NICE National Institute for Health and Care Excellence

2020 Surveillance of preterm labour and birth (NICE guideline NG25)

Surveillance report

Published: 25 June 2020

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Surveillance decision

We will update the NICE guideline on preterm labour and birth.

Reasons for the decision

New evidence and information identified during surveillance was initially considered not to have an impact on current guideline recommendations. However, stakeholder feedback raised concerns about the current recommendation to not routinely offer repeat courses of steroids. The feedback indicated that the recommendation was no longer justified and cited an independent patient data meta-analysis and a Cochrane review to support this view. After considering this evidence in detail, we are proposing to update the guideline to reconsider the recommendation around repeat courses of maternal corticosteroids.

The main areas considered during surveillance included:

Single and repeat use of corticosteroids

One updated Cochrane review concluded that repeat courses of maternal corticosteroids were safe and effective for women in suspected preterm labour. The original review had already been considered during guideline development and a recommendation of "do not routinely offer repeat courses of maternal corticosteroids" was created. No topic experts had mentioned this area and NICE did not identify any further evidence during the surveillance review. Therefore, stakeholders were asked at consultation to specifically comment on the implementation of this recommendation in practice. Seven stakeholders confirmed that they believed the recommendation around repeat courses should remain because of the potential risk of harm to the fetus and mother. NICE did not find any evidence of harm during the surveillance review.

The Royal College of Obstetricians and Gynaecologists highlighted further evidence in the form of an individual participant data meta-analysis, which stated that prenatal corticosteroids given to women at ongoing risk of preterm birth after an initial course reduced the likelihood of their baby needing respiratory support after birth and led to neonatal benefits. Additionally, the World Health Organization now recommends repeat courses of maternal corticosteroids for women in suspected preterm labour based on the updated Cochrane review within this area. Therefore, in light of this new evidence,

alongside the updated Cochrane review, we propose the guideline is updated to consider the safety and effectiveness of repeat courses of maternal corticosteroids.

Place of birth and transfer to centre with neonatal intensive care

During consultation, NICE asked stakeholders for a view on important gaps in the guideline. The main gap that 3 stakeholders raised was that it fails to highlight the recommended place of birth as an intervention to improve the outcome of preterm birth and the importance of in utero transfer during labour. The British Association of Perinatal Medicine (BAPM) guideline on perinatal management of extreme preterm birth before 27 weeks of gestation gives specific advice in this area. It is also stated in the UK Preterm Clinical Network guidelines for commissioners and providers on reducing preterm birth that it is now a priority NHS England recommendation for local maternity systems to take action to ensure that all women less than 27 weeks pregnant have their babies delivered in centres with a neonatal intensive care unit, and that local maternity systems and corresponding operational delivery networks have clear guidelines for antenatal transfer in the event of impending delivery at less than 27 weeks. NICE's guideline already mentions that clinicians should make an assessment on the need to transfer to another unit in recommendation 1.8.1. However, it is proposed that the recommendation should be refreshed to ensure that clinicians consider the NHS England guidance on saving babies' lives (version two): a care bundle for reducing perinatal mortality.

The use of antibiotics in preterm labour

Two stakeholders raised concerns around the 'treat all' approach with the use of antibiotics in preterm labour and noted that the guideline is not in line with current recommendations from the Royal College of Obstetricians and Gynaecologists Greentop guideline on prevention of early onset neonatal group B streptococcal disease. Recommendation 1.4.4 in NICE's guideline on preterm labour and birth refers to NICE's guideline on neonatal infection (early onset), which is currently being updated. The update is considering intrapartum antibiotics and maternal group B streptococcus status to guide the decision on timing of delivery in women with preterm prelabour rupture of membranes (P-PROM). Therefore, when this guideline publishes (expected March 2021), we will consider any amendments that could affect NICE's guideline on preterm labour and birth and will update it accordingly.

The efficacy of progesterone

The guideline recommendations on the clinical effectiveness of prophylactic progesterone on the prevention of preterm labour were updated in 2019. The review considered all current evidence and concluded that progesterone is safe and effective to use to prevent preterm labour. Three randomised controlled trials (RCTs) were considered during the surveillance review. One of these did not fully complete. One RCT suggested that there was no difference between the 2 groups when using progesterone, and the results of 1 RCT indicated that progesterone could decrease preterm birth when combined with other treatments such as indomethacin and treatment of bacterial vaginosis. No evidence was found through the surveillance review to contradict current recommendations. Therefore, this area of the guideline will not be updated at this time.

