National Institute for Health and Clinical Excellence

Diabetes in pregnancy (update)
Scope Consultation Table
4 July - 29 August 2012

Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
A. Menarini Diagnostics Ltd	1	4.3.2	This review is an opportunity to clarify best practice with regard to DKA prevention through education and self monitoring of blood ketones. DKA prevention is of particular importance to pregnant women because DKA in pregnant women with diabetes occurs more frequently, more rapidly, and at lower blood glucose levels(1) This is due to the baby's demands, taking glucose from the mother, and pregnancy hormones that inhibit insulin DKA occurs in 9% of diabetic pregnancies and is the major cause of foetal loss, with a mortality rate of 30-90%, when it occurs (2) 1. Yehia B et al. Hospital Physicians 2008:119-147 2. SchneiderM et al. Diabetes Care 2003;26(3):958-959 Monitoring for ketones is advised at 1.1.5 and 1.3.2 of current guidelines however this can be brought up to date by referring specifically to blood ketone testing rather than urine ketone testing for reasons of efficacy and compliance.	The developers are of the view that there would be no new evidence to warrant a change to the existing recommendations in the 2008 Diabetes in pregnancy guideline about the management of diabetic ketoacidosis and therefore did not consider this a priority for inclusion in the update scope The update scope has, however, been expanded to include the topic of the effectiveness of blood ketone monitoring when compared with urine ketone monitoring for women with type 1 and type 2 diabetes in the preconception period and for women with type 1, type 2 and gestational diabetes during pregnancy
A. Menarini Diagnostics Ltd	2	4.3.2	This is due to: 1. potentially life threatening nature of DKA 2. cost burden to NHS due to preventable hospitalisations 3. comparable cost of appropriately used blood ketone	The developers are of the view that there would be no new evidence to warrant a change to the existing recommendations in the 2008 Diabetes in pregnancy guideline about the

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			sensors is preferential to the cost of hospitalisations 4. increasing prevalence of DKA in type 1 group year on year **5. lack of efficacy of urine ketone testing** All people with diabetes who are planning pregnancy or are pregnant should receive education and be encouraged to monitor <u>blood</u> ketone levels at appropriate times, i.e. illness and periods of persistently elevated blood glucose, for the short term prevention of DKA.	management of diabetic ketoacidosis and, therefore, did not consider this a priority for inclusion in the update scope. The update scope has, however, been expanded to include the topic of the effectiveness of blood ketone monitoring when compared with urine ketone monitoring for women with type 1 and type 2 diabetes in the preconception period and for women with type 1, type 2 and gestational diabetes during pregnancy
A. Menarini Diagnostics Ltd	3	4.3.2	With regard to patient education and blood ketone monitoring, the guidelines should be consistent with the following publication: <u>Joint British Diabetes Societies Inpatient Care Group The Management of Diabetic Ketoacidosis in Adults - March 2010</u> **i.e.** 1. The resolution of DKA depends upon the suppression of ketonaemia and measurement of blood ketones now represents best practice in monitoring the response to treatment. 2. Improved patient education with increased blood glucose and ketone monitoring has led to partial treatment of DKA prior to admission with consequent lower blood glucose levels at presentation. 3. Patients with diabetes who are admitted with DKA should be counselled about the precipitating cause and early warning symptoms of DKA. Failure to do so is a missed educational opportunity. Things to consider are:	The developers are of the view that there would be no new evidence to warrant a change to the existing recommendations in the 2008 Diabetes in pregnancy guideline about the management of diabetic ketoacidosis and therefore did not consider this a priority for inclusion in the update scope. The update scope has, however, been expanded to include the topic of the effectiveness of blood ketone monitoring when compared with urine ketone monitoring for women with type 1 and type 2 diabetes in the preconception period and for women with type 1, type 2 and gestational diabetes during pregnancy

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			• Identification of precipitating factor(s) e.g. infection or omission of insulin injections • Prevention of recurrence e.g. provision of written sick day rules • Insulin ineffective e.g. the patient's own insulin may be expired or denatured. This should be checked prior to reuse • Provision of handheld ketone meters and education on management of ketonaemia	
Abbott Diabetes Care	1	4.3.1 (a)	We support the review of blood glucose targets for pregnant women with type 1, type 2 and gestational diabetes, and recommend that the targets be consistent with international guidelines: - Premeal, bedtime and overnight glucose 3.3-5.4 mmol/L (60–99 mg/dL) - Peak postprandial glucose 5.4-7.1 mmol/L (100–129 mg/dL) - HbA1C < 6.0%. • Standards of Medical Care in Diabetes – 2012. Diabetes Care. 2012;35:S11-63.	Thank you for your comment. This topic has been included in the update scope
Abbott Diabetes Care	2	4.3.1 (e)	With regards to the effectiveness of blood glucose monitoring in pregnant women with diabetes, we propose that the scope include preconception for pre-existing diabetes as well as monitoring during pregnancy.	The developers are of the view that the area of pre-conception care (with the exception of blood and HbA_{1c} targets and contraception which are included in the scope) was not a priority for update as there is unlikely to be any new evidence to update these recommendations The developers consider that the concern the stakeholder is seeking to highlight is not specific to preconception care, but rather about a

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				possible gap in the overall diabetes pathway regarding the details of routine care for women of childbearing age with pre-existing diabetes. The developers agree that this is an important issue for all four diabetes guidelines. Therefore, following discussion with NICE and the teams updating the other diabetes guidelines, it has been agreed that the recommendations on preconception care in the updated diabetes in pregnancy guideline (i.e. both those that appeared in the 2008 guideline and the updated recommendations on HbA_{1c} and blood glucose targets and contraception) will be cross-referenced wherever necessary in the guidelines covering routine care for women of childbearing age with pre-existing diabetes
Abbott Diabetes Care	3	4.3.1 (e)	We recommend that the scope reviews the use of continuous glucose monitoring in diabetes and pregnancy as an adjunct to conventional blood glucose monitoring. The British Society of Paediatric Endocrinology and Diabetes (BSPED) guidelines recommend the use of CGM for pregnant women when HbA1c is ≥ 6.1%, or if they experience recurrent hypoglycaemia. • British Society for Paediatric Endocrinology and Diabetes. Continuous glucose monitoring: consensus statement on the use of glucose sensing in outpatient clinical diabetes care 2009.	Thank you for your comment. The effectiveness of continuous glucose monitoring in pregnant women with diabetes when compared with intermittent capillary blood glucose monitoring is included in the update scope

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			(http://www.bsped.org.uk/clinical/clinical_supportedguidelines.html) • Murphy H et al. Changes in the glycaemic profiles of women with type 1 and type 2 diabetes during pregnancy. Diabetes Care. 2007; 30(11): 2785–91 • Murphy H, et al. Effectiveness of continuous glucose monitoring in pregnant women with diabetes: randomised clinical trial. Br Med J 2008; 337:a1680.	
Abbott Diabetes Care	4	4.3.1 (e)	We recommend that the scope evaluate the role of frequent self-monitoring of blood glucose for preconception and pregnant diabetic patients to assess their individual response to therapy and determine whether glycaemic targets are being achieved. • Kitzmiller J, et al. Managing preexisting diabetes for pregnancy: Summary of evidence and consensus recommendations for care. Diabetes Care. 2008;31:1060-79.	Thank you for your comment. The effectiveness of continuous glucose monitoring in pregnant women with diabetes when compared with intermittent capillary blood glucose is included in the update scope, as are blood and HbA_{1c} targets for women with type 1 and type 2 diabetes in the preconception period and for women with type 1, type 2 and gestational diabetes during pregnancy The developers are of the view that there is unlikely to be any new evidence to update the recommendations in the 2008 Diabetes in pregnancy guideline about monitoring in the preconception period and so this topic was not considered a priority for update The developers noted that this comment may overlap with a concern raised by other stakeholders that is not specific to preconception care, but rather about a possible gap in the

