochrane reviews. The authors of the surveillance report seem overly concerned with the outcomes of the small studies (n=24	Thank you for your comprehensive comments. Please note that NICE now proposes to update the guideline focussing on continuous glucose monitoring (see the response on page 1 for the rationale for this proposal.) As part of the surveillance review we considered the views of experts, some of which raised concerns around capacity in the NHS, but we did not base the decision to update or not update the guideline on the basis of this.

		for example) and relatively dismissive of the outcomes of the CONCEPTt study. The surveillance report also considers the studies referenced as 50 and 51 to be negative studies but ref 50 was likely to be underpowered to assess outcomes (n=130) and reference 51 is a conference abstract which makes it difficult to judge the quality of the data. Furthermore, in both studies, CGM was used for a fraction of the time that it was used in CONCEPTt and in the study referenced as 51, the CGM data were only available retrospectively, rather than in real time. These methodological differences could well explain these negative results. CONCEPTt, published in the Lancet, showed an NNT of 6-8 for prevention of NICU admission and neonatal complications. This surely alone justifies on a cost effectiveness level that introducing CGM for pregnant women with type 1 diabetes would be likely to save the NHS money while improving outcomes for mothers and babies. The consultation document mentions that the evidence in this area 'is not mature'. However, we would question whether it is reasonable to weigh all studies equally in this regard, regardless of size or quality. Surely a prospective study of >300 women with type 1 diabetes in pregnancy offers more robust information than a study of 24 women? Or a study of 5-7 days of CGM data available retrospectively every 6 weeks? Given the costs and time involved in running multicentre trials in this field, we think it is unlikely that further studies will add substantially to the evidence base here. Meanwhile, women and babies suffer because of delays updating guidance and the NHS loses out on a potentially cost-saving intervention.	Thank you for highlighting the issue with reference 51, Voormolen et al 2017. We have now corrected this reference to the full paper:

		3: Freestyle libre – a recent NICE technology document (MIB110) commented that the Freestyle libre device for 'flash' continuous glucose monitoring would be very beneficial to pregnant women with diabetes. However, the current guidelines do not reflect this so there is a lack of consistency between NICE documents. MIB110 states that many patients will buy the freestyle libre themselves, but of course this brings a lack of consistency and widens the health gap between rich and poor. Given the likely huge benefits of reducing admissions with hypos or DKA, reducing neonatal complications, reducing neonatal intensive care admission and reducing cost to the NHS, we feel adoption of some form of CGM should be considered urgently.	With regards to Freestyle libre, the evidence base within the MIB only included 1 small study in pregnant women with diabetes which was only available as a conference abstract. Furthermore, the abstract did not report on neonatal outcomes. As it is only available in abstract form it would be excluded from consideration in the surveillance review. As such, it would not be considered sufficient enough to change guideline recommendations.
Diabetes Technology Network UK	No	There have been important research findings which are likely to change the recommendations for CGM in pregnancy. Given the substantial benefits demonstrated in the Feig Lancet (Volume 390, No. 10110, p2347–2359, 25 November 2017) paper, the guidance (and clinical practice) should be updated to reflect the latest evidence. The CONCEPTT multicentre randomised controlled trial has shown: Pregnant CGM users spent more time in target and less time hyperglycaemic (27% *vs* 32%; p=0·0279) than did pregnant control participants. Neonatal health outcomes were significantly improved, with lower incidence of large	Thank you for your detailed comments. Please note that NICE now proposes to update the guideline focussing on continuous glucose monitoring (see the response on page 1 for the rationale for this proposal).

		for gestational age (odds ratio 0·51, 95% CI 0·28 to 0·90; p=0·0210), fewer neonatal intensive care admissions lasting more than 24 h (0·48; 0·26 to 0·86; p=0·0157), fewer incidences of neonatal hypoglycaemia (0·45; 0·22 to 0·89; p=0·0250), and 1-day shorter length of hospital stay (p=0·0091). This paper should change clinical practice and DTN-UK, as a group of clinicians specialising in diabetes, feel NICE should be updated to reflect these recent findings.	
Diabetes UK	No	Diabetes UK disagrees with this proposal and we are very concerned that the decision not to review NG3 is being proposed at this time. We think that the guideline should be updated now to reflect the additional evidence available. This is provided below. We are particularly concerned that the decision has been made not to take into account the recent evidence on benefits of CGM for women with Type 1 diabetes in pregnancy and their babies. A delay of two years would mean the current poor pregnancy outcomes for women with Type 1 diabetes are likely to be perpetuated longer than is necessary, whilst there is clear evidence of interventions that could improve these outcomes. 1.1.7 Preconception advice: the most recent National Pregnancy in Diabetes Audit Report, 2016 showed that only around one in twelve women were well prepared for pregnancy and that this had not changed since 2014. The definition of a 'well prepared for pregnancy' includes a first trimester HbA1c below 48 mmol/mol, taking 5 mg folic	Thank you for your thorough and helpful comments. With regards to continuous glucose monitoring, please note that NICE now proposes to update the guideline focussing on continuous glucose monitoring. Please see the response on page 1 for the rationale for this proposal. Regarding preconception advice, this was not highlighted by topic experts and we did not find any evidence that would change recommendations. Current guideline recommendations in section 1.1 preconception planning and care cover taking 5mg folic acid, target blood glucose and HbA1c levels in the preconception period, and safety of medicines for diabetes before and during pregnancy

		acid and coming off all adverse medication prior to pregnancy. The recommendations under 1.1.7 should address this. 1.1.10 Given the different BMI cut-off points for BAME groups, this recommendation should be reviewed so as not to apply a BMI of 27 for all groups, but rather allow for variation in different ethnic groups. 1.1.11 The advice to take folic acid (5 mg/day) should specify that it is *prescribed* folic acid and not those sold over the counter in pharmacies, which are considerably lower in strength. Unless this is stipulated, women may not be made aware. This is particularly important for women with diabetes who have lower uptakes of folic acid (as reported in the National Pregnancy in Diabetes Audit report 2016). 1.1.29 The Diabetes self-management education programme DESMOND - a course for people with Type 2 diabetes has included a pregnancy module. This is provided to women of child bearing age and informs them about the risks associated with diabetes and pregnancy and provides advice on preconception care and planning. We suggest this programme is referenced in the guideline. 1.2.16 We suggest that the advice on diet given to women with gestational diabetes includes nutrition management. We recommend this is part of an integrated package of education and clinical care as specified in the Diabetes UK nutritional guidelines. This section should also consider the evidence by the Institute of Medicine which shows that	Thank you for the suggestion on BMI cut-offs. A footnote will be added for clarity. Thank you for highlighting the issue with folic acid. We now propose to refresh this recommendation for clarity. Thank you for highlighting this education programme. NICE can only cross refer to tools that have been through the NICE endorsement process. NICE welcomes applications for endorsement of tools that support NICE guidelines and quality standards. Thank you for the suggestion on diet advice. NICE can only cross refer to tools that have been through the NICE endorsement process. NICE welcomes applications for endorsement of tools that support NICE guidelines and quality standards. NICE has a guideline on weight management before, during and after pregnancy (PH27), which covers aspects of diet advice.

		monitoring of weight during pregnancy is recommended and that the weight gain should not exceed the recommended rate on pre-pregnancy BMI set by the Institute of Medicine. 1.2.2 Risk assessment for gestational diabetes should consider adopting the IADPSG criteria as demonstrated by South West Essex: Diabetologia (2015)58:2671-2672. There is a lack of uniformity in the UK on the application of criteria for diagnosing gestational diabetes in order to prevent adverse pregnancy outcomes. We know that obstetricians are concerned that pregnant women are not being diagnosed appropriately and experiencing poorer outcomes as a result. 1.6.11 (lifestyle advice). We would like this guideline to include the recommendations given on weight control, diet and exercise from the Diabetes UK 2018 nutritional guidelines. 1.3.17 There is significant new evidence since the NG3 guideline was published in 2015. The CONCEPTT study published in 2017 on the use of CGM during pregnancy in patients with Type 1 diabetes unequivocally demonstrated that continuous wear CGM improves both glucose control and improved neonatal outcomes - likely to be attributed to reduced exposure to maternal hypoglycaemia. Based on this evidence, we consider that this recommendation (1.3.17) should be revised to recommend offering real time continuous-wear CGM to all pregnant women with Type 1 diabetes.	Thank you for your suggestion on diagnostic criteria. We reviewed the evidence in this area and did not find the evidence base consistent enough to change current recommendations. Thank you for suggesting the reference IADPSG criteria as demonstrated by South West Essex: Diabetologia (2015)58:2671-2672. We have checked this reference and would have excluded it as it is a letter to the editor. Thank you for the suggestion on lifestyle advice. As mentioned above, NICE can only cross refer to tools that have been through the NICE endorsement process. NICE has a guideline on weight management before, during and after pregnancy (PH27), which covers aspects of diet advice.

