NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Diabetes in pregnancy

Date of Quality Standards Advisory Committee post-consultation meeting:
8 October 2015.

2 Introduction

The draft quality standard for diabetes in pregnancy was made available on the NICE website for a 4-week public consultation period between 7 August and 7 September 2015. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 24 organisations, which included service providers, national organisations, professional bodies and others.

This report provides the Quality Standards Advisory Committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the Committee as part of the final meeting where the Committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the Committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the Committee should read this summary alongside the full set of consultation comments, which are provided in appendices 1and 2.

3 Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

3. Do you have an example from practice of implementing the NICE guideline(s) that underpins this quality standard? If so, please submit your example to the NICE local practice collection here. Examples of using NICE quality standards can also be submitted.

Stakeholders were also invited to respond to the following statement specific question:

1. For draft quality statements 3 and 6: Are services for pregnant women with diabetes provided by a joint diabetes and antenatal clinic, if not how are services provided?

4 General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

- The quality standard was welcomed.
- Statements could highlight the need for greater joint working between primary and secondary care.
- Some statements could be more outcomes focussed.

Consultation comments on data collection

- The National Pregnancy in Diabetes Audit collects data on a number of the statement measures.
- Data collection for the proposed quality measures would be possible.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

Women with diabetes planning a pregnancy are prescribed 5mg/day folic acid until 12 weeks gestation.

Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

- Stakeholders suggested re-wording statement to focus on prescribing folic acid as soon as possible.
- Expand statement to encompass other aspects or preconception care such as achievement of optimal glycaemic control and management of medicines.
- Define a timeframe for ‘planning a pregnancy’ within the statement.

5.2 Draft statement 2

Pregnant women with diabetes are supported to self-monitor their blood glucose levels during pregnancy.

Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

- Stakeholders felt it would be helpful to quantify the term ‘enough’ when referring to blood glucose monitoring strips.
- Terminology used in the measures requires refining.
- Stakeholders highlighted the support pharmacists can provide in blood glucose monitoring.

5.3 Draft statement 3

Women with pre-existing diabetes are seen at the joint diabetes and antenatal care clinic within 1 week of their pregnancy being confirmed.

Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

- Stakeholders commented that this would be challenging to achieve within the timescale.
- Clarification was needed the definition being used for ‘pregnancy being confirmed’, it was suggested to define it by gestation.
- Re-word statement to say ‘offered an appointment with’ and ‘a member of the joint diabetes and antenatal care team’.
- Clarify which members of the team a woman should see in early pregnancy.

Consultation question 4

Stakeholders made the following comments in relation to consultation question 4:

- Joint antenatal and diabetes clinics exist but some areas have different levels of service provision and the names of clinics can vary although the components are generally the same.

5.4 Draft statement 4

Pregnant women with pre-existing diabetes have their HbA1c levels measured at their booking appointment.

Consultation comments

Stakeholders made the following comments in relation to draft statement 4:

- Stakeholders question whether focussing on measurement of HbA1c at booking will improve care and whether it would be better placed at pre-pregnancy assessment.
- Suitability of the outcome measure was raised by stakeholders.

5.5 Draft statement 5

Pregnant women with pre-existing diabetes are referred for retinal assessment at their booking appointment.

Consultation comments

Stakeholders made the following comments in relation to draft statement 5:

- Clarify in the rationale that the expectation is that a retinal assessment referral at booking should ensure women with diabetes receive future referrals as needed.
- Stakeholders felt that it should be acknowledged that referral is a shared responsibility between primary and secondary care.

5.6 Draft statement 6

Pregnant women diagnosed with gestational diabetes are reviewed at the joint diabetes and antenatal care clinic within 1 week of diagnosis.

Consultation comments

Stakeholders made the following comments in relation to draft statement 6:

- Stakeholders suggested that the statement is reworded to say ‘reviewed by a member of the joint care clinic’.
- Stakeholders thought that the review should be ‘offered’ to women.
- Clarify whether clinic attendance is required or other arrangements such as home visits are suitable.
- Stakeholders expressed concern that there may be an adverse impact on a woman’s experience of care if they are attending a busy joint clinic.

Consultation question 4

Stakeholders made the following comments in relation to consultation question 4:

- Joint antenatal and diabetes clinics exist but some services have different levels of service provision and the names of clinics can vary although the components are generally the same.
- Stakeholders highlighted the need for these joint clinics to link with community services for lifestyle support.

5.7 Draft statement 7

Women who have had gestational diabetes have annual HbA1c testing.

Consultation comments

Stakeholders made the following comments in relation to draft statement 7:

- Some stakeholders felt the statement may be difficult to implement and measure in general practice.

6 Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

- Stakeholders suggested that a statement on insulin pump therapy for type 1 diabetes should be considered.