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				overall diabetes pathway regarding the details of routine care for women of childbearing age with pre-existing diabetes The developers agree that this is an important issue for all four diabetes guidelines. Therefore, following discussion with NICE and the teams updating the other diabetes guidelines, it has been agreed that the recommendations on preconception care in the updated diabetes in pregnancy guideline (i.e. both those that appeared in the 2008 guideline and the updated recommendations on HbA_{1c} and blood glucose targets and contraception) will be cross-referenced wherever necessary in the guidelines covering routine care for women of childbearing age with pre-existing diabetes
Cambridge University Hospitals NHS Foundation Trust	1		Should also include 1-weight management in diabetes in pregnancy	Thank you for your comment Weight management for women with pre-existing diabetes is covered by the recommendations in the preconception section of the 2008 Diabetes in pregnancy guideline and the update scope includes the topic of effectiveness of non-pharmacological interventions for women who have had gestational diabetes

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			2-identification of monogenic and other forms of diabetes	Screening and diagnosis of gestational diabetes are included in the update scope. The developers feel that diagnosis of other types of diabetes is not specific to pregnant women and, therefore, not a priority for inclusion in the update scope
			3-glucose management post steroids	The topic of glucose management after steroids for fetal lung maturation is covered by the recommendations in the 2008 Diabetes in pregnancy guideline. The developers are of the view that there would be no new evidence to warrant a change to the existing recommendations and therefore do not consider this a priority for inclusion in the update scope
			4-retinal screening in diabetes in pregnancy	The topic of retinal screening in diabetes in pregnancy is covered by the recommendations in the 2008 Diabetes in pregnancy guideline. The developers are of the view that there would be no new evidence to warrant a change to the existing recommendations and, therefore, do not consider this a priority for inclusion in the update scope
Cambridge University Hospitals	2		Outcomes should include long term outcomes in the offspring (eg obesity, diabetes)	Thank you for your comment. The developers acknowledge that long-term outcomes such as those mentioned by the stakeholder may be important. Outcomes for individual

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NHS Foundation Trust				reviews will be prioritised by the guideline development group on a case by case basis and may be influenced by study design and the volume of available evidence
Deaf Diabetes UK	1		- to remove access + communication barriers for Deaf BSL users who have diabetes, Deaf Parents with a Deaf or hearing Child or children who have diabetes + pregnant Deaf mothers who have diabetes / need to be aware of diabetes health condition during pregnancy to NHS Diabetes Care + Services + NHS Information relating to diabetes. Need to know what treatment/services they should be receiving to deal with the diabetes health condition. - unable to access to current NHS Diabetes Support Group in their local NHS area - making an appointment with their GP difficult due to phone system appointment only - some Doctors /Diabetes Nurse/Health Professionals display reluctant attitude to have a RSLI (Registered Sign Language Interpreter) with their Deaf Patient placing Deaf Patient in an uncomfortable environment - NHS's letter offering a hospital appointment omitting information if a RSLI has been booked as requested often leaving Deaf Patient with no choice but to cancel appointment via third party involvement to phone them on their Telephone voice number given in the letter to rearrange an appointment with a RSLI or bring a family member including a child to "interprete" to avoid cancelling the appointment. - some Doctors Surgeries have a Textphone but Deaf	Thank you for this comment which raises many important issues relating to provision of, and access to, services and information. As part of the NICE clinical guideline development process, the guideline development group will be required to consider the need to advance equality and prevent unlawful discrimination for each and every recommendation proposed. This means that the specific needs and preferences of individuals, including those protected by law, will be considered. This includes those who are deaf or hard of hearing. These considerations are documented in an equalities form which will be published on NICE's website. The issues raised affect diabetes care, as illustrated by the examples provided, but relate to quality of care more generally. Specific changes to the guideline scope have not been made in response to these comments, because the population and particular sub-groups to be covered would include people with diabetes who are deaf or hard of hearing. The guideline

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			Patients making a direct text phone call unanswered + had to use Typetalk Service which Receptionist Staff always answered quickly. Some Surgeries have Textphone Service facility but often unused / out of sight or unplugged. - NHS Information in written English + no BSL Format on information relating to diabetes but available in other written community spoken language. - Deaf people who have diabetes experience lack of communication support / lack of Deaf awareness amongst Doctors/Diabetes Nurse + Reception Staff leaving them feeling not receiving an inadequate consultation / not really clear or knowing much more about their diabetes condition /what are they supposed to do next or even know how to take the medicine prescribed to them / unsure about their ongoing healthcare plans / lack of aftercare support / lots of concern/confusion over altered diet advice advisable / insulin treatment / misunderstandings information relating to diabetes issues. The need for clearer writing from the Doctors on the use of medication in writing in plain English before Deaf Patients leave the surgery NHS Staff who learnt BSL commendable but are not trained to "Interprete" should not be used as "Interpreter" replacing RSLI. NHS BSL users helpful for informal situation like welcoming Deaf Patient on arrival, signposting them to correct department / Refreshment + Toilet facilities, checking if RSL booked arrived yet as good examples. - Deaf Patients struggled + missed their appts with a Tannoy Public Announcement system calling Patients's name at GP's	developers will therefore continue to adhere to the principles outlined above throughout the development of the guideline. The Patient and Public Involvement Programme (PPIP) and the Implementation team at NICE have also been informed of these issues. PPIP will help all the teams at NICE to ensure that these issues are considered during their work. When the diabetes guidelines are published, the Implementation team will help to raise these issues to staff working in the wider National Health Service (NHS).

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			Surgery / NHS Diabetes Care + Services + A&E department despite informing/reminding the Receptionist to alert them when their name called out but Receptionist often forget if busy. Feedback offered solutions that - all GP surgeries/NHS Diabetes Care + Services a) should ask/check Deaf person their communication preference b) should know how to get / book a RSLI (= Registered Sign Language Interpreter) who are registered with the NRCPD = The National Register of Communication Professionals working with Deaf + Deafblind People. NRCPD is supported by Signature. How to find/Book a RSLI? Visit www.signature.org.uk E: enquiries@nrcpd.org.uk / Tel 0191 383 1155 / Text 0191 383 7915 / Fax 0191 383 7914 c) should have a list of RSLI available on hand to save time with good planning ahead with booking a RSLI d) should comply with The Equality Act 2010 to provide RSLI provision for Deaf BSL users who need one. - all surgeries should have a way for Deaf BSl users to contact them directly to make an appointment with technology aid available (SMS/Email) - all surgeries / NHS Diabetes care + Services plus A&E departments should consider installing a visual patient system.	

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			Note more Surgeries are adopting this but should be a national standard practice including NHS Hospitals + A&E departments. - all NHS Staff particularly medical Staff who work directly with Deaf Patients should receive basic Deaf Awareness training including how to get / book a RSLI + how to work with RSLI / be familiar with their role to ensure effective communication with Deaf BSL user. Note Not appropriate to use a Child family member to take on "Interpreter" role. Not acceptable + must be discouraged. Sometimes Deaf BSL user may use an Adult family member / friend or husband/wife/partner not advisable + not to be encouraged as they only give a summary / confidentially an issue / controlling + often Health Professionals engaged with them instead of Deaf Patient. Deaf Patients need to be explained on the importance of using a RSLI to access full information + make an informed choice on their diabetes health condition. RSLI will always relay full account / full access of whats being said by NHS Professionals to Deaf Patient. RSLI to follow the NRCDP's Code of Conduct including confidentially + impartially. - need support for Deaf people with Type 1/2 diabetes / Deaf parents with their child/children with diabetes + pregnant Deaf mothers who have diabetes or need to understand their pregnancy related to diabetes to access information on all aspects of diabetes health condition in Deaf friendly format leaflets / DVD on specific diabetes related issues + via RSLI provision when needed + suitable BSL format for Deaf children too. Currently none available.	