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

		(Lancet 2017, 'Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised trial' Lancet.2017 Nov 25:390(1010):237-2359) We note that this 2018 surveillance review acknowledged the trial evidence on CGM, but we do not agree with the group's understanding of the results of this and specifically of the CONCEPTT trial. We think that the conclusion drawn by NICE about the pregnancy CGM studies included in this 2018 surveillance review, is misled. We attribute this due to the confusion around the way the term CGM is used (intermittent versus continuous), and the mixture of studies in this review. Other than the CONCEPTT trial, which used continuous-wear real time CGM, all the other RCT studies have used **intermittent** wear CGM (some using real time and some retrospective) and therefore their results are not comparable. The CONCEPTT trial used continuous-wear, real time CGM for women with Type 1 diabetes throughout their pregnancy and was the only study to focus on this group of patients with this intervention. The National Pregnancy in Diabetes Audit report for 2016, found that 59% of women with Type 1 diabetes are currently failing to achieve the pregnancy target for glucose control by the third trimester, 48% of babies are being born large for gestational age, and 40% of babies born to mothers with Type 1 diabetes need neonatal intensive care admission. We think that these negative	

		outcomes risk being perpetuated if this recommendation does not address this issue. In addition, the impact statement on antenatal care for women with diabetes identified new evidence on technology. This evidence, however, does not address the same research questions. One is focussed on gestational diabetes and the other on the closed loop system. We think it would be ill-advised to wait for the outcomes of these two studies as they will not provide additional evidence for women with type 1 and pregnancy/pre pregnancy. As far as we are aware, there are no new studies planned for this group of women with CGM and pumps. We are concerned about the impact statement: "There is ***new*** evidence that insulin pumps ***do not*** offer any advantages over multiple daily injections and may be associated with increased fetal complications, such as large for gestational age, although the evidence base is limited and potentially still immature." We cannot find any reference to this "new" evidence in the surveillance report and are not aware of any studies which demonstrate this poor outcome 1.3.16 While CSII is recommended during pregnancy, we would like this guideline to also recommend offering CSII during the preconception planning phase for women with diabetes whose blood glucose control is unobtainable by MDI. There is compelling evidence for HbA1c reduction with sensor augmented pump therapy.	Regarding insulin pumps, we did not find evidence to change current recommendations and are not proposing any update to this section of the guideline as a result of this.

		1.6.14 Postnatal care. Greater clarity needs to be given on where the HbA1c test should be performed and by whom. We are aware this is not happening which is of great concern given that 50 per cent of people diagnosed with gestational diabetes develop Type 2 diabetes within 5 years. This needs to be addressed so that people receive timely care and support in managing their diabetes and are 'not lost to follow up'	
JDRF and INPUT Patient Advocacy	No	JDRF disagrees with the proposal to not update the guideline. The evidence provided by the CONCEPTT trial sufficiently shows the benefits of Continuous Glucose Monitoring (CGM) to pregnant women and their babies, thus warranting an update to the guideline. 1.3.17 JDRF believes that the consultation has given too much weight to older, less relevant research, in comparison to the recently published CONCEPTT trial. As acknowledged in the consultation document, the CONCEPTT trial (47) (n=325 women with type 1 diabetes) found improvements in a range of neonatal outcomes with CGM plus standard care, compared with standard care alone, including neonatal intensive care admission, large for gestational age and neonatal hypoglycaemia. The CONCEPTT paper states that "the numbers of pregnant women needed to treat with CGM to prevent one new born complication are six for both neonatal intensive care admission and large for gestational age, and eight for	Thank you for your detailed comments. With regards to continuous glucose monitoring, please note that NICE now proposes to update the guideline focussing on continuous glucose monitoring. Please see the response on page 1 for the rationale for this proposal.

		neonatal hypoglycaemia. National and international clinical guideline recommendations in type 1 diabetes in pregnancy should be revised to recommend offering CGM to pregnant women with type 1 diabetes using intensive insulin therapy in the first trimester." By routinely offering CGM to all pregnant women with type 1 we could prevent approximately 275 babies being born with complications annually in England, Wales and the Isle of Man (based on the above findings and the number of pregnant women in England, Wales and the Isle of Man in the National Diabetes in Pregnancy Audit 2016). 48 (Techniques of monitoring blood glucose during pregnancy for women with pre-existing diabetes – Cochrane Database of Systematic Reviews 6), while thorough, is out of date. Three of the trials considered are from 1980, 1983 and 1984 and as acknowledged on Page 22, paragraph 1 of the consultation document, the review did not include the latest evidence from the CONCEPTT trial. One of the trials (50) referred to in this consultation focused on a single application of real time continuous glucose monitoring as an educational tool in pregnant women shortly after diagnosis of gestational diabetes (n=130 women), which was not associated with improvements in glycaemic control or pregnancy outcomes. Also trials (50) and (51) of intermittent use of continuous glucose monitoring for 5-7 days every 6 weeks in pregnant women with type 1 or type 2 diabetes requiring insulin (n=304 women) did not decrease the risk of large for	

		gestational age or glycaemic control. The continuous glucose monitoring and intensive treatment of type 1 diabetes trial (Oct 2008)* showed that for CGM to be beneficial it should be used continuously over a period of time, a finding borne out by CONCEPTT, where CGM was used continuously for approximately 24 weeks (from 10-12 weeks until the end of their pregnancy). The CONCEPTT trial found that improved outcomes for expecting women were accompanied by substantial reductions in newborn complications. The number of babies being born larger than average was reduced (53 percent vs. 69 percent); the number of babies admitted to intensive care for more than 24 hours decreased (27 percent vs. 43 percent); and the number of babies born with low blood sugar levels decreased (15 percent vs. 28 percent). On average, babies whose mothers had used the continuous glucose monitoring device also left hospital one day earlier than babies whose mothers used traditional monitoring (3.1 vs. 4 days).They also had half as many neonatal intensive care unit admissions over 24 hours. Overall, for every six mothers treated, one large birthweight baby and one neonatal intensive care unit admission were prevented. We believe that this study has significantly more relevance to the guideline than the other research considered. * Continuous glucose monitoring and intensive treatment of type 1 diabetes (2008) The Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study	

		Group.New England Journal of Medicine 2008;359:1464-1476 Page 23 re insulin pumps Much of the evidence considered is not appropriate for drawing such a conclusion about the relative effectiveness of pumps over multiple daily injections. Reference 30 and 31 conclude that there isn't sufficient evidence to make a judgement either way. In addition, reference 30 is a review which contains outdated papers from the 1980s and 1990s, and the authors themselves question the designs and methods used in the trials. References 33 and 34 refer to closed-loop systems rather than insulin pumps specifically. Furthermore, it is unclear what the "new evidence" referred to in the impact statement is. It would be concerning if the "new evidence" refers to reference 32, as that is a conference abstract and not the full paper, leading us to consider whether the full paper has not been reviewed appropriately. Whilst the evidence base is indeed still limited regarding the use of pumps, there is no compelling evidence to contraindicate pump use during pregnancy at this time, and the guidelines should reflect this and leave the option for this treatment open to women who would benefit from it.	Regarding insulin pumps, we did not find evidence to change current recommendations and are not proposing any update to this section of the guideline as a result of this. We appreciate that the evidence summary could be interpreted as being critical of insulin pumps and have reworded the section in the evidence summary. As mentioned, no changes to the guideline are proposed and the original recommendations will stand.
Medtronic Limited	No	See comments 1,2,3,4,and 5 as numbered in the ID column Comment 1	Thank you for your detailed comments. With regards to continuous glucose monitoring, please note that NICE now proposes to update the guideline focussing on continuous glucose monitoring. Please see the response on page 1 for the rationale for this proposal.

