Pre-term labour & birth

Consultation on draft guideline - Stakeholder comments table
17 February 2022 – 17 March 2022

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Stakeholder	Document	Page No	Line No	Comments	Developer's response
British Association of Perinatal Medicine	Guideline	General	General	BAPM is concerned that this guideline does not take into account the updated BAPM framework for extremely preterm birth (with specific concerns regarding gestational thresholds, antenatal consultations and parental information). It also contains some significant inconsistencies with respect to optimisation of the preterm infant (with specific reference to prediction of preterm birth and timing of optimal cord management)	Thank you for your comment. The scope of this update included the use of repeat doses of maternal corticosteroids only, so other sections of the guideline were not updated and this may include recommendations relating to extremely preterm birth. However, the committee recognised there may be a safety issue with recommendations relating to cord-clamping and cord milking so edited these recommendations, and have also passed your comments to the NICE surveillance team who are responsible for ensuring that guidelines are up to date.
British Association of Perinatal Medicine	Guideline	009 1.7.1	019 1.7.1	*If the clinical assessment suggests that the woman is in suspected preterm labour and she is 29+6 weeks pregnant or less, advise treatment for preterm labour as described in sections1.8 and 1.9. [2015]* This suggests that any woman who presents with symptoms of preterm labour <30/40 should be managed as per preterm labour including tocolysis, steroids and transfer to the appropriate neonatal unit. Steroids should be targeted and ONLY given when required. There is clear evidence that the optimal time for delivery post steroids is between 24 hours post steroids and 7 days. There is also evidence from cohort studies that babies born at term after receiving unnecessary antenatal steroids may have	Thank you for your comment. The section of the guideline on diagnosing preterm labour was not included in the scope of this update. However, the committee recognised that there may be new evidence relating to the use of tools such as QUiPP and the committee have highlighted this section as requiring an update. This information has therefore been passed to the NICE surveillance team who are responsible for ensuring that guidelines are up to date.

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				worse neurodevelopmental outcomes – caution is needed, and using predictive tests and tools is important to allow targeting of preterm optimisation measures. QUiPP: A tool to predict spontaneous preterm birth https://www.bapm.org/pages/194-antenatal-optimisation-toolkit	
British Association of Perinatal Medicine	Guideline	010 1.7.4	016 1.7.4	A cervical length of <15mm is NOT diagnostic of preterm birth – a woman may already have a shortened cervix and her cervical length should be used with FFN testing and app such as QUIPP. Suggest linking to the tools in the BAPM antenatal optimisation toolkit QUiPP: A tool to predict spontaneous preterm birth https://www.bapm.org/pages/194-antenatal-optimisation-toolkit	Thank you for your comment. The section of the guideline on diagnosing preterm labour was not included in the scope of this update. However, the committee recognised that there may be new evidence relating to the use of tools such as QUiPP and the committee have highlighted this section as requiring an update. This information has therefore been passed to the NICE surveillance team who are responsible for ensuring that guidelines are up to date.
British Association of Perinatal Medicine	Guideline	011 1.7.5	001 1.7.5	*Consider fetal fibronectin testing as a diagnostic test to determine likelihood of birth within 48 hours for women who are 30+0 weeks pregnant or more if transvaginal ultrasound measurement of cervical length is indicated but is not available or not acceptable.* As previously commented – BAPM disagrees with this recommendation - this management should be for any gestation from 22 weeks and not just >30/40 See above link to BAPM preterm framework and AO toolkit	Thank you for your comment. The section of the guideline on diagnosing preterm labour was not included in the scope of this update. However, the committee recognised that there may be new evidence and the committee have highlighted this section as requiring an update. This information has therefore been passed to the NICE surveillance team who are responsible for ensuring that guidelines are up to date.

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British Association of Perinatal Medicine	Guideline	011 1.7.7	021 1.7.7	*Do not use transvaginal ultrasound measurement of cervical length and fetal fibronectin testing in combination to diagnose preterm labour.* BAPM could not find evidence to support this recommendation. The BAPM antenatal optimisation toolkit, the NHSE MatNeoSIP programme all recommend the combination of Quantitative FFN, cervical length (and the QUIPP app) and this is consequently implemented into many units and networks in the UK.	Thank you for your comment. The section of the guideline on diagnosing preterm labour was not included in the scope of this update. However, the committee recognised that there may be new evidence relating to the use of tools such as QUiPP and the committee have highlighted this section as requiring an update. This information has therefore been passed to the NICE surveillance team who are responsible for ensuring that guidelines are up to date.
British Association of Perinatal Medicine	Guideline	013	004	*For women between 23+0 and 23 5 +6 weeks of pregnancy who are in suspected or esta42blished preterm labour, are having a planned preterm birth or have PPROM (see section1.3), discuss with the woman (and her family members or carers as appropriate) the use of maternal corticosteroids in the context of her individual circumstances. [2015]* BAPM disagrees with the gestational age thresholds here. Following publication of the BAPM toolkit for perinatal management of extreme preterm birth and RCOG guideline on antenatal steroids, where risk assessment and parental discussion deem that active management is an appropriate care pathway, antenatal steroids should now be considered even from 22 weeks onwards. Evidence: Meta-analysis showed reduction in mortality [N = 10109; OR = 0.47(0.39–0.56),	Thank you for your comment. The committee agreed that since 2015 the viability of babies born at 22 weeks has improved and so have made an editorial amendment to this recommendation to reduce the lower limit to 22+0 weeks.

