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CARE EXCELLENCE

Quality standards

Consultation summary report: Diabetes in pregnancy

Quality Standards Advisory Committee post-consultation meeting: 11 October 2022

1. Introduction

The draft quality standard for diabetes in pregnancy was made available on the NICE website for a 4-week public consultation period between 5 July and 9 August 2022. 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 11 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 appendix 1.

1. General comments

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

* General support for the quality standard and agreement that it broadly reflects the key areas for improvement.
* Stakeholder commented that terminology such as ‘good glucose control’ can be judgemental, suggesting the person is at fault. They suggested replacing this with in-target or above target glucose levels, also noting that ‘glucose levels’ is now a preferred term to ‘glucose control’.
* Stakeholder feels that statement 2, on women being seen within 1 week, is not a key area for quality improvement. Suggested that aiming for HbA1c<43mmol/mol after 24 weeks gestation should be included instead as this can be monitored through the National Pregnancy in Diabetes audit.

### Consultation comments on data collection

* Stakeholder noted that coding and standardised ways of working across services to collect the data would be challenging.
* Stakeholder felt the use of new technology and remote monitoring would be beneficial to aid collection of data in local systems.
* Stakeholder noted that systems are in place but that clinicians will need educational support to code correctly.
* Stakeholder commented that pregnancy is not always coded on the GP system.

### Consultation comments on resource impact

* Stakeholder commented that well-trained and supported staff are essential to deliver the quality care set out by this standard. They noted a recent report by the Health and Social Care Select Committee stated that an additional 2,000 midwives and 500 obstetricians are needed.
* Stakeholder commented that much of what is needed is already in place and is achievable but would require targeted education, especially around coding and recall systems.
* Stakeholder noted that in secondary and community care records might be written on paper or not ‘coded’ so it is hard to search the data.
* Stakeholder commented that the opportunity for cost saving would be to do this at scale across a Primary Care Network especially if they are all using the same computer system. This could lead to further cost saving, through improved health outcomes and reduced health inequalities, if this was implemented at scale.

1. Summary of consultation feedback by draft statement
   1. Draft statement 1

Women with diabetes who are of childbearing potential are offered pre-conception planning advice at diabetes care reviews. **[new 2022]**

### Consultation comments

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

General comments

* This statement is not achievable by local services. The National Pregnancy in Diabetes Audit data shows no change in pregnancy preparation over the past 7 years and ethnic and socio-economic healthcare inequalities in access to and uptake of pre-pregnancy care provision.

Statement

* Suggestion to reword statement to focus on advice about effective contraception until safe pregnancy glucose targets (HbA1c <48mmol/mol) are reached.

Measures

* Local systems and structures are in place to collect data.
* Process measure: the numerator should be contraception if not planning pregnancy or HbA1c<48mmol/mol or 5mg folic acid which is clearer and easier to measure than ‘advice about pre-conception planning’.
* Stakeholder identified two codes that GPs can use as part of the measures for this statement: folic acid advice pre-pregnancy and diabetic pre-pregnancy education. They noted that primary care clinicians may also use free text. They confirmed that, if the woman is seen in secondary care, particularly women with type 1 diabetes, this information cannot be coded.
* Within primary care, pre-conception counselling could be added into the diabetes review template, if there is time for this intervention and clinicians have undertaken appropriate training.

Equality and diversity considerations

* It was highlighted that women from some groups are less likely to access contraception to prevent unplanned pregnancy.
* Stakeholders felt that services should be organised and delivered in a way that facilitates attendance of women from ethnic minority groups at regular diabetes care reviews, including the offer of a professional interpreter if needed.

### Consultation question 4

For measurement purposes, an age range of 15 to 50 years has been suggested to identify women and girls of childbearing potential. Is this age range reasonable and, if you do not feel it is, please suggest the age range that should be used?

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

* Most stakeholders felt this age range was reasonable, with one suggesting increasing the upper age to 54.
* Stakeholders highlighted that pre-pregnancy counselling for young women should be age-appropriate. They also noted that some women may have made it clear to their healthcare professional that they do not intend to become pregnant.

### Issues for consideration

#### For discussion:

* Is the committee happy with the age range of 15-50 years based on stakeholder feedback?
* One stakeholder suggested the statement should be replaced with a statement on the provision of advice about contraception until HbA1c levels are below 48mmols/mol. Note that this was discussed at the prioritisation Quality Standards Advisory Committee where it was agreed that a statement on pre-pregnancy planning would be taken forward. One of the outcome measures for this statement is: Percentage of pregnancies in women with diabetes with early HbA1c less than 48 mmol/mol.
  1. Draft statement 2

Women with pre-existing diabetes are seen by members of the joint diabetes and antenatal care team within 1 week of informing their healthcare professional they are pregnant. **[2015, updated 2022]**

### Consultation comments

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

Statement

* There was a lack of agreement amongst stakeholders over whether this is useful statement.
* Suggestion to replace the quality statement with:
  + aim for HbA1c<43mmol/mol after 24 weeks gestation.
  + all women with pre-existing diabetes are seen as early as possible during pregnancy, with a target of before 8 weeks gestation.
  + offer an appointment within 1 week to allow triaging of those who require an urgent appointment.
* Suggestion to reword the statement to, for example, ‘have had contact with’ as a booking a face-to-face appointment within 1 week may not be possible.
* Pregnant women are not always seen by primary care as they can book in directly with the midwife. It is therefore important to consider who would refer them.

Measures

* The 1 week interval may not be practical to measure as this is not routinely coded.
* This statement may be hard to measure because these data are not routinely collected.
* Perinatal mortality is not an appropriate outcome measure for this statement, suggestion to use all adverse outcomes instead.