		We refer to the statement on page 1 “Reasons for the decision”: • “We found new evidence on continuous glucose monitoring, insulin pumps and diagnostic criteria for diagnosing gestational diabetes, which was not fully in line with the current recommendations. However, no impact on recommendations is expected due to heterogeneity across studies resulting in unclear benefits” It is misplaced to consider studies across diagnostic criteria for gestational diabetes, insulin pumps and CGM within the same review section, as diagnostic criteria for gestational diabetes is diagnostic, and insulin pumps and CGM provide therapy. We therefore ask that diagnostic criteria for gestational diabetes, pumps and CGM are each considered independently and separately in the review decision. Additionally, this also applies to the statement from the same section: • “It is anticipated that the evidence base for these areas may have further developed in 2 years’ time” The links to the further evidence are not for studies for CGM in pre-existing diabetes, but only for gestational diabetes and evidence is not transferable from one to the other. It is important that the evidence for CGM for pre -existing diabetes and for gestational diabetes is considered separately as pre -existing diabetes requires the early achievement of control to prevent malformations at conception and first trimester control is required to prevent irreversible late pregnancy complications (the foetal	Thank you for your comment. Please note that the surveillance proposal was a brief summary of the evidence base, and the full evidence was available in the evidence summary document. Whilst for succinctness, the surveillance proposal grouped together continuous glucose monitoring, insulin pumps and diagnostic criteria in a summary of the impact on the guideline, please note that the evidence summary document considered each of these issues separately under the relevant section of the guideline. The decision to update was taken separately for each area of the guideline.

		glucose steal phenomenon). While gestational Diabetes, shares with pre-existing diabetes , only the later pregnancy stage complications Ref: The foetal glucose steal: an underappreciated phenomenon in diabetic pregnancy macrosomia Diabetologia June 2016, Volume 59, Issue 6, pp 1089–1094 There are no planned studies which will be available in two years' time for CGM in pre-existing diabetes. The same can be said for Insulin pumps, there are no planned studies which will be available in two years' time for insulin pumps in pre-existing diabetes and so we ask that in the statement referenced above it is made clear this does not apply to CGM and insulin pumps. Comment 2 **Continuous Glucose Monitoring (CGM)** From the Impact Statement on page 23: • "There is new evidence of continuous glucose monitoring in pregnant women with type 1 diabetes. However, the evidence base appears mixed with 2 studies showing improved neonatal outcomes compared with standard care, but 5 studies showing no benefit or an increase in hypoglycaemia. As such, it is unlikely that the evidence base is mature enough to alter recommendation 1.3.17, which currently advises do not offer continuous glucose monitoring routinely to pregnant women with diabetes" One study, CONCEPTT, overwhelmingly supports the use of CGM in pregnant woman for improved neonatal	

		outcomes. CONCEPTT is an international randomised controlled trial and is in contrast to conflicting evidence from inferior studies referenced in the surveillance review We refer particularly to the statement • “but 5 studies showing no benefit or an increase in hypoglycaemia” In the comments below we have discussed the RCT’s and the 5 other studies. In the surveillance review, studies for the use of CGM in gestational diabetes and use of CGM in pre-existing diabetes have been combined which we consider to be misplaced as we have stated above. The focus of our comments for are the evidence reviewed for CGM in pre-existing diabetes. In the 2018 surveillance for CGM the reviewers found • The systematic review (44) included 3 RCT’s, (45,46,47) 2 for pre-existing diabetes and 1 for gestational diabetes and so RCT (45) for gestational diabetes should be separated for this review in the surveillance report. • In RCT (46) although the title indicates the use of Real Time CGM, in fact CGM was used “intermittently” for short periods of time and not “continuously” as it is designed. (only 5 women used CGM continuously) • In contrast RCT (47) “CONCEPTT” required woman to wear CGM continuously for at least 6 days per week during their pregnancy. CONCEPTT is a multicentre international RCT and randomised 325 women. Results indicates that CGM during pregnancy in woman with Type 1 diabetes is	

		associated with improved neonatal health outcomes attributed to reduced exposure to maternal hyperglycaemia. The numbers of pregnant women needed to treat with CGM to prevent one complication, according to Feig, the first author of a publication sponsored by JDRF, are 1. six for both neonatal intensive care admission 2. six for large for gestational age, and 3. eight for neonatal hypoglycaemia. CONCEPTT recognises prior evidence in the Research in Context section (including RCT (46) from 2013). • Additionally, the CONCEPTT control arm (no CGM) shows that the majority of pre-gestational diabetes pregnancies are still ending with negative outcomes (LGA-60% as a bench mark and malformations). Thus, not to update NG3 will perpetuate these poor results. To delay the review by another two years will further contribute to these poor outcomes. • The benefits found in CONCEPTT in the CGM arm, contrast alarmingly with the risk of complications found in The Confidential Enquiry into Maternal and Child Health-Diabetes; key findings for women. Diabetes major congenital malformations increased 2-fold (41.8 per thousand), still birth increased 4 to 5 times (26.8 per thousand) fold, and perinatal mortality rates increase 4-fold (41.8 per thousand with poor glycaemic control at the start of pregnancy being the most significant risk factor for still	

		births and congenital malformations. In the publication, Murphy et al "Improved pregnancy outcomes in women with type 1 and type 2 diabetes but substantial clinic-to-clinic variations: a prospective nationwide study", Diabetologia (2017) 60:1668–1677, shows improvements, though poor glucose control and high rates of perinatal morbidity continue. • There are two Cochrane reviews for CGM, one for gestational diabetes and one for pre-existing diabetes. The focus of our comments is for pre-existing diabetes. The Cochrane review for pre-existing diabetes (48) concludes that evidence is weak for the use of CGM in pregnant woman however the review did not include a review of the CONCEPTT study. The Cochrane review supports the need for a well-designed RCT and CONCEPTT meets this requirement • Trial (50) and (52) are both for gestational diabetes and so cannot be considered alongside CGM in pre-existing diabetes. Trial (51) is a conference abstract not a peer reviewed publication and so is of low value in comparison to an RCT such as CONCEPTT. CGM was also used intermittently and so was not continuous use Insulin Pumps Comment3 **Insulin Pumps** From the Impact Statement of Page 23: • "There is new evidence that insulin pumps do not offer any advantages over multiple daily injections and may be	Thank you for the information on insulin pumps. We did not find evidence (including the references provided below) to change current recommendations and are not proposing any update to this

		associated with increased foetal complications, such as large for gestational age, although the evidence base is limited and potentially still immature” Though the Cochrane review (30) was published in 2016 (new) it contains data from publications dating back over 30 years ago and so we question the relevance of this review in today’s healthcare settings. Farrar (30), author of the Cochrane review, states: “the limited and potentially low-quality evidence of the 4 trials included in this review prevents the drawing of meaningful conclusions regarding the effectiveness of one method of insulin administration over another in pregnancy for women requiring insulin supports the findings of another review” The studies included in this recent review are very small, outdated, and not adjusted for the different baseline risk for negative outcomes (BMI, T1DM vs T2DM). - Trossarelli 1984, N=12 T1DM; abstract only - Botta 1986, N=10, T1DM; - Carta 1986, N=29, T1DM 15, T2DM - Nosari 1993, N=21 T1DM - Mello 2005, N=71; Mello could not be included in the metanalysis Both CGM and insulin pump therapy should ideally be started before conception, while the above trials mostly started the intervention during the first semester.	section of the guideline as a result of this. We appreciate that the evidence summary could be interpreted as being critical of insulin pumps and have reworded the section in the evidence summary.

