

IPC High Risk. Electronic Fetal Monitoring Consultation

Name of stakeholder organisation	Section number	Comments	Developer response
Swansea University	1	Disagree – unless there is significant new high quality evidence to inform a change in practice	Thank you for this comment. Several stakeholders were of the opinion that this question should be reviewed and so it has been decided to proceed with a review. The interpretation of the existing evidence plus any new evidence identified will be considered by the Committee
Perinatal Institute	1	Agree with all recommendations	Thank you for this comment. Several stakeholders were of the opinion that this question should be reviewed and so it has been decided to proceed with a review
British Maternal and Fetal Medicine Society	1	Agree with the points omitted for review More specifics are required as to whether a pinard or a hand held Doppler or either should be utilised for such FH auscultation 1.4.12 No evidence could be found to support the removal of a CTG after a short a time as 20 minutes when it has been commenced for possible abnormalities – is this too short when in the earlier phases of labour when the contractions (and the hypoxic stress element) may be more infrequent/variable.	Thank you for this comment in support of the proposal to review this question. The additional information provided in the comment will be made available to the Guideline Committee during the review

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London Labour Ward Leads Group	1	In agreement	Thank you for this comment in support of the proposal to review this question
North Bristol Trust	1	<p>1.4.7: The FIGO Guidance suggests palpating the contractions and performing IA for a full minute both during and for at least 30 seconds after the contraction. Accepting that most recommendations regarding how to conduct intermittent auscultation are pragmatic as there is insufficient evidence base, performing IA as per FIGO advice would appear to maximise the opportunity of hearing any signs of fetal compromise during the time that the FH responds to/recovers from the effects of the contraction. In addition, it emphasises the importance of the midwife palpating contractions.</p> <p>The terminology in 1.4.9 &amp; 1.10.1 is incorrect: accelerations and decelerations are graphical features of a CTG, not auscultated findings. It may be possible to hear a slowing down or speeding up of the fetal heart rate that may be indicative of the FH recovering from the effects of a contraction.</p> <p>It would be helpful if you could add some additional pragmatic suggestions of what to do when the FH is auscultated above 160 bpm. FIGO recommend listening for 3 consecutive contractions and if FH is still more than 160 bpm, then further assessment is needed with a CTG and an obstetric review.</p> <p>It would be useful for the NICE guideline to at least refer to other guidelines that are based on the same conclusions.</p> <p>Implementation is key here. However good the analyses, if the recommendations are not implementable the guideline is wasted.</p>	Thank you for the information provided in the comment. This will be made available to the Guideline Committee during the review
National Childbirth Trust	1	It is unclear to us why this is under review as, to the best of our knowledge, there has been no new evidence on this topic since 2014. Therefore we are unable to support the the proposal to review these recommendations due to the lack of a clear rationale for the review and lack of transparency of the process being used to conduct the guideline	Thank you for this comment. Several stakeholders were of the opinion that this question should be reviewed and so it has been decided to proceed

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	<p>review. It would be helpful to know what new evidence is to be considered.</p> <p>However, if this guidance is to be reviewed, we are very clear that it needs input from expert methodologists alongside topic experts and sufficient experienced lay representatives.</p> <p>We would like to see NICE reintroduce grading of the recommendations A-D based on the varying levels of evidence and reintroduce Good Practice Points (GPPs) so there is greater clarity about the strengths and limitations of the evidence base on which the recommendations are made. Many of the monitoring recommendations appear to be GPPs and it would be really helpful and transparent for readers to know this. We believe that many of the recommendations in this document could be implemented with relatively little problem if there was transparency about the grading. The lack of transparency of NICE guidelines has concerned us ever since this grading was removed from NICE guidelines.</p> <p>If this guidance is being reviewed due to clinicians' struggling to put new recommendations into practice, we suggest that NICE should consider publishing EFM evidence and recommendations as a separate guideline (including the grading of the recommendations), not incorporated into Intrapartum Care (for women at high risk or low risk). CG190 is a huge document and IPC for women at high risk of complications is likely to be even bigger. Monitoring the baby during labour is relevant to both women at low-risk and women at high risk, so a separate document to cover all monitoring, rather than having monitoring for women at low risk in a separate document from monitoring for women at high risk, seems sensible.</p> <p>In addition, time pressured staff are unlikely to be reading the evidence which has fed into the recommendations, and therefore they cannot understand why they have been made or why they are important. If good evidence is to be adopted into practice it is crucial to make it</p>	<p>with a review. The interpretation of the existing evidence plus any new evidence identified will be considered by the Committee.</p> <p>The Committee will be supported by the developer's team, which includes methodologists.</p> <p>The comments regarding grading of recommendations and presentation of the evidence/recommendations have been highlighted with NICE</p>
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		accessible and transparent; if it is not possible to publish EFM guidance separately we suggest that each chapter should be available as a pdf. It would be helpful, in fact, if all full guideline chapters could be downloaded as separate pdfs to be read alongside more recent research or reviews, such as from Cochrane.. This would assist both clinicians and informed lay people in engaging with the evidence and recommendations.	
Royal College of Midwives	1	We agree with the proposal to review here in the context of intrapartum care for high risk women but do not agree that it is relevant to review for the guideline for healthy women and babies	Thank you for this comment in partial support of the proposal to review this question. Several stakeholders were of the opinion that this question should be reviewed in its entirety and so it has been decided to proceed with a review
Swansea University	10	Agree to proposal	Thank you for this comment in support of the proposal to review this question
Perinatal Institute	10	Recent findings from the INFANT study as presented at BMFMS 22/04/2016 suggest there is no difference. Full findings are still to be published. Agree for it to be reviewed.	Thank you for this comment in support of the proposal to review this question. The additional information provided in the comment will be made available to the Guideline Committee during the review
British Maternal and Fetal Medicine Society	10	As per the Infant Trial preview at BMFMS – automated interpretation does not – however there were acknowledged potential effects of the Trial which may have given a positive beneficial effect to those in the non-intervention arm – eg heightened CTG awareness, better teaching, use of central monitoring	Thank you for this comment. The information provided will be made available to the Guideline Committee during the review
London Labour Ward Leads Group	10	See INFANT study results.	Thank you for this comment. The information provided will be made available to the Guideline Committee during the review