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			- DDUK advocate positive working partnerships with NHS Diabetes Care + Services via education, training, research, services accessible, ensuring that the NHServices comply with the Equality Act 2010, understanding of / to improve awareness of Deaf BSL users who have diabetes needs to take control of / to manage their diabetes health condition better, raise confidence + make informed choice. NOTE Access + Communication issues are the main issues that the NHS needs to address if Deaf people with diabetes are to be provided with a service that truly to meet their needs / what NHS Diabetes Care + Services they should be receiving. Including knowing how to make complaints + understanding how the NHS work. NOTE NHS Services should offer RSLI provision for any Deaf Patient who needs one on ALL health matters affecting them.	
Department of Health	1	3.1 (general)	Mention of severe hypoglycaemia.	This section of the scope is a brief summary of the epidemiology of diabetes in pregnancy and the developers felt that the text about hypoglycaemia was already sufficiently detailed without the addition of severe hypoglycaemia. Bullets 'f' and 'g' already mention hypoglycaemia as potential risks to the woman and child. Furthermore, the current wording also makes clear that these bullets do not constitute a comprehensive list, but merely give some examples of possible complications
Department of	2	3.1a (second	Propose to replace with…	Thank you for your comment. This edit has been made

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Health		sentence)	'People who have diabetes for many years can develop long term microvascular complications including retinopathy, nephropathy and neuropathy as well as macrovascular complications of cardiovascular disease.'	
Department of Health	3	3.1b	Mention of high dose folic acid.	Thank you for your comment which the developers understand relates to section 3.2.b not 3.1.b. This edit has been made
Department of Health	4	3.1c (last sentence)	Propose to replace with… 'This is important because duration of diabetes is one of the strongest factors associated with micro-vascular complications and therefore it is more likely that women may enter pregnancy with established retinopathy, nephropathy or neuropathy.'	Thank you for your comment. This edit has been made
Department of Health	5	3.1d (general)	Who should be in the MDT:	This section of the scope is a brief summary of the epidemiology and current practice regarding diabetes in pregnancy and the developers feel that the text is already sufficiently detailed without the addition of these points The developers would, however, like to make the following clarifications for the stakeholder. • The issue of multidisciplinary working is covered by the recommendations in the 2008 Diabetes in pregnancy guideline and is likely to be covered to some extent by the topic of the effectiveness of specialist teams for pregnant women with diabetes in the update scope.

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			Vitamin D supplementation; Education and importance of good glycaemic control; Consideration of special needs of women from ethnic minority communities; Exercise advice;	• Vitamin D supplementation is part of routine care for all pregnant women and therefore covered by the published NICE Antenatal care guideline, the recommendations in which also apply to women with diabetes in pregnancy. • Education and the importance of good glycaemic control are covered by the recommendations in the 2008 Diabetes in pregnancy guideline and are likely to be covered to some extent by the included topic of targets for HbA_{1c} and blood glucose for women with type 1 and type 2 diabetes in the preconception period and for women with type 1, type 2 and gestational diabetes during pregnancy in the update scope. • The developers have expanded the text in section 4.1.1 to clarify the approach that will be taken to appraising evidence for different subgroups in relation to ethnicity. • Exercise is covered by the recommendations in the 2008 Diabetes in pregnancy guideline and is likely to be covered to some extent by the

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			Management of women already using or switched to CSII in pregnancy; Maintaining a healthy weight and weight loss where indicated.	topic of non-pharmacological interventions for gestational diabetes in the update scope. • The developers agree that insulin pump therapy can be a useful intervention for some women with diabetes in pregnancy but are of the view that the current recommendations in the 2008 Diabetes in pregnancy guideline are permissive regarding the use of pump therapy and that there is unlikely to be any new evidence to update these recommendations. • Weight management is covered by the recommendations in the 2008 Diabetes in pregnancy guideline and is likely to be covered to some extent by the included topic of non-pharmacological interventions for gestational diabetes in the update scope.
Department of Health	6	3.1d (second sentence)	Propose to replace with 'This includes women whose glucose intolerance resolves after pregnancy and as much as 20% whose glucose intolerance persists including women who had pre-existing undiagnosed type 2 diabetes prior to pregnancy. Women who have gestational diabetes are at increased risk of developing type 2 diabetes in the future.'	Thank you for your comment. The developers have incorporated the suggested wording into this section
Departm	7	3.1e	4 chamber echo.	Thank you for your comment which the

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ent of Health				developers understand relates to section 3.2.e. not 3.1.e. The sentence has been expanded to include screening for fetal monitoring
Department of Health	8	3.1g (general)	Insulin dose adjustment for breast feeding women.	This section is a brief summary of current practice regarding diabetes in pregnancy and the developers feel that the text is already sufficiently detailed without the addition of this point. Furthermore, the current wording also makes clear that these bullets do not constitute a comprehensive list, but merely give some examples of current practice regarding postnatal care
Department of Health	9	3.1g (grammatical)	'Fetal'is an American spelling: should this be 'foetal', the English spelling? If so: Propose to replace with: 'Foetal risks of pre-existing maternal diabetes include structural congenital abnormalities, macrosomia (birth weight above the 90th centile), intrauterine growth retardation (foetus is in lower 10th centile for gestational age) and unexplained foetal death.' 'Neonatal complications…hypocalcaemia and polycythaemia': 'Neonatal complications…hypocalcaemia, polycythaemia and neonatal death'	The spelling of fetal (as opposed to foetal) has been retained in accordance with the NICE style guide Thank you for your comment. This edit has been made
Department of Health	10	3.2b	Propose changes as follows: 'Preconception care aims to enable women with established diabetes to have a positive experience of pregnancy and childbirth and to minimize the risk of structural abnormalities in the foetus. It includes provision of information and education with emphasis on the importance of planning	This section is a brief summary of current practice regarding diabetes in pregnancy. The developers feel that the description of preconception care is sufficiently accurate without including all of the additional detail suggested by the stakeholder. They have, however,

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			pregnancy. Other important components of this stage of care include improving blood glucose control, assessment for and management of complications, change of potentially teratogenic medications to medication safe to use during pregnancy and high dose folic acid.'	added the words 'high-dose' in relation to the use of folic acid
Department of Health	11	General	Pre-conception counselling should include smoking (CG62): Aware all women should not smoke but smoking in long term also has more profound cardiovascular risk in women who have diabetes. In view that smoking is the biggest modifiable risk factor for developing cardiovascular disease feel important added.	Thank you for your comment. Smoking cessation is an important issue for all women and is therefore covered by the published NICE Antenatal care guideline, the recommendations in which also apply to women with diabetes in pregnancy. Given that the link between smoking and cardiovascular disease also exists in a non-pregnant population, the developers felt that this issue was a not priority for inclusion in the Diabetes in pregnancy update scope
Department of Health	12	General	Noted from CG63 Should there be a separate brief section: <u>Routine diabetes care for women of childbearing age:</u> Including 1.1.2.1 ? include**…** When initiated on medication for treatment of diabetes complications the benefits and potential teratogenic effect of medication should be discussed and documented in order that informed consent is obtained. One option is consideration of using medication considered safe to use in pregnancy. 1.1.2.2 should also be advised routinely as well as for those planning pregnancy.	Thank you for your comment which pertains to recommendations in the preconception care section of the 2008 Diabetes in pregnancy guideline rather than the update scope published for consultation. The developers are of the view that the area of preconception care (with the exception of blood and HbA_{1c} targets and contraception which are included in the update scope) is not a priority for update as there is unlikely to be any new evidence to update the existing recommendations Moreover, the developers consider that the concern the stakeholder is seeking

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				to highlight is not specific to preconception care, but rather about a possible gap in the overall diabetes pathway regarding the details of routine care for women of childbearing age with pre-existing diabetes The developers agree that this is an important issue for all four diabetes guidelines. Therefore, following discussion with NICE and the teams updating the other diabetes guidelines, it has been agreed that the recommendations on preconception care in the updated diabetes in pregnancy guideline (i.e. both those that appeared in the 2008 guideline and the updated recommendations on HbA_{1c} and blood glucose targets and contraception) will be cross-referenced wherever necessary in the guidelines covering routine care for women of childbearing age with pre-existing diabetes
Department of Health	13	General	Omissions considering adding: Preconception care Page 7 1) Smoking cessation advice **should be added despite**	Thank you for your comment which pertains to recommendations in the preconception care section of the 2008 Diabetes in pregnancy guideline rather than the update scope published for consultation Smoking cessation is an important issue for all women and is therefore covered by the published NICE