		Similar limitations mentioned in Farrar's review are described in the 2nd review (31): - Chico (2011) "mentioning the bias for baseline risk in retrospective trials: Baseline characteristics differ across the treatment groups: women using CSII have a more serious condition (i.e., longer duration of diabetes mellitus and a higher rate of prior malformations), the year of delivery reflects the timing of CSII and Lispro Insulin (LP) introduction in clinical practice, and the higher number of pregnancies of women with T1DM per year in the groups using LP reflects an increasing workload along the years". The most recent retrospective study included in this review (31) is from Poland (Wender-Ozegowska, E. et al 2013). The author states, that - this retrospective trial was not powered to detect any difference in outcome (N=128; 64 CSII and MDI each); - additionally, no women planned their pregnancies on CSII in this study, when it might be particularly beneficiary for further fetal development. Bruttomesso et al 2011 also raises baseline risk bias as a major limitation of his study: O - women treated with CSII had longer durations of diabetes and more chronic complications of diabetes. Rys (33) is an abstract only and can thus not be commented more in detail.	

		Comment 4 There is new evidence for the use of insulin pumps in pregnancy which has not been included in the surveillance review: 1. In the prospective trial Effect of Continuous Glucose Monitoring on Glycemic Control, Acute Admissions, and Quality of Life: A Real-World Study, Charleer (2018), results from Belgium show the benefits of Sensor Augmented Pump (SAP)therapy with active hypoglycemia protection (Low glucose suspend function) 66 women used SAP, recently published, this represents 15% of pregnant woman with Type 1 diabetes in Belgium. The results of 12 months follow up for all people in the registry showed a. 4fold reduction of hospitalization from 16% to 4% b. Reduced A1c c. improved QoL and reduced fear of hypoglycemia d. CEA results from modelling have thus been confirmed by real-world data e. This study shows pregnant women at high risk for severe hypos can thus improve glycemic control without increasing hypoglycemia and improve outcomes for pregnant women and their babies and is comparable to the CONCEPTT trial results. 2. A new study, Objectives and methods of the ORCHESTRA FOUNDATION Registry study: a multi-center	Thank you for providing these references. We have considered these studies for inclusion and the decisions are below. Charleer, 2018 https://www.ncbi.nlm.nih.gov/pubmed/29342264 Excluded as a cohort study and not in pregnant women. Orchestra study https://clinicaltrials.gov/ct2/show/NCT01779141 Excluded as not yet published.

		observational study of the use of insulin pump therapy in pregnant women with type 1 diabetes mellitus in Poland, Jacek Sieradzki et al (2018) will report results soon and will be available during an update of the guideline if the decision of the surveillance review is changed. Comment 5 We ask the review decision for CGM is changed independently of diagnostic criteria for gestational diabetes since the evidence from CONCEPTT helps clarify the role of CGM and warrants an update of the guideline. We ask the review decision for insulin pump therapy (and SAP) is changed independently of the diagnostic criteria for gestational diabetes as more recent evidence, not included in the surveillance review, helps clarify the role of insulin pump therapy and warrants an update of the guideline. The recommendations should advice woman in pre-conception to consider the use of technology e.g. CGM, Pump therapy or SAP if they are not at their target goals for control	Thank you for your suggestions. Apologies for any confusion, but for brevity the surveillance report summarised across areas. Each area of the guideline was considered independently, as described in the evidence summary. As noted above, NICE now propose a partial update for continuous glucose monitoring. Regarding insulin pumps, we did not find evidence (including the references provided above) to change current recommendations and are not proposing any update to this section of the guideline as a result of this.
National Obesity Forum	Yes	Because more research will be completed and become available within two years, as described. Furthermore, differing pract-ices are undertaken in different countries, which may become aligned in due course.	Thank you for your comment and support. With regards to continuous glucose monitoring, please note that NICE now proposes to update these recommendation. Please see the response on page 1 for the rationale for this proposal.

Northumbria Diabetes Service, National Pregnancy in Diabetes	No	The National Pregnancy in Diabetes Audit Clinical Advisory Group is very concerned at the decision not to review and update the NICE guideline NG3. There are 2 specific areas that we believe require updating: • The NPID audit clearly demonstrates the value of HbA1c as a predictor of risk during pregnancy in women with pre-gestational diabetes. It is surprise to us that this data (now consisting of 4 cycles of the National Audit, representing more than 10,600 pregnancies) has not been included in the review (https://digital.nhs.uk/data-and-information/clinical-audits-and-registries/our-clinical-audits-and-registries/national-pregnancy-in-diabetes-audit). We believe that the recommendation (1.3.8) to 'consider' offering women with pre-gestational diabetes in 2nd and 3rd trimester should be upgraded to a requirement rather than an option. This will be audited within NPID. • We recognise that the findings of the CONCEPTT trial were considered by the group in arriving at their decision not to update guideline NG3. However we disagree with the group's understanding of the outcomes of this trial. The CONCEPTT study is a large, multicentre, robust study. It unequivocally demonstrates that continuous wear CGM improves both glucose control and infant health outcomes (a halving in the odds ratio for large for gestational age infants, neonatal intensive care admissions and neonatal hypoglycaemia, and reduces length of hospital stay by a day. The number needed to treat to avoid an adverse infant outcome for women with type 1 diabetes is 6.	Thank you for your detailed comments. With regards to continuous glucose monitoring, please note that NICE now proposes to update the guideline focussing on continuous glucose monitoring. Please see the response on page 1 for the rationale for this proposal. Thank you for highlighting the NPID audit. The recommendations on HbA1c testing were updated in 2015 and the review authors and committee based this on the best available evidence available at the time (including RCTs, comparative and non-comparative studies). During our surveillance review we did not find new evidence that would change these recommendations.

		We believe that the reason that the reviewers have come to the conclusion that the evidence base for CGM is mixed, is due to confusion about the way that CGM has been used (continuous vs intermittent) and some conflation of the groups that are being studied (type 1, type 2 and gestational diabetes) in different studies. We believe that, based on CONCEPTT, the evidence is clear that for women with type 1 diabetes, continuous wear CGM is beneficial to their infants. This represents significant new evidence since guideline NG3 was published in 2015. This clear new evidence should prompt an update of the guideline. Given the current annual numbers of women with type 1 diabetes included in the NPID Audit (over 1500 women), deferral of updating of the guideline by 2 years may result in avoidable harm to up to 500 infants. I'm writing on behalf of the Clinical Advisory Group for the National Pregnancy in Diabetes (NPID) Audit group to express our collective concern at the decision by the NICE not to review clinical guideline NG3 and to strongly urge that this decision is reversed. The NPID Audit group is a part of the National Diabetes Audit portfolio with a deep and ongoing interest in the delivery of quality care for diabetes. The NPID Audit Advisory Group consists of clinical experts in diabetes, obstetrics, maternal medicine, midwifery, public health, academic research, audit and service users from across England and Wales. The Audit specifically measures the	

		processes and outcomes of care for women with pre-gestational diabetes during pregnancy against NICE derived quality standards. It is the largest database of systematically collected data on pregnancy in women with diabetes in the world. It is critically important to the function of the Audit that NICE guidance accurately reflects current evidence and best practice, and it is because we, as a group, are agreed that this has progressed in some important ways since the last guideline review that we are writing to urge that this be updated. This is particularly pressing because the poor outcomes of pregnancies for women with diabetes have remained static for over a decade and the consequences of these outcomes are huge for the infants and the women themselves.	
Public Health England	No	The guidance for diabetes in pregnancy and retinal assessment is currently as follows: Retinal assessment during pregnancy 1.3.24 Offer pregnant women with pre existing diabetes retinal assessment by digital imaging with mydriasis using tropicamide following their first antenatal clinic appointment (unless they have had a retinal assessment in the last 3 months), and again at 28 weeks. If any diabetic retinopathy is present at booking, perform an additional retinal assessment at 16–20 weeks. [2008, amended 2015]	Thank you for highlighting the issues with the retinal assessment pathway, we agree this needs further consideration. NICE propose to amend this section of the guideline to reduce any unnecessary retinal screening.