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	10	There will be a number of new studies available to inform this question. The SisPorto study has already concluded that there was no advantage.	Thank you for this comment. The information provided will be made available to the Guideline Committee during the review
National Childbirth Trust	10	Whilst there is no recommendation, the full CG190 states: “Computerised systems have not been demonstrated to be superior to expert interpretation of the FHR trace and no comparisons have been undertaken with routine care.” Is there new evidence on this?  We are aware that INFANT is due to be published but we are also aware that this trial did not focus on women at low risk, but rather women who were deemed to need continuous CTG , so namely women at increased risk of problems. So is there additional new evidence apart from the INFANT trial?	Thank you for this comment. The review will consider whether there is any new evidence (such as results from the INFANT trial) and interpretation of any previously identified evidence
Royal College of Midwives	10	We agree with the proposal to review.	Thank you for this comment in support of the proposal to review this question
Swansea University	11	Agree to proposal	Thank you for this comment in support of the proposal not to review this question
Perinatal Institute	11	Label CTG with reason for commencing CTG.	Thank you for this comment. The majority of stakeholders were of the opinion that this question should not be reviewed and so it has been decided not to proceed with a review
British Maternal and Fetal Medicine Society	11	Agree review not required	Thank you for this comment in support of the proposal not to review this question
London Labour Ward Leads Group	11	Consideration should be given to recommending electronic recording and storage of CTGs / electronic intrapartum record.	Thank you for this comment. The majority of stakeholders were of the opinion that this question should not be reviewed and so it has been decided not

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			to proceed with a review
National Childbirth Trust	11	We welcome Recommendations 1.10.55 and 1.10.56, and we see no need to review.	Thank you for this comment in support of the proposal not to review this question
Royal College of Midwives	11	We agree with the proposal not to review.	Thank you for this comment in support of the proposal not to review this question
Swansea University	12	Agree to proposal	Thank you for this comment in support of the proposal not to review this question
Perinatal Institute	12	Agree.	Thank you for this comment in support of the proposal not to review this question
British Maternal and Fetal Medicine Society	12	Agree review not required	Thank you for this comment in support of the proposal not to review this question
London Labour Ward Leads Group	12	In agreement	Thank you for this comment in support of the proposal not to review this question
National Childbirth Trust	12	We welcome Recommendations 1.10.57- 1.10.60 and see no reason to review them. Do these need to be highlighted as Good Practice Points?	Thank you for this comment in support of the proposal not to review this question. The majority of stakeholders were of the opinion that this question should not be reviewed and so it has been decided not to proceed with a review. NICE does not currently grade recommendations (although the terms 'offer' and 'consider' are used to convey the strength of recommendations)