- Stakeholders raised concern that there was not a statement on pre-pregnancy counselling. They suggested that such a statement should also include the use structured education programmes for women with diabetes, cover preconception glycaemic control and management of medicines.
- Stakeholders expressed support for a statement on screening for gestational diabetes.
- Stakeholders felt it was important to include healthy weight management and lifestyle behaviour promotion as prevention measures to avoid future gestational diabetes.
- Stakeholders expressed concern that there were no statements relating to the care of the neonate and felt a statement on the care of neonatal hypoglycaemia should be included.
- Stakeholders suggested the standard should also cover the intrapartum care of women with diabetes.

Appendix 1: Quality standard consultation comments table – registered stakeholders

ID	Stakeholder	Comment on or statement number	Comments
1	HQT Diagnostics	General	General Practitioners should test Fatty Acids at first presentation and adjust level to achieve: • **Omega-3 Index: >8%** • **Omega-6/3 Ratio: <3:1** • Re-test after 3 months This is proven to reduce Gestational Diabetes Omega-3 Poly Unsaturated Fatty Acids (PUFA) are involved in glucose level control and insulin sensitivity More at: http://www.expertomega3.com/omega-3-study.asp?id=2 http://www.expertomega3.com/omega-3-study.asp?id=21 http://jama.jamanetwork.com/article.aspx?articleid=2088851 http://www.ncbi.nlm.nih.gov/pubmed/?term=phinney+SD www.hqt-diagnostics.com
2	HQT Diagnostics	General	General Practitioners should test Vitamin D 25(OH)D at first presentation. Adjust the level to be between 100-150 nmol/L and re-test after 3 months This is proven to reduce Gestational Diabetes Vitamin D - with co-factors such as Calcium and Magnesium – helps to prevent and treat Diabetes

			This should reduce fatty deposition in the liver and also improve vascular reactivity. More at: www.vitamindwiki.com/Overview+Diabetes+and+vitamin+D www.vitamindwiki.com/Overview+Pregnancy+and+vitamin+D http://www.eurekaselect.com/72897/article
3	HQT Diagnostics	General	The primary objective of treatment or prevention for Diabetes should be to reduce the amount of Insulin that the body produces from carbohydrates, sugars and certain proteins. Refer patient to Dietitian or Nutritional Therapist for advice about Diet & Lifestyle (www.bda.uk.com or www.bant.org.uk) More at: http://www.ncbi.nlm.nih.gov/pubmed/?term=phinney+SD http://www.ncl.ac.uk/magres/research/diabetes/documents/Diabetes-Reversaloftype2studyJune14.pdf https://www.youtube.com/watch?v=FcLoaVNQ3rc https://www.youtube.com/watch?v=mAwgdX5VxGc http://www.biznews.com/category/lchf-health-summit/
4	UKCPA	General	I have no major concerns with the document and feel that it is working towards addressing the issues of diabetes in pregnancy. The section on supporting the use of continuous subcutaneous insulin (pump therapy) is very welcome. Improving access to pumps and ideally continuous blood glucose monitoring is essential to improving control of diabetes in pregnancy, and improving outcome for the mother and baby.

			Overall this an uncontroversial review.
5	The Royal College of General Practitioners	General	No comments about the other quality statements as printed.
6	Slimming World	General	We welcome the development of this important quality standard
7	NHS England	General	Thank you for the opportunity to comment on the above Quality Standard. I wish to confirm that NHS England has no substantive comments to make regarding this consultation.
8	Medtronic Limited	General	Following our previous comments regarding insulin pump therapy for type 1 diabetes in this patient population, we would like to resubmit this for your further consideration as a quality statement. This is particularly important because the uptake of insulin pump therapy in the UK has not reached the projected targets from the NICE TA 151 published in 2008, therefore it is clear that this is a critical area for improvement. A UK service level audit on insulin pump uptake published in 2013 (White et al., 2014) showed that: • Across the UK only 6% of adults with type 1 diabetes have received an insulin pump (13, 428 adults); • The uptake of insulin pump therapy in the UK falls well below the projected levels set out in the NICE TA 151, and that of other European countries (> 15%). Insulin pump therapy is a cost effective intervention, and should be prioritised as a highly efficient use of healthcare resources. This Quality Standard could play a key role in ensuring timely and appropriate access to this therapy in eligible type 1 diabetic patients before and during pregnancy if it were to be included as a quality area for improvement. Could the Committee please reconsider the inclusion of insulin pump therapy in the Quality Standard?
9	Royal College of Paediatrics and Child Health	General	Despite the introduction stating that standards may inform management of the baby, and the list of neonatal morbidities, there is no quality statement regarding management of the baby.

