

#### Consultation on draft guideline - Stakeholder comments table

#### 02/04/2019 to 30/04/2019

Stakeholder	Document	Page No	Line No	Comments	Developer's response
BHIVA	Guideline	General	General	BHIVA recommends the need to conduct routine antenatal HIV testing.	Thank you for your comment. Routine antenatal screening is out of scope for this guideline update, but is recommended to be offered to all pregnant women in NICE CG 62 (Antenatal care for uncomplicated pregnancies).
BMFMS	Guideline	5	11-30	The iPd meta analysis is currently being done on the use of progesterone to prevent preterm delivery. There is a significant chance that this will concur with the Norman results and therefore not show benefit of the use of progesterone. There is therefore a significant chance that this update will be out of date by the time (or shortly after) it is published.	Thank you for your comment, which has been passed to the NICE surveillance team which monitors guidelines to ensure that they are up to date.
BMFMS	Guideline	5	23	The evidence presented demonstrates that progesterone may give modest benefit in terms of prolonging pregnancy but no evidence of long term benefit. Given that lack of long term benefit and the heterogeneous nature of the evidence (with the largest study which was conducted in the UK) not showing benefit, it is surprising that NICE is recommending progesterone for women with either a history of mid-trimester loss or a short cervix but not offering (or even considering cerclage) in this group of women.	Thank you for your comment. The analysis of progesterone included a standard meta-analysis of published evidence, weighted according to the variance of the effect estimate from the individual studies. The committee noted that the OPTTIMUM study showed no statistically significant evidence of benefit for women with a variety of risk factors for preterm birth, but considered that the evidence of benefit for the specific subgroups of women (with either previous preterm birth or a short cervical length) was such that it was reasonable to offer progesterone to these women. Consideration of cerclage was out of scope for this guideline update, therefore the evidence was not



### Consultation on draft guideline - Stakeholder comments table

#### 02/04/2019 to 30/04/2019

					reviewed and the committee were unable to make recommendations regarding this.
BMFMS	Guideline	6	7	History of cervical trauma is too vague to be helpful. We would suggest that the sentence could be made clearer by including the phrase "including large loop excision of the transformation zone (LLETZ)"	Thank you for your comment. The definition of cervical trauma was omitted from the "terms used in this guideline" section of the guideline. This has now been corrected, and states "physical injury to the cervix including surgery; for example previous cone biopsy (cold knife or laser), large loop excision of the transformation zone (LLETZ) – any number) or radical diathermy."
Lactation Consultants of Great Britain and the Association of Naturopathic Practitioners	Evidence review	Page 16	Lines 33-35	<ul> <li>Risk factors for pre-term labour are mentioned purely as a diagnosis of physiological markers and issues and that had already occurred – and issues are not risks, by definition.</li> <li><i>"No subgroup analysis was possible for women with the other risk factors identified in the review protocol – preterm pre-labour rupture of the membranes, mid-trimester bleeding, previous cervical trauma or surgery or a positive fetal fibronectin test."</i></li> <li>There is no information about what might predispose a woman to these issues occurring in her pregnancy.</li> <li>Pre-term labour does not occur in a vacuum – these guidelines do not address any of the antecedents, triggers or drivers that are the true risk factors likely to result in pre-term labour. Therefore, in their current draft, the guidelines miss the opportunity to inform and</li> </ul>	Thank you for your comment. The committee identified clinical factors which would be considered as resulting in an increased risk of preterm labour for this review, in order to assess the efficacy of prophylactic progesterone. Whilst the committee agreed that there may be a variety of predisposing risks, a full review considering the wider issues which may contribute to preterm birth was out of scope for this update, therefore the committee were not able to make recommendations regarding this.