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Royal College of Midwives	12	We agree with the proposal not to review	Thank you for this comment in support of the proposal not to review this question
Baby Lifeline	2	<p><i>Caution</i></p> <p><i>Fetal neurological damage occurs through an alternative inflammatory pathway of brain damage in cases of chorioamnionitis. Therefore, even if the CTG trace is normal, fetal neurological damage may still occur. Therefore, it is vital to ensure that fetal heart rate cycling (alternate periods of reduced and normal baseline variability) and accelerations are maintained. If there is an increase in baseline fetal heart rate for the given gestation or recurrent, deep and prolonged decelerations (&gt;60 seconds) in the presence of clinical chorioamnionitis, consideration should be given to expedite delivery. Fetal scalp blood sampling (pH or lactate) should not be performed as the results would be falsely reassuring in fetal sepsis and there is no robust scientific evidence to support the use of FBS as an additional test of fetal wellbeing.</i></p>	Thank you for this comment. The information provided will be made available to the Guideline Committee during the review
Swansea University	2	Disagree – unless there is significant new high quality evidence to inform a change in practice	Thank you for this comment. The majority of stakeholders were of the opinion that this question should be reviewed and so it has been decided to proceed with a review. The interpretation of the existing evidence plus any new evidence identified will be considered by the Committee
British Maternal and Fetal Medicine Society	2	1. Concerns have been expressed that once a patient has a medical disorder associated with placental insufficiency that not recommending continuous electronic fetal monitoring seems inappropriate. For moderate hypertension treatment would be recommended but not a CTG which does not seem appropriate (especially with a lack of evidence to support such an arbitrary	Thank you for this comment. The information provided will be made available to the Guideline Committee during the review

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		<p>cut off).</p> <ol style="list-style-type: none"> <li>2. It was no clear why 24 hours was taken as prolonged ROM rather than hours</li> <li>3. Agree with omitted points to not review</li> <li>4. 1.10.3 – should this definition be changed to a temp of &lt;36 degree C as sepsis is known to present with low temperatures</li> <li>5. 1.10.1 – surely the maternal pulse rate should be palpated every time not just if there as FH abnormalities</li> <li>6. 1.10.7 – as above for 1.4.12</li> </ol>	
London Labour Ward Leads Group	2	<p>In agreement.          However specific mention could be made here of the risks of chorioamnionitis.  <i>Fetal neurological damage occurs through an alternative inflammatory pathway of brain damage in cases of chorioamnionitis. Therefore, even if the CTG trace is normal, fetal neurological damage may still occur. Therefore, it is vital to ensure that fetal heart rate cycling (alternate periods of reduced and normal baseline variability) and accelerations are maintained. If there is an increase in baseline fetal heart rate for the given gestation or recurrent, deep and prolonged decelerations (&gt;60 seconds) in the presence of clinical chorioamnionitis, consideration should be given to expedite delivery. Fetal scalp blood sampling (pH or lactate) should not be performed as the results would be falsely reassuring in fetal sepsis and there is no robust scientific evidence to support the use of FBS as an additional test of fetal wellbeing.</i></p>	<p>Thank you for this comment in support of the proposal to review this question. The additional information provided in the comment will be made available to the Guideline Committee during the review</p>
North Bristol Trust	2	<p>1.10.3 &amp; 1.10.4: This guidance is very confusing from the start.</p>	<p>Thank you for this comment in support of the proposal to review this question. The additional information provided in the comment will be made available to the Guideline Committee during the review</p>



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		<p>1.10.3 Advise continuous cardiotocography if any of the following risk factors are present or arise during labour:</p> <ul style="list-style-type: none"> <li>• suspected chorioamnionitis or sepsis, or a temperature of 38°C or above</li> <li>• severe hypertension (160/110 mmHg or above [see the NICE guideline on <a href="#">hypertension in pregnancy</a>]).</li> <li>• oxytocin use</li> <li>• the presence of significant meconium (see <a href="#">recommendation 1.5.2</a>)</li> <li>• fresh vaginal bleeding that develops in labour. <b>[new 2014]</b></li> </ul> <p>1.10.4 If any one of the following risk factors is present or arises during labour, perform a full assessment of all factors listed in <a href="#">recommendation 1.5.1</a>:</p> <p>As you can see there is a reference to other risk factors in 1.5.2, which is on P32 and also to 1.5.1, which is on P30. Therefore in addition to the risk factors in 1.10.3, we also need to take into account 5 additional factors, which are listed in 2 different sections of the guideline. It would be helpful if all of these risk factors could be collated in one section to aid implementation, and avoid the possibility of local clinicians missing out important information in their local guidelines.</p> <p>The recommendation in 1.10.7 needs more clarification as it could be extrapolated that where there has been an auscultated abnormality, the 20 minute CTG could be carried out in a low-risk birth centre setting. Surely, this is not what is intended? IA is equally available in tertiary units and therefore would it not be helpful to clarify that women at home or in a birth centre need to be transferred to a tertiary unit for assessment with a 20 min CTG and also an obstetric review, and then if all is normal, IA could be recommenced &amp; continued in the tertiary unit (or in an alongside birth centre). It would surely be unwise (and expensive) to transfer the mother back to the stand-alone birth centre, as there may be further abnormalities auscultated and then another transfer would be required.</p>	
National Childbirth Trust	2	As with Review Question 1, we are unable to support the proposal to review these recommendations as we are not aware of any new	Thank you for this comment. Several stakeholders were of