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				p<0.00001; LOE: Moderate] and severe IVH and PVL [N = 5084; OR = 0.71(0.61–0.82), p<0.00001; LOE: Low] after exposure to ANC in neonates born <25 weeks. ***Deshmukh, Patole. Antenatal corticosteroids for neonates born before 25 Weeks—A systematic review and meta-analysis*** https://www.bapm.org/resources/80-perinatal-management-of-extreme-preterm-birth-before-27-weeks-of-gestation-2019	
British Association of Perinatal Medicine	Guideline	015 1.12	018 1.12	***"*** *information about the likelihood of the baby surviving and other outcomes (including long-term outcomes) and risks for the baby, giving values as natural frequencies (for example, 1 in 100)"* *- " an opportunity to speak to a neonatologist or paediatrician"* The BAPM framework recommends that these perinatal counselling sessions, ahead of extremely preterm birth, follow the guidance set out in the framework, and are **joint perinatal consultations** including a neonatologist, obstetrician and midwife. We suggest amending this wording to map to the BAPM framework, but also including a a link here to the BAPM Extremely Preterm framework, the parental information leaflet and infographic for outcomes of babies born between 22& 26 weeks for standardisation of information	Thank you for your comment and for informing the committee of these resources to support conversations about preterm birth. It is not NICE practice to link to external materials such as these but they will be passed on to be considered by NICE where relevant support activity is being planned.

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				https://www.bapm.org/resources/80-perinatal-management-of-extreme-preterm-birth-before-27-weeks-of-gestation-2019 BAPM also feel that it is vital that women receive advice about the importance of maternal breast milk and about expressing as part of the **antenatal** consultation ahead of preterm birth. We suggest linking to the BAPM maternal breast milk toolkit and the PERIPrem breast milk parent leaflet https://www.bapm.org/pages/196-maternal-breast-milk-toolkit https://www.weahsn.net/wp-content/uploads/2021/07/Breast-Milk-Leaflet-English.pdf	
British Association of Perinatal Medicine	Guideline	017 1.13.1	025 1.13.1	*If a preterm baby needs to be moved away from the mother for resuscitation, or there is significant maternal bleeding: • consider milking the cord and • clamp the cord as soon as possible. [2015]* *Wait at least 30 seconds, but no longer than 3 minutes, before clamping the cord of preterm babies if the mother and baby are stable* BAPM disagrees with the recommendation for cord milking, and also for the recommendation of 30 seconds to 3 minutes. This does not reflect the evidence, nor national guidance, which all recommend **at least 60 seconds**. Almost all infants born <32 and more so born <28 weeks will	Thank you for your comment. The section of the guideline on cord clamping was not included in the scope of this update, but the committee recognised that there may be new evidence relating to the optimal timing for cord-clamping and the committee have highlighted this section as requiring an update. This information has therefore been passed to the NICE surveillance team who are responsible for ensuring that guidelines are up to date. As the committee agreed that inappropriate timing of cord-clamping or milking the cord may be a safety issue they agreed to delete this recommendation and amended the subsequent recommendation to state that usually clamping should be carried out

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				need "resuscitation" in some form hence clamping the cord immediately will mean we deprive them of a beneficial intervention. Optimal cord management/deferred cord clamping for at least **60 seconds** carries a mortality benefit of close to 30%, so it is VITAL that babies are not exposed to an excessive burden of mortality because of lack of implementation of this simple intervention. There are very few reasons as to why the cord needs to be clamped immediately, and many ways in which the baby can remain attached to the cord whilst neonatal resuscitation takes place. **https://www.bapm.org/pages/197-optimal-cord-management-toolkit** • Cord milking SHOULD NOT BE undertaken <32 weeks due to risk of IVH. (***risk ratio (RR): 1.95 (95% CI 1.01 to 3.76), p=0.05-Meta-analysis by Balasubramanian et al, 2020; Katheria, Reister et al. Association of Umbilical Cord Milking vs Delayed Umbilical Cord Clamping With Death or Severe Intraventricular Hemorrhage Among Preterm Infants***) • Position of the baby being lower than placenta is based on a very old study (Yao 1969). There have been studies later which have shown position of infant did not effectively influence volume of transfusion. Hence trying to position	after at least 60 seconds. The committee did not amend the recommendation about the position of the baby as they were not aware of any new evidence of benefit or harm.