Resource impact

* No additional resource is needed for this statement.

### Issues for consideration

#### For discussion:

* One stakeholder suggested this be replaced with a statement on HbA1c levels at 24 weeks gestation however the suggestion made is not in line with the NICE guideline recommendations.
  + The stakeholder also suggested an alternative statement of all women with pre-existing diabetes being seen as early as possible during pregnancy, with a target of before 8 weeks gestation. The guideline recommendation (table 1) states the joint diabetes and antenatal care booking appointment should be ‘ideally by 10 weeks’.
* Some comments from stakeholders that it is unclear what is meant by ‘seen’. A definition can be added.
  1. Draft statement 3

Women with diabetes are supported to self-monitor their blood glucose levels during pregnancy. **[2015, updated 2022]**

### Consultation comments

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

Statement

* If women with type 1 and type 2 use continuous glucose monitoring systems it is interstitial rather than blood glucose levels that are monitored. The statement should therefore state ‘glucose levels’.
* If lack of equipment is not a key challenge for women who do not require CGM the statement should focus on CGM.
* A stakeholder noted that there may be variation in CGM uptake when NHSE ring-fenced funding runs out in March 2023. Suggestion to amend the statement to:
  + Continuous glucose monitoring should be offered to all pregnant women with type 1 diabetes and to pregnant women with type 2 diabetes who are on insulin therapy and have problematic severe hypoglycaemia or have unstable blood glucose levels causing concern.

Measures

* Local systems and structures are in place to collect the data for these measures.
* Process measures c) and d): not relevant to the statement. The denominator for these measures is hard to determine and is difficult to use for comparison.
* Outcome measure b): suggestion to change to glycaemic complications (diabetic ketoacidosis or severe hypoglycaemia) as complications can worsen with sudden improved control as a result of supporting women with glucose self-monitoring.
* It is not possible to measure how regularly a person monitors their blood sugar levels.
* The data collection should be from the IT systems in secondary care.

Equality and diversity considerations

* The quality standard acknowledges that pregnant women with type 1 diabetes, or those with type 2 and are on insulin therapy and living in deprived areas or are of Black or Asian ethnicity are less likely to use rtCGM. It would be useful to set a benchmark of technology utilisation in these sub-populations.

Resource impact

* Additional investment is required to implement this quality statement.

### Issues for consideration

#### For discussion:

* As the main focus is on CGM, suggestion to use ‘glucose levels’ rather than ‘blood glucose levels’. Does the committee think this amendment should be made?
* Measurement: some other quality standards include the following wording for quality statements where there may be access issues: Services may want to use these measures to focus on dimensions of health inequality, for example by reporting data grouped by ethnicity or indices of deprivation. Would this be helpful for this quality statement?
* Suggestion to focus the statement on CGM if access to testing strips for women not using CGM is not a significant issue. Is this the case? Note that if the statement focusses solely on CGM, only women with type 1 diabetes would be included in the statement as per the guideline recommendations. The suggestion to include pregnant women with type 2 diabetes who are on insulin therapy and have problematic severe hypoglycaemia or have unstable blood glucose levels causing concern comes from a consider recommendation.
  1. Draft statement 4

Women diagnosed with gestational diabetes are offered postnatal and annual testing of blood glucose levels and referred to the NHS Diabetes Prevention Programme if eligible. **[new 2022]**

### Consultation comments

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

Statement

* Stakeholder was unclear whether women with gestational diabetes that is diagnosed following birth are included in the quality statement.
* The likelihood of developing type 2 diabetes is as high as 50% in the 5 years after a gestational diabetes pregnancy and recall of women diagnosed with gestational diabetes must be improved to address this.
* There is variability in primary care recall systems. This could link with health inequalities as the most stressed practices may be working in the most deprived areas where a more robust recall system is needed for women who are at-risk.
* Statement suggests annual blood glucose monitoring for women who had gestational diabetes. Stakeholder felt this does not match the guideline recommendation which states an annual HbA1c test should be offered.

Measures

* Systems for monitoring this statement are currently inadequate. This is a key area for improvement and better systems are urgently required as well as improved communication between maternity, diabetes and primary care providers.
* Data for uptake of NDPP in the women referred by primary care could be obtained from the report submitted to NHS England.
* National Diabetes Prevention Programme (NDPP) referral criteria is gestational diabetes and post-partum normoglycaemia (a normal concentration of sugar in the blood). Stakeholder felt the measures incorrectly suggest abnormality in blood sugar stability should also be present for eligibility for referral.
* Process measures c) and d) should take into account the NDPP eligibility criteria. The wording of the measures does not exclude diabetic range raised glucose levels or HbA1c levels.
* Outcome measure a) has no population comparator or good practice in non-pregnant population to measure against.
* Outcome measure b) data can only be collected at system levels rather than individual provider levels. It does not reflect the success of implementing the statement as there is no timeframe. Eventually diabetes will be diagnosed so implementation of the statement will not increase pick up rates but will enable earlier identification.

Resource impact

* No additional resource is required but better communication and pathways between maternity and primary care providers are needed.

### Issues for consideration

#### For discussion:

* Some confusion around the testing this statement relates to. The measures specify:
  + Women diagnosed with gestational diabetes who had a fasting plasma glucose test at 6 to 13 weeks after the birth
  + Women with previous gestational diabetes who have an annual HbA1c test
  + Women with gestational diabetes and raised blood glucose levels 6 – 13 weeks after birth who are referred into the NHS Diabetes Prevention Programme
  + Women with previous gestational diabetes and raised blood glucose levels at an annual HbA1c test who are referred into the NHS Diabetes Prevention Programme.
* Based on stakeholder feedback, measure d) is incorrect and should be amended if the committee agree.

