Appendix B: Stakeholder consultation comments table

2019 surveillance of Intrapartum care for healthy women and babies (2014)

Consultation dates: 9 to 22 January 2019

Do you agree with the proposal to update the guideline?			
Stakeholder	**Overall response**	**Comments**	**NICE response**
Midwifeexpert.com	Yes	New evidence needs to allow access to most up to date information	Thank you for your comment.
Guy's and St Thomas' Hospital	Yes	No comments provided	Thank you.
Diabetes UK	Yes	Diabetes UK recommends that the relevant guideline covering diabetes in pregnancy should be cross-referenced in this guideline: NICE Guideline NG3, Diabetes in pregnancy: management from preconception to the postnatal period	Thank you for your comment. The care of women with coexisting severe morbidities such as diabetes is out of scope for NICE guideline CG190, which covers healthy women with an uncomplicated pregnancy.
Swansea University	Yes	To disseminate the most recent evidence.	Thank you for your comment.

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University Hospital Southampton NHS Foundation Trust	Yes	**Perineal massage** Do not perform perineal massage in the second stage of labour". As the new evidence highlights some potential benefits to perineal massage, it is proposed that this recommendation is reviewed. AGREE needs to be less strong as it probably does no harm! **OASI** Consideration of impact of RCOG OASI care bundle? **IV oxytocin** I'm not sure we want to go to IV oxytocin for all women as this would be technically challenging in all areas, especially low risk ones	Thank you for your comments. Please see the separate responses below: 1. Perineal massage: thank you for your comment. 2. OASI: Thank you for highlighting this ongoing trial. We are now monitoring the progress of this trial and will assess the impact of the findings when they are available. 3. IV oxytocin: Thank you for your comment. We acknowledge your concerns around the feasibility of intravenous delivery of oxytocin across different birth settings. As well as considering the published evidence, the guideline committee will also consider other factors such as implementation barriers when formulating recommendations. As such, we will pass on these concerns to the developers so that they can consider this issue further when the guideline is updated.
Royal College of Midwives	Yes	Comment 1 Pag.2 Second stage of labour Other publications to be considered: -RCM Blue Top Guidance on care in labour for all women in all settings states 'there is some evidence that upright positions such as standing, squatting, kneeling up or using birth equipment to remain upright are associated with a reduction in the duration of the second stage of labour. Upright positions are associated with a significant reduction in instrumental deliveries."	Thank you for your comments. We have looked into your concerns regarding discrepancies between NICE recommendations and RCM Blue Top guidance. Please find separate responses below: Comment 1: It is noted that the recommendations in the RCM Blue Top Guidance on care in labour for all women in all settings do not distinguish between women with and without epidural, which is inconsistent with our update proposal. As stated in Appendix A, we identified new evidence that indicates the optimal position of the woman during the second stage of labour may be dependent on whether she has an epidural. For women

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		Comment 2 Pag 3. Intrapartum interventions to reduce perineal trauma Other publications to be considered: - RCM Blue Top Guidance on care in labour for all women in all settings 'there is god evidence that using a warm compress on the perineum and some evidence that perineal massage during birth mat help to reduce the rates of third and fourth degree tears'. Comment 3 Pag. 3 Third stage of labour The implications of the recommendation of IV oxytocin for active management should be carefully considered as this will mean all women will be offered IV cannulation in labour (this will effect out-of-hospital birth settings in particular). Comment 4 Pag.10 Pain relief Recommendations 1.2.10 should reflect the findings of acupressure and pain relief (pag.9) rather than discouraging its use.	without epidural, there was some indication that upright positions were associated with a reduction in episiotomies and fewer abnormal fetal heart rate problems. For women with epidural, findings suggest that upright positions significantly increase the chance of operative births (driven by an increase in caesarean sections). After reviewing the evidence behind the RCM recommendations, it is noted that one of the Cochrane reviews (Kibuka et al 2017) has recently been updated to include the results of the large NIHR-funded trial BUMPES. The updated version has been considered in this surveillance review and forms the basis of our update proposal in this area. Comment 2: It is noted that the recommendations in the RCM Blue Top Guidance are based on the results of a Cochrane review (Aasheim et al 2017) which was also considered in this surveillance review. As stated in Appendix A, we have proposed an update in the area of perineal massage based on the findings in this review, particularly as recommendation 1.13.12 currently states "do not perform perineal massage in the second stage of labour". With regards to the benefits of warm compresses, the review found no clear impact on all but one of the outcomes (3rd or 4th degree tears). This effect was driven by the results of one study and there was also no effect found for the secondary outcomes of 3rd degree tears and 4th degree tears separately. As the guideline does not have any recommendations on application of a warm compress, it was decided that the evidence base is insufficient to add new recommendations at this time. However, we will be reviewing the area of perineal techniques as part of the proposed update and the

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			discrepancy between RCM guidance and NICE guideline CG190 will be discussed. Comment 3: Thank you for your comment. We acknowledge your concerns around the feasibility of intravenous delivery of oxytocin across different birth settings. As well as considering the published evidence, the guideline committee will also consider other factors such as implementation barriers when formulating recommendations. As such, we will pass on these concerns to the developers so that they can consider this issue further when the guideline is updated. Comment 4: We have interpreted your comment to be regarding recommendation 1.3.10, which states "Do not offer or advise aromatherapy, yoga or acupressure for pain relief during the latent first stage of labour. If a woman wants to use any of these techniques, respect her wishes". The original guideline committee did not feel that there was sufficient evidence to support the provision of aromatherapy and acupressure during the latent first stage of labour. The new evidence described on page 9 is consistent with this decision, as there was still some uncertainty in the findings. Therefore it is unlikely that the guideline will be impacted, particularly as it already recommends "If a woman wants to use any of these techniques, respect her wishes".
British Intrapartum Care Society	Yes	No comments provided	Thank you.

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British Maternal & Fetal Medicine Society	Yes	No comments provided Have the results of the RESPITE trial been considered in the section which considered the evidence regarding Intravenous and intramuscular opioids? The trial was published in the Lancet 'Intravenous remifentanil patient-controlled analgesia versus intramuscular pethidine for pain relief in labour (RESPITE): an open-label, multicentre, randomised controlled trial DOI: https://doi.org/10.1016/S0140-6736(18)31613-1 Which should be included Have the results of the INFANT trial been considered in the section on Automated interpretation of CTG traces The trial was published in the Lancet - Brocklehurst P, Field D, Greene K, Juszczak E, Kenyon S, Linsell L, Mabey C, Newburn M, Plachcinski R, Quigley M, Schroeder E, Steer P.(2017) Computerised interpretation of fetal heart rate during labour (INFANT): a randomised controlled trial The Lancet , Jul 1;390(10089):28. doi: 10.1016/S0140-6736(17)31594-5 Over 47,000 women were randomised and use of computerised interpretation of cardiotocographs in women who have continuous electronic fetal monitoring in labour does not improve clinical outcomes for mothers or babies. Results due out shortly from the ANODE trial should be included in the evidence review when considering 'What is the effectiveness and safety of antibiotic prophylaxis in	Thank you for your comments. Please see the separate responses below: 1. RESPITE trial: Thank you for highlighting this trial. It was not identified in our searches, however it will not be added to Appendix A because it does not contain any pain score outcomes. Due to the large number of studies identified in the initial search, studies on pain relief were only included if they reported pain score items. However, we will pass on this study to developers for consideration in the update of the guideline. 2. INFANT trial: Thank you for highlighting this trial. It was identified in the searches but excluded because the results in the abstract did not distinguish between singleton and twin pregnancies (which are out of scope for NICE guideline CG190). However, we will pass on this study to developers for consideration in the update of the guideline. 3. ANODE trial: Thank you for highlighting this ongoing trial. We are now monitoring the progress of this trial and will assess the impact of the findings when they are available. 4. Definition of a local area: This varies across regions, but can sometimes be defined by clinical commissioning groups. 5. Comments on Table 9: Thank you for your comments on this recommendation. They will be passed on to the developers for consideration during the update of this guideline. 6. Recommendation 1.4.11: Thank you for your comments on this recommendation. To answer your question, it is has been suggested that auscultation can provide false reassurance as other noises can mimic fetal heartbeat.

		reducing infectious puerperal morbidities in women undergoing operative vaginal deliveries?' https://www.npeu.ox.ac.uk/anode 1.1.6Commissioners and providers[1] should ensure that all 4 birth settings are available to all women (in the local area or in a neighbouring area). **[2014]** What is the definition of an acceptable local area? **cTable 9 Other factors indicating individual assessment when planning place of birth** **Factor** Previous fractured pelvis Individual discussion? Think these few women should deliver in obs unit Table 9 – most of these women should deliver in obs unit Stillbirth/neonatal death with a known non-recurrent cause Pre-eclampsia developing at term Placental abruption with good outcome History of previous baby more than 4.5 kg	7. Recommendation 1.8.13: Thank you for your comments on this recommendation. They will be passed on to the developers for consideration during the update of this guideline.