			However, even with the best care in pregnancy if there is no quality statement for care of the baby the outcome could be poor or there could be inappropriate separation of mother and baby/formula supplementation etc.
10	Paediatrics and Child Health	General	We notice that there is no paediatrician listed in the advisory group (https://www.nice.org.uk/guidance/GID-QSD116/documents/diabetes-in-pregnancy-specialist-committee-members2). How can there be a baby free quality standard for pregnancy?
11	RCOG	General	The 2014 MBRRACE report stressed the need for all units to give pre-pregnancy counselling to women with pre-existing medical conditions in all possible settings. There is no quality standard for pre-pregnancy counselling of women with type 1 or 2 DM in general. There is only a standard for folic acid in those planning pregnancy. There should be an emphasis that all women of child bearing age with Type 1 or 2 have pre-pregnancy advice given in medical clinics.
12	RCOG	General	Although the NICE 2015 guideline on Diabetes in pregnancy clearly recommends on screening for GDM, there is no quality standard for units to use the screening recommendations
13	ABMU trust	General	The National Diabetes in Pregnancy audit collects data on pregestational diabetes relevant to these standards
14	The Royal College of Midwives	General	The RCM considers that this draft quality standard reflects several key areas for quality improvement and that if appropriate systems were available, it would be possible to collect the data for the proposed quality measures. 2 further key areas that should be addressed are outlined below.
15	Department of Health	General	I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.
16	Diabetes UK	General	These are very much process statements, and we are concerned that they will not be sufficient to raise the standard of care as they are not outcome focused. The standards need to include targets that would allow the processes outlined to be linked to outcomes. For example, statement 4 should include targets that can demonstrate that preconception care is leading to women conceiving with better HbA1c levels.

			Page 2, paragraph 2: The recommendation in this paragraph is not very clear and should be reworded to be consistent with other recommendations in the NICE guidelines (NG3) about appropriate testing (e.g. fasting glucose at 6-13 weeks or HbA1c at 13 weeks). Also, if this is meant to only highlight the need to exclude severe hyperglycaemia immediately postnatal, then that should be made clear.
17	British Maternal and Fetal Medicine Society	General	Overall the committee felt this document made sensible recommendations. Specific comments relating to each quality statement are given
18	Royal Pharmaceutical Society	General	The Royal Pharmaceutical Society (RPS) welcomes guidance on Diabetes in pregnancy; As experts in medicines pharmacists provide advice on how to take medicines (for diabetes), adverse effects, possible interactions and cautions, and to raise awareness and increase understanding of the condition and treatment. Community pharmacists provide a range of enhanced services as well as supplying medicines and advice on how to use medicines effectively. There are opportunities for pharmacists and pharmacy teams to raise awareness and provide information to support the management of diabetes and it's complications to women through the numerous interactions they have with patients every day. We would like to highlight recognition for community pharmacists as providers of advice on lifestyle, medicines and when to consult GPs or specialists. We recommend that pharmacists are included in the multidisciplinary care of women with diabetes who become pregnant or who develop diabetes during pregnancy alongside other healthcare professionals such as GPs, community midwives and healthcare professionals in joint diabetes and antenatal care teams. We would like to highlight that prescribers can recommend patients visit their community pharmacy for advice on treatments for diabetes, support for managing their blood glucose monitoring, counselling on how to use their blood glucose monitor, as well as insulin and insulin pumps, nutritional advice, advice on supplements such as

			folic acid, and to keep them informed of medical device alerts for blood glucose meters, test strips and insulin pens etc. Community pharmacists are regularly in contact with pregnant women purchasing medicines or via prescription for symptoms associated with pregnancy such as constipation, heartburn and indigestion. Due to regular interactions they are in a position to recognise undiagnosed symptoms of gestational diabetes and referral to GP. They are in a position to promote awareness of what to do and who to contact when a woman with diabetes becomes pregnant. They are also in a position to offer advice on postnatal diabetes care to include monitoring of blood glucose levels, medicines and breast feeding. The RPS *Shaping pharmacy for the future (Now or Never*) http://www.rpharms.com/models-of-care/report.asp report looks at how pharmacists are providing easy access to medicines, advice, review and care; better self-management of long-term conditions; better health through support to make lifestyle changes, and services which are integrated with other health professionals- so care is seamless, and it recommends ways to make these services more widespread.
19	Royal Pharmaceutical Society	General	Pharmacists can support with statements 3-7 by ensuring that any pregnant women who present in pharmacy are referred/signposted to relevant medical, antenatal and diabetic teams for appropriate assessments, care and follow up.
20	Royal College of Nursing	General	There needs to be a quality standard about improving diabetes control pre-conceptually to reduce the risk of fetal loss and anomalies. This is not evident within NICE quality Standard 22 (Antenatal Care) and we recommend this disease specific aspect needs to be considered here.
21	Obesity Group of the British Dietetic Association (formerly domUK)	General	We welcome this quality standard on an important aspect of health.
22	RCOG	Introduction	Is the text within brackets really necessary? The same meaning is conveyed by simply stating ‘this QS covers the management of women who are planning a pregnancy or who are already pregnant.