1. Suggestions for additional statements

A stakeholder suggested an additional statement area:

CGM research

* There is an urgent unmet need for more research regarding the use of CGM in pregnant women with type 2 diabetes, and to better understand what support they and their healthcare teams might need to make the best use of CGM data.

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# Appendix 1: Quality standard consultation comments table – registered stakeholders

| ID | Stakeholder | Section | Comments |
| --- | --- | --- | --- |
| **General** | | | |
| SH | National Pregnancy in Diabetes (NPID) audit advisory group | General | Judgement terminology eg ‘good blood glucose control’ can be perceived as blaming women. ‘Good’ or bad and should be replaced by in-target or above target glucose levels. Glucose levels is now preferred to glucose control. (Women with type 1 diabetes have no endogenous insulin so suggesting that they can ‘control’ glucose levels is perceived as unfair – likewise for women with type 2 diabetes for whom complex genetic, environmental and social determinants are relevant (See Diabetes UK for up to date language matters guidance) |
| SH | NHS England and Improvement |  | It is an obvious thing to say but you are assuming that ‘pregnancy’ is coded on the GP system and I don’t think it is coded as often as you think – perhaps another learning need. Again, using a standardised template would really help with data quality and make this much easier to search. |
| **Question 1 - Does this draft quality standard accurately reflect the key areas for quality improvement?** | | | |
| SH | Diabetes UK | Question 1 | Diabetes UK welcomes the updated quality standards in this draft and feels they broadly reflect the key areas of improvement for diabetes in pregnancy. |
| SH | Healthcare Safety Investigation Branch (HSIB) | Question 1 | HSIB responded to the following during topic engagement for this QS: HSIB has investigated cases were the planned timing of IOL has not been aligned to current guidance, and this has been considered to have contributed to the outcome. |
| SH | National Pregnancy in Diabetes (NPID) audit advisory group | Question 1 | Quality standard 1 (emphasising the importance of a contraception plan to prevent pregnancy until glucose targets are reached), standard 2 (emphasising the importance of offering continuous glucose monitoring to all pregnant women with type 1 diabetes and those with type 2 diabetes who are on insulin therapy and have problematic severe hypoglycaemia or have unstable blood glucose levels causing concern insulin) and standard 4 (emphasising the importance of postnatal glucose check, annual HbA1c and referral to the NHS Diabetes Prevention Programme (NDPP) accurately reflect the key areas for quality improvement. They would all benefit from some further clarification and re-phrasing as outlined below but we agree that these three quality standards (QS1, QS2, QS4) are key areas for improvement.  We do not agree that quality standard 2 (women being seen within 1 week) is a key area for improvement. Data from the NPID show that maternal glucose is the key modifiable risk factor for obstetric complications (preterm births <37 weeks, large for gestational age (LGA), neonatal care admission) and serious adverse pregnancy outcome (congenital anomaly, stillbirth, neonatal death). In type 2 diabetes rates of LGA (15.1 vs 38.7%) preterm births (16 vs 28.4%), neonatal care unit admissions (26.3 vs 42.2%) are all lower in women with HbA1c<43mmol/mol (6.1%) after 24 weeks gestation. The same HbA1c threshold after 24 weeks gestation is applicable to type 1 diabetes. We therefore suggest that quality standard 2 be updated to emphasise the importance of maternal glucose during pregnancy. A revised QS 2 would recommend that all women with pre-existing type 1 and type 2 diabetes are advised to aim for HbA1c<43mmol/mol (6.1%) after 24 weeks gestation. This can readily be monitored via NPID and will be far more likely to improve obstetric and neonatal outcomes than seeing women one week earlier. These data are available from the 2019-2020 NPID report, or at <https://pubmed.ncbi.nlm.nih.gov/35105295/> and are shown below. |
| SH | NHS England and Improvement | Question 1 | Yes. |
| SH | Royal College of General Practitioners | Question 1 | These appear sensible. It would be important to recognise how these standards will be measured. |
| **Question 2 - Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be for these to be put in place?** | | | |
| SH | Association Of British HealthTech Industries | Question 2 | We encourage the use of new technology and remote monitoring to aid collection of data in local systems. |
| SH | NHS England and Improvement | General | Great quality standard and I would have thought there would be a lot of clinical buy in to this, but the challenge is more around ‘coding’ and standardised ways of working (esp. using templates) across settings (primary / community / secondary care) to capture the information and using this to inform improved practice.  A lot of pregnancy related care is also done with community midwives and secondary care thus by-passing primary care. |
| SH | NHS England and Improvement | Question 2 | Systems are in place but need to educate clinicians to ‘code’ (often this info is free texted so can’t be searched) but if patient is in 2ary care (e.g. Type 1 DM) then they don’t code (often paper notes). They may write something in a clinic letter to primary care but that will most likely not be coded into primary care system so hard for local systems to then search for the data. It is feasible to be put in place but will need an educational support offer. |
| **Question 3 - Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any statement. Please describe any potential cost savings or opportunities for disinvestment.** | | | |
| SH | Diabetes UK | Question 3 | Well-trained and supported staff are essential to deliver the quality care set out by this standard and it is concerning that a recent report by the Health and Social Care Select Committee highlighted that, whilst England remains one of the safest countries to have a baby, the maternity workforce is facing increasingly unsustainable pressures.  The committee estimate an additional 2,000 midwives and 500 obstetricians are required to deliver a level of care Birthrate Plus consider the minimum standard for pregnancy and recommend that there must be a detailed and accountable plan from Government for how this shortfall can be addressed to ensure a higher standard of care. This is especially important for diabetes in pregnancy which is a complex area and requires healthcare professionals to have the opportunity to maintain continuous professional development and keep abreast of rapidly shifting advances in diabetes care and technology.  Reference: https://publications.parliament.uk/pa/cm5803/cmselect/cmhealth/115/report.html?mc\_cid=3b9fda5eea&mc\_eid=7c391b1b2c#heading-8 |