Identifying women at high risk for premature labour (including the use of transvaginal ultrasound scans)

Two topic experts and 2 stakeholders suggested that more information should be given regarding screening for women at high risk of premature labour to align with other guidelines in this area, such as the NHS England guidance on saving babies' lives (version two): a care bundle for reducing perinatal mortality. Identifying women at high risk of premature labour is outside the scope of this guideline and is also considered further by the UK National Screening Committee. Recommendation 1.9.3.1 in the NICE guideline on antenatal care for uncomplicated pregnancies states that routine screening for preterm labour should not be offered. Therefore, the guideline will not be updated to include this area.

Diagnostic testing for women under 30 weeks' pregnancy

One topic expert and 4 stakeholders believed that diagnostic testing should be considered for women under 30 weeks' pregnancy and the UK Preterm Clinical Network guidelines for commissioners and providers on reducing preterm birth suggest that fetal fibronectin testing should be used from 18 weeks' pregnancy. However, NICE's diagnostics guidance on biomarker tests to help diagnose preterm labour in women with intact membranes and 1 Cochrane review found insufficient evidence to support the use of fetal fibronectin for diagnosing preterm labour. During development of the NICE guideline, it was noted that a 'treat all' approach for women under 30 weeks' pregnancy was more cost effective than diagnostic testing. Four stakeholders queried the 'treat all' approach for women under 30 weeks' pregnancy. No evidence was found through surveillance that showed that

diagnostic testing would be more effective than a treat all approach in this population and therefore this area of the guideline will not be updated at this time.

Delivery (including mode of delivery, timing of delivery for women with P-PROM and delayed cord clamping)

No evidence was found through the surveillance review regarding mode of birth for women in preterm labour. A stakeholder suggested that caesarean section should not be considered first before vaginal breech delivery; however, the reasons for this were not given. NICE's guideline only recommends considering caesarean section for women presenting in suspected, diagnosed or established preterm labour between 26 weeks and 36 weeks of pregnancy with breech presentation and therefore no amendment to this area of the guideline is needed.

One topic expert requested further information around when women with P-PROM should deliver. Limited evidence was found through the surveillance review regarding the impact on neonatal outcomes of immediate or expectant management of delivery for this population and therefore no change will be made to this area of the guideline at this time.

One stakeholder suggested that cord milking was not beneficial, and that cord clamping should only occur after the baby cries. One topic expert suggested that delayed cord clamping should have a firmer recommendation in the guideline. There is now a much larger amount of evidence to support the current recommendations that delayed cord clamping is more beneficial to the preterm baby than immediate clamping. The current recommendation is for at least 30 seconds but no longer than 3 minutes, within which time it is presumed a stable baby will cry. No studies were found through the surveillance review to indicate that delayed cord clamping was not beneficial and no studies compared delayed clamping of 30 seconds with delayed clamping of 3 minutes or under, and therefore it is suggested that the current recommendations do not need amending at this time. No evidence was found through the surveillance review to contradict NICE's current recommendations around cord milking and the study provided by the stakeholder to suggest cord milking was not beneficial was never completed. Therefore, this recommendation will not be amended at this time.

The effectiveness of tocolysis and nifedipine

Two stakeholders did not consider tocolysis, specifically the drug nifedipine, to be effective at improving neonatal outcomes in women in preterm labour. The UK Preterm

Clinical Network guidelines for commissioners and providers on reducing preterm birth also do not consider tocolysis to be effective. Seven RCTs were found through the surveillance review, which considered the use of nifedipine. No studies were found that concluded that nifedipine was ineffective. In 2 RCTs, nifedipine was considered the safest drug when compared with ritodrine and magnesium sulfate.

Because of the lack of evidence to contradict the current recommendations and new evidence found that supports the current recommendation that tocolytics and nifedipine should be considered in women with suspected preterm labour, there will be no impact to this area of the guideline at this time.