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				infant inferior to introitus might impede provision of PEEP/ respiratory support https://www.weahsn.net/our-work/transforming-services-and-systems/periprem/periprem-bundle-delayed-cord-clamping/	
British Maternal & Fetal Medicine Society	Guideline	General	General	Thanks for your email. BMFMS doesn't have any comments.	Thank you for your support for the new recommendations.
Chelsea & Westminster NHS Foundation Trust	Guideline	General	general	The guideline uses the term cerclage throughout. Others such as RCOG have moved to using suture instead. Consistency and accessibility to lay readers might favour making the same change here	Thank you for your comment. The recently published RCOG greentop guideline on cervical cerclage (number 75, February 2022) uses the terminology cervical cerclage in its title and throughout its recommendations so it does not seem that RCOG have moved to using the term suture instead. However, the committee recognised that there may be new evidence relating to the use and timing of cerclage and the committee have highlighted this section as requiring an update, which may include a change in terminology. This information has therefore been passed to the NICE surveillance team who are responsible for ensuring that guidelines are up to date.
Chelsea & Westminster NHS	Guideline	General	General	The guideline covers management of threatened preterm labour as well as planned preterm birth. It is not immediately clear which sections apply or don't apply to each group.	Thank you for your comment. Additional headings have been added to the guideline to clarify the sections relating to care of women at risk of preterm labour (1.2 to 1.6), and those relating to

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Foundation Trust				For clarity, for the general reader, it would make better sense to state at section 1.2 that sections 1.2-1.8 relate to threatened PTL, and perhaps give a specific heading (Management options for women at risk of spontaneous preterm birth) and different colour to those sections. At section 1.9 a new heading such as "Preparation for spontaneous and planned preterm birth", and a new colour would add to the clarity	the care of women with suspected or established preterm labour. (1.7 to 1.14). It is not possible to add colour coding to the guideline due to accessibility issues.
Chelsea & Westminster NHS Foundation Trust	Guideline	020	Key recommendations and 1.9.4-1.9.6	Regarding research recommendations relating to use of repeat corticosteroids for fetal lung maturation, an emphasis on understanding the duration of effect of the 1st dose should be prioritised – if this turns out to be 14 rather than 7 days, then the need to consider a 2nd dose or course (with potential associated harms) is already greatly reduced	Thank you for your comment. This research recommendation does include the optimal timing between courses, which will address your question of whether repeats are less likely to be needed.
Newcastle upon Tyne Hospitals NHS Foundation Trust	Guideline	005 006	029 001 - 005	Recommendation 1.2.2 Consider prophylactic vaginal progesterone for women who have either: a history of spontaneous preterm birth (up to 34+0 weeks of pregnancy) or loss (from 16+0 weeks of pregnancy onwards) or results from a transvaginal ultrasound scan carried out between 16+0 4 and 24+0 weeks of pregnancy that show a cervical length of 25 mm or 5 less. We understand why NICE is making the recommendation given the overall findings of EPPPIC but we are concerned that it presents an equivalence between the two recommendations.	Thank you for your comment. The section of the guideline on the use of prophylactic vaginal progesterone and prophylactic cervical cerclage was not included in the scope of this update. However, the committee recognised that there may be new evidence relating to the use and timing of progesterone and cerclage and the committee have highlighted this section as requiring an update. This information has therefore been passed to the NICE surveillance team who are responsible for ensuring that guidelines are up to date.

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				The evidence in high risk women is nowhere near as strong as for those with a short cervix. In the supplementary data for EPPPIC in women with a CL that was not short the forest plots did not show a reduction in the rate of preterm birth. We feel that NICE guidance should acknowledge the difference whilst stating the relative lack of harm from prophylactic progesterone.	
Newcastle upon Tyne Hospitals NHS Foundation Trust	Guideline	006	004	Recommendation 1.2.2 Consider prophylactic vaginal progesterone for women who have either: results from a transvaginal ultrasound scan carried out between 16+0 and 24+0 weeks of pregnancy that show a cervical length of 25 mm or less. The UK preterm prevention commissioning guidance puts this as <25mm, can we query why NICE is ≤25mm.	Thank you for your comment. The section of the guideline on the use of prophylactic vaginal progesterone and prophylactic cervical cerclage was not included in the scope of this update. However, the committee recognised that there may be new evidence relating to the use and timing of progesterone and cerclage and the committee have highlighted this section as requiring an update. This information has therefore been passed to the NICE surveillance team who are responsible for ensuring that guidelines are up to date.
Newcastle upon Tyne Hospitals NHS Foundation Trust	Guideline	008	025	Recommendation 1.6 Rescue cervical cerclage It was agreed at the UK Preterm birth meeting 2021 that the use of the word rescue cerclage would stop and the term 'emergency' cerclage would be used instead. We recommend this is changed in the NICE guideline.	Thank you for your comment. The committee have made an editorial change to 'emergency cerclage'.
Newcastle upon Tyne Hospitals	Guideline	010	013	Recommendation 1.7.3 If the clinical assessment suggests that the woman is in suspected preterm labour and she is 29+6 weeks pregnant or less,	Thank you for your comment. The section of the guideline on diagnosing preterm labour was not included in the scope of this update. However, the