| SH | NHS England and Improvement | Question 3 | Much of what is needed is already in place and it is achievable but would require targeted education, especially around coding and recall systems. I think these should already be in place in a generic manner and so this ‘gestational’ element could be added.  The other issue is around variability of practice in general practice, but this could be improved through searches and a dashboard.  Another issue is in secondary and community care where records might be written on paper or not ‘coded’ so hard to search and see what is happening in these care settings.  There is a lot of information that can come back to primary care in a diabetes clinic letter and much, if not all, of this is not coded as too time consuming. I think this leads to duplication and potentially poor-quality patient care. As secondary care use more software then coding might be easier, also would be good if their clinic letters could have the key information clear to see and even better if it could be automatically ‘coded’ into GP system - there must be a way.  I think the opportunity for cost saving would be to do this at scale across a PCN especially if they are all on the same computer system rather then having each practice admin team do this.  Also cost saving (through improved health outcomes and reduced health inequalities) if this could be implemented at scale with a focus on improving the mean and reducing the spread. |
| SH | Royal College of General Practitioners | Question 3 | The systems should be able to undertake this with adequate resourcing as resources for pre-conception and annual review are relatively low in the population. We presume that the NICE guidance has already assessed the value of these interventions. |
| **Statement 1** | | | |
| SH | Association Of British HealthTech Industries | Statement 1 | Quality Statement 1, Pre-conception planning – ‘ensure HbA1c levels are below 48mmol/mol before pregnancy’,  • We believe that additional technologies which can aid achieving this level should be made readily available, namely inclusion of insulin pump therapy as recommended in existing NICE NG3 guidelines.  • There is also reference research which continues to highlight unmet need and the burden of Gestational diabetes mellitus (GDM). |
| SH | Cambridge University Hospitals NHS Trust | Statement 1 | Equality and diversity considerations – suggest include following: If English is a 2nd language, women should be offered the services of a professional interpreter service, provided by the care-giver. |
| SH | Diabetes UK | Statement 1 | The 2019-2020 National Pregnancy in Diabetes (NPID) audit data shows women with type 2 diabetes now make up 54% of diabetes pregnancies. This represents a doubling in the proportion of diabetes pregnancies in women with type 2 diabetes over the last two decades when compared to 27% in the 2002-2003 ‘Confidential Enquiries into Maternal Deaths in the United Kingdom’ (CEMACH) report. NPID also shows that there are seven times more type 2 diabetes pregnancies among women living in the poorest communities.  There is a lack of awareness both among women and healthcare professionals that developing type 2 diabetes between the ages of 18-39 years old is associated with a more severe form of the condition. Current approaches to offering ‘pre-conception counselling to women of childbearing ages’ need to be improved with  the NPID reporting seven out of eight women were not well prepared for pregnancy. This proportion has remained unchanged over the past seven years and also shows a clear social gradient with people from the most deprived areas less likely to reach optimal preparation compared to those in the least deprived.  We would strongly suggest adding more detail to this statement concerning contraception and the need for healthcare professionals to ensure that all women aged 15-50 years with diabetes are given information about safe and effective contraception until they are ready for pregnancy. It’s important that healthcare professionals are more actively engaged with the importance of contraception planning to prevent pregnancy until safe blood glucose targets are reached. Many poor outcomes are potentially preventable by supporting women to achieve tighter blood glucose targets and identifying those with higher HbA1c for more intensive support and review prior to conception.  References: NHS Digital. (n.d.). National Pregnancy in Diabetes Audit Report 2020. [online] Available at: <https://digital.nhs.uk/data-and-information/publications/statistical/national-pregnancy-in-diabetes-audit/2019-and-2020>.  www.publichealth.hscni.net. (n.d.). Saving Mothers’ Lives 2003-2005 | HSC Public Health Agency. [online] Available at: <https://www.publichealth.hscni.net/publications/saving-mothers-lives-2003-2005>. |
| SH | National Pregnancy in Diabetes (NPID) audit advisory group | Question 2 | Local systems and structures in place to collect data for quality standards 1 and 3. |
| SH | National Pregnancy in Diabetes (NPID) audit advisory group | Question 3 | Quality standard 1 (emphasising the importance of a contraception plan to prevent pregnancy until glucose targets are reached), is not achievable by local services. The NPID data shows no change in pregnancy preparation over the past 7 years and striking ethnic and socio-economic healthcare inequalities in access to and uptake of pre-pregnancy care (PPC) provision. The vast majority of women with early-onset type 2 diabetes are seen in primary care. Glycaemic management is largely inadequate with 25% untreated, 50% taking metformin alone, and 15% taking insulin (10% metformin & insulin, 5% insulin alone) before pregnancy. Dedicated regional PPC co-ordinators, with a focus on women from ethnic minorities and those living in areas of deprivation are required to systematically address this inequity. |