#### Consultation on draft guideline - Stakeholder comments table

02/04/2019 to 30/04/2019

				02/04/2019 to 30/04/2019	
				guide health professionals to take whatever steps they can to intervene, to reduce the risks for the vulnerable pregnant women in their care.	
Lactation Consultants of Great Britain and the Association of Naturopathic Practitioners	Guideline	General	General	Nutrition Although a balanced diet is generally accessible in industrialized countries, a switch to a high-fat and low-quality diet has led to an inadequate vitamin and mineral intake during pregnancy, so that recent data show the micronutrient intake and supplementation to be lower than recommended even in high-income countries, particularly for iron, folic acid, calcium and vitamin D3. Currently, even if there is insufficient evidence to support routine supplementation at the population level, we need to reduce the risk of pre-term labour and small for gestational age infants. We need to address the overall nutritional status of populations, women of reproductive age and especially pregnant women in impoverished areas. This should be an urgent priority. (Parisi, 2014) Parisi et al (2014) recommend that the new goal in industrialized countries needs to be an individualized approach that takes account of the phenotypic, genotypic and metabolic differences among individuals of the same population.	Thank you for your comment. Addressing possible risk factors for preterm birth (including nutritional issues) was out of scope for this update, therefore the committee were not able to make recommendations regarding this. Nutritional issues in pregnancy are currently managed through Department of Health recommendations based on advice from the Scientific Advisory Committee of Nutrition (SACN). This includes vitamin D, iron and folic acid.



#### Consultation on draft guideline - Stakeholder comments table

#### 02/04/2019 to 30/04/2019

1	1	1	T		
Lactation	Guideline	General	General	<ul> <li>Parisi, F., Laoreti, A. and Cetin, I. (2014).</li> <li>Multiple Micronutrient Needs in Pregnancy in Industrialized Countries. <i>Annals of Nutrition</i> <i>and Metabolism</i>, 65(1), pp.13-21.</li> <li><u>https://www.ncbi.nlm.nih.gov/pubmed/252</u> <u>27491</u></li> <li><b>1. Which areas will have the biggest</b></li> </ul>	Thank you for your comment. Addressing possible
Consultants of Great Britain and the Association of Naturopathic Practitioners				<ul> <li>impact on practice and be challenging to implement? Please say for whom and why?</li> <li>A better integration between Health and Social Care would be more likely to pick up the women who are at risk of pre-term labour because their social conditions are driving their poorer health conditions. This would be challenging to implement because of the split between Health and Social Care, when they are more like two sides of the same coin.</li> <li>It would be most challenging for the NHS and Public Health England to re-integrate.</li> <li>However, that is the driver behind prevention and the new focus of the NHS Long Term Plan.</li> <li>integration and coordination drive improved health and reduce both acute and long term costs.</li> </ul>	risk factors for preterm birth was out of scope for this update, therefore the committee were not able to make recommendations regarding this.
					Thank you for your comment. Addressing the root causes of preterm birth was out of scope for this



#### Consultation on draft guideline - Stakeholder comments table

02/04/2019 to 30/04/2019	04/2019 to 30/0	04/2019
--------------------------	-----------------	---------

				<ul> <li>2. Would implementation of any of the draft recommendations have significant cost implications?</li> <li>My concern is that the draft recommendations would maintain the status quo. The cost implications would be just as expensive and basically money-wasting and Quality of Life reducing for mothers, babies and health professionals alike, because the root causes of pre-term labour are not being addressed or mitigated.</li> </ul>	update, therefore the committee were not able to make recommendations regarding this.
Lactation Consultants of Great Britain and the Association of Naturopathic Practitioners	Guideline	General	General	<ul> <li>What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)</li> <li>A fundamental accounting and budgeting error has been introduced by splitting Social Care</li> </ul>	Thank you for your comment. Unfortunately the allocation of funding and integration of health and social care is beyond the scope of this guideline update.



#### Consultation on draft guideline - Stakeholder comments table

02/04/2019 to 30/04/2019

02/04/2019 to 30/04/2019	
and Health budgets. Re-Integration of Health	
and Social Care may be difficult, but it is	
unlikely to be worse than the poorer health	
consequences of the splitting that has taken	
place.	
Giving local councils the rights over social care	
finances without the responsibility of the	
impact on outcomes was well-intentioned in	
terms of self-determination but ultimately	
detrimental in terms of public health.	
Community outreach services have been cut	
due to public spending cuts in local councils.	
The councils make cuts to services to balance	
their books in line with central government	
spending cuts on local budgets. The many	
tangible and intangible savings that these local	
services make - never appear back in the	
Council accounting books. The benefits mean	
less strain on their local NHS services and the	
savings occur there, but are unseen. The cost	
saving benefits can neither be accounted for	
nor spent.	
When these Social Care services are cut, the	
council only see the savings in their budgets.	
They do not see (in their Social Care	
accounting books) that it is their local NHS that	
picks up the bill when people require more	
primary and urgent secondary care.	
Councillors may be well aware of it, but they	
counteries may be were aware of it, but they	