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			being applicable to women without diabetes **- increased risk of intrauterine growth retardation** - BUT has long term ramifications SMOKING is the biggest modifiable risk factor to reduce risk of cardiovascular events in the future for this patient group 2) Preconception advice for women with history of gestational diabetes - **At yearly review to assess for the development of diabetes provide information to women that in future pregnancies likely to have gestational diabetes. On confirming pregnancy will need to monitor capillary glucose readings and will be referred to diabetes antenatal team for review.** 1.1.1.3 Point 2.	Antenatal care guideline, the recommendations in which also apply to women with diabetes in pregnancy. Given that the link between smoking and cardiovascular disease also exists in a non-pregnant population, the developers feel that this issue is not a priority for inclusion in the Diabetes in pregnancy guideline update scope The developers are of the view that the area of preconception care (with the exception of blood and HbA_{1c} targets and contraception which are included in the update scope) was not a priority for update as there is unlikely to be any new evidence to update the existing recommendations. The topic of postnatal testing to detect glucose intolerance after pregnancy in women who have had gestational diabetes (but are not hyperglycaemic before they are transferred to community care) has however been included and the recommendations will be updated accordingly The developers are of the view that the recommendations on the management

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			? add 'including review of knowledge about hypoglycaemia and how to manage and treat hypoglycaemia' **(often people treat hypoglycaemia incorrectly with chocolate, milk or bread alone – so feel important advice reiterated)** **1.1.2.2 Point 3** make point clearer with regard to teratogenic medication review ' **that glycaemic targets, glucose monitoring, medications for diabetes (including insulin regimens for insulin-treated diabetes) and medications for complications of diabetes will need to be reviewed before and during pregnancy'** **Consider changing to…** 'that glycaemic targets, glucose monitoring and medications for diabetes (including insulin regimens for insulin-treated diabetes) before and during pregnancy. Medications for complications of diabetes will need review before pregnancy and if can cause potential harm to foetus be stopped prior to conception and converted to medication regarded as safe to use during pregnancy'.	of diabetes in pregnancy in the 2008 guideline provide relevant advice about how to manage and treat hypoglycaemia in pregnancy for women with pre-existing diabetes. Moreover, they feel that there is unlikely to be any new evidence to update these recommendations. The effectiveness of interventions for women with gestational diabetes is included in the update scope This is a suggested edit to one of the recommendations that appears in the preconception care section of the 2008 Diabetes in pregnancy guideline. The developers consider that the concern the stakeholder is seeking to highlight is not specific to preconception care, but rather about a possible gap in the overall diabetes pathway regarding the details of routine care for women of childbearing age with pre-existing diabetes The developers agree that this is an important issue for all four diabetes guidelines. Therefore, following discussion with NICE and the teams updating the other diabetes guidelines, it has been agreed that the recommendations on preconception care in the updated diabetes in pregnancy guideline (i.e. both those

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				that appeared in the 2008 guideline and the updated recommendations on HbA_{1c} and blood glucose targets and contraception) will be cross-referenced wherever necessary in the guidelines covering routine care for women of childbearing age with pre-existing diabetes
Department of Health	14	General	1.1.5.4 ? define 'hyperglycaemia' **to make clearer when to check for ketonuria / ketonaemia** **1.1.7.1** (could be misread either before conception or as soon as pregnancy is confirmed) **Angiotensin-converting enzyme inhibitors and angiotensin-II receptor antagonists should be discontinued preferably before conception or as soon as pregnancy is confirmed. Alternative antihypertensive agents suitable for use during pregnancy should be substituted.** **1.1.7.1** (could be misread either before conception or as soon as pregnancy is confirmed) **Statins should be discontinued preferably before pregnancy or as soon as pregnancy is confirmed.** Consider adding **including carbohydrate counting**: **1.1.9.1 Women with diabetes who are planning to become pregnant should be offered a structured education programme including carbohydrate counting as soon as possible if they have not already attended one**	The first part of this comment comprises several suggested edits to the recommendations that appear in the preconception care section of the 2008 Diabetes in pregnancy guideline. The developers consider that the concern the stakeholder is seeking to highlight is not specific to preconception care, but rather about a possible gap in the overall diabetes pathway regarding the details of routine care for women of childbearing age with pre-existing diabetes The developers agree that this is an important issue for all four diabetes guidelines. Therefore, following discussion with NICE and the teams updating the other diabetes guidelines, it has been agreed that the recommendations on preconception care in the updated Diabetes in pregnancy guideline (i.e. both those that appeared in the 2008 guideline and the updated recommendations on

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				HbA_{1c} and blood glucose targets and contraception) will be cross-referenced wherever necessary in the guidelines covering routine care for women of childbearing age with pre-existing diabetes
			1.2.2.1 Women with any one of these risk factors should be offered testing for gestational diabetes (see recommendation 1.2.2.4). (doesn't say when to test for gestational diabetes ie. Immediately) In Scoping document: '4.3.1 c) diagnostic criteria that should be used to diagnose diabetes in pregnant women using 75g oral glucose tolerance test' – **timing could be included here to be specific** **1.2.2.6** Women with gestational diabetes should be informed that good glycaemic control throughout pregnancy will reduce the risk of fetal macrosomia, trauma during birth (to themselves and the baby), induction of labour or caesarean section, neonatal hypoglycaemia and perinatal death. **? Replace with…** **Women with gestational diabetes should be informed that good glycaemic control throughout pregnancy will reduce the risk of foetal macrosomia, trauma during birth (to themselves and the baby), induction of labour or caesarean section, neonatal hypoglycaemia and perinatal death.** .'	The update scope contains topics on the effectiveness of screening for gestational diabetes in the first and second trimester The spelling of fetal (as oppose to foetal) has been retained in accordance with the NICE style guide
Department of Health	15	General	1.4 Intrapartum Care: 'This section should be read in conjunction with 'Intrapartum	Thank you for your comment which the developers understand to be read in conjunction with the first part of

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			care: care of healthy women and their babies during childbirth' (NICE clinical guideline 55), available from www.nice.org.uk/CG055. This guideline includes information on timing and mode of birth for uncomplicated births at term.'	comment 29 below Issues pertaining to the care of women during labour fall within the scope of the NICE Intrapartum care guideline (CG55; also currently undergoing update) because they are not specific to women with diabetes The developers acknowledge that the statements in the 2008 Diabetes in pregnancy guideline (CG63) and 2007 Intrapartum care guideline (CG55) do not align and will work with the team updating the Intrapartum care guideline to ensure that the overlap is clarified The recommendation that appears in the neonatal care section of the 2008 Diabetes in pregnancy guideline (CG63) pertains to the evidence review on neonatal care
Department of Health	16	General	**The CG55 guideline:** 'This guideline does not cover the care of women with …diabetes' 'Table 1: Medical conditions indicating increased risk suggesting planned birth at an obstetric unit … diabetes' 'Table 2: Other factors indicating increased risk suggesting planned birth at an obstetric unit … onset of gestational diabetes' SIGN guidelines: 7.9 Delivery:	Thank you for your comment, the first part of which the developers understand should be read in conjunction with comment 28 above and have responded accordingly

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			'Women with diabetes should be delivered in consultant-led maternity units under the combined care of a physician with an interest in diabetes, obstetrician and neonatologist.' **No mention in guideline where delivery should take place until 1.5 Neonatal Care section:** 1.5.1.1 Women with diabetes should be advised to give birth in hospitals where advanced neonatal resuscitation skills are available 24 hours a day. **? should have some reference to preferred location of delivery earlier under Intrapartum Care heading** 1.6.2 Information and follow-up after birth 1.6.2.3 Women who were diagnosed with gestational diabetes should be reminded of the symptoms of hyperglycaemia. 1.6.2.4 Women who were diagnosed with gestational diabetes should be offered lifestyle advice (including weight control, diet and exercise) and offered a fasting plasma glucose measurement (but not an OGTT) at the 6-week postnatal check and annually thereafter.	This is a quotation from the 2008 Diabetes in pregnancy guideline and the developers understand that comment 30 below gives the stakeholder's view on these
Department of Health	17	General	No mention in CG63 guidance - to inform women who have gestational diabetes that have increased risk of developing diabetes in the future ? modify 1.6.2.4 Consider changing to… Women who were diagnosed with gestational diabetes should be informed that 15-55% of women who have gestational diabetes develop diabetes in the future, which may be delayed or prevented by having a healthy lifestyle and not being overweight. Women should be offered lifestyle advice (including weight control, diet and exercise) and offered a	Thank you for your comment which pertains to recommendations in the postnatal care section of the 2008 Diabetes in pregnancy guideline rather than the update scope published for consultation. The topic of postnatal testing to detect glucose intolerance after pregnancy in women who have had gestational diabetes (but are not hyperglycaemic before they are transferred to community care) has