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NHS Foundation Trust				advise treatment for preterm labour as described in sections 1.8 and 1.9. Our understanding is this was based on a previous analysis by NICE from 2015 which found 'treat all' was more cost effective. It is also our understanding from our membership of the UK Preterm birth group that this recommendation was not widely adopted in the UK following the publication in 2015. During the creation of this guideline has NICE reached out to stakeholders to understand the reasons why this was not accepted into clinical practice? Since publication of this guideline there has been the development of QUiPP algorithm for symptomatic women. This has been endorsed by BAPM in the 2019 'Antenatal optimisation for preterm infants <34 weeks' toolkit. Furthermore the QUiPP algorithm has been trialled in a cluster RCT. This included women presenting below 30 weeks. The false negative rate in this study, using a risk of delivery within 7 days of ≥5%, was 0.7% (4 women). Of these 4 women all reattended and appropriately received antenatal corticosteroids (see the supplementary file 1). We are concerned that a recommendation based on a theoretical costing model will not be followed particularly when there are proven safe alternatives to a 'treat all' approach published and already widely adopted. In the North East and North Cumbria we now have a regional guideline using	committee recognised that there may be new evidence relating to the use of tools such as QUiPP and the committee have highlighted this section as requiring an update. This information has therefore been passed to the NICE surveillance team who are responsible for ensuring that guidelines are up to date.

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				QUiPP with a 5% threshold and we are aware that other regional groups are planning similar.	
Newcastle upon Tyne Hospitals NHS Foundation Trust	Guideline	018	015	Recommendation 1.14.1 If a preterm baby needs to be moved away from the mother for resuscitation, or there is significant maternal bleeding; consider milking the cord and clamp the cord as soon as possible. BAPM recommends that the only contraindications to optimal cord management are; need for maternal resuscitation in the face of a massive haemorrhage or fetal bleeding such as rupture vasa praevia, snapped cord or cord trauma. We are concerned that the NICE recommendations are too vague and open to interpretation. This is pertinent as there exists uncertainty about the safety of cord milking particularly at very preterm gestations with associations noted with intraventricular haemorrhage.	Thank you for your comment. The section of the guideline on cord clamping was not included in the scope of this update, but the committee recognised that there may be new evidence relating to the optimal timing for cord-clamping and the committee have highlighted this section as requiring an update. This information has therefore been passed to the NICE surveillance team who are responsible for ensuring that guidelines are up to date. As the committee agreed that inappropriate timing of cord-clamping or milking the cord may be a safety issue they agreed to delete this recommendation and amended the subsequent recommendation to state that usually clamping should be carried out after at least 60 seconds.
Newcastle upon Tyne Hospitals NHS Foundation Trust	Guideline	018	019	Recommendation 1.14.2 Wait at least 30 seconds, but no longer than 3 minutes, before clamping the cord of preterm babies if the mother and baby are stable The recent BAPM toolkit for optimal cord management in preterm babies recommends at least 60 seconds. We note the NNAP are reporting on the rates of optimal cord management using 60 seconds as the lower limit. We are concerned that by recommending 'at least 30 seconds' this will become the defacto target.	Thank you for your comment. The section of the guideline on cord clamping was not included in the scope of this update, but the committee recognised that there may be new evidence relating to the optimal timing for cord-clamping and the committee have highlighted this section as requiring an update. This information has therefore been passed to the NICE surveillance team who are responsible for ensuring that guidelines are up to date. As the committee agreed that inappropriate timing of cord-clamping

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					or milking the cord may be a safety issue they agreed to delete this recommendation and amended the subsequent recommendation to state that usually clamping should be carried out after at least 60 seconds.
NHS England / NHS Improvement	Guideline	General	General	This review focuses on specialised secondary care and interventions that would only usually take place in a maternity unit or ward. As such there is nothing in this guidance that is applicable to primary care nor should it have any impact on routine primary care practice.	Thank you for your comment and confirming that the impact on primary care will be negligible.
NHS England / NHS Improvement	Guideline	011	021	1.7.7 there is good evidence for the use of the QUIPP app which uses the combination of FFN and cervical length to provide risk information to women and clinicians on the diagnosis of preterm birth. This also adds in the clinical history of the woman. This app is widely used clinically in the UK and is part of the antenatal toolkit from BAPM and part of the pathway promoted by MatNeoSIP to not support use in this guideline would be u helpful for current practice	Thank you for your comment. The section of the guideline on diagnosing preterm labour was not included in the scope of this update. However, the committee recognised that there may be new evidence relating to the use of tools such as QUiPP and the committee have highlighted this section as requiring an update. This information has therefore been passed to the NICE surveillance team who are responsible for ensuring that guidelines are up to date.
NHS England / NHS Improvement	Guideline	013		1.9 to link to section 1.7 on the diagnosis of preterm birth it would be helpful to add a further recommendation on when to avoid giving antenatal corticosteroids when tests show likelihood of preterm labour is low (i.e. FFN below 50/5% risk or cervical length above 15mm). this would align with saving babies lives V2 and antenatal optimisation toolkit from BAPM	Thank you for your comment. The section of the guideline on diagnosing preterm labour (1.7) was not included in the scope of this update. However, the committee recognised that there may be new evidence relating to the prediction of when preterm labour is likely and the committee have highlighted this section as requiring an update. This information has therefore been passed to the