23	RCOG	Introduction	'mode of birth' is a category of outcome. It is not an outcome in itself. You may wish to consider changing this to 'vaginal delivery rate 'caesarean section rate.
24	The Royal College of Midwives	Introduction	There should be a statement in the standard recommending preconception counselling. Pregnancy outcomes for women with pre existing diabetes are likely to be more favourable if the woman has achieved excellent control of her diabetes preconception. Women with diabetes who are planning to become pregnant should be offered a structured education programme.
25	The Royal College of Midwives	Introduction	There should be a statement clearly addressing the need for information, education and advice about how diabetes will affect the pregnancy, birth and early parenting (such as breastfeeding and initial care of the baby). Midwives, who are key to the initial discussions, will need to have access to skilled members of the multidisciplinary team who can remain up to date with knowledge in this area.
26	UHBFT	Question 1	A key area for quality improvement highlighted in both the NICE NG3 guidance and the National Pregnancy in Diabetes (NPID) Audit is in preparation for pregnancy (www.hscic.gov.uk/npid). The quality standards only focus on whether or not folic acid was prescribed at 5 mg daily. NPID highlights all aspects of pre-conception care and in particular the suboptimal preparation for pregnancy for many women with Type 2 Diabetes (who in our area now comprise a majority of those with pre-gestational diabetes and exceed those with Type 1 Diabetes). There needs to be a focus on glycaemic control in these women pre-conceptually, as well as appropriate/inappropriate medication use as well as promotion of good lifestyle habits pre-pregnancy. Otherwise the focus falls almost totally on catching up during pregnancy to deal with the unmeasured suboptimal care prior to pregnancy. NPID also supports better working between primary and secondary care as whilst the majority of women with Type 1 Diabetes are looked after within specialist services, most women with Type 2 Diabetes are looked after within Primary care where there may be a lack of awareness/education in both health providers and patients about issues relating to pregnancy.
27	The Royal College of General Practitioners	Question 1	Does this draft quality standard accurately reflect the key areas for quality improvement?

			The College feels the draft quality standard does not cover screening of those at risk of gestational diabetes by GTT testing adequately. This is an area that is poorly achieved in some areas of the country and there is scope for quality improvement that could have the result of reducing risks to the mother and baby if gestational diabetes is diagnosed and treated early.
28	Slimming World	Question 1	We are concerned that the draft quality standards do not include or give reference to the importance of healthy weight management for women who have diabetes, are at risk of, or have developed gestational diabetes. We would suggest a specific standard be added which covers the importance of checking a woman's weight at booking and monitoring this throughout pregnancy. This should then be accompanied by support about managing weight gain throughout pregnancy – particularly important for those women who already have diabetes or who have been identified as at risk of gestational diabetes, to help reduce this risk. Furthermore, there is benefit in offering all women regular support throughout pregnancy to encourage healthy lifestyle behaviours. Ultimately preventing excess weight gain in pregnancy will in turn reduce the number of women retaining weight post-natally, thereby reducing numbers at risk of type 2 diabetes (and other weight-related co-morbidities).
29	Paediatrics and Child Health	Question 1	This draft QS with 7 Statements does not include Neonatal aspects of care. The NICE pathway on Diabetes in pregnancy overview, last updated 2 April 2015 includes Neonatal care for babies of mother with diabetes which is an important area for quality improvement in maternal and neonatal care. A review by NHSE has identified that Hypoglycaemia is the third commonest cause for full term admission to neonatal care (about 3000 admissions per year) which is most likely to be due to inconsistent management in babies of mother with diabetes.
30	Ferring Pharmaceuticals	Question 1	Does this draft quality standard accurately reflect the key areas for quality improvement? We would request NICE to include one quality standard to reflect another key area for

			quality improvement of intrapartum care of pregnant women with type 1 or type 2 diabetes and with gestational diabetes – elective birth by induction of labour, or by elective caesarean section if indicated. Elective birth by induction of labour is mentioned in the 'Diabetes in pregnancy quality standards' briefing document, but has not been included as a quality standard parameter in the proposed Diabetes in pregnancy NICE quality standard draft for consultation, August 2015. Inclusion of this quality standard will reflect quality improvement in the timing and mode of birth, as well as outcomes and risks for mother and baby.
31	Obesity Group of the British Dietetic Association (formerly domUK)	Question 1	We do not feel that this draft standard accurately reflects the key areas for quality improvement in their entirety. We are disappointed that weight management is not an explicit part of this standard. Given the role of overweight and obesity in the increased prevalence of diabetes, particularly gestational and type 2 diabetes, we believe that this is an essential aspect of care. We advocate adding a standard to reflect this; such that pregnant women with pre-existing diabetes have their body weight and BMI measured at their booking appointment. Those with raised BMI or sudden inappropriate weight gain should be counselled about appropriate weight gain throughout pregnancy and the importance of health eating, physical activity and appropriate portion sizes. Avoidance of inappropriately large gains in weight during pregnancy reduces the risk that women will retain excessive weight post-pregnancy, which will help with management of diabetes post-pregnancy. As the basis for discussions about weight, current NICE guidance on weight management before, during and after pregnancy could be used (these are not specific to diabetes but are useful with relation to weight). (https://www.nice.org.uk/guidance/ph27/resources/guidance-weight-management-before-during-and-after-pregnancy-pdf)
32	The Royal College of General Practitioners	Question 2	If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures? We do think this would be possible.