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		Extensive vaginal, cervical, or third- or fourth-degree perineal trauma Previous term baby with jaundice requiring exchange transfusion cTable 9 Other factors indicating individual assessment when planning place of birth Current pregnancy Antepartum bleeding of unknown origin (single episode after 24 weeks of gestation) BMI at booking of 30–35 kg/m2 Blood pressure of 140 mmHg systolic or 90 mmHg diastolic or more on 2 occasions Clinical or ultrasound suspicion of macrosomia Para 4 or more Recreational drug use Under current outpatient psychiatric care Age over 35 at booking cTable 9 Other factors indicating individual assessment when planning place of birth Fetal indications	

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		Fetal abnormality cTable 9 Other factors indicating individual assessment when planning place of birth Previous gynaecological history Major gynaecological surgery Cone biopsy or large loop excision of the transformation zone Fibroids 1.4.11 If fetal death is suspected despite the presence of an apparently recorded fetal heart rate, offer real-time ultrasound assessment to check fetal viability How would fetal death be suspected – only by not being able to pick up fetal heart rate? 1.8.13Inform the woman that pethidine, diamorphine or other opioids may interfere with breastfeeding. **[2007]** This is not documented or discussed	
Royal College of Paediatrics and Child Health	Yes	No comments provided	Thank you.
Birth Trauma Association	Yes	Page 2 – There appears to be an error in the table. It states that the use of tranexamic acid for the prevention of post partum haemorrhage does not have an impact, however in the appendix it states that evidence has been identified that may change the guidelines.	Thank you for your comments. Please see the separate responses below: 1. Table of page 2 of the consultation document: we can confirm that the table is correct. We found no impact of the evidence on the use of tranexamic acid for the

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		The CTG classification table has been identified as being too complicated by an expert; this is evidence to prompt further queries to other users of the table as to its efficacy and ease of use. Overall we welcome the updates to the risks for epidural analgesia and active management of the third stage. We are pleased that the use perineal massage is being studied further and that the guideline is being reviewed to take into account the practicalities of delayed cord clamping. As an organisation we feel that the wording around the woman's position and pushing during the second stage is not suitable. We feel that a woman should be encouraged at all stages during birth rather than discouraged at any point. As the evidence for the position with an epidural is conflicting between the Cochrane review and other trails we feel that further research is needed. We feel that encouraging the woman to adopt a comfortable position, whilst being aware of the benefits of other positions, promotes her free choice and dignity. As an organisation we are currently surveying our members about their decision making process and if it would have	prevention of postpartum haemorrhage (see section in Appendix A on 'Areas not currently covered in the guideline)). However, there may be an impact on its use for the management of postpartum haemorrhage once it has occurred (see section 1.14 in Appendix A). 2. CTG classification table: Thank you for your comment. After taking into account the views of stakeholders and topic experts, we plan to review the content of these tables to address the concerns around usability. As such, we will pass on your comment to the developers for consideration during the update of the guideline. 3. The woman's position and pushing in the second stage of labour: we acknowledge the importance of the wording around this issue and will pass on your concerns to the developers for consideration during the update of this guideline. 4. The decision-making process: thank you for this information. We will consider the results of this work once it is published.

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		changed if they had more education and knowledge. This has been raised as a research recommendation on page 49.	
Birth Companions	Yes	No comments provided	Thank you.
Royal College of Obstetricians and Gynaecologists	Yes	A thorough review of the new evidence with appropriate decisions to update guidance or not. The updates are in keeping with the recent document published by the RCM also. I agree with the proposed recommendations for update. I have no additional comments to make.	Thank you for your comments.
The Hillingdon Hospitals NHS Foundation Trusts	Yes	No comments provided	Thank you.
Northampton General Hospital Maternity Unit	Yes	Overall the changes proposed in the guideline are relatively minor and may have reduced impact on current services however there are areas that it would be useful to review I would be interested in what NICE think about the approach to CTG interpretation using fetal physiology as used by St Georges' and increasingly by other NHS trusts around the UK. I believe there is excellent data from these trusts on the reduced need for obstetric intervention (FBS, instrumental birth, caesarean section), as well as similar (if not better) neonatal outcomes when fetal physiology is used to interpret CTG, compared to standard CTG interpretation methods. I know that many trusts are also	Thank you for your comments. Please see the separate responses below: 1. CTG interpretation: We did not identify any evidence on using fetal physiology to interpret CTG, however we will pass this information on to the developers for consideration during the update of this guideline. 2. Position in the 2nd stage of labour: Thank you for raising these concerns. As stated in Appendix A, there is new evidence to suggest that upright positions significantly increase the chance of operative births in women with an epidural (driven by the increase in caesarean sections in this group). Furthermore, the new evidence found that

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		using these methodologies, and would welcome input from NICE. Concern is raised regarding the position for the 2nd stage of labour in women with an epidural as current advice supports the physiology of labour and the use of alternative more upright positions in labour and from observations appears to be effective and increase the woman's positive experience of labour	mothers may be more satisfied with their experience of childbirth by adopting a recumbent position. Please note that for women without epidural, the evidence suggests that upright positions may be associated with a shorter duration of the second stage of labour, a reduction in episiotomies and fewer abnormal fetal heart rate patterns. In light of this new evidence, we are suggesting that this section of the guideline is reviewed.
Royal College of Anaesthetists	Yes	No comments provided Recommendation 1.9.2 The suggested changes seem sensible. The side effects mentioned are important and women should be warned about them. We note that it is suggested that risks and benefits and implications for labour of epidurals be discussed with women who think they may want one but it is only the implications for labour that are mentioned. Rather than simply adding in the risks mentioned, would it be helpful to provide a link to a full list of risks and benefits of epidural analgesia as used in most units? An example can be found on the OAA website as this link https://www.labourpains.com/UI/Content/Content.aspx?ID=43 Recommendation 1.13.9 The BUMPES trial makes it important to change the recommendation for women with epidurals as is suggested by the review group. The suggested changes to the	Thank you for your comments. Please see the separate responses below: 1. Recommendation 1.9.2: Thank you for this information. It will be passed on to the developers for consideration during the update of this guideline. 2. Recommendation 1.13.9: Thank you for your comment, the guideline committee will consider the new evidence and review the need to update the section on the woman's position in the second stage of labour. 3. Recommendation 1.14.13: Thank you for your comment. 4. Recommendation 1.14.34: Thank you for your comment.

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		wording of the advice for women without epidural seem sensible. Recommendation 1.14.13 We agree that the wording of this recommendation should be changed to take account of the RCT mentioned and are pleased to see that the review team plan to check the publication status of the IMOX trial which may affect this recommendation. Recommendation 1.14.34 We agree with the recommendation to consider use of tranexamic acid early in postpartum haemorrhage rather than only in severe ongoing haemorrhage. We do not think there is yet enough evidence to support routine use to prevent haemorrhage	
NCT	Yes	Under Surveillance proposal (p1, line 3-4) it is important to specify which active management. It is currently unclear whether it refers to 'active management of labour' or 'active management of third stage of labour'. Recommendation 1.14.7 (as cited on p38) is about active management of third stage and not active management of labour. Under Third Stage (p3) the sub heading should be 'Active management of third stage of labour' rather than 'Active management of labour' Care of the Woman after Birth (recommendation 1.16, p43). The ANODE trial is very relevant to this section and is due to publish shortly https://www.npeu.ox.ac.uk/anode	Thank you for your comments. Please see the separate responses below: 1. Clarification of active management: thank you for highlighting this issue. We have addressed this by amending the subheading of the documents for this surveillance review. 2. ANODE trial: Thank you for highlighting this ongoing trial. We are now monitoring the progress of this trial and will assess the impact of the findings when they are available.

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Royal College of Nursing		Nurses in the field of Intrapartum care for healthy women and babies have reviewed the proposal and have no comments to submit at this stage.	Thank you for your comments.
University of York	Yes	No comments provided	Thank you.
Action on Smoking and Health	Not answered	No comments provided	Thank you.
Ferring Pharmaceuticals Ltd.	Yes	We will request for the four below articles to be included in the literature review (attached), as we feel these provide relevant information for the updated guidelines. 1. Gallos ID, Papadopoulou A, Man R, Athanasopoulos N, Tobias A, Price MJ, Williams MJ, Diaz V, Pasquale J, Chamillard M,Widmer M, Tunçalp Ö, Hofmeyr GJ, Althabe F, Gülmezoglu AM, Vogel JP, Oladapo OT, Coomarasamy A. Uterotonic agents for preventing postpartumhaemorrhage: a networkmeta-analysis. Cochrane Database of Systematic Reviews 2018, Issue 12. Art. No.: CD011689. DOI: 10.1002/14651858.CD011689.pub3. 2. Widmer M. N Engl J Med. 2018 Aug 23;379(8):743-752. doi: 10.1056/NEJMoa1805489. Epub 2018 Jun 27. Heat-Stable Carbetocin versus Oxytocin to Prevent Hemorrhage after Vaginal Birth.	Thank you for your comments. Please see the separate responses below: 1. Gallos et al 2018: Thank you for highlighting this review. It was not identified by our searches because it was published after the search cut-off date. We have since added the review to Appendix A for consideration (see section 1.14). 2. Widmer et al 2018: Thank you for highlighting this review. It was not identified by our searches and has since been added to Appendix A for consideration (see section 1.14). 3. WHO recommendations: The surveillance team at NICE do not consider guidelines from other organisations as an evidence type, however we will pass on this information to the developers during the update of this guideline. 4. Van der Nelson et al 2019: Thank you for highlighting this ongoing trial. As stated in Appendix A, we are monitoring

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		3. WHO recommendations: uterotonics for the prevention of postpartum haemorrhage. Geneva: World Health Organization; 2018. Licence: CC BY-NC-SA 3.0 IGO. 4. van der Nelson et al. Trials (2019) 20:4. Intramuscular oxytocin versus oxytocin/ ergometrine versus carbetocin for prevention of primary postpartum haemorrhage after vaginal birth: study protocol for a randomised controlled trial (the IMox study). Additional Doc1 Additional Doc2 Additional Doc3 Additional Doc4	the progress of this trial and will consider the results when they are available.
University Hospitals Birmingham NHS Foundation Trust (UHB)	No	Pain relief in labour: Regional analgesia- agree with proposed update Second stage of labour: Position of the woman- will need clear wording and clarification on risks and benefits for women with and without epidural. Intrapartum intervention to reduce perineal trauma- agree with proposed update	Thank you for your comments. We acknowledge your concerns around the feasibility of intravenous delivery of oxytocin across different birth settings. As well as considering the published evidence, the guideline committee will also consider other factors such as implementation barriers when formulating recommendations. As such, we will pass on these concerns to the developers so that they can consider this issue further when the guideline is updated. In response to your comment on the use of tranexamic acid in the management of postpartum haemorrhage, as above, we will pass this query on to the developers for consideration during the update of the guideline so that they can discuss implementation barriers.

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		<u>Third stage of labour</u> Delivery method of oxytocin during active management: Has any consideration given for implication for practice with this proposed change? Impact on women regarding the need for IV access for third stage i.e. What about women in MLU's and homebirths when active third stage is requested? This has the possibility of reducing homebirth rates and deliveries in stand-alone MLUs. Would this be administered by a midwife or obstetrician only? Midwives do not qualify IV drug trained- this is an additional skill and could impact on continuity of care and women's experiences during birth. Does there need to be improved guidance on counselling women for physiological third stage also. Active management of third stage- agree with proposed update Delayed cord clamping- agree with proposed update Management of postpartum haemorrhage-	

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		Tranexamic acid usage for treatment of PPH- guidance needed as to whether this would this be in obstetric units only and exclude first line in MLU and homebirth scenarios	
Lactation Consultants of Great Britain	Yes	No comments provided	Thank you.
Department of Health and Social Care	Not answered	I wish to confirm that the Department of Health and Social Care has no substantive comments to make, regarding this consultation.	Thank you for your comment.