| SH | National Pregnancy in Diabetes (NPID) audit advisory group | General – split general comment and added to the relevant statements | Some of the terminology used (e.g. ‘childbearing potential’ and ‘pre‑conception planning’) is unhelpful and potentially contributes to healthcare professionals’ (HCP) bias/unconscious bias and lack of engagement especially among women from more diverse and socioeconomically deprived backgrounds. Terminology such as women ‘who are of childbearing potential’ may inadvertently disadvantage to younger and older aged women. Qualitative research suggests that ‘childbearing potential’ is often misinterpreted as meaning women in their twenties and thirties and those in stable relationships. We strongly suggest replacing ‘childbearing potential’ with women aged 15-50 years so that HCPs are clear that this advice is widely applicable, and no woman missed out on these important diabetes care processes. This will also facilitate searching for eligible women using electronic medical records in primary or in specialist care.  Likewise, ‘pre‑conception planning’ is not a term accessible to or used by women in their normal lives. More accessible terminology would be ‘Women with diabetes aged 15-50 years are offered an effective contraception method to prevent pregnancy until safe glucose targets are reached’. |
| SH | National Pregnancy in Diabetes (NPID) audit advisory group | Statement 1 | We agree with the intention but strongly suggest rewording QS1 replacing “Women with diabetes who are of childbearing potential are offered pre‑conception planning advice at diabetes care reviews” with ‘Women with diabetes aged 15-50 years are offered an effective contraception method to prevent unplanned pregnancy. Contraception should be continued until safe pregnancy glucose targets (HbA1c <48mmol/mol) are reached’ This provides far clearer recommendations than QS1 in its current format.  There are now more births in women with early-onset type 2 diabetes (diagnosed <39 years) compared to those with type 1 diabetes (4,540 vs 3,745 livebirths during 2019-2020). Women with type 2 diabetes, women from Black and ethnic minority groups and those from deprived backgrounds are far less likely to access safe effective contraception to prevent unplanned pregnancy. Women and HCPs need far clearer advice to ensure that all women with diabetes aged 15-50 years are either offered safe effective contraception to prevent unplanned pregnancy or that they are taking high dose (5 mg per day) folic acid and aiming for HbA1c<48mmol/mol before pregnancy. The numerator should be hard outcomes (contraception if not planning pregnancy or HbA1c<48mmol/mol or 5mg folic acid) which is more concrete and easier to measure than ‘advice about pre‑conception planning’. HCPs and women are not aware of the severe metabolic consequences of early-onset type 2 diabetes and these women are missing out on key diabetes care processes. Clearer use of language may be more helpful for women and HCPs alike. |
| SH | NHS England and Improvement | Statement 1 | Agree with statement but is reliant on the clinician ‘coding’, there are 2 codes I found 1. ‘folic acid advice pre-pregnancy’ 2. ‘Diabetic pre-pregnancy education’. I am not sure that primary care clinicians reliably code this information but may free text it. If patient seen in secondary care (esp. type 1 DM), then no way of coding this information. |
| SH | NHS England and Improvement | Page 6 | P6 Equality and diversity considerations  *Healthcare professionals should actively encourage these women to attend regular diabetes care reviews, where the importance of pregnancy planning can be emphasised.*  This statement does not appear to reflect factors that require consideration from an equity perspective. It may be helpful to suggest that services should be organised and delivered in a way that facilitates attendance of these women at regular diabetes care reviews. |
| SH | Royal College of General Practitioners | Question 2 | Within a primary care context, pre-conception counselling could easily be added into the diabetes review template, assuming there is available time for this intervention – and clinicians have had the opportunity to undertake appropriate training. |
| **Question 4 – statement 1 - For measurement purposes, an age range of 15 to 50 years has been suggested to identify women and girls of childbearing potential. Is this age range reasonable and, if you do not feel it is, please suggest the age range that should be used?** | | | |
| SH | Association Of British HealthTech Industries | Question 4 | We believe the age range for Quality Statement 1 is reasonable. |
| SH | Diabetes UK | Question 4 | We think this age range is reasonable. |
| SH | Healthcare Safety Investigation Branch (HSIB) | Question 4 | HSIB considers this timeframe reasonable |
| SH | National Pregnancy in Diabetes (NPID) audit advisory group | Question 4 | The suggested age range of 15 to 50 years is very reasonable and, as outlined above, far preferrable to give precise guidance that can be used by HCPs and databases than women of ‘childbearing potential’ |
| SH | NHS England and Improvement | Question 4 | Agree medically with the age range, but pre-pregnancy counselling for children (usually with type 1 DM) might not be socially unacceptable. From my point of view, we need to think through how this could be done in a sensitive / sensible way and for some children, it would not be appropriate.  There might be some very rare cases of a child <15 and with diabetes getting pregnant as there will be with woman >50 getting pregnant. I don’t think you can have a ‘catch all’ measure on this so support 15 to 50 from my point of view. |
| SH | NHS England and Improvement | Page 6 | Definition of childbearing potential:  Technically the average age of menarche ~13 and menopause ~51  It is the highest threshold that is most significant as these women are at highest risk of GDM. My inclination would be to increase to the next 5-year band i.e. to 54 so these women are not excluded (many of us have cared for women >50 yrs. who have IVF abroad). |
| SH | Royal College of General Practitioners | Question 4 | The age range is we suspect (though have not checked data) more commonly broken with pregnancies in the under 15yr category compared to over 50 year category in people with diabetes. The important categorisation here is that the information is sensitive to the woman’s situation – for example annually discussing preconception advise in a 40 year who has no intention of becoming pregnant may annoy patients quite rightly. We are aware that this can be quickly covered and addressed in primary care. |
| **Statement 2** | | | |
| SH | Cambridge University Hospitals NHS Trust | Statement 2 | Outcome measure – suggest: All adverse outcomes rather than perinatal mortality alone |