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					NICE surveillance team who are responsible for ensuring that guidelines are up to date.
NHS England / NHS Improvement	Guideline	013	009	All interventions included in the guideline to optimise babies prior to birth quote a lower gestation for use. This does not align with current thinking, evidence and recommendations from BAPM in relation to extreme prematurity. We would favour not quoting a lower limit or making clear that these interventions should definitely be offered from 24+0 and should be considered from earlier gestations	Thank you for your comment. The committee agreed that since 2015 the viability of babies born at 22 weeks has improved and so have made an editorial amendment to this recommendation to reduce the lower limit to 22+0 weeks. The committee did not agree that it was appropriate to remove the lower limit, as below 22 weeks viability was still very unlikely. The recommendations already state that corticosteroids should be offered from 24+0 weeks.
NHS England / NHS Improvement	Guideline	014	009	1.10.1 – This is aligned to our work and we agree on the measurement and specifics	Thank you for your comment and agreement with this recommendation.
NHS England / NHS Improvement	Guideline	018	019	1.14.2 - Wait at least 30 seconds, but no longer than 3 minutes is reference in the British Association for Perinatal Medicine (BAPM) toolkit but is not what we have suggested as a measure within our programme. *Proportion of babies less than 34+0 weeks gestation that receive optimal management of the cord (waiting 60 seconds before clamping the umbilical cord after delivery where feasible).*	Thank you for your comment. The section of the guideline on cord clamping was not included in the scope of this update, but the committee recognised that there may be new evidence relating to the optimal timing for cord-clamping and the committee have highlighted this section as requiring an update. This information has therefore been passed to the NICE surveillance team who are responsible for ensuring that guidelines are up to date. As the committee agreed that inappropriate timing of cord-clamping or milking the cord may be a safety issue they agreed to delete this recommendation and

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					amended the subsequent recommendation to state that usually clamping should be carried out after at least 60 seconds.
NHS England/NHS Improvement	Guideline	General	General	It has been raised by the NHSE LGBT staff network that the guidance included the attached wording. The following line has been raised as quite upsetting and badly worded in terms of trans inclusion: 'The guideline uses the terms 'women' or 'mother' throughout. These should be taken to include people who do not identify as women but are pregnant or have given birth'. Our team (the LGBT health team) have been working on several projects looking at trans and non-binary people's experiences of accessing maternity services, including a piece of work on inclusive language. This has involved considerable engagement with various groups and has been part of a conversation with other organisations such as RCM and RCOG, with the hope we can all move towards inclusive language together. We would really like to offer our support in the language used in this and other such documents. We recently worked to add a trans status question to the CQC Maternity services survey. This found that 1% of respondents reported that their gender	Thank you for your comment. The NICE editorial team are currently developing the policy to ensure the use of gender-neutral and more inclusive language where appropriate in NICE guidelines. As this policy has not yet been approved, we have been unable to make these changes in this guideline, but this will be implemented in future guidelines later in 2022.

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				was different that their sex registered at birth. This was a large proportion and reasserts the importance of including this group in our language and policy. I hope we can work with NICE to improve this language.	
Royal College of Midwives	Guidance	General	General	Although this consultation only require comments on the changes related to two particular interventions to prevent pre-term labour, we would strongly encourage to add an additional paragraph on the Continuity of carer model's positive impact on pre-term birth. This will also mirror the advice on the Green top guidelines regarding Continuity of carer. Midwifery continuity of care is the only health system intervention shown to reduce preterm birth (PTB) and improve perinatal survival. Consider reviewing the followings: https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1003350 https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD012505.pub2/full	Thank you for your comment. The committee discussed the fact that the recent Ockenden report has recommended the 'suspension of midwifery continuity of carer model until – and unless – safe staffing is shown to be present' and therefore the committee agreed not to add any advice relating to this to the guideline.

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Royal College of Midwives	Guidance	General	General	Health inequalities (especially linked to ethnicity and social deprivation) remain a serious cause of concerns for women and babies accessing maternity care in the UK. We suggest drawing data from the latest MBRRACE and the NMPA and focus on how to support and improve outcomes and address inequalities. MBRRACE (2021) Saving Lives, Improving Mother's Care. NMPA (2021) Ethnic and socio-economic inequalities in NHS maternity and perinatal care for women and their babies.	Thank you for your comment. The committee agreed to add details from the latest MBRRACE data relating to perinatal mortality for women from certain ethnic groups and deprived areas to the guideline, as you suggest and in line with other recent NICE guidelines for antenatal care, postnatal care and inducing labour.
Royal College of Midwives	Guidance	004	General	The RCM welcomes the updates in recommendations to the Pre-term labour and birth guidance. We suggest emphasising further the important role maternity healthcare professionals have in the decision-making process and how translation services MUST be used when having those discussions with women and their families who needs them.	Thank you for your comment. The section of the guideline on information and support contains a link to the NICE guideline on patient experience in adult NHS health services which includes details of how healthcare professionals should support people to make decisions, and on the use of interpreters. This information has not therefore been repeated in the recommendations. In addition, some information from the most recent MBRRACE report on perinatal mortality has been added to this section of the guideline.