		1.3.25 Diabetic retinopathy should not be considered a contraindication to rapid optimisation of blood glucose control in women who present with a high HbA1c in early pregnancy. [2008] 1.3.26 Ensure that women who have preproliferative diabetic retinopathy or any form of referable retinopathy diagnosed during pregnancy have ophthalmological follow up for at least 6 months after the birth of the baby. [2008, amended 2015] 1.3.27 Diabetic retinopathy should not be considered a contraindication to vaginal birth. [2008] The pathway above has produced an unnecessary burden on local programmes when women present to the screening programme as pregnant for their initial assessment between 13-16 weeks, without a screen in the last three months. If as described above, any diabetic retinopathy is present at the initial screen they would need to be rescreened at 16-20 weeks, in theory this could lead to two screens in quick succession, potentially 2 screens within 2 weeks. Following discussion with the clinical panel of the NDESP programme advisory group it was decided that this additional screen at 16-20 weeks would be unnecessary for women presenting with diabetes for their initial assessment between weeks 13-15 who had background retinopathy (R1) present.	

		The programme advisory group determine that it would be clinically acceptable for this group of women with evidence of background retinopathy at their initial screening (13-16 weeks) to not have the 16-20 week screen but still require the 28 week screen. Therefore NDESP is requesting an addition to the existing pathway to include the following wording: If a pregnant woman with pre-existing diabetes presents for retinal assessment at 13-16 weeks without a screen in the last 3 months and background retinopathy is present (R1), the 16-20 week screen is not required and the woman can be screened again at 28 weeks. Since its introduction we have become aware of a nuance of late presenting women with background retinopathy (R1) being screening too often sometimes in quick succession and would like a slight modification as outlined in the document above. Response from the NHS diabetic eye screening programme (NDESP) in response to consultation RE: NICE guideline on NG3 Diabetes in pregnancy: management from preconception to the postnatal period. **The guidance for diabetes in pregnancy and retinal assessment is currently as follows:** Retinal assessment during pregnancy 1.3.24 Offer pregnant women with pre-existing diabetes retinal assessment by digital imaging with mydriasis using	

		tropicamide following their first antenatal clinic appointment (unless they have had a retinal assessment in the last 3 months), and again at 28 weeks. If any diabetic retinopathy is present at booking, perform an additional retinal assessment at 16–20 weeks. [2008, amended 2015] *1.3.25 Diabetic retinopathy should not be considered a contraindication to rapid optimisation of blood glucose control in women who present with a high HbA1c in early pregnancy. [2008]* *1.3.26 Ensure that women who have preproliferative diabetic retinopathy or any form of referable retinopathy diagnosed during pregnancy have ophthalmological follow-up for at least 6 months after the birth of the baby. [2008, amended 2015]* *1.3.27 Diabetic retinopathy should not be considered a contraindication to vaginal birth. [2008]* The pathway above has produced an unnecessary burden on local programmes when women present to the screening programme as pregnant for their initial assessment between 13-16 weeks, without a screen in the last three months. If as described above, any diabetic retinopathy is present at the initial screen they would need to be rescreened at 16-20 weeks, in theory this could lead to two screens in quick succession, potentially 2 screens within 2 weeks. Following discussion with the clinical panel of the NDESP programme advisory group it was decided that this	

		additional screen at 16-20 weeks would be unnecessary for women presenting with diabetes for their initial assessment between weeks 13-15 who had background retinopathy (R1) present. The programme advisory group determine that it would be clinically acceptable for this group of women with evidence of background retinopathy at their initial screening (13-16 weeks) to not have the 16-20 week screen but still require the 28 week screen. Therefore NDESP is requesting an addition to the existing pathway to include the following wording: *If a pregnant woman with pre-existing diabetes presents for retinal assessment at 13-16 weeks without a screen in the last 3 months and background retinopathy is present (R1), the 16-20 week screen is not required and the woman can be screened again at 28 weeks.*	
Royal College of Nursing	Yes	The research and evidence base is in date at this time. As already commented on, works over the next two years may provide further information	Thank you for your comments and support. With regards to continuous glucose monitoring, please note that NICE now proposes to update the guideline focussing on continuous glucose monitoring. Please see the response on page 1 for the rationale for this proposal.
Department of Health and Social Care	No response	Wish to confirm that the Department of Health and Social Care has no substantive comments to make, regarding this consultation.	Thank you for your response.
Royal College of Pathologists	Yes	No comments provided	Thank you for your support. With regards to continuous glucose monitoring, please note that NICE now proposes to update the

			guideline focussing on continuous glucose monitoring. Please see the response on page 1 for the rationale for this proposal.
King's College Hospital NHS Foundation Trust	No	The recently published CONCEPTT trial [47] provides RCT evidence that, in women with type 1 diabetes, RT-CGM, offered continuously (rather than intermittently) throughout pregnancy from the first trimester, versus standard care alone results in improvement in a range of neonatal outcomes compared with standard care alone, including neonatal intensive care admission, large for gestational age and neonatal hypoglycaemia without increase in maternal hypoglycaemia. In our view these data are strong enough to recommend RT-CGM routinely in women with type 1 diabetes from early pregnancy. We therefore think section 1.3.17 'Do not offer continuous glucose monitoring routinely to pregnant women with diabetes' should be reviewed and updated specifically for women with type 1 diabetes. We note (page 21 of consultation document) that 5 other RCTs of RT-CGM in pregnancy were identified with varying outcomes. However, 3 of these are in women with GDM [45, 50, 52] whom we believe should be considered separately from women with T1DM. The 2 in pre-existing diabetes used CGM intermittently only, in contrast to the continuous use examined in CONCEPTT. Given the complexity of such trials, and the robust data from CONCEPTT, it is unlikely that there will be another trial of CGM in type 1 diabetes of comparable size to	Thank you for your comprehensive comments. Please note that NICE now proposes to update the guideline focussing on continuous glucose monitoring. Please see the response on page 1 for the rationale for this proposal.

		expand the evidence base in this group in the foreseeable future.	
NICE diabetes type 1 guideline (NG17) is considered alongside diabetes in pregnancy (NG3) at the next surveillance review due to the overlaps in potential interventions, such as insulin, insulin pumps and continuous glucose monitoring			
Stakeholder	**Overall response**	**Comments**	**NICE response**
Royal College of Obstetricians and Gynaecologists (RCOG)	Yes	The support staff who care for women with various forms of hyperglycaemia in pregnancy are shared, as are the medical staff in most instances. It is artificial, therefore, to have the guidelines separated.	Thank you for your comments.
Leeds Teaching Hospitals NHS Trust	No	This just adds delay to the necessity for review of the pregnancy guidelines.	Thank you for your comment. As detailed on page 1, NICE is now proposing to update the guideline for continuous glucose monitoring.
Novo Nordisk Ltd	No	We agree that it would be sensible to consider updating both guidelines concurrently, given the areas of overlap. However, current published evidence exists that could contribute to the good care and clinical outcomes provided to pregnant women and their unborn children and a decision not to consider an update for a further 2 years is not providing the best clinical guidance for supporting and managing women who are pregnant. It is our understanding that the Type 1 Diabetes NG17 guideline is also due for surveillance consultation in 2018 as the current manual states updates are considered at 3	Thank you for your comments. As detailed on page 1, NICE is now proposing to update the NG3 guideline for continuous glucose monitoring. Thank you for your support regarding undertaking NG17 surveillance at the same time as NG3.

