NICE National Institute for Health and Care Excellence

Surveillance report (exceptional review) 2017 – Preterm labour and birth (2015) NICE guideline NG25

Surveillance report

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Surveillance decision

We will plan an update of the following section of the guideline:

- Prophylactic vaginal progesterone

Reason for the decision

The OPPTIMUM study on vaginal progesterone prophylaxis compared with placebo for pre-term labour and birth was highlighted by guideline stakeholders as potentially impacting on the guideline recommendations.

This was a randomised controlled trial carried out in women at risk of preterm birth (because of previous spontaneous birth at ≤34 weeks and 0 days of gestation, or a cervical length ≤25 mm, or because of a positive fetal fibronectin test combined with other clinical risk factors for preterm birth. The results suggest that progesterone had no significant effect on the primary obstetric outcome (odds ratio adjusted for multiple comparisons [OR] 0.86, 95% confidence interval [CI] 0.61–1.22) or neonatal outcome (OR 0.62, 0.38–1.03), nor on the childhood outcome (cognitive score, progesterone group versus placebo group, 97.3 [SD 17.9] versus 97.7 [SD 17.5]). These results were considered to impact on the following guideline recommendations:

- 1.2.1 Offer a choice of either prophylactic vaginal progesterone or prophylactic cervical cerclage to women:
  - With a history of spontaneous preterm birth or mid-trimester loss between 16+0 and 34+0 weeks of pregnancy and
  - In whom a transvaginal ultrasound scan has been carried out between 16+0 and 34+0 weeks of pregnancy that reveals a cervical length of less than 25 mm.
- 1.2.2 Offer prophylactic vaginal progesterone to women with no history of spontaneous preterm birth or mid-trimester loss in whom a transvaginal ultrasound scan has been carried out between 16+0 and 34+0 weeks of pregnancy that reveals a cervical length of less than 25 mm.

The results of the OPPTIMUM study were discussed with the guideline committee chair

who indicated that 'the OPPTIMUM study reduces confidence in the recommendation to prescribe progesterone to prevent preterm birth'. On that basis, the proposal to update the section in the guideline on prophylactic vaginal progesterone was discussed with additional topic experts at a workshop for the pregnancy guideline suite. Topic experts agreed that this new evidence could impact on the guideline recommendations and felt that an update was warranted. However, as this was placebo controlled trial, and the guideline currently recommends prophylactic vaginal progesterone or prophylactic cervical cerclage, then the results of this study will only inform one of the recommended choices. No additional literature searches were conducted to identify additional studies in this area.

Decision: The following review question should be updated:

- What is the clinical effectiveness of prophylactic progesterone (vaginal or oral) in preventing preterm labour in pregnant women considered to be at risk of preterm labour and birth?

Other clinical areas

This exceptional surveillance review was carried out to allow us to consider the impact of the study described above on the guideline recommendations. We did not search for new evidence relating to this guideline as part of this focused surveillance.

Equalities

No equalities issues were identified during the surveillance process.

Overall decision

After considering the new evidence and views of topic experts, we decided that a partial update is necessary for this guideline.

See how we made the decision for further information.

How we made the decision

Exceptionally, significant new evidence may mean an update of a guideline is agreed before the next scheduled check of the need for updating. The evidence might be a single piece of evidence, an accumulation of evidence or other published NICE guidance.

For details of the process and update decisions that are available, see ensuring that published guidelines are current and accurate in 'Developing NICE guidelines: the manual'.

New evidence

We were notified of 1 new study which could impact on current guideline recommendations. The results of this study were considered in detail to determine an impact on guideline recommendations.

Views of topic experts

We considered the views of topic experts, including those who helped to develop the guideline.

Views of stakeholders

Stakeholders are consulted only if we decide not to update the guideline following checks at 4 and 8 years after publication. Because this was an exceptional surveillance review, and the decision was to update, we did not consult on the decision.

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

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