NICE National Institute for Health and Care Excellence

2018 surveillance of diabetes in pregnancy: management from preconception to the postnatal period (NICE guideline NG3)

Surveillance report

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Surveillance decision

We will partially update the NICE guideline on diabetes in pregnancy (NG3). The update will focus on the role of continuous glucose monitoring for women with type 1 diabetes who are planning to become pregnant or already pregnant.

During surveillance editorial and factual corrections were identified.

Reason for the decision

The evidence

This section provides a summary of the areas that will be updated and the reasons for the decision to update.

1.3 Antenatal care for women with diabetes

There is new evidence on continuous glucose monitoring. In particular, the CONCEPTT trial has published which experts deem to be a landmark trial that provides the best available evidence for the foreseeable future. The CONCEPTT trial found improvements in a range of neonatal outcomes with continuous glucose monitoring plus standard care, compared with standard care alone, and advocates routine usage in pregnant women with type 1 diabetes. This could potentially alter recommendation 1.3.17, which currently advises do not offer continuous glucose monitoring routinely to pregnant women with diabetes.

The CONCEPTT trial also included the use of continuous glucose monitoring during the preconception period. There were less clear benefits during the planning pregnancy stage, possibly due to the small sample size, but the authors noted that women may be uncomfortable changing monitoring modality during early pregnancy, thus initiating continuous glucose monitoring pre-pregnancy may be of benefit. This evidence could potentially impact on section 1.1 on continuous glucose monitoring during preconception planning and care.

As such, a partial update is proposed focused on continuous glucose monitoring in women with type 1 diabetes who are planning to become pregnant or already pregnant.

The evidence identified in relation to other areas of the guideline supports current recommendations or is not expected to impact on current recommendations due to insufficient evidence or heterogeneity across studies resulting in unclear benefits.

For further details and a summary of all evidence identified in surveillance, see appendix A.

Overview of 2018 surveillance methods

NICE's surveillance team checked whether recommendations in diabetes in pregnancy (NICE guideline NG3) remain up to date.

The surveillance process consisted of:

- Initial feedback from topic experts via a questionnaire.
- Input from stakeholders on known variations in practice and policy priorities.
- Literature searches to identify relevant evidence.
- Assessing the new evidence against current recommendations and deciding whether or not to update sections of the guideline, or the whole guideline.
- Consulting on the decision with stakeholders and considering comments received during consultation.

For further details about the process and the possible update decisions that are available, see ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual.

Evidence considered in surveillance

Search and selection strategy

We searched for new evidence related to 4 areas of the guideline which were highlighted by topic experts as potentially having new evidence that could change recommendations: diagnostic criteria, HbA1c testing, insulin therapy (including insulin pumps), and continuous glucose monitoring.

From these 4 searches, we found 38 studies published between 1 June 2014 and 9 February 2018.

We also included:

- 2 unique studies identified by topic experts
- 13 Cochrane reviews identified as relevant across the guideline
- 2 studies identified by searches undertaken in the 2011 surveillance
- 1 RCT published after our search cut-off date that was highlighted by stakeholders

From all sources we considered 56 studies to be relevant to the guideline.

See appendix A: summary of evidence from surveillance for details of all evidence considered, and references.

Selecting relevant studies

The standard surveillance review process of using RCTs, full economic evaluations of relevance to the UK and systematic reviews was used for this search. The only deviation from this was the inclusion of cohort studies for NICE criteria for diagnosing gestational diabetes and cohort studies for HbA1c testing in the 2nd and 3rd trimester of pregnancy. The inclusion of cohort studies for these areas was to ensure recent relevant evidence was not omitted and was in line with the approach taken in the guideline.

Ongoing research

We identified ongoing research that may impact the guideline. Of the ongoing studies identified, 4 studies were assessed as having the potential to change recommendations; therefore we plan to regularly check whether these studies have published results, and evaluate the impact of the results on current recommendations as quickly as possible. These studies are:

- Cochrane review protocol: Fetal biometry for guiding the medical management of women with gestational diabetes mellitus for improving maternal and perinatal health.
- Cochrane review protocol: Early pregnancy screening for identification of undiagnosed pre-existing diabetes to improve maternal and infant health.
- ClinicalTrials.gov Identifier: NCT03326232. Real time continuous glucose monitoring. Study end date July 2018.