| SH | National Pregnancy in Diabetes (NPID) audit advisory group | Statement 2 | The statement that ‘Women with pre-existing diabetes **are seen** by members of the joint diabetes and antenatal care team within 1 week of informing their healthcare professional they are pregnant’ is not realistic and not applicable to all women with pre-existing diabetes. The National Pregnancy in Diabetes (NPID) audit data show that gestational age at first antenatal contact ranges from 4 to 12 weeks (median 7/40) in type 1 and from 5 to 15 weeks (median 9/40) in type 2 diabetes (<https://pubmed.ncbi.nlm.nih.gov/33516295/>).  Clearly women at later gestations and those with higher HbA1c should be prioritised for earlier antenatal clinic review than those at 4-6 weeks gestation, or those who are already well prepared for pregnancy with HbA1c<48mmol/mol and taking 5mg folic acid. We suggest replacing QS2 with a statement regarding maternal HbA1c targets during pregnancy, specifically aiming for HbA1c<43mmol/mol (6.1%) after 24 weeks gestation. Alternatively re-wording QS2 that women with pre-existing diabetes **are offered an appointment** by members of the joint diabetes and antenatal care team within 1 week. This allows appropriate clinical triaging of those who do and do not require an urgent appointment.  This statement may be hard to measure because these data are not routinely collected (NPID collects gestational age at first contact which is more useful). A more helpful quality standard would be a recommending that all women pre-existing diabetes are seen as early as possible during pregnancy, with a target of before **8 weeks gestation.** We should explicitly be aiming to close the 2-week gap of being seen at 7 versus 9 weeks between women with type 1 and type 2 diabetes. This is earlier than the current NICE recommendation of 10 weeks gestation. Furthermore, perinatal mortality is an appropriate outcome measure for maternal HbA1c after 24 weeks. It is not an appropriate outcome measure for being seen within one week. |
| SH | National Pregnancy in Diabetes (NPID) audit advisory group | Question 3 | No additional resource is required for QS2. |
| SH | NHS England and Improvement | Statement 2 | In our area and from a primary care point of view, we don’t often see pregnant woman as they book straight in with the midwife, but this is done via our reception who direct them. So would need to think through who is best to refer them – the practice or the midwife (who could do that on receiving the referral – probably more reliable to engage with the midwives on this one rather then multiple practices with high turnover of reception staff).  Practically, not sure how you would measure the ‘1 week’ interval given that this sort of thing isn’t routinely coded as it might be with a cancer 2 week wait referral. Also, not sure how the midwives record their information (is it paper notes or electronic) making it harder to automatically search this care standard. If all community colleagues used the same system and recorded on a standardised template, then it might be easier to measure this time frame. |
| SH | National Pregnancy in Diabetes (NPID) audit advisory group | Question 2 | Systems are in place to measure gestational age at first antenatal contact for QS2 but not the number of weeks between referral and first antenatal contact (which we do not believe is a key area for improvement).. |
| SH | Royal College of General Practitioners | Question 2 | Statements 2 and 3 link very much to our specialist colleagues. It would be good to get communication to the primary care team if these proposed interventions occur – but the collection should be from the IT systems of our specialist colleagues. It would be sensible. |
| SH | Royal College of Physicians | Statement 2 | The RCP is grateful for the opportunity to respond to the above consultation. We have liaised with our Joint Committee for Obstetric Medicine and would like to comment as follows.  Our experts ask whether the term ‘seen’ could be clarified, and suggest it would be reasonable to say, ‘have had contact with’ or ‘had a consultation with’. Our experts have concerns that booking a face-to-face appointment within 1 week may not always be possible or acceptable to women and the choice of how that interaction is delivered would strengthen the statement. |
| **Statement 3** | | | |
| SH | Association Of British HealthTech Industries | Question 3 | NICE acknowledges that recent changes to guidelines on glucose monitoring for people with diabetes will have a financial resource impact. Additional investment is required to implement new guidelines and these proposed quality standards. |
| SH | Association Of British HealthTech Industries | Statement 3 – also included under question 1 for now | Quality Statement 3, Women with diabetes are supported to self-monitor their blood glucose levels during pregnancy  • Recent updates to NICE guidelines stress a greater utilisation of technology for monitoring glucose for people with type 1 and type 2 diabetes who intensively use insulin.  • The proposed quality standard acknowledges that pregnant women with type 1 diabetes, or those with type 2 and are on insulin therapy and living in deprived areas or are of Black/Asian ethnicity are less likely to use Real-Time Continuous Glucose Monitoring (rtCGM). It is therefore important for services to work closely with these groups to ensure they are aware of the benefits of rtCGM and that they can access it and any additional equipment such as blood glucose meter, insulin pump if they want to use it. It would be useful to set a benchmark of technology utilisation in this sub-population.  • It is widely accepted that glycaemic control during pregnancy is critical. The quality of testing technologies to monitor this is crucial and independent assessment of accuracy of blood glucose meters can help ensure this. |
| SH | Cambridge University Hospitals NHS Trust | Statement 3 | Process measures c) and d). Not indicative of the quality standard in itself which eludes to the ability to self monitor glucose. The denominator in both these instances is hard to determine and does not lend itself to comparison as subjective elements to the eligibility. |
| SH | Cambridge University Hospitals NHS Trust | Statement 3 | Outcome measure: Maternal diabetic complications. Suggest this refers to “glycaemic complications” ie DKA/severe hypo rather than “diabetes complications” as complications can worsen with sudden improved control (desired outcome) as a result of supporting women with glucose self monitoring as well as can be a consequence of pregnancy itself. |