Recommendation 1.9.9 in the guideline advises that pushing should be delayed for at least 1 hour in women with regional analgesia, upon confirmation of full cervical dilation.

Could you provide information on the adherence to this recommendation in practice? If applicable, please give reasons for any implementation issues

Stakeholder	Overall response	Comments	NICE response
Midwifeexpert.com	Yes	Standard practice – if head is high or in OP position discussion with mother highlights change in management/action/ position	Thank you for this feedback.
Guy's and St Thomas' Hospital	Not answered	No comments provided	Thank you.
Diabetes UK	No	No comments provided	Thank you.

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NICE – Quality and leadership, Quality standards	N/A	No comments provided	Thank you.
Swansea University		• Both commentators agree that in their experience delayed pushing for 1 hour is adhered to in the main. • Deviations from this occur with the two points already given in the existing guidelines. However, they wish to add that maternal and fetal compromise is also a factor in limiting the 1 hour timeline. The phrase 'at least' an hour suggests more than however in practice it is generally after an hour.	Thank you for this feedback.
University Hospital Southampton NHS Foundation Trust		Currently in our Trust guidance is to wait an hour for descent if no complications otherwise. However, recent papers suggest not delaying pushing – we are discussing as a group whether to adopt this practice. References: Alison G. Cahill, MD, MSCI[1]; Sindhu K. Srinivas, MD, MSCE[2]; Alan T. N. Tita, MD, PhD[3,4]; et al Effect of Immediate vs Delayed Pushing on Rates of Spontaneous Vaginal Delivery Among Nulliparous Women Receiving Neuraxial Analgesia *JAMA*. 2018;320(14):1444-1454. doi:10.1001/jama.2018.13986) and large cohort study Yee et al 2016 (Yee LM[1], Sandoval G, Bailit J, Reddy UM, Wapner RJ, Varner MW, Caritis SN, Prasad M, Tita AT, Saade G, Sorokin Y, Rouse DJ, Blackwell SC, Tolosa JE; Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Maternal-Fetal Medicine Units (MFMU) Network. Maternal and Neonatal	Thank you for this feedback. We are aware of the study by Cahill et al (2018) and have since added a summary of findings to Appendix A. The study by Yee et al (2016) does not meet our inclusion criteria for study type because it is an observational cohort study. In this surveillance review and in the original protocol for the guideline, this study type was not considered for this review question.

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		Outcomes With Early Compared With Delayed Pushing Among Nulliparous Women. Obstet Gynecol. 2016 Nov;128(5):1039-1047).	
Royal College of Midwives	Yes	There is variation between areas however delay of pushing for at least 1 hour upon confirmation of full dilatation has been included and practiced in several local guidelines for some time. Implementation in those areas where not in place may require clinicians' training as any change in practice can take some time to be adhered to.	Thank you for this feedback.
British Intrapartum Care Society	Yes	This is standard practice in most maternity units according to the responses from BICS members.	Thank you for this feedback.
British Maternal & Fetal Medicine Society	Not answered	No comments provided	Thank you.
Royal College of Paediatrics and Child Health	Not answered	No comments provided	Thank you.
Birth Trauma Association	N/A	No comments provided	Thank you.
Birth Companions	Not answered	No comments provided	Thank you.

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Royal College of Obstetricians and Gynaecologists		I can only comment from my own hospital where we do (usually successfully) advocate delayed pushing in those with an epidural. I do not see any real problems implementing this in those motivated to do so.	Thank you for this feedback.
The Hillingdon Hospitals NHS Foundation Trusts	Yes	Current practice within the unit If there are signs of fetal distress then the hour is not observed.	Thank you for this feedback.
Northampton General Hospital Maternity Unit		This is routine practice within the Maternity unit unless the clinical situation deems otherwise	Thank you for this feedback.
Royal College of Anaesthetists		We have experience of a unit which undertakes approximately 7000 deliveries pa with an epidural rate of about 30% where this recommendation is usually adhered to. The exception would be where there is evidence of fetal distress or at least a suspicious CTG in which case pushing may be commenced earlier.	Thank you for this feedback.
NCT		No comment	Thank you.
Royal College of Nursing	Not answered	No comments provided	Thank you.
University of York		The students accessing maternity care services in our local areas inform us that this practice is common.	Thank you for this feedback.

Action on Smoking and Health	Not answered	No comments provided	Thank you.
Ferring Pharmaceuticals Ltd.	Not applicable	No comments provided	Thank you.
University Hospitals Birmingham NHS Foundation Trust (UHB)	Yes	This guidance is stated within trust local intrapartum care guideline, 'Upon confirmation of full cervical dilatation in a woman with regional analgesia, unless the woman has an urge to push or the baby's head is visible, pushing should be delayed for at least 1 hour and longer if the woman wishes, after which actively encourage her to push during contractions'. This is adhered to in practice.	Thank you for this feedback.
Lactation Consultants of Great Britain	No	No comments provided	Thank you.
Department of Health and Social Care	Not answered	No comments provided	Thank you.

Do you have any comments on areas excluded from the scope of the guideline?

Stakeholder	Overall response	Comments	NICE response
Midwifeexpert.com	No	No comments provided	Thank you.

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Guy’s and St Thomas’ Hospital	Yes	Along with your expert I would strongly agree that there is dissatisfaction with the NICE guideline on CTG interpretation with different methods of interpretation across England. Many units are using FIGO (plus or minus physiological interpretation). Even if there is no new evidence this needs to be considered and included in any update	Thank you for your comment. After taking into account the views of stakeholders and topic experts, we plan to review the content of these tables to address the concerns around usability. As such, we will pass on your comment to the developers for consideration during the update of the guideline.
Diabetes UK	No	No comments provided	Thank you.
NICE – Quality and leadership, Quality standards	No	No comments provided	Thank you.
Swansea University		Fundal pressure – the commentators feel that fundal pressure should not be removed from the guidelines. It should be clearly stated that fundal pressure should NOT be used in normal birth.	Thank you for your comment. There are currently no recommendations in NICE guideline CG190 about fundal pressure. As stated in Appendix A, we identified a Cochrane review on the use of fundal pressure during the second stage of labour. The review concluded that there is insufficient evidence to draw conclusions on the benefits and harms of fundal pressure. Therefore, it was decided that there would be no impact on the guideline at this point.
University Hospital Southampton NHS Foundation Trust	Yes	Use of TXA for women >500ml Tranexamic acid for all women >500mls – Not sure in women who have stopped bleeding already	Thank you for your comment regarding the guidance on tranexamic acid in the management of postpartum haemorrhage. The new evidence included women after birth following a pregnancy of at least 24 weeks' gestation with a diagnosis of primary postpartum haemorrhage. Postpartum haemorrhage in this case was defined differently across studies, with some defining it as having blood loss of 500ml or more. Therefore the use of tranexamic acid for women with blood loss greater than 500ml is covered by the new evidence.

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			We did not identify any evidence in women with blood loss greater than 500ml that had stopped bleeding. However, we will pass on your query to the developers for consideration during the scoping phase of this guideline as part of the update process.
Royal College of Midwives	No	No comments provided	Thank you.
British Intrapartum Care Society	No	No comments provided	Thank you.
British Maternal & Fetal Medicine Society	No	No comments provided	Thank you.
Royal College of Paediatrics and Child Health		On page 44 it appears that there will be no addition to the guideline with respect to diagnosing the foetal head position. The commenter agrees with this decision; however, it is noted that the more important question as to whether ultrasound should routinely be used in early labour to confirm presentation (cephalic versus breech) was not addressed in this revision.	Thank you for your comment. We did not identify any evidence on the routine use of ultrasound in early labour to confirm presentation, however we will pass on your concern to the developers for consideration during the scoping phase of this guideline as part of the update process.
Birth Trauma Association	Yes	Place of Birth needs to be reviewed in view of the increasing importance of providing informed consent following the Montgomery	Thank you for your comments. Please find the separate responses below: 1. Place of birth and consent: Section 1.1 of the guideline advises that providers should explain the different choices

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		versus Lanarkshire study. Additionally, much of the Birthplace study on which current recommendations are based, specifically warned that its data could not be extrapolated if services were reconfigured. This is exactly what has happened - obstetric units have been centralised and small ones closed meaning FMU transfer distances have increased in many areas. This is resulting increasing public, coroner service and media discontent about the assessment and safety of freestanding midwifery units mainly for first time mothers and where they are distant from obstetric units. https://www.mirror.co.uk/news/uk-news/nervous-first-time-mums-heartbreak-13880544 Despite configuration changes, there has been no robust monitoring of outcomes to confirm or refute the outcome evidence that birth in a	available to women when deciding place of birth. This involves a detailed discussion around the risks associated with each setting and the possible reasons for transfer to an obstetric unit. By following these recommendations, providers are encouraged to enable women to make an informed decision on their place of birth as well as supporting them in their choice (see recommendation 1.1.2). In addition, the case of Montgomery versus Lanarkshire relates to a woman with diabetes, which is a condition considered outside the scope of NICE guideline CG190 (intrapartum care for healthy women and babies). However, there are recommendations on discussing the risks of mode of birth in section 1.4 of NICE Guideline NG3 (Diabetes in pregnancy: management from preconception to the postnatal period). 2. Service reconfiguration: We acknowledge that maternity services in the UK are undergoing changes, particularly in relation to the Maternity Transformation Programme as discussed in Appendix A. As you have stated, we did not find any new evidence in this surveillance review that would confirm or contradict current guidance on freestanding midwifery units. However, we will pass on your concerns to the developers for consideration during the update of the guideline. 3. Birthplace study: Thank you for highlighting the paper by Holloway et al 2015. This paper was not identified in the search as this surveillance review only considered randomised controlled trials, systematic reviews and qualitative studies. However, we will pass on your

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		freestanding midwifery unit is as safe as birth in an OU or AMU for first time mothers. Further follow on studies from Birthplace recommends further information for women which is not currently reflected in the guidance (transfer times/older mothers) https://www.ncbi.nlm.nih.gov/pubmed/26334076	comment to the developers for consideration during the scoping phase of this guideline as part of the update process.
Birth Companions		Birth Companions is a charity that works to improve the lives of perinatal women and babies facing severe, multiple disadvantage through practical frontline work in prisons and the community, and through research and policy development. **1. We would like to suggest an updated guideline considers:** ***The evidence base in relation to the needs of women facing severe multiple disadvantage with complex social factors, and how best to address them***. At Birth Companions we use the term severe, multiple disadvantage to refer to women who face at least three or more 'complex social	Thank you for your comments, we have reviewed these and find them to be more related to the NICE guideline on pregnancy and complex social factors: a model for service provision for pregnant women with complex social factors (CG110). We have forwarded your comments for consideration by the review team during the next check of this guideline.