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				The information provided must be flexible, clear and culturally-relevant. Using some of the INFORMATION from the MBRRACE lay summary can be helpful to tailor the advice.	
Royal College of Nursing	Guideline	General	General	We do not have any comments to add on this consultation. Thank you for sending.	Thank you for your support for the new recommendations.
Royal College of Obstetricians and Gynaecologists	Guideline	General		In answer to the questions posed by NICE – the main challenge is going to be the cost implications and drug availability for a huge rise in progesterone prescription – offer the drug to all women with a prior PTB.	Thank you for your comment. The recommendations about the use of progesterone were not amended as part of this update, and so there are no cost implications as a result of this update.
Royal College of Obstetricians and Gynaecologists	Guideline	004	017	This suggests explaining to women the long term complications associated with preterm birth. In the context of someone in labour, where the effect of tocolysis is modest as best, I think this would go against the earlier 1.1.1 recommendation that women may be anxious. There is little that can be done to alter the situation for the woman once in established PTL – apart from the risk mitigating steps that are described below. I can see how at perivaibilty gestation that this might influence the decision for active resuscitation vs comfort care, but applying this to all PTB I think may leave psychological harm for the family. Would it be worth splitting these recommendations between those with planned PTB vs those in pre term labour.	Thank you for your comment. The recommendation suggests the topics that should be included in the discussion, and these are all valid for any preterm birth. However, the detail of that information would need to be tailored to each individual situation and would depend on the gestational age of the baby.

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Royal College of Obstetricians and Gynaecologists	Guideline	005	016	For this population the size of the benefit from prog and cerclage are implied to be equal. I am unsure if this is the case.	Thank you for your comment. The recommendations on progesterone and cerclage were not within the scope of this update. However, the committee were aware that since this update was carried out new evidence relating to the use and timing of cerclage may have become available. The committee have therefore highlighted this section as requiring an update. This information has therefore been passed to the NICE surveillance team who are responsible for ensuring that guidelines are up to date.
Royal College of Obstetricians and Gynaecologists	Guideline	005	018	The stated gestation of 34+0 appears to be at odds with that of 34+6. In the recently published RCOG Green-top guideline 74: Antenatal corticosteroids to reduce neonatal morbidity and mortality. This needs to be clarified and/or aligned to avoid any confusion at the front line of clinical delivery of care, especially as the Green-top guideline is described as a supplement to the NICE guidance.	Thank you for your comment. The cut-of point of 34+0 weeks (above which maternal corticosteroids should be considered, not offered)was based on evidence which was analysed in a sub-group of 34 to 36 weeks. This contrasts with RCOG who analysed in a sub-group up to 34+6 weeks. As this section of the guideline was not included in the scope of this update, the committee were unable to change this but have highlighted this section as requiring an update. This information has therefore been passed to the NICE surveillance team who are responsible for ensuring that guidelines are up to date.
Royal College of Obstetricians and	Guideline	005	020	It would be beneficial to the reader to add the specific weight in grams that the birthweight is reduced by rather than by stating the reduction is small, to give context for the reader.	Thank you for your comment. The weight in grams by which the birthweight is reduced has now been included in the rationale section to give the reader context. The mean difference for the overall

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Gynaecologists					estimate (all studies pooled together) is 114 grams.
Royal College of Obstetricians and Gynaecologists	Guideline	005	020	Regarding birthweight reduction it would be useful to add some data about how birthweight correlates with likelihood of neonatal complications (separate from gestational age) i.e. to give the reader an idea of whether the birthweight reduction actually affects overall prognosis.	Thank you for your comment. Unfortunately it is not possible to comment on whether birthweight reduction correlates with neonatal complications, as the neonatal outcomes were not stratified by birthweight (as per the protocol). The impact of repeat courses of maternal corticosteroids on the neonatal outcomes, chronic lung disease, intraventricular haemorrhage, growth at 2 years, neurodevelopmental delay were reported and the committee also commented on the need for respiratory support.
Royal College of Obstetricians and Gynaecologists	Guideline	005	022 - 026	This statement is somewhat vague and does not convey enough of the meaningful information outlined in the narrative of pages 26 (line 18 – 28) and 27 (line 1-9). It may be more helpful to simply express caution for gestations of less than 30 weeks and when fetal growth restriction is evident.	Thank you for your comment. This recommendation has been amended to advise caution in gestations of less than 30 weeks and in babies with suspected growth restriction, as you suggest.
Royal College of Obstetricians and Gynaecologists	Guideline	005	023	"higher doses" – could you please state what is meant by higher doses – what actual dose is the document referring to?	Thank you for your comment. The rationale section has been clarified to state that higher doses refers to more than 24 mg of total dose of repeat course, as indicated by the evidence.
Royal College of Obstetricians and	Guideline	005	027	The stated maximum of 2 courses of corticosteroids is at odds with the 3 courses stated in Table 11 (page 21) of the recently published RCOG Green-top guideline 74. As mentioned earlier, further	Thank you for your comment. The committee are aware of the discrepancy with the recommendation in GTG 74. Owing to the paucity of evidence around the optimal number of