33	Obesity Group of the British Dietetic Association (formerly domUK)	Question 2	If the systems and structure are available we feel that it will be possible to gather the data for the proposed measures.
34	The Royal College of General Practitioners	Question 3	Do you have an example from practice of implementing the NICE guideline(s) that underpins this quality standard? Sorry unable to provide any examples.
35	The Royal College of General Practitioners	Question 4	Are services for pregnant women with diabetes provided by a joint diabetes and antenatal clinic, if not how are services provided? I believe in areas where there is a consultant obstetric physician, joint diabetes and antenatal clinics may not be necessary and this situation can provide optimum care and should not be discouraged.
36	North East Essex Diabetes Service	Question 4	Membership of MDT Some units will have a highly trained specialist midwife who will do the work as the nurse and also midwife, other members will be dietitian, Obstetrician, physician, is this acceptable?
37	UCLH	Question 4	At UCLH services for pregnant women are provided by a weekly joint diabetes and antenatal clinic. This is a clinic of 50-80 women who may be seeing the obstetric team, diabetes team, dietetics or midwives. Both of these quality standards (3&6) propose that all women with pre-existing diabetes are seen in the joint clinic within a week of positive pregnancy test and women diagnosed with gestational diabetes are seen within a week. At UCLH these women are initially seen within a week by a member of the Diabetes/Antenatal Clinic team initially to look at glycaemic control or teach blood glucose monitoring and for dietetic review and then be reviewed in the joint clinic which would be within 2 weeks. For existing patients of UCLH with type 1 and type 2 diabetes it is generally possible for them to be seen by a member of the joint diabetes/antenatal team within a week once we have been contacted. However there may be a delay from when the woman has a positive pregnancy test and sees her GP to when we are contacted and we

			have a no control over this.
38	Obesity Group of the British Dietetic Association (formerly domUK)	Question 4	We suggest that the diabetes and antenatal clinics link effectively with local community services for lifestyle support. This also relates to the final statement, when GPs are responsible for the HbA1c annual testing, if they are also responsible for BMI, PA checks and taking appropriate action to link to weight management and lifestyle support services.
39	Obesity Group of the British Dietetic Association (formerly domUK)	Question 4	We suggest that the diabetes and antenatal clinics link effectively with local community services for lifestyle support. This also relates to the final statement, when GPs are responsible for the HbA1c annual testing, if they are also responsible for BMI, PA checks and taking appropriate action to link to weight management and lifestyle support services.
40	RCOG	1	Suggest modifying the last sentence as 'if a woman with diabetes has an unplanned pregnancy, she should be prescribed high dose folic acid as soon as possible' rather than 'as soon as pregnancy is confirmed'. This would remove the delay in commencing folate whilst waiting/accessing for a pregnancy test. As high dose folate needs to be given preconceptually, this approach is more efficient even if the pregnancy test is negative.
41	Royal College of Physicians of Edinburgh	1	The Royal College of Physicians of Edinburgh ("the College") supports this statement as pre-pregnancy planning and preconception counselling are very important for women with diabetes. The College would also like to see the issues of achieving optimal glycaemic and medicines management pre-pregnancy featured in this Quality Standard as research in this area has indicated a shortfall in this regard.
42	ABMU trust	1	This should also include an evaluation of diabetic control before pregnancy. All diabetic women should be reviewed in a pre conception clinic.
43	British Medical Association	1	We believe this Quality Statement is challenging as prescription of high strength folic acid will require education of women with diabetes and a particular focus on those of childbearing age. Doctors will still have to rely on women with diabetes to inform them that they are trying to conceive in order to get a prescription at least three months before conception. The relatively small numbers of such cases indicates that it might take some time before this becomes regular practice.

44	Royal College of Nursing	1	The quality statement 1 expands on the need to prescribe folic acid in the pre-conceptual period therefore, there needs to be an improvement in blood glucose control during this period as well.
45	Diabetes UK	1	This statement is too narrow and should include full preconception counselling – not just this one area. We suggest that the Quality Standard is updated to include a statement about preconception awareness. With 50% of pregnancies unplanned, it is important to support more women with diabetes to plan their pregnancies and seek preconception advice. We suggest including an additional quality statement to that effect, which includes: - all clinicians in contact with women with diabetes having a responsibility to use every opportunity to ask about pregnancy plans, advise about contraception and document contraception use. - At a point where a woman is planning pregnancy, she should be referred for preconception care from a specialist team, where high dose Folic Acid should be prescribed, glucose control optimised, complications addressed and medications changed to those that are safe in pregnancy.
46	British Maternal and Fetal Medicine Society	1	Prescription of high dose folic acid is more likely to have an impact on health if it is given pre-conception or at a stage of pregnancy prior to organogenesis. The committee therefore recommends that the statement should read “Women with diabetes planning a pregnancy are prescribed high dose folic acid from 3 months pre conception until 12 weeks of gestation”. The principal clinical challenge is to ensure that folic acid is prescribed in a timely manner.
47	Royal Pharmaceutical Society	1	We would like to highlight that pharmacists, due to their accessibility, are in a position to raise awareness and educate women with diabetes planning a pregnancy that they should take 5mg/day folic acid from at least 3 months before conception until 12 weeks of gestation. They are in a position to provide pre-conception advice regarding folic acid as well as