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

Overview of 2020 surveillance methods

NICE's surveillance team checked whether recommendations in the NICE guideline on preterm labour and birth remain up to date.

The surveillance process consisted of:

- Feedback from topic experts via a questionnaire.
- A search for new or updated Cochrane reviews and national policy.
- Consideration of evidence from previous surveillance.
- Examining related NICE guidance and quality standards and NIHR signals.
- A search for ongoing research.
- Examining the NICE event tracker for relevant ongoing and published events.
- Literature searches to identify relevant evidence.
- Assessing the new evidence against current recommendations to determine whether or not to update sections of the guideline, or the whole guideline.
- Consulting on the proposal not to update with stakeholders.
- Considering comments received during consultation and making any necessary changes to the proposal.

After consultation, the decision changed to update.

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 the whole guideline.

We found 48 studies in a search for randomised controlled trials (RCTs) published between 1 January 2015 and 31 October 2019.

We also included:

- 1 relevant study from a total of 7 identified by topic experts
- 5 studies identified in comments received during consultation of the 2020 surveillance proposal.

From all sources, we considered 54 studies to be relevant to the guideline.

See appendix A for details of all evidence considered, and references.

Selecting relevant studies

We searched for RCTs and systematic reviews; however, because of the large volume of studies identified, only RCTs with sample sizes of 50 and over, and Cochrane reviews, were included.

Overall, the new evidence either was considered to support the current recommendations, was outside of the scope of this guideline or was deemed insufficient in volume or quality to impact on the recommendations.

Ongoing research

We checked for relevant ongoing research; of the ongoing studies identified, 7 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:

- Evaluating hormone treatments for women at increased risk for preterm birth

- The safety of out-patient compared with in-patient treatment in women with preterm prelabor rupture of the membranes (PPROM) prior to 34 weeks of gestation
- C-STICH2: Rescue cervical stitching to prevent miscarriage and premature birth
- The EQUIPTT Study: Evaluating whether clinicians using the QUIPP app make more appropriate management decisions for women who arrive to hospital thinking they may be in preterm labour
- Can a test of preterm labour (quantitative fetal fibronectin) help diagnosis and clinical decision making?
- Early compared to delayed umbilical cord clamping in very small prematurely born babies: a study to know which one is better for infant health
- Stitch, progesterone or pessary: a randomised controlled trial

Intelligence gathered during surveillance

Views of topic experts

We considered the views of topic experts who were recruited to the NICE Centre for Guidelines Expert Advisers Panel to represent their specialty. For this surveillance review, topic experts completed a questionnaire about developments in evidence, policy and services related to the guideline.

We received 4 questionnaire responses: from a midwife, a maternal-fetal medicine and obstetrics specialist, a labour ward and delivery education lead and an obstetrics specialist. Two felt that the guideline should be updated and 2 did not express an opinion.

Areas raised in topic expert feedback included:

- Identifying women at high risk for premature labour, which is outside of the scope for this guideline.
- The gestational age for giving magnesium sulfate, fetal steroids and tocolytics. Only 1 study was found about the use of magnesium sulfate, which had similar effects on fetal neuroprotection regardless of gestational age and therefore supported NICE's recommendations.

- The efficacy of progesterone (see the section on reasons for the decision).
- Techniques for cervical cerclage (including suture material). No evidence was found in this area.

Views of stakeholders

Stakeholders are consulted on all surveillance reviews except if the whole guideline will be updated and replaced. Because this surveillance proposal was to not update the guideline, we consulted with stakeholders.

Overall, 12 stakeholders commented. Comments were received from a private healthcare company, a clinical reference group, 4 royal colleges, a university hospitals trust, a pharmacy association, an operational delivery network, a society and 2 charities. Three of the stakeholders agreed with the proposal not to update the guideline and 8 did not agree. One stakeholder did not comment. The main reasons for disagreeing with the proposal not to update included:

- place of birth and in utero transfer
- use of antibiotics in preterm labour
- single and repeat use of corticosteroids.

See the section on reasons for the decision for further details.

See appendix B for full details of 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

No equalities issues were identified during the surveillance process.

Overall decision

After considering all evidence and other intelligence and the impact on current recommendations, we decided that an update is necessary.

ISBN: 978-1-4731-3699-1