- ISRCTN56898625 Automated insulin delivery among pregnant women with type 1 diabetes. Expected publication 2022.

In addition, a topic expert advised that the HAPO study is due to publish an update. NICE contacted study authors who confirmed that this is planned but there are no publication dates as yet. NICE will continue to monitor this study.

Intelligence gathered during surveillance

Views of topic experts

We sent questionnaires to 11 topic experts and 5 responded. The topic experts either:

- participated in the guideline committee who developed the guideline or
- were recruited to the NICE Centre for Guidelines Expert Advisers Panel to represent their specialty.

The topic experts provided comments indicating that there was potential new evidence related to the guideline, in particular in relation to section 1.2 (gestational diabetes) and section 1.3 (antenatal care). The views of topic experts were considered during the surveillance review, see appendix A: summary of evidence from surveillance for details of how the concerns from topic experts have been addressed.

Views of stakeholders

Stakeholders are consulted on all surveillance decisions except if the whole guideline will be updated and replaced. Because this surveillance decision was initially not to update the guideline, we consulted on the decision.

Overall, 17 stakeholders commented. The vast majority of stakeholders disagreed that diabetes in pregnancy NICE guideline (NG3) should not be updated at this time, with the primary area requiring update being continuous glucose monitoring. Other areas were also suggested for update, such as diagnostic criteria, HbA1c testing, insulin pumps and insulin analogues. However, evidence in these areas of the guideline was generally supportive of current recommendations or not expected to impact the guideline due to heterogeneity across studies resulting in unclear benefits.

During consultation we also received feedback that there may be value in undertaking surveillance of diabetes in pregnancy NICE guideline (NG3) and type 1 diabetes NICE guideline (NG17) together in the future, as long as it did not impede consideration of type 2 diabetes and gestational diabetes for NG3.

See appendix B for stakeholders' comments and our responses.

See ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual for more details on our consultation processes.

Equalities

Several equality issues were raised during the process, such as cultural and language barriers, deprivation, and learning disabilities. These issues do not differ from those raised during the development of the guideline. During development, the guideline committee deemed that all guideline recommendations apply equally to all groups protected under equality and anti-discrimination legislation and no changes to recommendations were needed to address inequalities.

Editorial and factual inaccuracies

During surveillance of the guideline we identified the following points in the guideline that should be amended.

Refresh of recommendations

An amendment to recommendation 1.1.11 to clarify that a prescription is needed for 5mg folic acid, to reduce the risks of women inadvertently using a lower dose over-the-counter formulation.

An amendment to the recommendations on retinal screening, section 1.3, to add a caveat to reduce unnecessary retinal screening.

Editorial amendments

An editorial amendment to add a footnote at the end of 1.1.10 to clarify BMI in different ethnic groups. Suggested wording: The BMI cut-off should consider the variation in risk for different ethnic groups, see the NICE guideline on BMI (PH46).

An editorial amendment to add a footnote to the end of bullet point 1 of recommendation 1.2.11, to provide a link to the DVLA guidance on diabetes and driving. Suggested footnote: Advice for women on driving with diabetes is available from the DVLA website.

An editorial amendment to footnote 4. The amended footnote will be: [4] At the time of surveillance review (April 2018) the UK marketing authorisation for glibenclamide varied between different brands with regards to use in pregnancy. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Good practice in prescribing and managing medicines and devices for further information.

An editorial amendment to footnote 8. The amended footnote will be: [8] Note that the threshold for defining a moderate and high risk of developing type 2 diabetes postnatally for women who have had gestational diabetes is different from that given in the NICE guideline on preventing type 2 diabetes, because of the different populations.

Overall decision

After considering all evidence and intelligence, and the impact this has on current recommendations, we decided that a partial update is necessary, focusing on continuous glucose monitoring for women with type 1 diabetes who are planning to become pregnant or already pregnant.

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