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			fasting plasma glucose measurement (but not an OGTT) at the 6-week postnatal check and annually thereafter. Also consider swapping order of 1.6.2.3 and 1.6.2.4	been included and the recommendations will be updated accordingly
Department of Health - National Clinical Director for Diabetes (Additional comments)	1		For the first time, all four major NICE clinical guidelines for diabetes care are being updated around the same time. Different guideline committees are responsible for each, sometimes even different organisations. This is an excellent opportunity to update diabetes care. It also presents a high risk for duplication and confusion. Diabetes care is a continuum. The girl with Type 1 diabetes becomes an adult. She may become pregnant, as may a woman with Type 2 diabetes. Most diabetes care is the same whatever the age or type of diabetes. It is essential that these four guidelines are consistent in the advice they provide so that confusion does not arise as the patient moves from one situation to another. It is also essential that duplication and confusion are avoided from the point of view of healthcare professionals, providers and commissioners. It also seems a great waste of time for four committees to duplicate effort over issues communal to all four guidelines. It is therefore absolutely essential that arrangements are made, so that each of the guideline committees is linked to the others to ensure consistency in guidance, and save resource. It is also strongly advisable to agree, before work starts, what areas are communal to all guidelines, and how such work is to be tackled. These areas will include: • Prompt accurate diagnosis;	Thank you for your comments. We agree. NICE has set up a steering committee to oversee the production of these pieces of guidance. The group, which includes guideline development group chairs, staff from all three guidance-producing centres and staff from NICE, will identify and act on any gaps or overlaps across the different guidance topics in order to ensure that the final guidance produced is complementary and consistent.

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			• Emotional and psychological support for patients, family and carers; • Diabetes education; • Care planning; • Initial management – lifestyle and medication; • Nutrition, including weight normalisation; • Exercise; • Patient self monitoring; • Routine clinical monitoring – annual and interim review: identification of risk factors for complications so as to prevent them; detection of complications; detection of common co-morbidities (e.g. depression, thyroid etc) risk stratification; • Risk factor management e.g. glucose control, blood pressure and cholesterol control; • Prevention and management of acute complications (e.g. high and low glucose) (this includes diabetes care in hospital); • Prevention and management of longer term complications; • Integrated multi-disciplinary care; • Audit and outcome measurement. The main drugs used are largely the same: • Glucose-lowering; • Insulins; • Oral, non-insulin injectable; • Blood pressure lowering; • Cholesterol lowering;	

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			• Renoprotective.	
Diabetes Management and Education Group (DMEG)	1		Should also include 1-weight management in diabetes in pregnancy 2-identification of monogenic and other forms of diabetes 3-glucose management post steroids 4-retinal screening in diabetes in pregnancy	Thank you for your comment Weight management for women with pre-existing diabetes is covered by the recommendations in the preconception section of the 2008 Diabetes in pregnancy guideline and the update scope includes the topic of effectiveness of non-pharmacological interventions for women who have had gestational diabetes Screening and diagnosis of gestational diabetes is included in the update scope. Diagnosis of other types of diabetes is not specific to pregnant women and, therefore, not a priority for inclusion in the update scope. The topic of glucose management after steroids for fetal lung maturation is covered by the recommendations in the 2008 Diabetes in pregnancy guideline. The developers are of the view that there would be no new evidence to warrant a change to the existing recommendations and therefore do not consider this a priority for inclusion in the update scope The topic of retinal screening in

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				diabetes in pregnancy is covered by the recommendations in the 2008 Diabetes in pregnancy guideline. The developers are of the view that there would be no new evidence to warrant a change to the existing recommendations and, therefore, do not consider this a priority for inclusion in the update scope
Diabetes Management and Education Group (DMEG)	2		Outcomes should include long term outcomes in the offspring (eg obesity, diabetes)	Thank you for your comment. The developers acknowledge that long-term outcomes such as those mentioned by the stakeholder may be important. Outcomes for individual reviews will be prioritised by the guideline development group on a case by case basis and may be influenced by study design and the volume of available evidence
Diabetes UK	1	4.3.2.(d)	Due to the importance of avoiding unplanned pregnancy and the importance of blood glucose levels at the point of conception, we disagree with the proposed exclusion of contraception from the list of clinical topics, especially as this clinical issue is not covered in the scopes for *Type 1 diabetes in adults* or *Diabetes in children and young people.*	Thank you for your comment. The Diabetes in pregnancy update scope has now been expanded to include the effectiveness of oral hormonal contraceptives in women with diabetes compared with women without diabetes The developers agree that this is an important issue for all four diabetes guidelines. Therefore, following discussion with NICE and the teams updating the other diabetes guidelines, it has been agreed that the recommendations on preconception

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				care in the updated diabetes in pregnancy guideline (i.e. both those that appeared in the 2008 guideline and the updated recommendations on HbA_{1c} and blood glucose targets and contraception) will be cross-referenced wherever necessary in the guidelines covering routine care for women of childbearing age with pre-existing diabetes
ELCENA JEFFERS FOUNDATION	1	General	EJF members agree the whole document has vital information for family life and diabetes in pregnancy. Education is needed in the ethnic population in explaining the facts of Diabetes and Pregnancy.	Thank you for your comment. The scope has been amended to specify that, where the evidence supports it, women with an ethnicity associated with a high prevalence of diabetes will be given special consideration. However, the topic of education has been excluded as this was not considered a clinical priority for update. The guideline developers will inform the implementation team at NICE about these comments to facilitate improvements to services at the implementation stage, since implementation will apply to education as well as the topics that are being updated
Faculty of Dental Surgery	1	general	The Dental team including Oral medicine specialists play a major role in screening for oral care in adult and paediatric patients with diabetes. Through oral screening, adult and paediatric patients with undiagnosed diabetes presenting with oral signs and symptoms suggestive of diabetes can be referred to the physician for further evaluation.	Thank you for your comment. The developers are of the view that this issue is also relevant to a non-pregnant population. For this reason they concluded that it was not priority for the Diabetes in pregnancy guideline update scope

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Faculty of Dental Surgery	2	general	Through educating patients on improving oral health and preventing development of oral complications associated with diabetes, they can improve the metabolic control of diabetes.	Thank you for your comment. The developers are of the view that this issue is also relevant to a non-pregnant population. For this reason they concluded that it was not priority for the Diabetes in pregnancy guideline update scope
Faculty of Dental Surgery	3	general	Through working with both the physician and the nutritionist, they play an important role in ensuring that the patient's glycaemic control is optimised in order to prevent systemic complications of diabetes.	Thank you for your comment. The developers are of the view that this issue is also relevant to a non-pregnant population. For this reason they concluded that it was not priority for the Diabetes in pregnancy guideline update scope
Faculty of Dental Surgery	4	general	They can discuss indications and contraindications of medications for treatment of oral complications in patients with systemic complications associated with diabetes.	Thank you for your comment. The developers are of the view that this issue is also relevant to a non-pregnant population. For this reason they concluded that it was not priority for the Diabetes in pregnancy guideline update scope
Faculty of Dental Surgery	5	general	They can also reduce co-morbidity factors resulting from diabetes by supporting patient's in tobacco-use cessation programs.	Thank you for your comment. The developers are of the view that this issue is also relevant to a non-pregnant population. For this reason they concluded that it was not priority for the Diabetes in pregnancy guideline update scope
Hindu Council UK	1	4.1.1	Our comments are as follows: The group that should also be included if not specific are the pregnant women from South Asian, African and African Caribbean communities where there may be a greater prevalence of diabetes	Thank you for your comment. The scope has been amended to specify that, where the evidence supports it, women with an ethnicity associated with a high prevalence of diabetes will be given special consideration