### Consultation on draft guideline - Stakeholder comments table

02/04/2019 to 30/04/201	9
-------------------------	---

			,	02/04/2019 to 30/04/2019	
				are pressured by the government and their constituents to balance their books, so they do. The NHS prime objective is to care for the sick – so they have no choice but to spend the money or turn sick people away. Hence many NHS trusts are in deficit. This has implications for pre-term labour as it does for all other health conditions. There are examples of good practice and integrated care in the UK, but currently they are few and far between. The NHS Long Term Plan is predicated on integration but in the review sessions I listened to, no-one in that room was quite sure how to make it happen. I hope that the authors of the Long Term Plan have examples of good practice on which to build.	
Lactation Consultants of Great Britain and the Association of Naturopathic Practitioners	Guideline	19	Lines 7- 9	Risk mitigation for pre-term labour? The only reference I could find on risk mitigation was to progesterone, on page 19, lines 7-9. <i>"There is good evidence for the use of</i> <i>progesterone to reduce preterm birth, however</i> <i>studies do not define the optimal gestational</i> <i>age that this treatment should be started and</i> <i>stopped."</i> If there is there any guidance for health professionals on identifying women at higher	Thank you for your comment. Identification of risk factors for preterm labour was out of scope for this guideline update, therefore the evidence was not reviewed and we are unable to make the changes that you suggest. However, your comment has been passed to the NICE surveillance team which monitors guidelines to ensure they are up to date.



### Consultation on draft guideline - Stakeholder comments table

02/04/2019 to 30/04/2019

UZ/U4/2019 to 30/04/2019	
risk for premature labour and how to reduce that risk, it would be sensible to include it, or at least reference / provide links to where this information already exists.	
The majority of pre-term births occur in women living in socially adverse conditions, even in the UK. Sadly, women with fewer years of formal education, unsupported and / or on low incomes, BAME populations and refugees are more likely to be living in adverse conditions.	
Women's health care providers are increasingly aware that chronic stressors such as poverty, ongoing perceived stress and anxiety, intimate partner violence, and experiences of racism - are associated with an increased incidence of preterm birth. The prevalence rates of preterm delivery in cases with food insecurity, stress, and inadequate prenatal care were 2, 9.1 and 13.2 times higher than those who did have food security, did not experience stress, and received adequate care during pregnancy. (Dolatian et al, 2018)	
While it is difficult within the NHS to help women who do not attend pre-natal care, for those that do attend, food insecurity, partner violence and stress can be asked about gently and referral to local support groups and	



#### Consultation on draft guideline - Stakeholder comments table

02/04/2019 to 30/04/2019

02/04/2019 to 30/04/2019	
possibly outreach community services	
encouraged, where they exist.	
Many women who are hospitalised during	
pregnancy are extremely anxious. These	
women are, by nature of the reasons for their	
hospitalisation – those most likely to deliver	
prematurely. It is these most	
vulnerable women who are less optimistic and	
(probably realistically) see their health as poor.	
Health care professionals may not be aware of	
how anxious women are, and women and their	
hospital caregivers had poor agreement on	
ratings of the woman's health status. (Barber	
et al, 2015)	
Midwives are well placed to help women by	
recognising their distress, supporting informed	
optimism, and guiding women toward realistic	
coping strategies and using existing social	
support networks. (Latendresse G, 2009)	
Dolatian, M., Sharifi, N. and Mahmoodi, Z.	
(2018). Relationship of socioeconomic status,	
psychosocial factors, and food insecurity with	
preterm labor: A longitudinal	
study. International Journal of Reproductive	
<i>BioMedicine</i> , 16(9), pp.563-570.	
https://www.ncbi.nlm.nih.gov/pubmed/306	
<u>43863</u>	
Barber, C. and Starkey, N. (2015). Predictors	
of anxiety among pregnant New Zealand	
women hospitalised for complications and a	