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		factors'; many women we support experienced many more. Please refer to Birth Companions' *Impact Report 2017-18* for more information about the factors *we* map and how they co-occur for the women that we support. This approach acknowledges the extremely varied individual factors women can experience including (but not limited to) safeguarding issues and/or social services involvement (including women who are separated from their babies), vulnerably housed women, women involved in sex work, women affected by the criminal justice system, women who have spent time in care and women who have experienced sexual abuse as children and/or as adults. Pregnant women with multiple, complex needs are less likely to access maternity care, or will receive less of it, have poorer maternal and infant outcomes, and are more likely to experience perinatal mental health problems (Thomson, G and Balaam, M (2016) *Birth Companions Research Project: Experiences and Birth Outcomes of Vulnerable Women*, University of Central Lancashire). Accessing maternity care later in the pregnancy can mean that women have additional needs regarding information and communication during the intrapartum period, such as comprehensive and accessible	

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		information about what choices are available to them, additional time and discussion with staff to understand the different stages of labour and any medical interventions, and a calm environment that reduces the possibility of unwanted interactions with other patients or staff. Existing evidence explores the experiences of perinatal women facing severe multiple disadvantage and how best to address their needs. Two pieces of work examining the impact of specialist, targeted perinatal support models – the Vulnerable Adults and Babies Midwifery Team at the Whittington Hospital in London (Thomson, G and Balaam, M (2016) *Birth Companions Research Project: Experiences and Birth Outcomes of Vulnerable Women*, University of Central Lancashire) and the work of Birth Companions (Clewett, N and Pinfold, V (2015) *Evaluation of Birth Companions' Community Link Service*, McPin Foundation) – can be accessed here and here. In relation to intrapartum care, these studies note that women facing severe multiple disadvantage were less likely to have a birth partner and often found that a lack of continuity in their care,	

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		as well as a lack of sensitivity to their needs and emotional state among healthcare staff, contributed to negative birth experiences. A literature review of evidence on supporting vulnerable mothers and babies in the community can be accessed here. (Samele, C, Clewett, N, Pinfold, V (2015) *Supporting Vulnerable Pregnant Women and New Mothers in the Community*, McPin Foundation). A section of this reviews the evidence on continuous care throughout labour and states that, "continuous support during labour should be standard practice rather than the exception; and women should be encouraged to have a companion of their choice." In 2018, we worked with charity Revolving Doors on Revolving Doors on a peer research project in East London Local Maternity System, employing trained researchers with lived experience to understand the experiences of perinatal women facing severe multiple disadvantage and to co-produce practical recommendations mapped against Better Births. The final report, *Making Better Births a reality for women with multiple disadvantages* includes a range of findings and recommendations on improving maternity care for perinatal women facing severe multiple disadvantage. A number	

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		of these are particularly relevant to the intrapartum period, including that women may fear and mistrust statutory services (often due to fear of social services intervention), that breaches of confidentiality such as having to meet with social workers on a ward with other patients present are a common experience, and that many women had experience of being treated differently to other women by healthcare staff, sometimes feeling that midwives were cold and judgemental towards them. The report emphasises the importance of continuity of carer during the perinatal and intrapartum period, as well as the benefits of using specialist midwives, but also notes that even in the absence of these elements, “a compassionate and non-judgemental approach had a significant impact on women’s satisfaction”. Birth Companions volunteers have in recent months made the organisation aware of examples of poor practice they have witnessed in the care of for women during the intrapartum period. These include instances of women in early labour being sent back home to unsuitable accommodation, with no way to get back to the hospital; of vaginal examinations going ahead	

		without informed consent from the woman, or continuing after a woman had asked for the examination to stop; and of staff making inappropriate comments about rape and FGM. Volunteers have also raised concerns that women from minority ethnic backgrounds are not always listened to when communicating their health needs to staff and that women in need of translation services were not able to access this. Where volunteers have highlighted good practice, this has often involved healthcare staff taking time to ensure that the woman understood what was happening and what her choices were and explicitly asking for consent before the woman was touched or examined. **2. We would like to suggest:** ***An examination of how women's experiences of trauma impact on their experiences of care during the intrapartum period, and of how a trauma-informed approach to maternity care could address these issues.*** The perinatal period, including intrapartum care, provides a golden opportunity to triage, engage and work with vulnerable women to improve their lives and outcomes for their children. Maternal health services are unique in that many vulnerable women who present	

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		might not engage with, or may mistrust other services. However, pregnancy is often a point at which women with complex needs most want to make changes and accept offers of help. If care is developed with vulnerability and trauma in mind, the knock-on effect will be that the pathway experience will be greatly improved for all services users. It is also important to acknowledge that women can be considered vulnerable for reasons beyond those highlighted above and that pregnancy and childbirth in themselves are recognised as having the potential to trigger trauma in those who would normally be excluded from conventional vulnerability criteria. For example, the 11% of women who are survivors of childhood sexual abuse (not all of whom would fall into the multiple/complex needs cohort), those experiencing perinatal mental ill-health and those who have experienced previous miscarriage, stillbirth, traumatic births or birth related complications. Reshaping service pathways that take into account the need of the most vulnerable will also result in services that are safer and more accessible to all pregnant women. Agenda Alliance for Women and Girls at Risk recommends that all services coming into contact with women who have experienced	

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		abuse should be able to manage and respond to their needs. They state that services should "understand the impacts of violence and abuse on women's lives and be offering support around these issues. 'Routine enquiry' (asking women and girls whether they have experienced violence and abuse) should become standard practice across a range of health and support services and be accompanied by proper support for those who disclose past or present experiences of abuse". (McManus, S, Scott, S and Sosenko, F (2016) *Joining the dots: The combined burden of violence, abuse and poverty in the lives of women*, Agenda Alliance for Women and Girls at Risk). 'Trauma-informed care' is an approach to understanding and meeting the needs of people who have experienced trauma. NHS England are currently funding the development of guidelines for trauma-informed maternity services, due to be published in 2019, and we recommend that this publication is taken into account when reviewing these guidelines. Trauma-informed care in the perinatal period is a study that looks at the evidence base in relation to the impact of trauma in experiences	

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		and outcomes of mothers and babies, and at both aspects of care in the UK and overseas. Findings from *Making Better Births a reality for women with multiple disadvantages* show that large numbers of women facing disadvantage have experienced significant, concurrent and recent trauma. This trauma may result from a range of factors including experience of domestic violence, previous separation from children and experiences of sexual violence and trafficking. While we advocate for a trauma-informed approach across all statutory and voluntary services, this is particularly pertinent during the intrapartum period. This is a challenging and stressful time and women may find aspects of labour and birth triggering, particularly vaginal examinations, receiving pain medication or having groups of medical staff in the room. **3. Birth Companions has worked with perinatal women affected by the criminal justice system in England and Wales for the last 22 years, providing frontline services in prisons and the community, and on improving the care women experience across the country. We suggest that this guideline provide:**	

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		A specific section on women affected by the criminal justice system (women in custody and the community) There is a wealth of recently published research on the experiences of perinatal women in the prison system that advocate for improvements in the care this group receives from a range of stakeholders including healthcare professionals. These include (Kennedy, A et al (2016) *Birth Charter for Women in Prison in England and Wales*, Birth Companions), (Public Health England (2018) *Gender Specific Standards to Improve Health and Well-being for Women in Prison in England*) and (Cuthbert, C et al (2015) *All Babies Count – Spotlight on the Criminal Justice System – An Unfair Sentence*, NSPCC/ Barnardo's). The Royal College of Midwives and Birth Companions recently made a submission to the Parliamentary Health and Social Care Committee's review of healthcare in prison. As well as looking at maternity care in prison, some of this research also explores the experiences of women in the hospital, finding that women coming from prison to give birth have experiences of feeling judged and treated harshly by midwives due to being clearly marked out as a prisoner. As Birth Companions' Birth Charter notes, "Research has demonstrated the importance of respecting a woman's dignity and privacy during birth and breastfeeding. In birth, we know that a stressful environment can	

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		impact on labour and mother/baby bonding (Buckley, 2015)." HM Prisons and Probation Service provide guidance (*PSI 33/2015 – External Prisoner Movement*) for prison officers on attending the hospital with a woman for a birth. This guidance outlines the rights the woman has to ask officers to remain outside of the room while she is in labour, to attend the hospital and give birth without being handcuffed or restrained and the responsibilities of officers in supporting the woman. NHS staff should have access to the HMPPS guidance, to ensure they are aware of what rights are available to women coming from prison to give birth. **4. We would like to suggest the guidance contains:** ***A specific section on women referred to maternity services because of safeguarding or child protection concerns/ with social services involvement during the perinatal period/ experiencing separation from their babies/ who have experienced repeated separations from their babies.*** Kelly Wilkes, a practitioner with the Pause Project is developing an approached called *Me in*	

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		Mind to support healthcare professionals to work with women who are being separated from their children in a compassionate and trauma-informed manner. This approach emphasises the importance of motivational, non-judgemental and supportive behaviour towards the woman and the use of language and tone in a mindful and empathetic way. It also makes logistical suggestions such as having a sticker on the woman's case notes so all staff involved in the labour and birth are aware of her situation and the need for extra care in their approach; and for staff to keep to one side any important items that could be put in a 'memory box' for women to take home once they have been separated. Wilkes also reminds healthcare staff that babies and mothers being separated still benefit from skin to skin and breastfeeding after the birth, and that these activities should be encouraged if the mother is keen to do so or asks for advice on what she can do with the baby after the birth. As discussed above, these women are likely to receive visits from social services staff during their time at hospital. It is therefore essential that they are placed in a private room in order to ensure confidentiality when discussing personal matters with social services staff, as well as to protect the identity of the woman or any children or vulnerable adults she	