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Hindu Council UK	2	General	Many women from South Asia, particularly Hindu women, who are pregnant, will undergo several religious sacraments. The Hindu Council UK and the temples could be used as a means to disseminate information including any educational programmes	Thank you for your comment. Offers to support implementation of the guideline update once it is published would be welcomed
INPUT Patient Advocacy	1	4.3.1	In order to improve 4.4 d maternal outcomes relating to diabetes control and postnatal mental health, this update should consider the timing of withdrawal of continuous subcutaneous insulin infusion when it has only be funded for the term of the pregnancy. When it has been removed in the delivery room it has caused great distress and affected clinical and mental outcomes.	Thank you for your comment. The developers agree that insulin pump therapy can be a useful intervention for some women with diabetes in pregnancy but are of the view that the current recommendations in the 2008 Diabetes in pregnancy guideline are permissive regarding the use of pump therapy and that there is unlikely to be any new evidence to update these recommendations. The practice reflected in the stakeholder's comment is not recommended in the 2008 guideline
Juvenile Diabetes Research Foundation	2	General	Insulin pumps therapy is regarded as an effective mechanism of treatment for type 1 diabetes. JDRF would like to see discussion of insulin pumps during pregnancy and labour included in the final scope.	Thank you for your comment. The developers agree that pump therapy can be a useful intervention for some women with diabetes in pregnancy but were of the view that the current recommendations in the 2008 Diabetes in pregnancy guideline were permissive regarding the use of pump therapy and that there was unlikely to be any new evidence to update these recommendations
Juvenile Diabetes Research	1	4.3.1 - E	A clinical trial is currently being undertaken regarding the use of Continuous Glucose Monitors for women who are pregnant with type 1. JDRF believes that this area should be included in the final scope	Thank you for your comment. The effectiveness of continuous glucose monitoring is included in the update scope

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Foundation				
Lilly UK	1	General	Eli Lilly agrees with the overall content of the draft scope for "Diabetes in pregnancy"	Thank you for your comment
National Childbirth Trust	4	General	Overall, the scope seems to be highly medicalised and lack any reference to the importance of woman-centred care. The importance of women-centred care is illustrated by an extract from the National Service Framework for Diabetes quoted on page 121 of the current full Diabetes in pregnancy guideline: 'Diabetic pregnancy is associated with an increased risk of complications during labour and delivery… However, it should be remembered that some women's experience of a "medicalised" and high-intervention labour and delivery is a negative and frightening one. This need not be the case if they are helped to feel in control, are involved in decision-making and kept informed, and if they are supported by calm and competent professionals.' Despite this quote being used, in the 252 pages of the full guideline, there are only 8 occurrences of the word "midwife", 7 occurrences of the word "midwives" and 5 occurrences of the word "midwifery", and many of these are simply listed contributing organisations. It seems that more attention needs to be paid to ensuring that women receive both the very best medical and midwifery care. This should include strategies to keep care normal where possible with positive attention on providing for the support and information needs of women with diabetes and their families during the transition to motherhood and fatherhood. As women with diabetes, including gestational diabetes, are at higher risk, they will also only be offered care in an obstetric unit. Attention should, therefore, be paid to enabling these women to have as normal a labour and birth as	Thank you for your comment. The developers agree with the stakeholder's concern that the guidance needs to be patient focused. The principle of patient-centred care is intrinsic to the NICE process, and the NICE Patient and Public Involvement Programme (PPIP) oversee its implementation by, for example, assisting the developers in recruiting a minimum of two lay representatives to the guideline development group and commenting on the draft guidance While every effort will be made to ensure that the updated guidance is patient-centred, the developers note that it will only be possible to amend recommendations that fall within the final scope for the update The developers would like to highlight that the inclusion of the topic of gestational age specific risk of intrauterine death in type 1, type 2 and gestational diabetes and the optimal timing of delivery means that one area where changes may be possible is the section on intrapartum care. This review will seek to establish whether

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			possible, for example with opportunities to be upright and mobile and use a birth pool.	the 2008 recommendation that all women with diabetes in pregnancy who have a normally grown fetus should be offered elective birth through induction of labour, or by elective caesarean section if indicated, after 38 completed weeks, may be updated Furthermore the developers feel that it is important to highlight that both the current Diabetes in pregnancy guideline and the update when published are designed to supplement the suite of NICE guidelines designed for women who do not have diabetes, and this includes Antenatal care (CG62) and Intrapartum care (CG55). When viewed in the context of the overall pregnancy pathway the role of midwifery-led care is more prominent. The developers would also like to clarify that issues pertaining to the care of women during labour generally (such as the use of a birth pools) fall within the scope of the Intrapartum care guideline (CG55; also currently undergoing update) because these are not specific to women with diabetes
National Childbirth Trust	1	3.1	You say in b) that up to 5% of the approximately 700,000 women who give birth in England and Wales each year have diabetes, and you say in c) that less than 1% of women have pre-existing diabetes. This suggests that less than 5% of all pregnant women develop gestational diabetes, but in e) you say that at least 5% of women in the UK have gestational	Thank you for your comment which highlighted an error in the draft scope. The developers have now corrected the text

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			diabetes (although this figure will vary greatly depending upon the local population). These percentages do not seem to add up and this should be clarified. Overall, we feel that some editing is needed to create a more integrated and flowing introduction.	
National Childbirth Trust	2	3.2 g	We would suggest adding "Advice regarding long-term diet and other lifestyle changes and care in any future pregnancy" to the list.	This section is a brief summary of the current practice regarding diabetes in pregnancy and the developers felt that the text was already sufficiently detailed without the addition of this point. Furthermore, the current wording also makes clear that these bullets do not constitute a comprehensive list, but merely give some examples of current practice regarding postnatal care
National Childbirth Trust	3	4.4	You say that no more than seven outcomes will be prioritised for each topic. What is the rationale for this? The number of outcomes should be based on their importance and not be limited beforehand.	This statement reflects a standard process that is common across the clinical guidelines programme. The maximum number of outcomes reported in each review is dictated by the GRADE approach to appraising evidence that NICE have now adopted. The GRADE working group has conducted research that indicates that decision making is more effective when the reporting of outcomes is limited to seven. For more information see the website http://www.gradeworkinggroup.org/index.htm . The final decision about the number of outcomes reported for each review rests with the guideline development group
NHS	1	General	NHS Direct welcome this guideline update and have no	Thank you for your comment

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Direct			comments on the scope.	
Novo Nordisk Ltd	1	3.2 & 4.3	Novo Nordisk would like to highlight the fact that treatment with insulin detemir can be considered during pregnancy (but any potential benefit must be weighed against a possibly increased risk of an adverse pregnancy outcome).	The developers are of the view that there would be no new evidence to warrant a change to the existing recommendations in the 2008 Diabetes in pregnancy guideline about the use of particular types of insulin and therefore did not consider this a priority for inclusion in the update scope
Royal College of Midwives	1	General	The Royal College of Midwives considers the scope of this update to be appropriate and has no further comments at this point.	Thank you for your comment
Royal College of Nursing	1		Nurses caring for people with diabetes in pregnancy were invited to submit comments to inform on the draft scope for the clinical guidelines. Feedback from them suggest that there is no further information to submit at this stage on behalf of the Royal College of Nursing. Thank you for the invitation to participate, we look forward to participating in the next stage of the appraisal.	Thank you for your comment
Royal College of Obstetricians and Gynaecology	1	General	Well written and presented	Thank you for your comment
Royal College of	2	section 3.2 (g)	If this is covered elsewhere or in another guideline it would be helpful to refer to or summarise the guidance	Postnatal care is covered by the recommendations in the 2008 Diabetes in pregnancy guideline and is likely to

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Obstetricians and Gynaecology				be covered to some extent by the topics of method and timing of postnatal testing for type 2 diabetes for women who have had gestational diabetes in the update scope
Royal College of Obstetricians and Gynaecology	3	section 4.3.2 (d)	Advice about contraception methods for women with diabetes will not be covered (by the original or the update). contraception is mentioned in the introduction.	Thank you for your comment. The Diabetes in pregnancy update scope has now been expanded to include the effectiveness of oral hormonal contraceptives in women with diabetes compared with women without diabetes The developers agree that this is an important issue for all four diabetes guidelines. Therefore, following discussion with NICE and the teams updating the other diabetes guidelines, it has been agreed that the recommendations on preconception care in the updated diabetes in pregnancy guideline (i.e. both those that appeared in the 2008 guideline and the updated recommendations on HbA_{1c} and blood glucose targets and contraception) will be cross-referenced wherever necessary in the guidelines covering routine care for women of childbearing age with pre-existing diabetes
Royal College of Paediatri	5	4.1.1 c	We agree that young women of reproductive age with diabetes whose care has not yet been transferred from paediatric to adult services is an important area that needs review. We would recommend input from a paediatric	Thank you for your comment. The developers will consider appointing an expert advisor with experience in paediatric diabetes care at a later