#### Consultation on draft guideline - Stakeholder comments table

02/04/2019 to 30/04/2019

				02/04/2019 (0 30/04/2019	
				community comparison group. <i>Midwifery</i> , 31(9), pp.888-896. <u>https://www.ncbi.nlm.nih.gov/pubmed/259</u> <u>87104</u> Latendresse, G. (2009). The Interaction Between Chronic Stress and Pregnancy: Preterm Birth from A Biobehavioral Perspective. <i>Journal of Midwifery &amp; Women's</i> <i>Health</i> , 54(1), pp.8-17. <u>https://www.ncbi.nlm.nih.gov/pubmed/191</u>	
Poole Hospital NHS Foundation Trust	Guideline	General	General	<u>14234</u> GBS prophylaxis needs to be considered RCOG guideline on 'Prevention of Early-onset Neonatal Group B Streptococcal disease 'recommends Intra partum Antibiotic prophylaxis in confirmed preterm labour.	Thanks you for your comment. Prophylactic antibiotics for GBS are covered by NICE CG 149 (Neonatal infection (early onset): antibiotics for prevention and treatment) and we have added a cross-reference to the guideline as recommendation 1.11.1
Poole Hospital NHS Foundation Trust	Guideline	1	General	We are concerned that this recommendation may imply to all PTB inclusive of singleton and twins, It would be more appropriate to 'preterm labour and birth for singleton pregnancy' as topic	Thank you for your comment. This review includes data from women with singleton pregnancy (multiple pregnancy was an exclusion criteria for trials), and the use of prophylactic progesterone for women with multi-fetal pregnancy is covered by NICE CG 129.
Poole Hospital NHS Foundation Trust	Guideline	5	15	A history of spontaneous preterm birth between before 37 weeks (specified the gestation) or mid trimester loss between 16+0 and 34+0 weeks of pregnancy.	Thank you for your comment. We have amended the wording of this recommendation for greater clarity, and it now states "a history of spontaneous preterm birth (up to 34+0 weeks of pregnancy) or mid-trimester loss (from 16+0 weeks of pregnancy onwards)"

### Consultation on draft guideline - Stakeholder comments table

02/04/2019 to 30/04/2019

				02/04/2019 to 30/04/2019	
Poole Hospital NHS Foundation Trust	Guideline	5	26	<ul> <li>This recommendation will be a challenging change in practice because it implies that a TVS should be carried out to all women at high risk of PTB. This is not a standard practice yet, how are we capturing this group of women? should NICE consider a risk assessment tool and offer TVS cx- length scan? OR</li> <li>All singleton gestations should have TVU CL Screening in second trimester? (ref: Am J Obstet Gynaecol and society of maternal and fetal medicine 206, 376-386 2012 by Berghella V.) given the fact that there is a good evidence for the use of progesterone to reduce preterm birth. OR</li> <li>to state, 'results from TVS carried out between 16+0 and 24+0 weeks with prior PTB and/or cervical trauma show a cervical length of 25mm or less.</li> <li>Q: What is the best practice for Transvaginal USS for cx length measurement? A single measurement of &lt;25mm or average of 3 measurement is &lt;25mm? to avoid variation in measurement. Is there any strict quality criteria?</li> </ul>	Thank you for your comment. The use of transvaginal ultrasound to screen for women at risk of preterm birth was out of scope for this guideline update, therefore the committee were unable to make recommendations regarding which women should be offered screening and the technique used for screening. As some advice regarding the use of cervical length scanning is present in the Saving Babies' Lives care bundle, a link to this document has now been added to the evidence report. We will also pass the information and references you have supplied to the NICE surveillance team which monitors guidelines to ensure that they are up to date.
Poole Hospital NHS	Guideline	9	21-26	What is the rationale in management of women is different from 29+6 weeks to 30+0 weeks in suspected preterm labour?	Thank you for your comment. Assessment and management of preterm labour was out of scope for this guideline update, therefore the evidence was not reviewed and we are unable to make the changes