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		years and it was published along with NG3 in 2015. Therefore these two guidelines can indeed be considered and updated together commencing in 2018.	
Royal College of Paediatrics and Child Health	No answer	No comments provided	Thank you.
Royal College of Physicians and Surgeons of Glasgow	No	Both reviewers consider that that the clinical issues encountered in pregnancy are a unique subgroup of general Type 1 issues, and deserve special focus. Pre-existing diabetes in pregnancy requires intense management pre-pregnancy, throughout and with detailed postnatal planning. Guidance for gestational diabetes should be considered separately. It is a milder temporary condition, generally requiring less intense measures (e.g. less likely to suffer hypoglycaemia and unlikely to require carbohydrate counting etc).	Thank you for your comments. The proposal to undertake surveillance of diabetes in pregnancy alongside type 1 diabetes would not preclude consideration of type 2 diabetes in pregnancy and gestation diabetes for NG3. The aim was simply to ensure interventions such as continuous glucose monitoring and insulin pumps are considered for both guidelines as these are areas of rapid evidence development and we are conscious that one guideline may inadvertently fall behind the other in terms of recommending these technologies if we do not attempt to look at them in tandem, as well as hopefully managing any overlaps and any potential synergy of the evidence base.
Association of British Clinical Diabetologists	No	Due to the reasons described above, no. However if the decision is made not to update NG3 now then, yes.	Thank you for your comments. As detailed on page 1, NICE is now proposing to update the guideline for continuous glucose monitoring.

Cambridge Universities NHS Foundation Trust	No response provided	It is certainly beneficial that NICE recommendations are consistent where the remit of guidelines overlaps. However, to delay cost-saving interventions to the NHS for 2-4 years while new guidance is developed and checked for consistency seems excessive. Realistically, if the next surveillance period starts in 2 years' time, it will be many more years before guidance is updated.	Thank you for your comments. As detailed on page 1, NICE is now proposing to update the guideline for continuous glucose monitoring.
Diabetes Technology Network UK	No	The pregnancy guide should be updated sooner in light of the above.	Thank you for your comments. As detailed on page 1, NICE is now proposing to update the guideline for continuous glucose monitoring.
Diabetes UK	No response provided	We agree that it would be useful that these two guidelines are looked at together but would stress that there is new evidence to strongly suggest the need to update the NICE guideline NG3 now. In addition, the pregnancy guideline covers issues relating to populations other than Type 1 diabetes which also need addressing and updating, as noted above. For consistency, we would also support a partial update of NG17.	Thank you for your support regarding undertaking NG17 surveillance at the same time as NG3. As detailed on page 1, NICE is now proposing to update the guideline for continuous glucose monitoring. We will consider new evidence in relation to NG17 when it goes through its surveillance process but we do not have any known reason now to update it.
JDRF and INPUT Patient Advocacy	Yes	We agree it would be useful for the two guidelines to be looked at together, but would like to stress that there is enough evidence now to update the NICE NG3 guideline.	Thank you for your comments. As detailed on page 1, NICE is now proposing to update the guideline for continuous glucose monitoring.

Medtronic Limited	Conditional	If the current recommendation not to review is not reversed following the consultation process, we agree with this proposal	Thank you for your comments. As detailed on page 1, NICE is now proposing to update the guideline for continuous glucose monitoring.
National Obesity Forum	Yes	Although type 1, type 2, gestational, MODY, LADA, iatrogenic diabetes must be clearly delineated, as the distinctions are unclear and muddled, and often mixed within the same paragraphs. Treatment and assessment issues are vastly different in each area; differences which are not clearly separated here. This risks becoming one huge guideline, so must become more easily navigatable, bearing in mind that GPs, for instance have thousands of guidelines per year to digest, and may be approaching this with little or no knowledge. There is minimal point in a guideline written for experts by experts, when there is a sea of ignorance amongst HCPs who need a basic education in order to understand guidelines	Thank you for your comments. The proposal to undertake surveillance of diabetes in pregnancy alongside type 1 diabetes would not preclude consideration of the differences in the different populations. The aim was simply to ensure interventions such as continuous glucose monitoring and insulin pumps are considered for both guidelines as these are areas of rapid evidence development and we are conscious that one guideline may inadvertently fall behind the other in terms of recommending these technologies if we do not attempt to look at them in tandem.
Northumbria Diabetes Service, National Pregnancy in Diabetes	No	The NPID Audit 2016 shows that half of women with pre-gestational diabetes have type 2 diabetes. This proportion is increasing annually. Type 2 diabetes results in similar risks to the infants of women with Type 1 diabetes and NPID demonstrates that fewer women are well prepared for pregnancy. It is inappropriate to consider the focus for of recommendations for pregnancy to be linked solely to recommendations for type 1 diabetes and essential that	Thank you for your comments. The proposal to undertake surveillance of diabetes in pregnancy alongside type 1 diabetes would not preclude consideration of type 2 diabetes in pregnancy and gestation diabetes for NG3. The aim was simply to ensure interventions such as continuous glucose monitoring and insulin pumps are considered for both guidelines as these are areas of rapid evidence development and we are conscious that one guideline may inadvertently fall behind the other in terms of recommending these technologies if we do not attempt to look at them in tandem.

		recommendations for type 2 diabetes are also developed with the needs of women who may become pregnant. Women who develop gestational diabetes (i.e. do not already have diabetes prior to pregnancy) are much more common than women with pre-gestational diabetes. These also require issues of diagnosis and diabetes prevention to be considered separately from the type 1 diabetes guideline review.	
Public Health England	Yes	No comments provided	Thank you for your response.
Royal College of Nursing	Yes	This makes good sense and would agree here.	Thank you for your response and support for the proposal.
Royal College of Pathologists	Yes	No comments provided	Thank you for your response.
King's College Hospital NHS Foundation Trust	Yes	No comments provided	Thank you for your response.
Do you have any comments on areas excluded from the scope of the guideline?			
Stakeholder	**Overall response**	**Comments**	**NICE response**
Royal College of Obtetricians and Gynaecologists (RCOG)	No	No comments provided	Thank you for your response.