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Gynaecologists				clarification and/or alignment would help to minimise any confusion.	courses, this recommendation and that in GTG 74 were based on the evidence and expert opinion. The committee discussed the benefits and harms and agreed the evidence did not support the use of more than 2 courses of corticosteroids due to associated reductions in birthweight.
Royal College of Obstetricians and Gynaecologists	Guideline	005	029	Could you please check if 'consider' is the appropriate wording? This suggests less strength of recommendation compared to recommendation 1.2.1 where it says 'offer'	Thank you for your comment. 'Consider' is the term used in NICE guidelines to reflect a recommendation where the evidence is less certain, whereas 'offer' is used where there is a better degree of certainty. In this case the use of 'consider' and 'offer' is appropriate and reflects the evidence.
Royal College of Obstetricians and Gynaecologists	Guideline	007	015	I would suggest 'a plan is in place' could be reworded to 'a plan is made'	Thank you for your comment. The committee have made an editorial change to 'a plan is made and documented'.
Royal College of Obstetricians and Gynaecologists	Guideline	007	015	The phrase used in the recommendation 'she should return' strongly implies that in this situation the woman should be discharged from hospital. Admission for observation may be the more appropriate course of action in some cases particularly with earlier gestation and non-cephalic presentation. Would it be clearer to say 'should be reassessed' which then does not imply anything	Thank you for your comment. The committee have made an editorial change to 'should be reassessed' as you suggest.

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Royal College of Obstetricians and Gynaecologists	Guideline	007	026	In a co-amoxiclav statement it says as prophylaxis for intrauterine infection. I wonder if it would be clearer and more consistent to state that here also.	Thank you for your comment. The committee have made an editorial change and added in 'as prophylaxis for intrauterine infection'.
Royal College of Obstetricians and Gynaecologists	Guideline	009	015	I would suggest 'a plan is in place' could be reworded to 'a plan is made'	Thank you for your comment. The committee have made an editorial change to 'a plan is made and documented'.
Royal College of Obstetricians and Gynaecologists	Guideline	010	016	Are there any caveats for this recommendation which are dependent on the fetal presenation?	Thank you for your comment. The section of the guideline on diagnosing preterm labour was not included in the scope of this update. However, the committee recognised that there may be new evidence and the committee have highlighted this section as requiring an update. This information has therefore been passed to the NICE surveillance team who are responsible for ensuring that guidelines are up to date.
Royal College of Obstetricians and Gynaecologists	Guideline	011	021	As I read the recommendations in this section, I found the position of the phrase not to use FFN and Cx length in combination rather awkward where it is position towards the end. I would suggest, that reading this AFTER the prior recommendations could lead to confusion. I wonder if it could be stated beforehand. Perhaps the recommendations first off if neither	Thank you for your comment. The section of the guideline on diagnosing preterm labour was not included in the scope of this update. However, the committee recognised that there may be new evidence and the committee have highlighted this section as requiring an update. This information has therefore been passed to the NICE surveillance team who are responsible for

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				FFN not Cx length available are first, then the statement about avoiding combinations of assessment. Then this followed by action with FFN result only. And action followed by Cx length.	ensuring that guidelines are up to date, and this update will include any necessary rewording or reordering of the recommendations.
Royal College of Obstetricians and Gynaecologists	Guideline	012	013	The erythromycin dose, and Mg SO4 dose is stated elsewhere. Is there a similar dose for nifedipine which could be included here?	Thank you for your comment. The dose of nifedipine for tocolysis is now included in the BNF and so has not been included in the guideline.
Royal College of Obstetricians and Gynaecologists	Guideline	012	019	It is reasonable to avoid the use of tocolysis, particularly in centre with Level 3 neonatal care available? The recommendation suggest it should always be given, especially in later pre term gestations where the likely benefits are less.	Thank you for your comment. The recommendations on whether or not to start tocolysis already include consideration of the availability of an appropriate level of neonatal care and so the committee did not make any changes to these recommendations.
Royal College of Obstetricians and Gynaecologists	Guideline	014	001	This seems like a very extremely subdivided rephrase of discuss 'benefits and risks'. I am unsure why this was emphasised in this way for this intervention.	Thank you for your comment. An editorial change has been made to 'benefits and risks' as you suggest.
Royal College of Obstetricians and Gynaecologists	Guideline	015	012	I wonder if 'think about' could be replaced with 'consider'	Thank you for your comment. The committee agreed that if a woman developed signs of renal failure, there was a risk of hypermagnesaemia, which in turn could lead to cardiac conduction defects, neuromuscular effects and muscle weakness. The committee therefore agreed that the wording 'think about' was not strong enough