			glycaemic control, diet , contraception, diabetes complications and alcohol intake.
	Obesity Group of the British Dietetic Association (formerly domUK)	1	We agree with this statement, as the current CMACE/RCOG Joint Guideline: Management of Women with Obesity in Pregnancy are still in need of adequate dissemination to GPs and midwives. https://www.rcog.org.uk/globalassets/documents/guidelines/cmacercogjointguidelinemanagementwomenobesitypregnancya.pdf
48	The Royal College of General Practitioners	2	Throughout this statement data sources and what it means for service providers etc., keeps mentioning “enough” BG testing strips, but does not clarify this. It might be helpful to say that the NICE guidance mentions testing BG at least four times/day in pregnancy and this would help understand what “enough means” (i.e. at least 120 strips/month). The strips come in pots of 50 each. There is a large difference in the cost of the strips and this may vary between primary and secondary care. It would have been helpful to state that the strips should be provided by secondary care, as they are responsible for the patients care for diabetes and not primary care. This would also make sure that “enough” are issued, prevent patients from having to chase around to order from a GP and go to a chemist and make sure that there is no dispute between primary and secondary care about which strips are issued (this can be very confusing for patients).
49	RCOG	2	Suggest removing subjectivity by replacing ‘feel’ with ‘are’ as in ‘the number in the denominator who are supported’. This attribute is also easy to measure.
50	Diabetes UK	2	This could benefit from being expanded to include the need to make sure women know how to interpret results from self-monitoring of blood glucose levels, how to make changes to their lifestyle and/or therapy, and who to contact to support them to make such changes.
51	British Maternal and Fetal Medicine Society	2	The committee supports this statement.
52	Royal Pharmaceutical Society	2	Pharmacists are in a position to offer support to manage blood glucose monitoring including how to use blood glucose meters and test strips. They can also advise on the use of insulin pens and pumps if required for treatment. They can raise awareness and educate patients on the importance of maintaining

			optimal blood glucose control to prevent congenital abnormalities and reduce the risk of pregnancy complications.
53	RCOG	3	The NICE guideline suggests that women should be offered 'immediate contact with a joint diabetes and antenatal clinic to women with diabetes who are pregnant.' In the quality standards this has been altered to being seen at a joint diabetic and obstetric clinic within a week of their pregnancy being confirmed. While women with diabetes need to be seen by a diabetologist and an early pregnancy scan done to confirm viability, they do not need any specific obstetric input at this stage. By setting this quality standard we are suggesting that women with a positive pregnancy test need to attend a specialist diabetic obstetric clinic when clearly this isn't the case.
54	E&N Herts NHS Trust	3	It is almost impossible to ensure that every patient with Type1/2 diabetes or GDM is seen by diabetologist, obstetrician, specialist midwife and dietitian within a week. We only have one of each on site, and have to take leave, on-calls etc into consideration. 2 weeks would be more realistic, or stating that the patient needs to be seen by at least ONE of midwife/diabetologist/obstetrician within a week
55	ABMU trust	3	Replace antenatal care with the word obstetric
56	The Royal College of Midwives	3	We welcome the useful description of the multidisciplinary team and the inclusion of a midwife here.
57	Lactation Consultants of Great Britain	3	Should be 'able to be seen' or 'offered appointment to take place within one week' - as sometimes mothers cannot or do not want to attend a clinic within a week. In this case an earlier appointment with the diabetes specialist midwife or similar should be arranged to start the process.
58	Lactation Consultants of Great Britain	3	The importance of educating women about the risks of not breastfeeding and the associated health outcomes in relation to diabetes for both mothers and infants should be made clearer in this standard. This should be covered at an antenatal contact. Of course, there is this information which you have, no doubt, already come across; http://www.unicef.org.uk/BabyFriendly/News-and-Research/Research/Diabetes/.
59	Lactation Consultants of Great Britain	3	Of note, there are several large studies taking place currently examining whether antenatal expression of colostrum for diabetic mothers to be would increase the