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Leeds Teaching Hospitals NHS Trust	No	No comments provided	Thank you for your response.
Novo Nordisk Ltd	Yes	The scope of the 2015 update excluded consideration of analogue insulins. The current recommendation (1.1.22) relating to rapid-acting analogues was retained from the 2008 guideline, now 10 years old, and does not advocate the use or continuation of rapid acting analogues in pregnancy, The recommendation 1.1.23 to use isophane insulin as the first choice for long-acting insulin in pregnancy does not take into account the published RCT's demonstrating safety in pregnancy. Not all insulin analogues have randomised controlled trial data in pregnancy. It is important to differen tiate medications that have a strong evidence base, including randomised controlled trials data, which give confidence for use in pregnancy. Novo Nordisk recommends that a separate sub-section on insulin detemir and aspart is included to reflect randomised clinical trials data in pregnancy. Insulin detemir In an open-label randomised controlled non-inferiority clinical trial 310 women with type 1 diabetes were treated with insulin detemir (n=152) or NPH (Neutral Protamine Hagedorn) insulin (n=158) both in combination with insulin aspart up to 12 months before pregnancy (48%) or during pregnancy at 8-12 weeks (52%). The primary analysis aimed to demonstrate non-inferiority of insulin detemir to NPH with respect to HbA1C at 36 gestational weeks. Insulin detemir demonstrated non-inferiority to NPH insulin (HbA1C at 36 weeks 6.27% for insulin detemir and 6.33%) (full analysis set, -0.06% [95% CI -0.21 to 0.08]; per	Thank you for your comments. During the 2018 surveillance we searched for all types of insulin therapy, including insulin analogues. We found several reviews, including a large Cochrane review of 53 studies. However, we did not find evidence that would change recommendations at this time. We shall note this issue for future surveillance.

		protocol, -0.15% [-0.34 to 0.04]). Fasting plasma glucose was significantly lower with insulin detemir versus NPH at both 24 and 36 gestational weeks. Major and minor hypoglycaemia rates during pregnancy were similar between groups (Mathiesen et al., 2012). Secondary analyses of perinatal and obstetric outcomes were analysed. For insulin detemir and NPH, there were 128 and 136 live births, 11 and 9 early fetal losses, and two and one perinatal deaths, respectively. Gestational age at delivery was greater for children from the insulin detemir arm than the NPH arm (treatment difference: 0.49 weeks [95% CI 0.11;0.88], p=0.012). Sixteen children had a malformation (IDet: n=8/142, 5.6%; NPH: n=8/145, 5.5%). There was no significant difference between the two arms with respect to composite pregnancy outcome (birthweight <10th or >90th percentile for gestational age and sex; preterm delivery; early fetal death; perinatal mortality; neonatal fatality; major malformations). (Hod et al., 2014) References: Mathiesen ER, Moshe H, Ivanisevic M, et al. Maternal efficacy and safety outcomes in a randomized, controlled trial comparing insulin detemir with NPH insulin in 310 pregnant women with Type 1 Diabetes. Diabetes Care 35:2012–2017, 2012. Hod M, Mathiesen ER, Jovanovic L, et al. A randomized trial comparing perinatal outcomes using insulin detemir or neutral protamine Hagedorn in type 1 diabetes. J Matern Fetal Neonatal Med 27(1):7–13, 2014. Insulin aspart An open-label randomised trial has been conducted comparing treatment with insulin aspart (n=157) with human insulin (HI) (n=165) in basal-bolus therapy in 322	Thank you for providing these references. These were not part of our evidence summary as they published before our search start date of June 2014. Please note that studies published prior to June 2014 will automatically be excluded as they have been considered previously in surveillance or during guideline development. We have considered these studies for inclusion and the decisions are below. (Mathiesen et al., 2007) Excluded as before our search cut-off point Hod et al. (2007) Excluded as before our search cut-off point

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		women with type 1 diabetes who were pregnant or planning a pregnancy. The primary endpoint was major hypoglycaemia during pregnancy. Major hypoglycaemia occurred at a rate of 1.4 vs. 2.1 episodes/year exposure with insulin aspart and HI, respectively (relative risk 0.720 [95% CI 0.36 –1.46]). HbA1C was comparable with HI in second and third trimesters. At the end of first and third trimesters, average postprandial plasma glucose increments were significantly lower with insulin aspart than HI (p=0.003 and p=0.044, respectively), as were mean plasma glucose levels 90 min after breakfast (p=0.044 and p=0.001, respectively). (Mathiesen et al., 2007) Hod et al. (2007) analysed fetal and perinatal outcomes concluding that fetal outcomes using insulin aspart was comparable with HI with a tendency toward fewer fetal losses and preterm deliveries. For insulin aspart and HI, respectively, there were 137 and 131 live births and 14 and 21 fetal losses. Perinatal mortality was 14 and 22 per 1000 births; number of congenital malformations was 6 and 9; mean birthweight corrected for gestational age was 3438 g and 3555 g (p=0.091). Mean gestational age was 37.6 vs 37.4 weeks. Preterm delivery occurred in 20.3% (insulin aspart) and 30.6% (HI) of pregnancies (p=0.053). References: Mathiesen ER, Kinsley B, Amiel SA, et al. Maternal glycemic control and hypoglycemia in type 1 diabetic pregnancy: a randomized trial of insulin aspart versus human insulin in 322 pregnant women. Diabetes Care 30(4):771-6, 2007. Hod M, Damm P, Kaaja R, et al. Fetal and perinatal outcomes in type 1 diabetes pregnancy: a randomized study comparing insulin aspart with human insulin in 322 subjects. Am J Obstet Gynecol 198(2):186.e1-7, 2008. Fast-acting insulin aspart	

		The current guideline (NG3) emphasises the importance of post-prandial glucose control, with specific targets for 1-hour and 2-hour post meal capillary plasma glucose. Novo Nordisk submit the following evidence to support the achievement of these targets. As shown by Mathiesen et al (2007), pregnant women treatment with insulin aspart compared to human insulin had significantly lower postprandial plasma glucose at the end of both first and third trimesters. As detailed below, fast-acting insulin aspart (faster aspart) further improves post-prandial glucose increments compared to insulin aspart (Russel-Jones et al, 2017) in non-pregnant participants with type 1 diabetes. Faster aspart is a formulation of insulin aspart with the excipients L-arginine and niacinamide. Both excipients are listed by the American Food and Drug Administration as generally recognised as safe (GRAS). These excipients allow a faster appearance in the bloodstream (4.9 minutes vs. 11.2 minutes) compared with insulin aspart, as tested in clamp studies of non-pregnant participants with Type 1 diabetes (Heise et al, 2015). A randomised treat to target clinical trial conducted in non-pregnant participants with type 1 diabetes randomised to receive faster aspart (n=381) or insulin aspart (n=380) met its primary endpoint of non-inferiority with respect to HbA1C (estimated treatment difference [ETD] faster aspart - insulin aspart -0.15% [95%CI -0.23;-0.07]). Post prandial glucose (standardised meal test) in the faster aspart arm was reduced compared to insulin aspart at 2 hours (primary endpoint) (ETD faster aspart - insulin aspart; -0.67 mmol/L [95% CI -1.29;-0.04]; p=0.0375]; superiority confirmed) and at 1 hour (ETD faster aspart - insulin aspart; -1.18mmol/L [95% CI -1.65;-0.71]; p<0.0001).	Thank you for providing these references. We have considered these studies for inclusion and the decisions are below. (Heise et al, 2015) Excluded as not in pregnant women with diabetes (Russell-Jones D, 2017) Excluded as not in pregnant women with diabetes

		Faster aspart can be used in pregnancy (SmPC) References: Heise T. et al. Faster-acting insulin aspart: earlier onset of appearance and greater early pharmacokinetic and pharmacodynamic effects than insulin aspart. Diabetes, Obesity and Metabolism 17(7):682-688, 2015. Russell-Jones D, Bode BW, de Block C, et al. Fast-acting insulin aspart improves glycemic control in basal-bolus treatment for type 1 diabetes: results of a 26-week multicenter, active-controlled, treat-to-target, randomized, parallel-group trial (onset 1). Diabetes Care 40:943–950, 2017. Novo Nordisk Limited; Fiasp Summary of Product Characteristics The CONCEPTT trial was set up to examine the effectiveness of continuous glucose monitoring (CGM) on maternal glucose and obstetric and neonatal health outcomes. It met its primary endpoint of an improvement in HbA1C and demonstrated that an extra 100 minutes per day were spent in the target glucose range. Non-severe hypoglycaemia was reduced and neonatal health outcomes were significantly improved. The recommendations from this trial were that CGM should be offered to all pregnant women with type 1 diabetes Reference: Feig D et al. Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial. Lancet vol 390 (10110): 2347-2359, 2017	Thank you your comments on CONCEPTT and continuous glucose monitoring. As noted above, NICE now propose a partial update on continuous glucose monitoring.