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		may be connected with who are under safeguarding proceedings. Making Better Births a reality for women with multiple disadvantages recommends that specialist midwives are used more often to support women facing disadvantage. We believe that this would be particularly positive for women experiencing separation or social services intervention and should be implemented as standard practice in order to ensure their specific needs are understood and addressed. **5. We would also like to suggest that:** ***NICE includes women with experience of severe and multiple disadvantage who have given birth in the consultation process when updating this guideline, as well as other guidelines for the care of perinatal women.*** As our *Making Better Births a reality for women with multiple disadvantages* research demonstrates, consulting directly with this group of women can provide important insights into the improvement of care for all perinatal women and shed light on potential solutions to disparities in outcomes for different groups of women. Birth Companions' Lived Experience Team is available for consultation and coproduction. The team is made up of women with lived experience of multiple disadvantage,	

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		including those with experience of pregnancy, birth and early parenting in prison. **6. While we understand the need for this consultation to remain specific to the intrapartum period, the core comments made above could be applied throughout maternity care. We therefore look forward to the opportunity to comment further on NICE clinical guideline 110 on pregnancy and complex social factors when this is updated.**	
Royal College of Obstetricians and Gynaecologists	Agree with excluded areas	No comments provided	Thank you.
The Hillingdon Hospitals NHS Foundation Trusts	Yes	We have noticed that the use of Carbetocin has reduced our postpartum haemorrhages post caesarean section. We stopped using oxytocin solely for active management as there was a significant increase in the numbers of post-partum haemorrhage. We reverted back to Syntometrine which reduced the number of post-partum haemorrhages. Tranexamic acid is used in post-partum haemorrhage	Thank you for your comments. Please see the separate responses below: 1. Oxytocin and tranexamic acid: Thank you for this information. After the consultation period for this update decision, we identified new evidence on the use of carbetocin and have included it for consideration in this surveillance review. However, there is still uncertainty in this area so there is no impact on the guideline at this point. We are tracking the progress of an ongoing trial in this area and will consider the results when they are published. See Appendix A for more details.

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		It has been noted that the side effect of fever with an epidural has resulted in an increase in documentation of sepsis. The FIGO criteria for CTG is easier to interpret than the current NICE guidance	2. CTG interpretation: Thank you for your comment. After taking into account the views of stakeholders and topic experts, we plan to review the content of these tables to address the concerns around usability. As such, we will pass on your comment to the developers for consideration during the update of the guideline.
Northampton General Hospital Maternity Unit	No	No comments provided	Thank you.
Royal College of Anaesthetists	No	No comments provided	Thank you.
NCT	Not answered	No comments provided	Thank you.
Royal College of Nursing	Not answered	No comments provided	Thank you.
University of York	No	No comments provided	Thank you.
Action on Smoking and Health	Yes	Smoking is a major risk factor for adverse outcomes in the intrapartum period for both women and their babies, but it is not identified in the proposed guidance. Reference to smoking during current pregnancy should be included in section 1.1 'Place of Birth', specifically in Table 7 'Other factors indicating	Thank you for your comments. Please see the separate responses below: 1. Thank you for highlighting the studies by DiFranza et al 1995 and Ananth et al 1996. These studies were not identified through the surveillance review because they were published outside of the literature search cut-off

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		increased risk suggesting planned birth at an obstetric unit'. Smoking during pregnancy carries significant risks for the mother and baby during and after the intrapartum period and should be considered a relevant risk factor when determining a women's planned place of birth and potential need for obstetric care. Evidence demonstrating that smoking significantly increases risk of perinatal mortality and low birth weight, an important factor associated with infant morbidity and mortality[1] is well established: • A 1995 systematic review and meta-analysis of the effect of maternal smoking on perinatal mortality, using data from 23 cohort studies, including 657,288 pregnancies, found a 26% increase in the risk of perinatal deaths (RR 1.26, 95% CI 1.19 to 1.34) [1] • A 2007 cohort study analysed results from 1,070 intrapartum stillbirths, finding that smoking mothers were 50% more likely to experience intrapartum fetal death as compared with nonsmoking mothers (RR 1.5; 95% CI 1.3 to 1.7). Furthermore,	dates and were available for consideration when the guideline was developed. 2. Thank you for highlighting the study by Shobeiri et al 2017. This study was not identified in the search and has since been added to Appendix A for consideration in this surveillance review. 3. Thank you for highlighting the study by Aliyu et al 2007, as this study looks at the association between smoking during pregnancy and stillbirth it is more suitable for consideration in the guideline on smoking: stopping in pregnancy and after childbirth. We will log this item for consideration in the next review of this guideline. 4. Thank you for highlighting the study by Lumley 2009, as this study examines the effect of interventions for promoting smoking cessation during pregnancy it is more suitable for consideration in the guideline on smoking: stopping in pregnancy and after childbirth. We will log this item for consideration in the next review of this guideline. 5. Thank you for highlighting the study by Hayashi et al 2011. This study was published outside of the search cut-off dates for this surveillance review so will not be added to Appendix A, however we have reviewed the findings because this area was not considered in previous surveillance reviews. The results indicate that women who smoke during pregnancy have a significantly higher risks for the following obstetric complications: preterm rupture of membrane, chorioamnionitis, incompetent cervix, threatened premature delivery, placental abruption and pregnancy-induced hypertension. It is noted that the majority of these complications are covered in tables 6 and

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		women who smoked 10 to 19 cigarettes per day were at a higher risk (RR 1.7 95% CI 1.4-2.0) [2] • In a systematic review of 22 studies, based on data from 347,553 pregnancies, women who smoke had an 82% increase in risk (RR 1.82, 95% CI 1.67 to 1.97), compared with non-smokers, of giving birth to a low birth weight baby. [2] • Additional evidence that the association between smoking and low birth weight comes from randomized trials of smoking cessation during pregnancy showing that birth weight is increased when the mother quits smoking.[3,4] Each year in the UK, an estimated 14,000 to 19,000 babies are born with low birth weight attributable to maternal smoking [5] In addition to increased risk of child mortality, smoking during pregnancy also causes complications during the intrapartum period including: • Placenta previa (placenta growing in the lowest part of the uterus) RR 1.27 95% CI 1.18 to 1.35[6];	7 of the guideline. It is also important to note that CG190 shares an interactive flowchart with CG62 (antenatal care) which contains recommendations on identifying women who smoke during pregnancy to offer early intervention. As such, the risks associated with smoking during pregnancy and the recommended care pathway for these women is already covered in existing NICE guidance. 6. Thank you for highlighting the additional publications by the Department of Health and Social Care and the British Medical Association. These reports were not identified through the surveillance review because they were published outside of the literature search cut-off dates. Both reports give a high-level overview of the harms associated with smoking, highlighting the importance of smoking cessation services particularly in maternity services. This is an area extensively covered in NICE guidance already (see NICE guidelines CG62, PH26 and PH48), therefore no impact on CG190 is expected.

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		• Placental abruption (early separation of the placenta from the uterus) RR 2.05, 95% CI 1.75 to 2.4[7]; • Preterm rupture of membrane age-adjusted risk ratio (aRR) 1.67, 95% CI 1.43 to 1.96; [8] • Chorioamnionitis (inflammation of fetal membrane associated with prolonged labour) aRR 1.65 95% CI 1.36 to 2.00; [9] • Incompetent cervix aRR 1.63, 95% CI 1.35 to 1.96; [9] • Threatened premature delivery aRR 1.38 95% CI 1.17 to 1.64;**Error! Bookmark not defined.** [9] • Pregnancy induced hypertension aRR 1.2 95% CI 1,01-1.41. [9] Rates of smoking in pregnancy are still significant across England, with 10.5% of mothers in England smoking at the time of delivery (SATOD), according to the most recent figures. Furthermore, there is significant variation in SATOD rates across CCGs in England, with rates ranging from 2.3% to 24.9%. [10]	

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		Smoking at the point of delivery therefore remains a relevant and significant issue across England and given the substantial risk smoking carries for the intrapartum period, should be considered a relevant issue for inclusion in section 1.1 'Place of Birth', specifically in Table 7 'Other factors indicating increased risk suggesting planned birth at an obstetric unit'. Smoking should be considered a relevant risk factor when determining a women's planned place of birth and potential need for obstetric care. [1] Royal College of Physicians. Passive smoking and children. 2010 [2] DiFranza JR, Lew RA. Effect of maternal cigarette smoking on pregnancy complications and sudden infant death syndrome. J Fam Pract 1995;40:385–94. [3] Aliyu MH, Salihu HM, Wilson RE, Kirby RS. Prenatal smoking and risk of intrapartum stillbirth. *Arch Environ Occup Health*. 2007 Summer;62(2):87-92. doi: 10.3200/AEOH.62.2.87-92. [4] UK Department of Health, Independent Scientific Committee on Smoking and Health. Fourth report. *Department of Health*, 1988. [5] Lumley J, Chamberlain C, Dowswell T et al. Interventions for promoting smoking cessation during	

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		pregnancy. *Cochrane Database Syst Rev* 2009;3(CD001055). [6] British Medical Association. Smoking and reproductive life: the impact of smoking on sexual, reproductive and child health. London: *BMA*, 2004. [7] Shobeiri F, Jenabi E. Smoking and placenta previa: a meta analysis. *J Matern Fetal Neonatal Med*. 2017 Dec;20(24): 2985-2990. doi: 10.1080/14767058.2016.1271405. [8] Ananth CV, Savitz DA, Luther ER. Maternal cigarette smoking as a risk factor for placental abruption, placenta previa, and uterine bleeding in pregnancy. *Am J Epidemiol*. 1996 Nov 1;144(9):881-9. [9] Hayashi K, Matsuda Y, Kawamichi Y, Shiozaki A, Saito S. Smoking during pregnancy increases risks of various obstetric complications: a case-cohort study of the Japan Perinatal Registry Network database. *J Epidemiol*. 2011;21(1):61-6. [10] NHS Digital. Statistics on women's smoking status at time of delivery, England – Quarter 2018-19. 2018.	
Ferring Pharmaceuticals Ltd.	No	No comments provided	Thank you.
University Hospitals Birmingham NHS	Yes	Raised BMI 35-40 in multiparous women new evidence suggests these women would be	Thank you for your comments. Please see the separate responses below:

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Foundation Trust (UHB)		suitable for AMU as per *RCOG Obesity guideline 2018*. Consider RCOG draft Scientific paper stating babies with estimated fetal weight above 4kg rather than 4.5kg are classed as macrosomic and at increased risk of associated complications- should these be classified as recommend delivery in obstetric unit An acknowledgement of continuity of carer in view of Better Births recommendations WHO recommendations: non-clinical interventions to reduce unnecessary caesarean sections needs to be included in review of evidence 1.1.8 & 1.1.17 Removal of reference to Supervisor of midwives	1. BMI: We will pass on this comment to the developers for consideration during the scoping phase of the guideline update process. 2. Fetal weight: NICE guideline CG190 does not define macrosomia, therefore this information is unlikely to impact recommendations. However, we will pass on your comment to the developers for consideration during the update of the guideline. 3. Continuity of care: As stated in Appendix A, the recommendations in the Better Births report around continuity of care are consistent with recommendation 1.7.3 which links to NICE guidance on patient experience in adult NHS services. Therefore, it was decided that no change to the recommendations is necessary. 4. WHO recommendations: We will pass on this comment to the developers for consideration during the update of the guideline. 5. Supervisor of midwives: Thank you for your comment. We are not aware of any changes to the job roles mentioned in NICE guideline CG190, however we will pass on your comment for consideration during the scoping phase of the guideline update process.
Lactation Consultants of Great Britain	Yes, please see notes	**Impact of intrapartum drugs and procedures on breastfeeding** LCGB welcomes the recommendations on skin to skin immediately after birth. However, having searched the rest of the document, LCGB finds no reference to the impact of intrapartum drugs or procedures on the the	Thank you for your comments. Please see the separate responses below: 1. Intrapartum drugs and breastfeeding: The effect of oxytocic drugs on infant feeding is not in scope for NICE

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		ability of the baby and the mother to initiate breastfeeding effectively. As breastfeeding / receiving breastmilk is the single most important factor influencing an infant's immune system, microbiome and life-long health, this is a serious omission. There are literally dozens of studies demonstrating the negative impact of intrapartum drugs such as pethidine (a narcotic rather than an effective analgesic) on breastfeeding, but epidural anaesthesia is also associated with the highest rates of abandoning breastfeeding by six months. Although epidurals may not be a sole cause, as they are often part of a spiral of intervention with other drugs and procedure. Breastfeeding difficulties after an epidural are more frequent in the first week postpartum and breastfeeding cessation is more common, despite over 80% of women choosing and wishing to breastfeed. Given the high rates of epidurals in the UK and our dismally low numbers of breastfeeding mothers, it is time to take the research on this area into account when re-examining intrapartum guidelines. **Intense breastfeeding support often required after epidurals** In the UK we do not yet have lactation consultants employed in every maternity hospital and community setting to provide the intense support that most women clearly need to establish effective breastfeeding in the crucial first week, after the impact of the UK's current routine intrapartum and postpartum procedures.	guideline CG190. However, the guideline does recommend informing the woman that pethidine, diamorphine or other opioids may interfere with breastfeeding (recommendation 1.8.13). With regards to the impact of epidurals on breastfeeding, we did not identify any evidence in this area during the surveillance review, however we will pass on your comment to the developers for consideration during the update of this guideline. 2. Breastfeeding support: The textbook by Walker (2006) is not an evidence type that NICE considers. However, for recommendations on breastfeeding support, please see the NICE guideline on postnatal care which contains more detailed recommendations in this area (see section 1.3). 3. Scandinavian practice: The personal communication by Dr Righard is not an evidence type that NICE considers. However, the aspects of care mentioned in your comment are consistent with NICE recommendations on the care of mother and baby. For example, recommendation 1.1.2 states that providers should support women in their choice of setting wherever they choose to give birth. Recommendation 1.2.2 describes various techniques and practices to put the woman at ease by respecting her personal space and encouraging her to adapt the environment to meet her individual needs. Also, recommendations 1.15.7 and 1.15.8 recommend encouraging the woman to have skin to skin contact and avoiding separating mother and baby in the first hour. 4. Uninterrupted first feed and separation of the mother and baby: The guideline recommends initiating breastfeeding as soon as possible after birth, ideally within 1 hour

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| | | For references and to be brief here, may we refer you to the 4th edition of Marsha Walker's "Breastfeeding Management for the Clinician - evidence-based practice"; chapter 'Maternity Care Practices and Breastfeeding', pages 231 to 247, and the many associated references.

Scandinavian intrapartum care practices
One of the reasons Scandinavia has raised its breastfeeding rates from a parity with ours in the 1970's to 96+% today, is that they have changed their intrapartum care practices. (Dr. Lennart Righard, research paediatrician; personal communication.) Their emphasis now is on reducing the mother's adrenaline and increasing oxytocin by either supporting the woman to deliver in her own home, or if in a birthing unit or hospital ,not moving her from one room to another after admittance; keeping the lights dimmed; being as unobtrusive as possible; reducing the number of people, interruptions and talking and allowing the mother to retreat into her own mental space to give birth. They have almost completely stopped using the narcotic, pethidine for several reasons, among them that it often seriously depresses the baby's ability to breathe, breastfeed and self-organise its state of alertness, for days. The baby struggles to metabolise the narcotic and remains drugged during the "sensitive period" where it would otherwise be most able to access and use its instincts. Obstetric staff also put the baby skin to skin below the mother's breasts and allow the baby to rest and then crawl up to self attach. | (recommendation 1.15.9). Furthermore, the guideline also states that providers should avoid "separation of a woman and her baby within the first hour of the birth for routine postnatal procedures, for example, weighing, measuring and bathing, unless these measures are requested by the woman, or are necessary for the immediate care of the baby" (see recommendation 1.15.8).
5. Outcome cost savings: Thank you for highlighting the study by Hitzert et al 2017. This study was not identified in the searches and does not meet the inclusion criteria for this surveillance review because it is an economic analysis not based in the UK.
6. Impact of drug abuse in labour: This area is out of scope for NICE Guideline CG190. However, please see the NICE guideline on pregnancy and complex social factors for recommendations on care of pregnant women who misuse substances (alcohol and/or drugs).
7. Risks of intrapartum care drugs: We did not find any evidence in this surveillance review on the link between intrapartum care and autism. The papers you have highlighted by Moy et al (2019) and Wagner et al (2017) do not meet the inclusion criteria at NICE as they are animal studies.
Thank you for highlighting the study by Smallwood et al (2016). This type of study does not meet the inclusion criteria of the surveillance review because it is a survey.
Thank you for highlighting the paper by Gregory et al (2014), it was not identified in this surveillance review because it was published outside of the literature search cut-off dates. After further consideration, this study is out |

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| | | See short video here: https://www.youtube.com/watch?v=_VnhY2g4M_8

Intrapartum/Postpartum care - uninterrupted first feed
That first, uninterrupted feed is given paramount importance, as research shows that it is the single most effective way to facilitate effective, long term breastfeeding. Only once the first feed has taken place do routine assessments and measurements take place. These simple interventions, although they may seem almost an impossible ideal in the current UK maternity system (a reason to review and update these guidelines), have resulted in reduced Caesareans, improved birth outcomes, massively more positive evaluation of the maternity services and effective breastfeeding.

Crying and worse outcomes
Any separation of the baby from the mother causes protest, crying and a disorganisation of the baby's state.
It should be noted that wise and kindly clinicians who keep the baby in skin to skin on the mother's body, in the transition from intrapartum to postpartum care, support the baby's self regulation and optimise the closure of the foramen ovale and ductus arteriosus. Their care in preventing the infant from crying at separation from contact with the mother's body, while also facilitating effective suckling, also reduces the risk of intracranial haemorrhage.(See Martha Walker's text | of scope for NICE guideline CG190 because it relates to induction and augmentation of labour.
Thank you for highlighting the paper by Glasson et al (2004), it was not identified in this surveillance review because it was published outside of the literature search cut-off dates. After further consideration, this study does not meet the inclusion criteria for this surveillance review as there is inadequate statistical detail in the abstract.
Thank you for highlighting the paper by Hattori et al (1991), it was not identified in this surveillance review because it was published outside of the literature search cut-off dates. It will not be considered further because there is no abstract available for this study.
Thank you for highlighting the study by Kurth et al (2011), it was not identified in this surveillance review because it was published outside of the literature search cut-off dates. After further consideration, this study does not meet the inclusion criteria for this surveillance review because it is an observational study.
The study by Kroll-Desrosiers et al (2017) was not identified in the searches for this surveillance review, however it does not meet the inclusion criteria because it is an observational study.
8. Early life trauma and/or perinatal depression: NICE guideline CG190 does not cover the intrapartum care of women with life trauma or prenatal depression. These areas are covered by the NICE guideline on pregnancy and complex social factors (CG110) and antenatal and postnatal |

		and diagrams on the opposite actions of crying and suckling on p.246 and 247 of "Breastfeeding Management for the Clinician"; chapter 'Maternity Care Practices and Breastfeeding.) **Outcome cost savings** Dutch research underpins the more recent Scandinavian intrapartum care culture and is more cost effective - (another key consideration for NICE), and their Outcomes are also better. The total adjusted mean costs for births planned in a birth centre, in a hospital and at home under the care of a community midwife were €3327, €3330 and €2998, respectively. There was no difference between the score on the OI for women who planned to give birth in a birth centre and that of women who planned to give birth in a hospital. Women who planned to give birth at home had better outcomes on the OI (higher score on the OI). Hitzert, M., Hermus, M., Boesveld, I., Franx, A., van der Pal-de Bruin, K., Steegers, E. and van den Akker-van Marle, E. (2017). Cost-effectiveness of planned birth in a birth centre compared with alternative planned places of birth: results of the Dutch Birth Centre study. *BMJ Open*, 7(9), p.e016960. **Long term impact of drugs used in labour - drug abuse** LCGB notes with concern that there are no considerations or references to the potential long term impact of drugs used in labour and delivery on the infant as it grows up.	mental health (CG192). Your comments have been passed on for consideration when these guidelines are reviewed. 9. Risks associated with caesarean section: NICE guideline CG190 does not cover the risks associated with caesarean section, however we will log your comment for consideration in the NICE guideline on caesarean section (CG132). The paper by Adami et al (1996) was not identified through this surveillance review because it was published outside of the literature search cut-off dates. It will not be considered further because it does not meet the inclusion criteria for study type, as it is a case-control study. Thank you for highlighting the study by Yip et al (2017). NICE guideline CG190 does not cover the risks associated with caesarean section, however we will log your comment for consideration in the NICE guideline on caesarean section (CG132). 10. Wilm's tumour: Thank you for highlighting the paper by Lindblad et al (1992). This paper was not identified through the surveillance review because it was published outside of the literature search cut-off dates. It will not be considered further because it does not meet the inclusion criteria for study type, as it is a case-control study. 11. Prophylactic antibiotics: The use of prophylactic antibiotics to prevent infection in the newborn baby is covered in the NICE guideline on neonatal infection (early onset) which is currently being updated. We will pass on your comments to the developers for consideration during the update of this guideline.