			duration, exclusivity and early initiation of breastfeeding, thereby reducing adverse outcomes associated with early introduction of formula, and prevent excessive weight loss and low blood sugar in newborns. There is currently an RCT examining this underway, and the study is due to be completed at the end of this year (Diabetes and Antenatal Milk Expressing {DAME}: A randomised controlled trial. Forster D, Jacobs S, Amir L, Davis P, Walker S, Opie G, McEgan K, Moorhead A, McNamara C, Aylward A, Donath S, Ford R, Gold L, East C)
60	British Medical Association	3	This Quality Statement will be a major challenge for secondary care, even allowing for small numbers. The rule is very tight, and there is not a robust mechanism in place that would help achieve it. Additionally, bearing in mind that most women first do a home test, further clarification is needed as to what is considered the date a pregnancy is confirmed, e.g. is it the date that the sample is taken, the date of the result, or the date that the result is communicated? We believe that best results would be achieved if the patient can directly access the hospital clinic, as soon as she believes she is pregnant. However, unless there is a change in policy, this would work well for patients with type 1 diabetes, who are usually already in that system, but not for all patients with type 2 diabetes who might not be.
61	Royal College of Nursing	1	The quality statement 1 expands on the need to prescribe folic acid in the pre-conceptual period therefore, there needs to be an improvement in blood glucose control during this period as well.
62	Royal College of Nursing	3	This statement refers to the first contact with joint diabetes and antenatal clinic with the aim of improving diabetes control ‘during early pregnancy’.
63	Diabetes UK	3	Prior to 8 weeks women will need to have extremely good glucose control, so the key point of contact for most women should be a diabetes specialist team. After 8 weeks the main contact can be the obstetric team unless there is a specific need for obstetrics prior to 8 weeks.
64	British Maternal and Fetal Medicine Society	3	The committee supports this statement. However, we note that the statement does not specify which week of gestation this will be, and it may be helpful to incorporate this information. Also the way the service is provided in different hospitals may vary (e.g. joint or separate consultations with different team members), so it may make it easier to evaluate service provision if the words ‘or equivalent’ are added to the statement, “Proportion of women with [pre-existing] diabetes who are seen at the joint diabetes

			and antenatal clinic, or equivalent, within 1 week…", and to the equivalent statements throughout the text accompanying this statement.
65	Obesity Group of the British Dietetic Association (formerly domUK)	3	We are pleased to see that the role of dietitians within the joint diabetes and antenatal care clinic is explicitly acknowledged.
66	RCOG	4	Outcome measure that has been chosen is mode of birth. Mode of birth will be affected by the HbA1c level at booking and during pregnancy, not whether it is done or not.
67	ABMU trust	4	An HbA1c done at booking reflects good or bad glycaemic control before conception. It is by then academic and probably too late in terms of improving glycaemic control to reduce the risk of miscarriage and fetal anomalies. It does though give the clinician an idea of the battle ahead and an idea about preconception glycaemic control. It would be more useful to check that the HbA1c is satisfactory before conception as a quality standard.
68	British Medical Association	4	Booking visits are Midwife led, so their protocols will need amendment to allow HbA1c and retinopathy referral at that time.
69	British Maternal and Fetal Medicine Society	4	The committee is concerned that this recommendation will not improve care. Although it will reflect how well controlled a woman will have been before pregnancy (and will give an indication of her risk of having a pregnancy complicated by congenital malformation), measurement of HbA1C at booking is unlikely to result in improved pregnancy outcome. In contrast, HbA1C at pre-pregnancy assessment would enable action to be taken to improve glycaemic control, and this is likely to improve pregnancy outcome by reducing the risk of congenital malformation. We recommend that this statement is altered to reflect this. Furthermore, it will not be necessary to measure HbA1C if this was performed by the primary care doctors in the preceding 4 weeks.
70	InDependent Diabetes Trust	5	Comment about Quality statement 5: Retinal assessment at booking appointment. The Rationale states: 'Pregnant women should therefore be screened more often for diabetic retinopathy.' It then points out that assessment should be offered at the booking appointment, however from a patient perspective, I would wish to know what

			is meant by 'screened more often'. Is this every 2 weeks, once a month or what is the timescale? The timescale may be dictated by the initial assessment and if so this should be stated. We believe this should be clarified and the title of Quality Statement 5 changed to 'Retinal assessment at booking appointment and during pregnancy'. If this is followed through then the Structure needs to be changed to read: Evidence of local arrangement and written clinical protocols to ensure that pregnant women with pre-existing diabetes are referred for retinal assessment at their booking appointment and as necessary / more often during the pregnancy.
71	British Medical Association	5	Booking visits are Midwife led, so their protocols will need amendment to allow HbA1c and retinopathy referral at that time.
72	British Maternal and Fetal Medicine Society	5	The committee supports this statement. We also recommend that this should be viewed as a shared responsibility between secondary and primary care in the first trimester. A retinal screen will not be necessary if the screen was performed in the preceding 2-3 months.
73	RCOG	6	Need to delete the word 'that' Proportion of women diagnosed with gestational diabetes who <u>that</u> are reviewed at the joint diabetes and antenatal clinic within 1 week of diagnosis.
74	RCOG	6	Services for gestational diabetes are provided in different ways depending on local resources. In many units this means that women with gestational diabetes are managed at a midwife led GDM clinic with input from a diabetic nurse specialist and a dietician and referred to a Consultant clinic if there are complications eg baby >95th centile, patient commenced on metformin. For women who are well controlled on diet alone there is no evidence that outcomes are improved by attending a specialist diabetic consultant. Kim Hinshaw has developed an interesting digital technology aided service 'Florence' in Sunderland which seems to work very well.
75	RCOG	6	On the face of it, this is reasonable, but it is common practice for those with borderline results to see the diabetic nurse first to arrange home monitoring to ensure that, when they are seen at the clinic, they can comply with standard 1.2.13. They would then be