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cs and Child Health			diabetologist during the review, as this clinical scenario will ordinarily require multi-disciplinary care, either in an adolescent or transitional setting.	stage. Their decision will be informed by the availability of evidence that is specific to young, pregnant women with diabetes and whether the guideline development group consider that it will be necessary to provide recommendations that are unique to this group
Royal College of Paediatrics and Child Health	1	4.3.2.b & 4.4.c	Further clarification is needed with regards to neonatal care. The matter is confused when in 4.3.2.b it says that neonatal care will not be updated, whereas in 4.4.c neonatal outcomes are mentioned as being included.	Neonatal outcomes are included to the extent that they will be used to evaluate management strategies but neonatal care as a topic is not to be covered
Royal College of Paediatrics and Child Health	6	4.3.2 d (Areas from the original guideline that will not be updated) Advice about contraception methods for women with diabetes.	In this section about advice for contraception methods for women with diabetes, we would suggest that guidance to a sexually active diabetic adolescent should be added and this would require input during the review process from a paediatrician specialising in adolescent medicine.	Thank you for your comment. The Diabetes in pregnancy update scope has now been expanded to include the effectiveness of oral hormonal contraceptives in women with diabetes compared with women without diabetes The developers agree that this is an important issue for all four diabetes guidelines. Therefore, following discussion with NICE and the teams updating the other diabetes guidelines, it has been agreed that the recommendations on preconception care in the updated diabetes in pregnancy guideline (i.e. both those that appeared in the 2008 guideline and the updated recommendations on

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				HbA_{1c} and blood glucose targets and contraception) will be cross-referenced wherever necessary in the guidelines covering routine care for women of childbearing age with pre-existing diabetes The developers will consider appointing an expert advisor with experience in paediatric diabetes care at a later stage. Their decision will be informed by the availability of evidence that is specific to young, pregnant women with diabetes and whether the guideline development group consider that it will be necessary to provide recommendations that are unique to this group
Royal College of Paediatrics and Child Health	2	4.4	It is also unclear whether the proposed seven outcomes are counted for individual bullet point as an outcome.	The layout of this section is determined by the NICE scope template. Each bullet point listed would be considered as one of the seven outcomes included in each review
Royal College of Paediatrics and Child Health	3	4.4.c	It is most appropriate to see neonatal outcomes included, as these are important outcomes in management of diabetes in pregnancy.	Thank you for your comment
Royal College	4	4.4.c & 4.4.d	It is important to link maternal outcomes and neonatal outcomes (e.g. mode of delivery to respiratory distress)	Where feasible, data to support such interpretations will be extracted for

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of Paediatrics and Child Health			wherever possible.	studies included in each systematic review conducted for the guideline, but there will be no specific review question on, for example, mode of birth
Royal College of Pathologists	1	4.4 d)	Few centres now use fructosamine to monitor diabetes control in pregnancy, and there are no plans to discuss its use in the update. Suggest consider removing it as a relevant maternal outcome.	The developers agree that fructosamine is no longer used in current clinical practice and have chosen not to include this type of test in the screening or diagnostic reviews for this reason. However, they are aware that, due to its use historically, it may be reported as an outcome in the literature and concluded that it would be prudent to take an inclusive approach in this context at the scoping stage. Outcomes for individual reviews will be prioritised by the guideline development group on a case by case basis and may be influenced by study design and the volume of available evidence
Sanofi	2	4.4d	Fructosamine as a measure of blood glucose has been removed from the type 1 diabetes guideline scope since HbA1c is now the standard measure, is this also the case in diabetes in pregnancy?	The developers agree that fructosamine is no longer used in current clinical practice and have chosen not to include this type of test in the screening or diagnostic reviews for this reason. However, they are aware that, due to its use historically, it may be reported as an outcome in the literature and concluded that it would be prudent to take an inclusive approach in this context at the scoping stage. Outcomes for individual reviews

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				will be prioritised by the guideline development group on a case by case basis and may be influenced by study design and the volume of available evidence
Wockhardt UK Limited	1	4.3.1	Under 4.3.1, Key clinical issues that will be covered, the issue of long-term safety of genetically-modified (GM) insulins should be addressed. The question "What are the long-term safety issues associated with the use of GM insulins?" should be listed under 4.3.1 Key clinical issues that will be covered (Areas not in the original guideline that will be included in the update). This is of paramount importance in the treatment of pregnant women with diabetes. Any potential effect of GM insulins on the developing foetus should be investigated and the guideline should include relevant advice – reassuring or otherwise - son their use in pregnant women.	The developers are of the view that there would be no new evidence to warrant a change to the existing recommendations in the 2008 Diabetes in pregnancy guideline about the use of particular types of insulin and therefore did not consider this a priority for inclusion in the update scope

These organisations were approached but did not respond:

Action on Pre-Eclampsia
Airedale NHS Trust
Alere
All Wales Dietetic Advisory Committee
Allocate Software PLC
Aneurin Bevan Health Board
Anglesey Local Health Board
Arrowe Park Hospital
Association for Improvements in the Maternity Services
Association of Anaesthetists of Great Britain and Ireland
Association of British Clinical Diabetologists

Association of British Healthcare Industries
Association of Clinical Pathologists
Association of Radical Midwives
Astrazeneca UK Ltd
Baby Lifeline
Barnsley Primary Care Trust
Bayer plc
Bedfordshire Primary Care Trust
Birmingham Women's Health Care NHS Trust
BirthChoice UK
Black and Ethnic Minority Diabetes Association
Bliss
Bolton Hospitals NHS Trust
Bradford and Airedale Primary Care Trust
Bradford District Care Trust
Bradford Royal Infirmary
Breastfeeding Network
Bristol Health Services Plan
Bristol-Myers Squibb Pharmaceuticals Ltd
British Association of Perinatal Medicine
British Association of Prosthetists & Orthotists
British Dietetic Association
British Infection Association
British Maternal & Fetal Medicine Society
British Medical Association
British Medical Journal
British National Formulary
British Psychological Society
Buckinghamshire Hospitals NHS Trust
C. R. Bard, Inc.
Calderdale Primary Care Trust
Camden Link
Capsulation PPS
Capsulation PPS
Care Quality Commission (CQC)
Central & North West London NHS Foundation Trust

Central Lancashire Primary Care Trust
Central London Community Healthcare
Children, Young People and Families NHS Network
CHKS Ltd
City and Hackney Teaching Primary Care Trust
City Hospitals Sunderland NHS Foundation Trust
Cochrane Pregnancy & Childbirth Group
Colchester Hospital University NHS Foundation Trust
Commission for Social Care Inspection
Community Diabetes Consultants
Confidential Enquiry into Maternal and Child Health
Co-operative Pharmacy Association
Countess of Chester Hospital NHS Foundation Trust
Coventry and Warwickshire Cardiac Network
Croydon Primary Care Trust
Cytyc UK Limited
Daiichi Sankyo UK
Department for Communities and Local Government
Department of Health, Social Services and Public Safety - Northern Ireland
Det Norske Veritas - NHSLA Schemes
Doncaster Primary Care Trust
Dorset Primary Care Trust
Doula UK
Dudley Group Of Hospitals NHS Foundation Trust
East and North Hertfordshire NHS Trust
East Midland Ambulance Services NHS
Eastbourne District General Hospital
Elective Cesarean
Eli Lilly and Company
English National Forum of LSA Midwifery Officers
Equalities National Council
Evidence based Midwifery Network
Faculty of Public Health
Federation of Ophthalmic and Dispensing Opticians
Ferring Pharmaceuticals
Fibroid Network Charity