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		Perinatal medication as a potential risk factor for adult drug abuse is examined in several studies. As drug abuse is such a growing, distressing and costly factor of modern society, LCGB would suggest that it is incumbent on NICE to examine the research in this area. Retrospective study of 200 opiate addicts born in Stockholm from 1945 to 1966 using siblings as controls. In subjects who had subsequently become addicts a significant proportion of mothers had received opiates, barbiturates or both and these mothers had received nitrous oxide for longer and more often. Jacobson, B., Nyberg, K., Gronbladh, L., Eklund, G., Bygdeman, M. and Rydberg, U. (1990). Opiate addiction in adult offspring through possible imprinting after obstetric treatment. BMJ, 301(6760), pp.1067-1070. The study group included 69 drug abusers. The control group included 33 non addicted siblings of drug abusers. 3 (or more)doses of opiates or barbiturates given to the mother at birth were associated, for the child, to a risk of becoming addicted multiplied by 4.7 (95% CI = 1.00 -44.1). Nyberg, K., Buka, S. and Lipsitt, L. (2000). Perinatal Medication as a Potential Risk Factor for Adult Drug Abuse in a North American Cohort. *Epidemiology*, 11(6), pp.715-716.	12. Obesity: NICE guideline CG190 does not cover the risks associated with caesarean section, however we will log your comment for consideration in the NICE guideline on caesarean section (CG132). 13. Microbiome: NICE guideline CG190 does not cover the risks associated with caesarean section, however we will log your comment for consideration in the NICE guideline on caesarean section (CG132).

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		Birth record data were gathered for 412 forensic cases comprising suicide victims, alcoholics, and drug addicts born in Stockholm after 1940 and who died there in 1978 - 1984. Comparison with 2901 controls. Suicides involving asphyxiation were closely associated with asphyxiation at birth; suicides by violent mechanical means were associated with mechanical birth trauma; drug addiction was associated with opiate or barbiturate administration to mothers during labor. Jacobson, B., Eklund, G., Hamberger, L., Linnarsson, D., Sedvall, G. and Valverius, M. (1987). Perinatal origin of adult self-destructive behavior. *Acta Psychiatrica Scandinavica*, 76(4), pp.364-371. Two possible risk factors for drug addiction were weighed against each other: perinatal factors and risk factors associated with the phenomenon of 'contagious' transmission of drug addiction in certain residential areas during adolescence. According to this matched case control study of 200 amphetamine addicts and 200 opiate addicts, the fact of being born in certain hospitals was a risk factor for becoming drug addicted. The variable residential area has not been able to explain the uneven distribution of drug abusers. Nyberg, K., Allebeck, P., Eklund, G. and Jacobson, B. (1993). Obstetric medication versus residential area as perinatal risk factors for subsequent adult drug	

		addiction in offspring. *Paediatric and Perinatal Epidemiology*, 7(1), pp.23-32. **Intrapartum care and autism** There is no reference anywhere to the association found between modern interventions in intrapartum care and the precipitous rise in autism cases worldwide and here in the UK. There may be several factors within intrapartum care that may contribute or create additive risks during this sensitive period. For example, Syntocinon or Pitocin (synthetic oxytocin) has been investigated in animal models of autism and the biological impact of synthetic oxytocin on oxytocin receptors in the brain. Although it works effectively on increasing contractions in the uterus, it may block oxytocin receptors in the mother's brain and breasts and inhibit their sensitivity and growth in numbers during priming period of labour and the postpartum. It would also pass through the placenta during labour into the baby's bloodstream and brain. Synthetic oxytocin does not have the same calming, prosocial effect that is found in animal models with natural oxytocin, and it may block normal oxytocin receptors, leading to difficulties in breastfeeding and potential impact on mood in the perinatal and postnatal period of both mother and infant. This has been thoroughly studied but the conclusions do not seem to have filtered down into intrapartum care so far.	

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		The mouse model of autism on the effects of a biological oxytocin metabolite, but not synthetic oxytocin, is illuminating. Moy, S., Teng, B., Nikolova, V., Riddick, N., Simpson, C., Van Deusen, A., Janzen, W., Sassano, M., Pedersen, C. and Jarstfer, M. (2019). Prosocial effects of an oxytocin metabolite, but not synthetic oxytocin receptor agonists, in a mouse model of autism. Neuropharmacology, 144, pp.301-311. Wagner, S. and Harony-Nicolas, H. (2017). Oxytocin and Animal Models for Autism Spectrum Disorder. Behavioral Pharmacology of Neuropeptides: Oxytocin, pp.213-237. Syntocinon has been researched, both retrospectively and prospectively, in studies in the birth records of those infants who have gone on to develop autism. Below are a few of the conclusions and references. Children born in a certain hospital in Japan were more at risk of becoming autistic. In this hospital children were usually delivered by the 'Kitasato University method' which is characterised by a complex combination of sedatives, anaesthetic agents and analgesics together with a planned delivery induced by oxytocin or prostaglandins a week before the expected date of delivery. Hattori, R., Desimaru, M., Nagayama, I. and Inoue, K. (1991). Autistic and developmental disorders after	

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		general anaesthetic delivery. *The Lancet*, 337(8753), pp.1357-1358. Across the five countries, emergency or planned CS is consistently associated with a modest increased risk of ASD from gestational weeks 36 to 42 when compared with vaginal delivery. Yip, B., Leonard, H., Stock, S., Stoltenberg, C., Francis, R., Gissler, M., Gross, R., Schendel, D. and Sandin, S. (2016). Caesarean section and risk of autism across gestational age: a multi-national cohort study of 5 million births. *International Journal of Epidemiology*, p.dyw336. No difference in gestational age at birth (including the proportion of premature infants), weight for gestational age, head circumference, or length were observed between cases and control subjects. Pre-eclampsia did not appear as a risk factor. These negative findings tend to give more importance to perinatal factors. Compared with their siblings, cases were more likely to have been induced (OR, 1.40; 95% CI, 1.03-1.90), experienced fetal distress (OR 1.64), had an Apgar score at 1 minute of 6 or less, and needed longer than 1 minute to breathe spontaneously. Compared with control subjects, cases were more likely to be born after induction (OR 1.43; 95% CI 1.12-1.83), to be born by elective c-section(OR 2.05. P<.001), or to be born by emergency c-section (p .01).	

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		Glasson, E., Bower, C., Petterson, B., de Klerk, N., Chaney, G. and Hallmayer, J. (2004). Perinatal Factors and the Development of Autism. *Archives of General Psychiatry*, 61(6), p.618. Compared with children born to mothers who received neither labor induction nor augmentation, children born to mothers who were induced and augmented, induced only, or augmented only experienced increased odds of autism after controlling for potential confounders related to socioeconomic status, maternal health, pregnancy-related events and conditions, and birth year. The observed associations between labor induction/augmentation were particularly pronounced in male children. This study suggests that induction/augmentation during childbirth is associated with increased odds of autism diagnosis in childhood. Gregory, S., Anthopolos, R., Osgood, C., Grotegut, C. and Miranda, M. (2014). Association of Autism With Induced or Augmented Childbirth in North Carolina Birth Record (1990–1998) and Education Research (1997–2007) Databases. *Obstetrical & Gynecological Survey*, 69(1), pp.7-9. This study surveyed mothers of ASD and non-ASD children to determine possible effects of labor and delivery (L&D) drugs on the development of ASD. The survey was administered to mothers; however, the results were analyzed by child, as the study focused on the development of autism. Furthermore, an	

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		independent ASD dataset from the Southwest Autism Research and Resource Center was analyzed and compared. Indeed, L&D drugs are associated with ASD (p = .039). Moreover, the Southwest Autism Research and Resource Center dataset shows that the labor induction drug, Pitocin, is significantly associated with ASD (p = .004). We also observed a synergistic effect between administrations of L&D drugs and experiencing a birth complication, in which both obstetrics factors occurring together increased the likelihood of the fetus developing ASD later in life (p = .0003). The present study shows the possible effects of L&D drugs, such as Pitocin labor-inducing and analgesic drugs, on children and ASD. Smallwood, M., Sareen, A., Baker, E., Hannusch, R., Kwessi, E. and Williams, T. (2016). *Increased Risk of Autism Development in Children Whose Mothers Experienced Birth Complications or Received Labor and Delivery Drugs*. This study surveyed mothers of ASD and non-ASD children to determine possible effects of labor and delivery (L&D) drugs on the development of ASD. The survey was administered to mothers; however, the results were analyzed by child, as the study focused on the development of autism. Furthermore, an independent ASD dataset from the Southwest Autism Research and Resource Center was analyzed and compared. Indeed, L&D drugs are associated with ASD (p = .039). Moreover, the Southwest Autism Research and Resource Center dataset shows that the labor induction drug, Pitocin, is significantly associated with	