			seen the week after, and that becomes a more useful visit. Suggest adding 'if undertaking home monitoring prior to the clinic visit, then to be seen within 2 weeks.
76	E&N Herts NHS Trust	6	It is almost impossible to ensure that every patient with Type1/2 diabetes or GDM is seen by diabetologist, obstetrician, specialist midwife and dietitian within a week. We only have one of each on site, and have to take leave, on-calls etc into consideration. 2 weeks would be more realistic, or stating that the patient needs to be seen by at least ONE of midwife/diabetologist/obstetrician within a week
77	ABMU trust	6	Replace antenatal care with the word obstetric
78	Lactation Consultants of Great Britain	6	Should be 'able to be seen' or 'offered appointment to take place within one week' as above statement 3. The actual guidance NG3 DOES say 'are offered' not 'are seen'.
79	British Maternal and Fetal Medicine Society	6	The committee supports this statement.
80	UCLH	6	At UCLH services for pregnant women are provided by a weekly joint diabetes and antenatal clinic. This is a clinic of 50-80 women who may be seeing the obstetric team, diabetes team, dietetics or midwives. Both of these quality standards (3&6) propose that all women with pre-existing diabetes are seen in the joint clinic within a week of positive pregnancy test and women diagnosed with gestational diabetes are seen within a week. At UCLH these women are initially seen within a week by a member of the Diabetes/Antenatal Clinic team initially to look at glycaemic control or teach blood glucose monitoring and for dietetic review and then be reviewed in the joint clinic which would be within 2 weeks. For existing patients of UCLH with type 1 and type 2 diabetes it is generally possible for them to be seen by a member of the joint diabetes/antenatal team within a week once we have been contacted. However there may be a delay from when the woman has a positive pregnancy test and sees her GP to when we are contacted and we have a no control over this.
81	North East Essex Diabetes Service	6	Women with GDM seen within 1 week diagnosis in Joint diabetes /ANC In some cases women are seen within the week of result being notified but not in clinic setting but by member of the specialist team to start testing with dietary discussion , then following week in Clinic.

			Discussion will take place at this initial time and then reinforced at clinic attendance. Some areas will have separate dietitian/midwife clinic for newly diagnosed, again does this constitute the MDT?
82	Obesity Group of the British Dietetic Association (formerly domUK)	6	We are pleased to see that the role of dietitians within the joint diabetes and antenatal care clinic is explicitly acknowledged.
83	Obesity Group of the British Dietetic Association (formerly domUK)	6	We are concerned with the possible adverse impact of busy joint clinics on patient experience.
84	Obesity Group of the British Dietetic Association (formerly domUK)	6	We acknowledge the critical importance of engaging with women with gestational diabetes early in their pregnancies because of their own increased risk of type 2 diabetes post pregnancy, and the risks to their babies of diabetes and obesity in later life. We strongly advocate lifestyle education to include increased promotion of breastfeeding for women with Type 2 and gestational diabetes as an intervention to reduce risk of their offspring being overweight or obese and/or developing type-II diabetes in later life.
85	RCOG	7	Interesting, but extremely difficult to assess in practice. Might be easier to assess whether appropriate information about 6 week post natal glucose check and longer term annual HbA1C has been passed to the GP.
86	Royal College of Physicians of Edinburgh	7	The College welcomes this statement as it is vital that there is follow up of women with gestational diabetes post-partum to assess whether glycaemic control has returned to normal and use of ongoing programmes to prevent future diabetes. However, in terms of detection this quality statement refers only to women who have previously had gestational diabetes. Screening and detection of gestational diabetes is a controversial but very important area – the College would suggest that the Quality Standard includes a measure of whether a screening process is in place and measures of the quality of that process.
87	British Medical Association	7	We believe this standard is going to be difficult to implement. It would require a code to be entered in the patient's record (assuming a consistent diagnostic criterion) so

			that primary care is aware. However, there will be no existing reminders (similar to QOF) on the computer systems to remind or prompt GPs that this is due or overdue. Since it is unlikely that every GP surgery would develop its own search and reminder protocols, GPs would need to rely on the system providers help improve this aspect of patients safety. System providers will however be competing with a whole host of other development needs for the computer systems.
88	British Maternal and Fetal Medicine Society	7	The committee supports this statement.

Registered stakeholders who submitted comments at consultation

- ABMU trust
- British Maternal and Fetal Medicine Society
- British Medical Association
- Department of Health
- Diabetes UK
- E&N Herts NHS Trust
- Ferring Pharmaceuticals
- HQT Diagnostics
- InDependent Diabetes Trust
- Lactation Consultants of Great Britain
- Medtronic Limited
- NHS England
- North East Essex Diabetes Service

- RCOG
- Royal College of Nursing
- Royal College of Paediatrics and Child Health
- Royal College of Physicians of Edinburgh
- Royal Pharmaceutical Society
- Slimming World
- The Royal College of General Practitioners
- The Royal College of Midwives
- UCLH
- UHBFT
- UKCPA