#### Consultation on draft guideline - Stakeholder comments table

02/04/2019 to 30/04/2019

				02/04/2019 to 30/04/2019	
Foundation Trust				It states that if the clinical assessment suggests that the women is in suspected preterm labour and she is 29+0 weeks pregnant or less, advise treatment for preterm labour?	that you suggest. However, your comment has been passed to the NICE surveillance team which monitors guidelines to ensure that they are up to date.
				Does the clinical assessment is adequate? Does it result in over treatment with antenatal corticosteroids? (especially timing of steroids matters)	
Poole Hospital NHS Foundation Trust	Guideline	9	20	Question 3: Needs some clarity on cervical assessment by digital examinations? If clinical assessment suggests established labour if digital examination confirms cervical dilatation is more than 4 cm dilated with regular contractions, confirms an established Preterm labour. Should we consider Transvaginal cervical length or Fibronectin? If clinical assessment suggests threatened labour If digital examination confirms cervical dilatation is less than 4 cm dilated with persistent symptoms, should we offer TVU cx length if available or Fibronectin?	Thank you for your comment. Assessment and management of preterm labour was out of scope for this guideline update, therefore the evidence was not reviewed and we are unable to make the changes that you suggest. However, your comment has been passed to the NICE surveillance team which monitors guidelines to ensure that they are up to date.
Poole Hospital NHS Foundation Trust	Guideline	12	10-15	1.9.2 and 1.9.3 - can be consolidated to one paragraph	Thank you for your comment. These two recommendations have been amalgamated into a single recommendation, as you suggest.

### Consultation on draft guideline - Stakeholder comments table

02/04/2019 to 30/04/2019

		 02/04/2019 to 30/04/2019	
Royal College of Midwives	Evidence review A General		Thank you for your comment. Unfortunately a review of cerclage or pessary was out of scope for this guideline update and therefore the committee were not able to make recommendations regarding this. Your comments regarding the IPD analysis have been passed to the NICE surveillance team which monitors guidelines to ensure that they are up to date. The committee agreed that determining which women are most at risk of preterm birth can be challenging. However, the risk factors for preterm birth that were included in this review were based on the committee's experience, and those risk factors which have been studied in trials assessing the efficacy of prophylactic progesterone. However, the committee agreed that care must be individualised and the guideline recommends discussing the risks and benefits of prophylactic treatment with the woman and taking her preferences into account (recommendation 1.2.1)



#### Consultation on draft guideline - Stakeholder comments table

02/04/2019 to 30/04/2019

				02/04/2019 10 30/04/2019	
				<ul> <li>what circumstances, each intervention will be most effective. Care must, therefore, always be individualised, taking into account the women's wishes, and following a discussion with a clinician able to discuss the potential risks and benefits of each intervention." (p.63, https://www.england.nhs.uk/publication/saving- babies-lives-version-two-a-care-bundle-for- reducing-perinatal-mortality/).</li> <li>Shennan, A.H. and Suff, N., 2018. Inconclusive evidence for optimal preterm birth prevention. BJOG: An International Journal of Obstetrics &amp; Gynaecology. Thornton, J., 2016. Progesterone for preterm labour. BJOG: An International Journal of Obstetrics &amp; Gynaecology, 123(12), pp.2000-</li> </ul>	
Royal College of Midwives	Guideline	General	General	2000. The need for individualised care needs to be emphasised throughout the guidance document and not just in the disclaimer at the beginning (which is seldom referred to practice).	Thank you for your comment. The committee agree that care should be individualised, but considered that adding this throughout the guideline would lead to unnecessary repetition rather than further clarity.
Royal College of Midwives	Guideline	General	General	The guideline does not address thoroughly the issue faced by some women that will need to be moved to another hospital depending on the prematurity of their baby. The neonatal review was very clear that babies should be born in the right place (as of course they should) and the implication of that is that women will be moved. For women this is often a source of distress as they may find themselves giving birth in an unexpected place	Thank you for your comment. Considering place of care was out of scope for this update, therefore the committee were not able to make recommendations regarding this.