		The National Diabetes in Pregnancy audit results 2016 showed that less than 16% of women with type 1 diabetes had an HbA1c under 48mmols/mol in the first trimester and 40% of women had an HbA1c less than 48mmols/mol in the third trimester and there has been little improvement since the audit began Reference: www.digital.nhs.uk/data-and-information/clinical-audits-and-registries/national-pregnancy-in-diabetes-audit Women with diabetes who are pregnant should be given every opportunity to have access to the latest support and treatment to enable them to control and manage their diabetes at this critical time for their health and that of the unborn child. We would strongly recommend that the guideline is updated now to assess all available evidence contributing to best care of women with diabetes in pregnancy, and modified to include a risk-benefit discussion and that the published safety data for analogue insulins (insulin aspart and levemir) is included to enable clinicians to have this conversation with pregnant women and enable them to make an informed choice.	
Royal College of Paediatrics and Child Health	No answer	No comments provided	Thank you.
Royal College of Physicians and Surgeons of Glasgow	No	No comments provided	Thank you for your response.

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Association of British Clinical Diabetologists	No	No comments provided	Thank you for your response.
Cambridge Universities NHS Foundation Trust	No response provided	Research recommendations – no 31. The role of CGM in women with T1DM preparing for pregnancy has been assessed in the CONCEPTt study. We acknowledge that the role of GCM in women with T2DM is unknown, but a more pressing concern is the lack of access women with T2DM have to pre-pregnancy planning. The reasons for this are unclear. We would wonder if extending the scope of this guideline to include recommendations to primary care would be important.	Thank you for your comments. With regards continuous glucose monitoring, NICE is proposing to update this area of the guideline (please see page 1 for the rationale). The issue of T2DM pre-pregnancy planning has been noted.
Diabetes Technology Network UK	No	No comments provided	Thank you for your response.
Diabetes UK	No response provided	There is no section in this guideline that address the care that women and their partners should receive during pregnancy. This includes services such as counselling and support services for addressing pregnancy and diabetes distress, and pre-conception advice following an adverse outcome such as a still birth. Such a section should be included. There is growing evidence of the risks associated with obesity among pregnant women. We would like this guideline to mention the importance of monitoring weight to ensure appropriate weight gain during pregnancy so as to minimise the risk of developing gestational diabetes.	Thank you for your comments. These issues have been noted. We have a guideline on weight management before, during and after pregnancy (PH27), which covers aspects obesity in pregnancy.

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JDRF and INPUT Patient Advocacy	No	No comments provided	Thank you for your response.
Medtronic Limited	Yes	There is no review for the use of Sensor Augmented Pump therapy in Pregnancy	Thank you for your comment. During the 2018 surveillance we searched for all types of insulin therapy, including various types of insulin pump therapy. However, we only found 1 small trial (16 women) that compared closed loop with sensor augmented pump therapy (Stewart, 2016), which was not deemed substantial enough to change recommendations at this time. We shall note this issue for future surveillance.
National Obesity Forum	No response provided	Primary care GP and nurse management of long-term type 1 vs type 2 patients for whom they may have provided care for many years. Primary care must be included in the diagnosis in all types of diabetes including MODY, LADA etc.	Thank you for your comments. This issue has been noted.
Northumbria Diabetes Service, National Pregnancy in Diabetes	No response provided	No comments provided	Thank you.
Public Health England	No	No comments provided	Thank you for your response.
Royal College of Nursing	Yes	Not at this time	Thank you for your response.
Royal College of Pathologists	No	No comments provided	Thank you for your response.

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King's College Hospital NHS Foundation Trust	Yes	We believe the scope of future guidelines should be extended to include early pregnancy screening for identification of undiagnosed pre-existing type 2 diabetes. We note the proposed Cochrane review protocol mentioned on page 3 of the consultation document.	Thank you for your response. This suggestion has been noted for consideration at the next surveillance review.

Do you have any comments on equalities issues?			
Stakeholder	**Overall response**	**Comments**	**NICE response**
Royal College of Obtetricians and Gynaecologists (RCOG)	No	No comments provided	Thank you for your response.
Leeds Teaching Hospitals NHS Trust	No	No comments provided	Thank you for your response.
Novo Nordisk Ltd	Yes	NG3 as it stands does not give women who are pregnant the same level of choice and access to analogue insulins as those with type 1 diabetes who are not pregnant. With published RCTs demonstrating safety in pregnancy of some analogue insulins (insulin aspart and levemir), we believe this guideline needs to be updated to ensure equity of choice and treatment for pregnant women with diabetes.	Thank you for your comments. The guideline provides recommendations on management of diabetes during pregnancy that have been developed based on the best available evidence for the populations under consideration.
Royal College of Paediatrics and Child Health	No answer	No comments provided	Thank you for your response.

Royal College of Physicians and Surgeons of Glasgow	No	No comments provided	Thank you for your response.
Association of British Clinical Diabetologists	No	No comments provided	Thank you for your response.
Cambridge Universities NHS Foundation Trust	No response provided	The current system where affluent women can pay for access to CGM means that women from deprived backgrounds and their infants are at a great disadvantage. Furthermore, women with learning difficulties were considered likely to benefit greatly from freestyle libre use in MIB110 while these patients are often less likely to access technology privately.	Thank you for your comments. We appreciate that women from deprived backgrounds and with learning disabilities face inequalities in access to care. The guideline recommendations are intended to apply equally to all groups protected under equality and anti-discrimination legislation. During guideline development no recommendation was identified that needed to be adapted/changed for specific groups.
Diabetes Technology Network UK	No	No comments provided	Thank you for your response.
Diabetes UK	No response provided	This guideline should recommend that information and advice about diabetes in pregnancy needs to be culturally and language appropriate and tailored to meet the needs of everybody. For example, the risk of developing gestational diabetes is higher among women from a South Asian, Black or African Caribbean or Middle Eastern background and the risk of developing type 2 diabetes is higher among African-Caribbean, Black African, and South Asian women. (Diabetes UK 2017, Gestational Diabetes)	Thank you for your comments. The guideline recommendations are intended to apply equally to all groups protected under equality and anti-discrimination legislation. During guideline development no recommendation was identified that needed to be adapted/changed for specific groups.
JDRF and INPUT Patient Advocacy	No	No comments provided	Thank you for your response.

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Medtronic Limited	No	No comments provided	Thank you for your response.
National Obesity Forum	No response provided	Inequalities issues exist within S. Asian Polynesian and other populations etc regarding obesity, delayed diagnosis of diabetes, deprivation and lifestyle and other issues. Obesity and overweight are not fully assessed: A woman with a BMI 27 shouldn't necessarily be losing weight pre-pregnancy, and arguably should be persuaded to initially maintain weight, and then gain at a closely monitored rate with increasing gestation. A woman with type 2 diabetes will have to work much harder to lose weight than a woman without diabetes, and the evidence of benefit of weight loss from an 'overweight' status pre-conception is poor, and carries a risk of eliminating vital & essential nutrients by way of an over-strict dietary regime.	Thank you for your comments. The guideline recommendations are intended to apply equally to all groups protected under equality and anti-discrimination legislation. During guideline development no recommendation was identified that needed to be adapted/changed for specific groups.
NICE – Quality and Leadership programme	No	No comments provided	Thank you for your response.
Northumbria Diabetes Service, National Pregnancy in Diabetes	No response provided	No comments provided	Thank you.
Public Health England	No	No comments provided	Thank you for your response.
Royal College of Nursing	Yes	All appears to be appropriate	Thank you for your response.

Royal College of Pathologists	No	No comments provided	Thank you.
King's College Hospital NHS Foundation Trust	No	No comments provided	Thank you.