| SH | National Pregnancy in Diabetes (NPID) audit advisory group | Statement 3 | Increasingly women with type 1 and those with type 2 are using continuous glucose monitoring (CGM) systems and are therefore monitoring interstitial rather than blood glucose levels. Thus QS3 should be updated to ‘Women with diabetes are supported to self-monitor their glucose levels during pregnancy’. Continuous glucose monitoring should be offered to all pregnant women with type 1 diabetes and to pregnant women with type 2 diabetes who are on insulin therapy and have problematic severe hypoglycaemia or have unstable blood glucose levels causing concern. Applying this statement to pregnancies complicated by gestational diabetes (GDM) may be hard to measure because these data are not routinely collected. The NPID audit will continue to collect data on CGM and Libre use in type 1 and type 2 diabetes pregnancies, but this is not feasible for pregnancies with GDM. |
| SH | National Pregnancy in Diabetes (NPID) audit advisory group | Question 2 | Local systems and structures in place to collect data for quality standards 1 and 3. |
| SH | National Pregnancy in Diabetes (NPID) audit advisory group | Question 3 | For QS3 there is growing concern regarding variation in CGM uptake across CCGs after the current NHSE ring-fenced funding runs out (March 2023). Clearer guidance specifically mentioning that ‘Continuous glucose monitoring should be offered to all pregnant women with type 1 diabetes and to pregnant women with type 2 diabetes who are on insulin therapy and have problematic severe hypoglycaemia or have unstable blood glucose levels causing concern’ would be preferred. |
| SH | NHS England and Improvement | Statement 3 | Regular monitoring of blood sugar levels is clearly important, but I can’t see how you would be able to check on this as it would be patient held and not coded. The health professional could ask about regularity of testing but hard to search that externally. Knowing that the patient has the means to test could be a good proxy measure as you have suggested and would be easy to search. |
| SH | NHS England and Improvement | QS3 | Page 10. *Proportion of pregnant women with gestational or pre-existing diabetes who have access to equipment to regularly test their blood glucose levels.* |
| SH | NHS England and Improvement | QS3 | QS3 on Self-monitoring. I wasn’t aware lack of equipment was a key challenge for women who don’t require CGM. But I might not be up to date on this nationally. If this is not a key concern, a focus on CGM would help avoid the message being diluted. If it is, obviously leave as is. |
| SH | Royal College of General Practitioners | Question 2 | Statements 2 and 3 link very much to our specialist colleagues. It would be good to get communication to the primary care team if these proposed interventions occur – but the collection should be from the IT systems of our specialist colleagues. It would be sensible. |
| **Statement 4** | | | |
| SH | Cambridge University Hospitals NHS Trust | Statement 4 | DPP referral criteria is GDM and post partum **normoglycaemia**. It is not essential for non-diabetic dysglycaemia to be present as well |
| SH | Cambridge University Hospitals NHS Trust | Statement 4 | Process measure c) and d) . Should take into account DPP eligibility criteria as in comment above. As it stands the wording of the measures c) and d) is ambiguous as does not exclude diabetic range raised glucose levels or HbA1c levels. For non-GDM patients it is non-diabetic range dysglycaemia that is eligibility criteria. |
| SH | Cambridge University Hospitals NHS Trust | Statement 4 | Outcome measure 1: GDM is not harbinger of Type 1 diabetes and there is no population comparator or good practice in non-pregnant population to measure against. “Identification of pre-existing type 1 diabetes in women who were diagnosed with gestational diabetes” compared to “?” |
| SH | Cambridge University Hospitals NHS Trust | Statement 4 | Outcome measure 2: Also does not reflect the success of implementing QS – as there is no temporality. Eventually diabetes will be diagnosed. Implementation of standard will not increase pick up rates but will enable earlier identification. Duration since last normal HbA1c prior to diabetes/impaired glycaemia diagnosis will be a better indicator as it will measure if annual testing has occurred. The longer the duration between tests, the greater potential for untreated diabetes and consequent poorer outcomes.  Collection of this data can only occur at system levels rather than individual provider levels. |
| SH | Diabetes UK | Statement 4 | Research has shown that the likelihood of developing type 2 diabetes is as high as 50% in the 5 years after a gestational diabetes pregnancyand we know that recall of women diagnosed with gestational diabetes must be improved to address this. Attaching the gestational diabetes SNOMED code 11687002 to all correspondence can help primary care practices to automate these processes.  Reference: Vounzoulaki E, Khunti K, Abner SC, Tan BK , Davies MJ, Gillies CL. Progression to type 2 diabetes in women with a known history of gestational diabetes: systematic review and meta-analysis. BMJ. 2020 May 13;369:m1361. doi: 10.1136/bmj.m1361 |
| SH | Healthcare Safety Investigation Branch (HSIB) | Statement 4 | HSIB investigations have included cases where a diagnosis gestational diabetes is apparent only following birth: for example from placental histology results. Should this QS be extended to include those mothers whose diagnosis of GDM was made after birth? |
| SH | National Pregnancy in Diabetes (NPID) audit advisory group | Statement 4 | QS4 could be revised to note that NDPP eligibility has being expanded to include all women with past or current GDM following confirmation of normoglycaemia; (FPG < 5.5mmol/l / HbA1c < 42 mmol/mol). |
| SH | National Pregnancy in Diabetes (NPID) audit advisory group | Question 2 | The systems for monitoring QS4 which women with GDM are referred for post-natal glucose check, annual HbA1c and NHS Diabetes Prevention Programme (NDPP) are currently inadequate. This is a key area for improvement and better systems are urgently required as well as improved communication between maternity, diabetes and primary care providers. |
| SH | National Pregnancy in Diabetes (NPID) audit advisory group | Question 3 | No additional resource is required but better communication and pathways between maternity and primary care providers are needed for QS4 to be implemented. |