#### Consultation on draft guideline - Stakeholder comments table

02/04/2019 to 30/04/2019

				02/04/2019 to 30/04/2019	
				or ending up in a different unit to their baby. The London SCN have produced guidance on babies being born in the right place: <u>http://www.londonscn.nhs.uk/wp-</u> <u>content/uploads/2018/11/FINAL-Pan-London-</u> IUT-Guidance.pdf	
Royal College of Midwives	Guideline	5	18	Definition of short cervix: The decision to change the definition of a short cervix to ≤ 25 mm is not in line with the first NHS commissioning guideline on preterm birth or the revised Saving Babies Lives Care Bundle (published March 2019) (https://www.england.nhs.uk/publication/saving -babies-lives-version-two-a-care-bundle-for- reducing-perinatal-mortality/; https://www.tommys.org/sites/default/files/Pret erm%20birth%20guidelines.pdf). As these are likely to become the most widely used, this decision should be reconsidered.	Thank you for your comment. The evidence identified for this review included women with a cervical length of less than or equal to 25mm, therefore the recommendations reflect this. Whilst there is a subtle difference between this cut-off (less than or equal to 25mm) and that used in the Saving Babies Lives Care Bundle (less than 25mm), the recommendations are not opposed to each other.
Royal College of Midwives	Guideline	9	21	1.7.3 - Treat-all strategy for TPTL <30/40: This paragraph is shaded in grey therefore you may not accept this comment. We suggest a review as this guideline continues to advocate a treat- all strategy for women with symptoms of TPTL under 30 weeks gestation without reference to either of the two most reliable tests, CL or fetal fibronectin. This was a surprising recommendation from the first publication and not one that experts in the field support. It will have undoubtedly have led to unnecessary hospital admissions and interventions, in-utero transfers, antenatal bed and neonatal cot blocking, which can result in more dangerous	Thank you for your comment. Assessment and management of preterm labour was out of scope for this guideline update, therefore the evidence was not reviewed and we are unable to make the changes that you suggest. However, your comment has been passed to the NICE surveillance team which monitors guidelines to ensure that they are up to date.



#### Consultation on draft guideline - Stakeholder comments table

02/04/2019 to 30/04/2019

				ex-utero transfer. This all results in avoidable anxiety for women, separation from their families, and substantial, unnecessary, NHS expenditure. Results of the EQUIPTT study, due out in the next year, should be considered in the next review of this guideline (Watson et al. 2019). Watson, H.A., Carlisle, N., Kuhrt, K., Tribe, R.M., Carter, J., Seed, P. and Shennan, A.H.,	
				2019. EQUIPTT: The Evaluation of the QUIPP app for Triage and Transfer protocol for a cluster randomised trial to evaluate the impact of the QUIPP app on inappropriate management for threatened preterm labour. <i>BMC Pregnancy and Childbirth</i> , 19(1), p.68.	
Royal College of Obstetricians and Gynaecologi sts	Guideline	5	General	Prophylactic vaginal and prophylactic cervical cerclage. The updated recommendations seem sensible and are clear to understand.	Thank you for your comment.
Royal College of Obstetricians and Gynaecologi sts	Guideline	5	17	Does this cervical length also apply to those who have had LLETZ or cone biopsies?	Thank you for your comment. The evidence review did not identify studies conducted specifically in women with previous cervical surgery. However, in the absence of specific evidence, the guideline committee agreed that this cervical length would be an appropriate threshold to use for all women, regardless of previous surgery or not.



#### Consultation on draft guideline - Stakeholder comments table

02/04/2019 to 30/04/2019

	O de la la	0.7	0		
Royal College of Obstetricians and Gynaecologi sts	Guideline	6–7	General	The RCOG will soon publish a Green-top Guideline on the care of women with suspected PPROM. This refers to and is aligned with the NICE 2015 Preterm labour and birth guideline. I am satisfied that the proposed NICE update is still consistent with the soon-to-be published Green-top.	Thank you for your comment.
Royal College of Obstetricians and Gynaecologi sts	Guideline	8	27	Consider adding: That rescue cerclage might also allow a baby who might not otherwise make it beyond a pre- viable gestation to reach a gestation where it might survive but with long term impairment	Thank you for your comment. Rescue cerclage was out of scope for this guideline update, therefore the evidence was not reviewed and we are unable to make the changes that you suggest.
Royal College of Obstetricians and Gynaecologi sts	Guideline	9	General	I'm not clear why TVS isn't an option <30 weeks.	Thank you for your comment. Diagnosis and assessment of preterm labour was out of scope for this guideline update, therefore the evidence was not reviewed and we are unable to make the changes that you suggest. However, your comment has been passed to the NICE surveillance team which monitors guidelines to ensure that they are up to date.
Royal College of Obstetricians and Gynaecologi sts	Guideline	12	10	I agree with the change in wording from 'Consider' to 'Offer'. This reflects the current evidence and is now consistent with the soon- to-be published RCOG Green-top Guideline on PPROM. Better to change 'Offer maternal corticosteroids for women' to 'Offer maternal corticosteroids to women' to be consistent with recommendation 1.9.3	Thank you for your comment. The two recommendations have now been amalgamated into a single recommendation, and the wording use is as you describe ("offer maternal corticosteroids to women")
Royal College of	Guideline	General	General	The reviewer had no concerns with this draft guidance	Thank you for your comment.