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		ASD (p = .004). We also observed a synergistic effect between administrations of L&D drugs and experiencing a birth complication, in which both obstetrics factors occurring together increased the likelihood of the fetus developing ASD later in life (p = .0003). The present study shows the possible effects of L&D drugs, such as Pitocin labor-inducing and analgesic drugs, on children and ASD. Smallwood, M., Sareen, A., Baker, E., Hannusch, R., Kwessi, E. and Williams, T. (2016). Increased Risk of Autism Development in Children Whose Mothers Experienced Birth Complications or Received Labor and Delivery Drugs. *ASN Neuro*, 8(4), p.175909141665974. Results revealed a strong predictive relationship between perinatal Pitocin exposure and subsequent childhood ADHD onset (occurring in 67.1% of perinatal Pitocin cases vs. 35.6% in non-exposure cases, $\chi(2)=16.99$, $p<.001$). Fetal exposure time, gestation length, and labor length also demonstrated predictive power, albeit significantly lower. Kurth, L. and Haussmann, R. (2011). Perinatal Pitocin as an Early ADHD Biomarker: Neurodevelopmental Risk?. Journal of Attention Disorders, 15(5), pp.423-431. One team hypothesized that women exposed to peripartum synthetic oxytocin would have a reduced risk of postpartum depressive and anxiety disorders compared with those without any exposure. Contrary to their hypothesis, their results	

		indicated that women with peripartum exposure to synthetic oxytocin had a higher relative risk of receiving a documented depressive or anxiety disorder diagnosis or antidepressant/anxiolytic prescription within the first year postpartum than women without synthetic oxytocin exposure. Kroll-Desrosiers, A., Nephew, B., Babb, J., Guilarte-Walker, Y., Moore Simas, T. and Deligiannidis, K. (2017). Association of peripartum synthetic oxytocin administration and depressive and anxiety disorders within the first postpartum year. *Depression and Anxiety*, 34(2), pp.137-146. **Women who have experienced early life trauma and/or prenatal depression** Intrapartum care clinicians may wish to check whether women have experienced early life trauma and/or prenatal depression when considering options for intrapartum care.. These women are at especial risk of endogenous oxytocin deficiency, so might be particularly impacted by the effects of Syntocinon on their future mental health and their capacity to breastfeed.. They are at risk of a "multiple whammy", as follows: • initial lower than normal oxytocin levels due to life stressors • syntocinon in labour impacts their capacity to use their available oxytocin receptors and production in the brain ○ this inhibits oxytocin's primary bonding effect	

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		• the huge surges of oxytocin that would be associated with a more natural birth process are inhibited and this produces a negative feedback spiral • Syntocinon not only blocks available receptors but also inhibits the growth of additional receptors and oxytocin production that would normally occur in the “sensitive period” during and after the birth of their child • The reduced receptors would produce difficulty with breastfeeding due to the reduced oxytocin availability. ○ “let-down of the milk” and milk removal (oxytocin’s other role) is inhibited, ○ which then further reduces endogenous oxytocin production that would normally be associated with breastfeeding many times each day and night. • This reduces the mothers’ physiological opportunities to produce endogenous oxytocin for both themselves and their infants in the early days, weeks, months and years. As oxytocin is the bonding, soothing and “love” hormone, this reduces the fundamental mammalian drive towards sensitive, responsive parenting and also an infant’s innate responsiveness and developing capacity for empathy. • Inability to breastfeed reinforces the mothers’ low feelings of self-worth and personal efficacy. **Non-Hodgkins Lymphoma**	

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		Other untoward effects of intrapartum care that results in Caesarean section may be an increase in the number of children who go on to develop non-Hodgkins lymphoma. Mothers of children with NHL were more likely than mothers of controls to have undergone Cesarean section [Odds ratio (OR) 1.6] and to have been exposed to paracervical anesthesia during delivery (OR 1.8). Children with NHL were more likely than controls to have endocrine-metabolic disorders (OR 3.3). This study is one of the largest focusing on the etiology of childhood NHL. Most of the maternal and perinatal characteristics studied did not markedly affect risk for childhood NHL, which may be due to maternal and perinatal factors not included in these data or to exposures later in life. Adami, J., Glimelius, B., Cnattingius, S., Ekbom, A., Hoar Zahm, S., Linet, M. and Zack, M. (1996). Maternal and perinatal factors associated with non-Hodgkin's lymphoma among children. *International Journal of Cancer*, 65(6), pp.774-777. **Wilm's tumour** Wilm's tumour is another unhappy example. Wilms'-tumor children were more likely to have mothers who had been exposed to penthrane (methoxyflurane) anesthesia during delivery than mothers of controls (odds ratio (OR) = 2.4; 95% confidence interval (CI) 1.1 to 5.1); this excess risk was higher in females than males and increased with age at diagnosis. Wilms'-tumor cases were also more likely to	

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		have had physiologic jaundice (OR = 2.3; 95% CI 1.1 to 5.0). Higher parity of the mother decreased the risk of Wilms' tumor among females (OR = 0.7; 95% CI 0.5 to 1.0). Lindblad, P., Zack, M., Adami, H. and Ericson, A. (1992). Maternal and perinatal risk factors for Wilms' tumor: A nationwide nested case-control study in Sweden. *International Journal of Cancer*, 51(1), pp.38-41. **Prophylactic Antibiotics** An area that is not currently considered from the baby's point of view with in the guidelines, although mentioned in terms of mothers on page 46 under "Prophylactic antibiotics for operative vaginal delivery", is late-onset serious bacterial infections (sepsis) associated with intrapartum prophylactic antibiotic use. There is some research on this that might suggest intrapartum antibiotics may be used with more caution. Considering all types of intrapartum antibiotics, more case (41%) than control infants (27%) had been exposed to intrapartum antibiotics (adjusted odds ratio [OR]: 1.96; 95% confidence interval [CI]: 1.05-3.66), after controlling for hospital of delivery. The association was stronger when intrapartum antibiotherapy was with broad-spectrum antibiotics (adjusted OR: 4.95; 95% CI: 2.04-11.98), after	

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		controlling for hospital of delivery, maternal chorioamnionitis, and breastfeeding. Bacteria that were isolated from infected infants who had been exposed to intrapartum antibiotics were more likely to exhibit ampicillin resistance (adjusted OR: 5.7; 95% CI: 2.3-14.3), after controlling for hospital of delivery, but not to other antibiotics that are commonly used to treat SBI in infants. Glasgow, T. (2005). Association of Intrapartum Antibiotic Exposure and Late-Onset Serious Bacterial Infections in Infants. *PEDIATRICS*, 116(3), pp.696-702. **Obesity** Obesity is a current headline that is most associated with caesarean birth. There is a strong association between CS and increased offspring BMI, overweight and obesity in adulthood. Given the rising CS rate worldwide there is a need to determine whether this is causal, or reflective of confounding influences. Darmasseelane, K., Hyde, M., Santhakumaran, S., Gale, C. and Modi, N. (2014). Mode of Delivery and Offspring Body Mass Index, Overweight and Obesity in Adult Life: A Systematic Review and Meta-Analysis. *PLoS ONE*, 9(2), p.e87896. **The Microbiome** New research on the microbiome is also heavily implicated a widely divergent microbiome from the	

		norm after Caesarean delivery than after vaginal delivery. There is lifelong difficulty in establishing the more biologically normal microbiome derived from the vagina that is associated with more microbial diversity; improved immune system health and less tendency to overweight. For many more references and information on this subject, see “ the Microbiome Effect”, by Toni Harman and Alex Wakeford. New intrapartum and immediate postpartum procedures to provide the caesarean-delivered baby with swabs of the mother’s vaginal secretions may be in order. For all the reasons above, LCGB would urge the NICE team to recommend many of the intrapartum practices and structures provided in Better Birth and now current in Scandinavia and the Netherlands. These have been found to be more cost effective, with better outcomes, higher maternal satisfaction and much better breastfeeding rates than we achieve with our current system of intrapartum care here in the UK. We know that thoughtful procedures (and watchful but unobtrusive care as far as possible) supports a labouring women’s natural production of oxytocin and a more effective labour and birth. Such care reduces the spiral of intervention, syntocinon, narcotics, analgesics and ultimately Caesarean section. There is already substantial research evidence that the modern, technological and actively “managed” way of	

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		birth in the UK can have unforeseen consequences that may last a lifetime. Gentler, less time-driven practices may ultimately save lives, promote better health and save money.	
Department of Health and Social Care	Not answered	No comments provided	Thank you.

Do you have any comments on equalities issues?

Stakeholder	Overall response	Comments	NICE response
Midwifeexpert.com	Yes	Cultural and ethnicity sensitivity need to be taken into account and ensure that privacy/dignity is respected	Thank you for your comment.
Guy's and St Thomas' Hospital	Not answered	No comments provided	Thank you.
Diabetes UK	No	No comments provided	Thank you.
NICE – Quality and leadership, Quality standards	No	No comments provided	Thank you.
Swansea University	No	No comments provided	Thank you.

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University Hospital Southampton NHS Foundation Trust	No	No comments provided	Thank you.
Royal College of Midwives	No	No comments provided	Thank you.
British Intrapartum Care Society	None	No comments provided	Thank you.
British Maternal & Fetal Medicine Society	No	No comments provided	Thank you.
Royal College of Paediatrics and Child Health	No	No comments provided	Thank you.
Birth Trauma Association	No	No comments provided	Thank you.
Birth Companions	No	No comments provided	Thank you.
Royal College of Obstetricians and Gynaecologists	No issues.	No comments provided	Thank you.

The Hillingdon Hospitals NHS Foundation Trusts	Not answered	No comments provided	Thank you.
Northampton General Hospital Maternity Unit	No	No comments provided	Thank you.
Royal College of Anaesthetists	No	No comments provided	Thank you.
NCT	Not answered	No comments provided	Thank you.
Royal College of Nursing	Not answered	No comments provided	Thank you.
University of York	Yes	Unsure of the meaning of this question? Equality of what and whom? Are you referring to the equality and diversity of the women and families midwives care for? To ensure equality for the consultation, a more realistic timescale should be applied. 13 days is not adequate time for a thorough review of the guidelines. We would strongly suggest extending this.	Thank you for your comment. In this section of the consultation, we are looking for feedback on any concerns you may have around the impact of the guideline on equality issues. For further information, see NICE's equality objectives and equality programme 2016–2020 which summarises NICE's legal and other equality obligations and describes NICE's approach to meeting them, particularly the process of equality impact assessment. NICE uses this approach to consider not just equality in relation to groups sharing the characteristics protected by the Equality Act (2010) but also health inequalities arising from socioeconomic factors or associated with the shared circumstances, behaviours or conditions of particular groups (for example, looked-after children, people who are homeless, people who misuse drugs and people in

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			prison). Identifying such groups is an aspect of NICE's compliance with both general public law requirements to act fairly and reasonably, and human rights obligations. Thank you for your feedback regarding the stakeholder consultation timescale, please note that the aim of the consultation is to get stakeholder views on the surveillance proposal and not the whole guideline. However, we will make a note of this concern and bear this in mind for future topics where the evidence base is particularly large.
Action on Smoking and Health	Not answered	No comments provided	Thank you.
Ferring Pharmaceuticals Ltd.	No	No comments provided	Thank you.
University Hospitals Birmingham NHS Foundation Trust (UHB)	No	No comments provided	Thank you.
Lactation Consultants of Great Britain	No	No comments provided	Thank you.
Department of Health and Social Care	Not answered	No comments provided	Thank you.

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