| SH | NHS England and Improvement | Statement 4 | Easy to measure as long as the patient has been correctly coded for:   * ‘diabetes’ or ‘gestational diabetes’ (usually this would be done), * pregnancy (as previously mentioned I think this is variable), * ‘referral to diabetes prevention programme’ (I think this is usually done)   Your question is about measurement but what this could uncover is the variability and unreliability of the primary care recall systems and this could also link with health inequalities as it might be that the most stressed practices are working in the most deprived areas where a more robust recall system is needed to get at risk patients back. This requires a reliable recall system and then practice / PCN processes to run it. A dashboard would highlight issues and variability, but also opportunities to improve. |
| SH | Reed Wellbeing | Statement 4 | Data for uptake of NDPP in the women referred by primary care, this would be able to be taken from the report submitted to NHS England to make sure the NDPP service is fit for purpose for women who are pregnant.  Guidance on speed of referral from after the fasting plasma glucose test at 6 to 13 weeks after the birth. |
| SH | Reed Wellbeing | Question 1 | The NDPP (NHS Diabetes Prevention Programme) services can support to collect data for the quality statement 4. |
| SH | Royal College of General Practitioners | Question 2 | Statement 4 as it stands appears to suggest annual blood glucose monitoring (not fasting even) for people who had gestational diabetes. Most of the screening now for other reasons is based on annual hba1c levels and not fasting or random glucose. Indeed, in the relevant NICE guidance 1.6.14 it is recommended that people who had gestational diabetes have an annual hba1c (like other indications) – so we would recommend that the statement 4 is changed to fit in with guidance and suggest use of hba1c annually. |
| **Additional areas** | | | |
| SH | Diabetes UK |  | The Continuous Glucose Monitoring in pregnant women with type 1 diabetes (CONCEPTT) trial has shown the importance of using CGM throughout pregnancy, including during labour and birth. There is an urgent unmet need for more research regarding the use of CGM in pregnant women with type 2 diabetes, and to better understand what support they and their healthcare teams might need to make the best use of CGM data.  The recent NPID data show that baby deaths (stillbirth or death of a baby during in the first 28 days), preterm births, large for gestational age (LGA) birthweight and neonatal care unit admissions are all lowest in women with HbA1c less than 43 mmol/mol after 24 weeks gestation. The data suggests that women with type 2 diabetes may be even more vulnerable to smaller changes in blood glucose during pregnancy compared to women with type 1 diabetes.  Tighter blood glucose targets are shown to reduce the rates of preterm birth, large for gestational age birthweight and neonatal care admissions both in type 1 and type 2 diabetes. In type 1 diabetes, large birthweight rates were still as high as 50% with a HbA1c target of less than 48mmol/mol but were close to 30% in those with HbA1c less than 43mmol/mol. Women with type 2 diabetes and a HbA1c less than 43mmol/mol had rates of large birthweight approximating those of the background maternity population. It is important that the latest evidence emerging in this area is recognised and reflected in guidance to support pregnant women in reaching the lowest possible HbA1c targets.  Reference: Feig, D. S. et al. (2017) “Continuous Glucose Monitoring in Pregnant Women with Type 1 Diabetes (conceptt): A Multicentre International Randomised Controlled Trial,” The lancet, 390(10110), pp. 2347–2359. |
| **Question 5 - Do you have an example from practice of implementing the NICE guideline that underpins this quality standard? If so, please provide details on the comments form.** | | | |
| SH | Association Of British HealthTech Industries | Question 5 | ABHI welcomes the opportunity to highlight best practice and work to expand the use of similar approaches elsewhere. |
| SH | NHS England and Improvement | Question 5 | I don’t have an example from primary care (as said previously type 1 diabetics in our area are cared for by secondary care, so only relevant to type 2 diabetics who are seen in GP diabetes clinics) but it would be important to get some sort of base line search to see where we are starting from with this. As stated previously, it might be that it is happening but not coded or not happening in a systematic way so I would anticipate a low base. Optimistically, with local system training around the patient education element but also the importance of coding I think you would see an improvement in uptake.  I don’t know of any practices that code the clinic letters from 2ary care pertaining to this quality standard. |
| SH | National Pregnancy in Diabetes (NPID) audit advisory group | Question 5 | We’ve held regional CCG meetings explaining that NDPP eligibility has now being expanded to include all women with past or current GDM following confirmation of normoglycaemia; (FPG < 5.5mmol/l / HbA1c < 42 mmol/mol) during the postnatal glucose check or annual HbA1c measurement. Following advice from primary care we’ve added the GDM **SNOMED code 11687002** to all primary care correspondence to improve GDM coding in primary care. A national GDM audit is planned so systems are encouraged to ensure that GDM is accurately reported and recorded on the MSDS. |
| SH | Royal College of General Practitioners | Question 5 | We are not aware of any examples of implementation specifically – though have been aware that many with diabetes, and many women are provided with preconception counselling within the primary care context when presenting for other reasons. |
| **No comments** | | | |
| SH | Royal College of Nursing |  | No comments. |
| SH | Royal College of Paediatrics and Child Health |  | No comments. |
| SH | Royal College of Pathologists |  | No comments. |

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

## Registered stakeholders who submitted comments at consultation

* Association Of British HealthTech Industries
* Cambridge University Hospitals NHS Trust
* Diabetes UK
* Healthcare Safety Investigation Branch
* National Pregnancy in Diabetes (NPID) audit advisory group
* NHS England and Improvement
* Reed Wellbeing
* Royal College of General Practitioners

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