#### Consultation on draft guideline - Stakeholder comments table

#### 02/04/2019 to 30/04/2019

	1		1		
Paediatrics and Child Health					
Royal College of Paediatrics and Child Health	Guideline	1.2.3	5 of 26	It may be helpful to provide comments on what the indications are (if there are any) for stopping prophylactic progesterone – i.e. at which stage of threatened preterm labour should this prophylaxis be discontinued	Thank you for your comment. The committee have given a suggested duration of treatment for prophylactic progesterone (until at least 34 weeks). The decision to discontinue treatment when a woman is in established preterm labour would be left to the discretion of the healthcare professional.
Royal College of Paediatrics and Child Health		1.9.2		Current NNAP standards state that 85% of eligible mothers should receive at least one dose of antenatal steroids; rather than the 80% which is quoted in this table.	Thank you for your comment. This has now been corrected to a target of 85%.
	Guideline	(Table 2)	26 of 26	RCPCH [2019], NNAP 2018 Annual Report on 2017 data [Online]. Available from <u>https://www.rcpch.ac.uk/sites/default/files/2018</u> <u>-</u> <u>10/2018 nnap report on 2017 data final v8.</u> <u>pdf</u> [Accessed April 2019] - see page 24	
Royal College of Physicians (RCP)	General	General	General	The RCP is grateful for the opportunity to respond to the above consultation. In doing so we would like to endorse the response submitted by the RCPCH. We have also liaised with our expert in obstetrics and although most of the content of this guideline is not relevant to physicians we would like to make the following comment.	Thank you for your comment. We have responded below, under the relevant entry.
Royal College of Physicians (RCP)	Guideline	12	23	Whether or not to use corticosteroids should take into account whether or not the woman has pre-existing or gestational diabetes and if	Thank you for your comment. We have now added a cross reference to the NICE guideline on managing diabetes in pregnancy, which makes

### Consultation on draft guideline - Stakeholder comments table

02/04/2019 to 30/04/2019

				given close monitoring of blood glucose and ketonaemia (if type 1 diabetes) is imperative	recommendations on the use of antenatal corticosteroids for women with diabetes.
UK National Screening Committee (UK NSC)	Guideline	Pg 5 (short)l	Line 13 and 23 Recom mendati ons 1.2.1 and 1.2.2	Thank you for giving the committee the opportunity of commenting on this guideline update. We are happy that the updated recommendations now are referring to women considered at an increased risk of pre-term birth. However, we are slightly concerned about the fact that there is not clarity on which women are referred to a transvaginal ultrasound scan between 16+0 and 24+0 weeks of pregnancy to measure cervical length. As you helpfully noted in the section 'Other factors the committee took into account' (pg17 line 24 full review update document) cervical scanning is not part of routine antenatal care in the UK, and recommendations on population screening are under the remit of the UK NSC. Therefore, we would like to suggest that you emphasise this by saying that cervical length measurements by ultrasound scan between 16+0 and 24+0 weeks of pregnancy are performed following a clinical concern, not as routine for every woman. It would also be helpful, if a note could be added about the fact that screening for pre-term labour is not	Thank you for your comment. We have now added some detail to the "rationale and impact" section, to state that there is variation in practice currently, and that cervical length scanning is offered due to clinical concern, rather than routinely. Identifying which women benefit from cervical length scanning was out of scope for this guideline update, therefore we are unable to make the other changes you suggest. However, we have now included a link to the Saving Babies' Lives care bundle in the evidence review, which provides some guidance as to which women should be offered cervical length scanning, and added a note to the evidence review regarding the role of the NSC.