Gateshead Primary Care Trust
George Eliot Hospital NHS Trust
Gloucestershire Hospitals NHS Foundation Trust
Gloucestershire LINk
Great Western Hospitals NHS Foundation Trust
Group B Strep Support
Guy's and St Thomas' NHS Foundation Trust
Hammersmith and Fulham Primary Care Trust
Havering Primary Care Trust
Health Protection Agency
Health Quality Improvement Partnership
Healthcare Improvement Scotland
HemoCue Ltd
Hertfordshire Partnership NHS Trust
Homerton Hospital NHS Foundation Trust
Humber NHS Foundation Trust
Independent Healthcare Advisory Services
Independent Midwives Association
Information Centre for Health and Social Care
Innermost Secrets Ltd
Institute for Womens Health
Institute Metabolic Science
Institute of Biomedical Science
Institute of Health and Society
Insulin Dependent Diabetes Trust
Insulin Pump Awareness Group - Scotland
Janssen
JBOL Ltd
Johnson & Johnson
Johnson & Johnson Medical Ltd
karimahs cuisina
KCI Europe Holding B.V.
KCI Medical Ltd
King's College Hospital - Weston Education Centre
King's College Hospital NHS Foundation Trust
Kingston Hospital

Knowsley Primary Care Trust
La Leche League GB
Lancashire Care NHS Foundation Trust
Launch Diagnostics
Leeds Community Healthcare NHS Trust
Leeds Primary Care Trust (aka NHS Leeds)
Leeds Teaching Hospitals NHS Trust
Lesbian, gay, bisexual and trans domestic abuse forum
Lewisham University Hospital
LifeScan
Liverpool PCT Provider Services
Liverpool Primary Care Trust
Liverpool Women's NHS Foundation Trust
Luton and Dunstable Hospital NHS Trust
Maidstone and Tunbridge Wells NHS Trust
Maidstone Hospital
Maternity Action
Maternity and Health Links
McCallan Group, The
McDonald Obstetric Medicine Society
Medicines and Healthcare products Regulatory Agency
Medtronic
Medway NHS Foundation Trust
Merck Serono
Merck Sharp & Dohme UK Ltd
Mid and West Regional Maternity Service Liasion Committee
Mid Staffordshire NHS Foundation Trust
midwifeexpert.com
Midwives Information and Resource Service
Ministry of Defence
Multiple Births Foundation
National Clinical Guideline Centre
National Collaborating Centre for Cancer
National Collaborating Centre for Mental Health
National Collaborating Centre for Women's and Children's Health
National Concern for Healthcare Infection

National Diabetes Inpatient Specialist Nurse
National Diabetes Nurse Consultant Group
National Institute for Health Research Health Technology Assessment Programme
National Kidney Research Foundation
National Obesity Forum
National Patient Safety Agency
National Perinatal Epidemiology Unit
National Prescribing Centre
National Public Health Service for Wales
National Treatment Agency for Substance Misuse
NDR UK
Neonatal & Paediatric Pharmacists Group
Nester Healthcare Group Plc
Newcastle upon Tyne Hospitals NHS Foundation Trust
NHS Blood and Transplant
NHS Bournemouth and Poole
NHS Clinical Knowledge Summaries
NHS Connecting for Health
NHS Cornwall and Isles Of Scilly
NHS Derbyshire county
NHS Fetal Anomaly Screening Programme
NHS Kirklees
NHS London
NHS Manchester
NHS Midlands and East
NHS Milton Keynes
NHS Newcastle
NHS Nottingham City
NHS Nottinghamshire County
NHS Plus
NHS Plymouth
NHS Sefton
NHS Sheffield
NHS South Central
NHS Sussex
NHS Trafford

NHS Yorkshire and the Humber Strategic Health Authority
Norfolk Suffolk & Cambridgeshire Strategic Health Authority
North Cheshire Hospitals NHS Trust
NORTH EAST LONDON FOUNDATION TRUST
North Essex Mental Health Partnership Trust
North Middlesex University Hospital NHS Trust
North Somerset Primary Care Trust
North Tees and Hartlepool NHS Foundation Trust
North West London Perinatal Network
North Yorkshire & York Primary Care Trust
Northumbria Diabetes Service
Northumbria Healthcare NHS Foundation Trust
Nottingham City Hospital
Nova Biomedical UK
Nutrition and Diet Resources UK
Nutrition Society
Obstetric Anaesthetists' Association
Owen Mumford Ltd
Oxford Centre for Diabetes, Endocrinology and Metabolism
Oxford University Hospitals NHS Trust
Pennine Acute Hospitals NHS Trust
PERIGON Healthcare Ltd
Perinatal Institute
Pfizer
Plymouth Hospitals NHS Trust
Powys Local Health Board
Primary Care Diabetes Society
Primary Care Pharmacists Association
Programme development Group in Maternal and Child Nutrition
Public Health Agency
Public Health Wales NHS Trust
Queen Elizabeth Hospital
Queen Mary's Hospital NHS Trust
RCM Consultant Midwives Forum
Regional Maternity Survey Office
RioMed Ltd.

Roche Diagnostics
Rotherham Primary Care Trust
Royal Berkshire NHS Foundation Trust
Royal Brompton Hospital & Harefield NHS Trust
Royal College of Anaesthetists
Royal College of General Practitioners
Royal College of General Practitioners in Wales
Royal College of Ophthalmologists
Royal College of Paediatrics and Child Health , Gastroenetrology, Hepatology and Nutrition
Royal College of Physicians
Royal College of Physicians of Edinburgh
Royal College of Psychiatrists
Royal College of Psychiatrists in Scotland
Royal College of Radiologists
Royal College of Surgeons of England
Royal Cornwall Hospitals NHS Trust
Royal Free Hospital NHS Foundation Trust
Royal National Institute of Blind People
Royal Pharmaceutical Society
Royal Society of Medicine
Royal Surrey County Hospital NHS Trust
Royal United Hospital Bath NHS Trust
Royal West Sussex NHS Trust
Salford Royal Foundation Hospital
Sands, the stillbirth and neonatal death charity
Sandwell and West Birmingham Hospitals NHS Trust
Sandwell Primary Care Trust
Scarborough and North Yorkshire Healthcare NHS Trust
School of Midwifery
Scottish Intercollegiate Guidelines Network
SEE BETSI CADWALADR - North Wales NHS Trust
Sheffield Primary Care Trust
Sheffield Teaching Hospitals NHS Foundation Trust
SNDRi
Social Care Institute for Excellence

Society and College of Radiographers
South Asian Health Foundation
South Devon Healthcare NHS Foundation Trust
South East Coast Ambulance Service
South Tees Hospitals NHS Trust
South West Yorkshire Partnership NHS Foundation Trust
Southend Hospitals NHS Foundation Trust
Southern Health & Social Care Trust
St Mary's Hospital
Stockport Clinical Commissioning Pathfinder
Stockport Primary Care Trust
Sunderland Royal Hospital
Sure Start Tamworth
Swansea NHS Trust
Tameside Hospital NHS Foundation Trust
The Association for Clinical Biochemistry
The Association of the British Pharmaceutical Industry
The British In Vitro Diagnostics Association
The Princess Alexandra Hospital NHS Trust
The Rotherham NHS Foundation Trust
The Whittington Hospital NHS Trust
Tiny Tickers
UK Anaemia
UK Clinical Pharmacy Association
UK National Screening Committee
UK Specialised Services Public Health Network
UK Thalassaemia Society
United Lincolnshire Hospitals NHS
University College London
University College London Hospital NHS Foundation Trust
University Hospital of North Staffordshire NHS Trust
University Hospitals Bristol NHS Foundation Trust
University of Huddersfield
University of Leicester
Vifor Pharma UK Ltd
Walsall Local Involvement Network

Weight Concern
Welsh Endocrine and Diabetes Society
Welsh Endocrinology and Diabetes Society
Welsh Government
Welsh Scientific Advisory Committee
West Hertfordshire Hospital Trust
West Herts Hospitals NHS Trust
West Middlesex University Hospital NHS Trust
West Midlands Antenatal Diabetes Association
West Midlands Perinatal Institute
Western Cheshire Primary Care Trust
Wiltshire Primary Care Trust
Wirral University Teaching Hospital NHS Foundation Trust
Worcestershire Acute Hospitals Trust
Worthing Hospital
Wrightington, Wigan and Leigh NHS Foundation Trust
Wye Valley NHS Trust
York Hospitals NHS Foundation Trust
Yorkshire and The Humber Maternity Network
Young Diabetlolgists Forum