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					and the dose of magnesium should be reduced or stopped, and so have made an editorial amendment to state this.
Royal College of Obstetricians and Gynaecologists	Guideline	018	001	I wonder if '*midline* uterine incision' is preferable to *vertical* uterine incision. Perhaps any incision which is not in the lower uterine segment is the more encompassing term which carries with it the risk to future pregnancy.	Thank you for your comment. The committee agreed that vertical uterine incision emphasised that this was not in the lower uterine segment and so did not make the change you requested. However, they were aware that this type of incision may be referred to as a 'classical' incision and so added that to the recommendation for clarity.
Royal College of Obstetricians and Gynaecologists	Guideline	018	015	Milking the cord may have benefit at certain gestations when delayed cord clamping may not be possible. However there is a risk of harm/ICH/sudden volume shifts at very pre term gestations. This recommendation if followed may lead to harm with this mechanism.	Thank you for your comment. The section of the guideline on cord clamping was not included in the scope of this update, but the committee recognised that there may be new evidence relating to the optimal timing for cord-clamping and the committee have highlighted this section as requiring an update. This information has therefore been passed to the NICE surveillance team who are responsible for ensuring that guidelines are up to date. As the committee agreed that inappropriate timing of cord-clamping or milking the cord may be a safety issue they agreed to delete this recommendation and amended the subsequent recommendation to state that usually clamping should be carried out after at least 60 seconds.
Royal College of	Guideline	018	015	Is the term Optimal Cord Clamping preferred by the BAPM to Delayed Cord Clamping.	Thank you for your comment. The term 'delayed cord clamping' has not been used in this

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Obstetricians and Gynaecologists					guideline, which just refers to 'timing of cord-clamping'.
Royal College of Obstetricians and Gynaecologists	Guideline	026	017	Rec 1.9.2 and 1.9.3 – the gestations suggested for giving steroids are not consistent with the latest RCOG guideline on antenatal cortical steroids (Green-top guideline no. 74)	Thank you for your comment. The committee were aware that the cut-of point of 34+0 weeks (above which maternal corticosteroids should be considered, not offered) was based on evidence which was analysed in a sub-group of 34 to 36 weeks. This contrasts with data used by RCOG which was analysed in a sub-group up to 34+6 weeks, and this led to the differences between the NICE guideline and the RCOG guideline. The other difference relates to the upper cut-off limit of 35+6, whereas RCOG advises 36+6. However, this RCOG recommendation is based on very low quality evidence and the RCOG guideline qualifies this recommendation with the caveat 'in very late preterm gestation women (from 35+0 weeks) the use of antenatal corticosteroids should be considered in light of the balance of risks and benefits'. As this section of the guideline was not included in the scope of this update, the committee were unable to change these limits but have highlighted this section as requiring an update. This information has therefore been passed to the NICE surveillance team who are responsible for ensuring that guidelines are up to date.

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Royal College of Paediatrics & Child Health	Guideline	General	General	Useful information provided with up-date relevant issues covered	Thank you for your support for the new recommendations.
Royal College of Paediatrics & Child Health	Guideline	013 Full	009 1.9.2	The Draft document states "Offer steroids between 34-35+6 weeks" The NICHD 2016 RCT looked at women between GA 34-36+5 wks. There was a significant reduction in severe respiratory neonatal outcomes although more risk of neonatal hypoglycaemia. However the authors state "there were no reported adverse events related to hypoglycemia, which was not associated with an increased length of hospital stay. Infants with hypoglycaemia were discharged on average 2 days earlier than those without hypoglycemia, which suggests that the condition was self-limiting" Gyamfi-Bannerman C, Thom EA, Blackwell SC, Tita ATN, Reddy UM, Saade GR et al. for the NICHD Maternal-Fetal Medicine Units Network. Antenatal Betamethasone for 612 Women at Risk for Late Preterm Delivery. N Engl J Med 2016;374:1311–20 The authors of the NICHD trial performed a secondary analysis and argued that giving antenatal betamethasone at GA 34 to 36+5 weeks was "associated with a statistically significant decrease in health care costs and with improved	Thank you for your comment. The committee noted that the guideline already includes a recommendation for maternal corticosteroids to be considered (although not offered) up to 36+5 weeks. As this section of the guideline was not included in the scope of the update and the committee had not reviewed the evidence they therefore did not agree to change this to an 'offer' recommendation. However, the study you have referenced has been passed to the NICE surveillance team who are responsible for ensuring that guidelines are up to date.

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				outcomes; thus, this treatment may be an economically desirable strategy." Gyamfi-Bannerman C, et al. Cost-effectiveness of Antenatal Corticosteroid Therapy vs No Therapy in Women at Risk of Late Preterm Delivery. A Secondary Analysis of a Randomized Clinical Trial. JAMA Pediatr 2019; 173(5):462-468.	

**None of the stakeholders who comments on this clinical guideline have declared any links to the tobacco industry.*