### Consultation on draft guideline - Stakeholder comments table

02/04/2019 to 30/04/2019

			recommended by the UK NSC and it is one of the conditions that the UK NSC regularly reviews.	
University Hospital Southampton	5	13	<ul> <li>The benefit of progesterone has been decided on the background of lots of small studies (with the risk of P hacking) that they have given equal weight to and hence not followed the recent large recent study showing no benefit of progesterone and does not recommend its use (Norman et al 2018). This said the IPD analysis from Jane Norman is still awaited and should be out in September.</li> <li>Also they have suggested treatment for a women found to have a coincidental short cervix (i.e. those having a TV scan for placental localisation). There is good evidence that population screening is not effective and this group have a completely different risk which I think needs to be clear.</li> </ul>	Thank you for your comment. The analysis of progesterone included a standard meta-analysis of published evidence, weighted according to the variance of the effect estimate from the individual studies. The committee noted that the OPTTIMUM study showed no statistically significant evidence of benefit for women with a variety of risk factors for preterm birth, but considered that the evidence of benefit for the specific subgroups of women (with either previous preterm birth or a short cervical length) was such that it was reasonable to offer progesterone to these women. Your comments regarding the IPD analysis have been passed to the NICE surveillance team which monitors guidelines to ensure that they are up to date. The review did not consider whether population screening was an effective intervention, as this was out of scope for the update. However, the committee noted that several trials included in the results for "women with a short cervical length" included women with no other risk factors for preterm birth. Therefore they agreed that it was reasonable to consider prophylactic progesterone for women with an identified short cervical length but no other risk factors for preterm birth.



### Consultation on draft guideline - Stakeholder comments table

02/04/2019 to 30/04/2019

					Given the uncertainty in this area the committee also made research recommendations to address this issue.
West of England Academic Health Science Network	Guideline	12	5	The current guideline states for corticosteroids: <b>1.9 Maternal corticosteroids</b> 1.9.1 For women between 23+0 and 23+6 weeks of pregnancy who are in suspected or established 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. <b>[2015]</b> 1.9.2 Offer maternal corticosteroids for women between 24+0 and 25+6 weeks of 10 pregnancy who are in suspected or established preterm labour, are 11 having a planned preterm birth or have P-PROM. <b>[2015, amended 2019]</b> <b>Our suggestion is to add the same statement about considering</b>	Thank you for your comment. The committee agreed that there is an inconsistency in the current guideline regarding the use of corticosteroids and magnesium sulfate for women between 23+0 and 23+6 weeks. Therefore, a recommendation has been added to discuss the use of magnesium sulfate for women between 23+0 and 23+6 weeks who are in established preterm labour or having a planned preterm birth within 24 hours, to be consistent with the similar recommendation on the use of corticosteroids.



Consultation on draft guideline - Stakeholder comments table

02/04/2019 to 30/04/2019

02/04/2019 to 30/04/2019	 
Magnesium Sulphate 23+0 – 23+6 weeks, in consultation with the woman and family.Where active management is planned for babies below 24+0 weeks 	
<ul> <li>5.11 Magnesium sulphate to be offered to women between 24+0 and 29+6 weeks of pregnancy, and considered for women between 30+0 and 33+6 weeks of pregnancy, who are in established labour or are having a planned preterm birth within 24 hours.</li> <li>5.12 Ensure the neonatal team are involved when a preterm birth is anticipated, so that</li> </ul>	



### Consultation on draft guideline - Stakeholder comments table

02/04/2019 to 30/04/2019

02/04/2019 to 30/04/2019					
				they have time to discuss options with parents prior to birth and to be present at the delivery. 5.13 For women between 23 and 24 weeks of gestation, a multidisciplinary discussion should be held before birth between the neonatologist, obstetrician and the parents about the decision to resuscitate the baby. If resuscitation is agreed to be attempted, women should be offered magnesium sulphate and steroids timed according to the above recommended intervals to birth.	
West of England Academic Health Science Network	Guideline	13	4	The current guideline states for Magnesium Sulphate: <b>1.10 Magnesium sulfate for</b> <b>neuroprotection</b> 3 1.10.1 Offer intravenous magnesium sulfate for neuroprotection of the baby to women between 24+0 and 29+6 weeks of pregnancy who are: □ in established preterm labour or	Thanks you for your comments. We think that this comment refers to the use of magnesium sulfate for women at 23+0 to 23+6 weeks gestation. A recommendation has now been added to discuss this with the women.