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		<p>evidence on this question.</p> <p>With regard to recommendation 1.10.2, Appendix P of the full guideline is very clear on how CTG does not improve outcomes for low risk women and their babies and has very limited usefulness as a screening test, as reflected in the fetal heart rate interpretation 'evidence to recommendations' section of CG190 chapter 10. Clinicians should not intervene unless there is clear evidence of benefit and clear evidence that the intervention does more good than harm (applies also to 1.10.7).</p> <p>We suggest that recommendation 1.10.6 should be clearly labelled as a Good Practice Point. We think there are many other GPPs throughout this document.</p>	<p>the opinion that this question should be reviewed and so it has been decided to proceed with a review. The interpretation of the existing evidence plus any new evidence identified will be considered by the Committee. The additional information provided in the comment will be made available to the Guideline Committee during the review. However, NICE does not currently grade recommendations (although the terms 'offer' and 'consider' are used to convey the strength of recommendations)</p>
Royal College of Midwives	2	<p>We agree with the proposal to review here in the context of intrapartum care for high risk women but do not agree that it is relevant to review for the guideline for healthy women and babies</p>	<p>Thank you for this comment in partial support of the proposal to review this question. Several stakeholders were of the opinion that this question should be reviewed in its entirety and so it has been decided to proceed with a review</p>
Swansea University	3	<p>Disagree – unless there is significant new high quality evidence to inform a change in practice</p>	<p>Thank you for this comment. Several stakeholders were of the opinion that this question should be reviewed and so it has been decided to proceed with a review. The interpretation of the existing evidence plus any new evidence identified will be considered by the Committee</p>

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Perinatal Institute	3	Agree with the need to review.	Thank you for this comment in support of the proposal to review this question
British Maternal and Fetal Medicine Society	3	Agree a review would be appropriate	Thank you for this comment in support of the proposal to review this question
National Childbirth Trust	3	NCT has no comment to make regarding this proposal. It would be helpful to know where exactly in the guideline it is proposed to answer this question.	Thank you for this comment. The question will be reviewed and the Guideline Committee will consider how and where to reflect the evidence in the recommendations
Royal College of Midwives	3	We do not agree with the proposal to review here as this question was adequately addressed in CG 190 and we are not aware of any recent evidence that would change recommendations.	Thank you for this comment. Several stakeholders were of the opinion that this question should be reviewed in its entirety and so it has been decided to proceed with a review
Midwifeexpert.com	4	There should be a “fresh Eyes” approach ? every two hours by a colleague even if a CTG remains normal	Thank you for the information provided in the comment. This will be made available to the Guideline Committee during the review
University of Nottingham	4	<p>Previous NICE guidance had three words for describing each component of the FHR. Reassuring, non-reassuring and abnormal. And three different words for classifying the whole trace. Normal, suspicious and pathological. Many colleagues put a lot of effort into teaching colleagues about the difference between classifying a feature and classifying the whole trace.</p> <p>But the new guidance uses very similar words for the individual features and for the whole trace. As follows:</p>	Thank you for this comment. The information provided will be made available to the Guideline Committee during the review

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		<p>For individual features the new guideline uses Normal/reassuring, Non-reassuring abnormal</p> <p>For the overall classification it uses CTG is normal/ reassuring CTG is non-reassuring and suggests need for conservative measures CTG is abnormal and indicates need for conservative measures AND further testing CTG is abnormal and indicates need for urgent intervention</p> <p>Many colleagues find the use of such similar terms confusing.</p> <p>Ever since we tried to use the new terminology in Nottingham, our CS/CTG review meetings have degenerated into endless queries of “Are you talking about the feature, or the whole classification?”</p>	
Baby lifeline	4	<p>The Guideline Table proposed by NICE 2014 was too complex, illogical (i.e. recommendation to give fluids for a high baseline fetal heart rate, which may be secondary to fetal infection) and is not user friendly. The more complex the guideline is, greater the likelihood of CTG misinterpretation which may lead to intrapartum stillbirths, hypoxic-ischaemic encephalopathy (HIE) as well as unnecessary operative interventions (emergency caesarean sections and operative vaginal births), all of which increase risks to the fetuys and the woman as well as would expose the midwives and obstetricians to medico-legal consequences.</p> <p>The guideline recommends a single value for baseline variability (&gt;5 bpm) as opposed all other international guidelines (5-25 bpm) which may lead to obstetricians and midwives missing the ‘saltatory’ pattern (&gt;25 bpm) associated with an acutely evolving hypoxia leading to hypoxic-ischaemic encephalopathy (HIE) and perinatal deaths. Although, this was highlighted to the NICE GDG in 2014 these concerns were unfortunately disregarded resulting in unnecessary harm to</p>	<p>Thank you for this comment. The information provided will be made available to the Guideline Committee during the review.</p> <p>Regarding the request that the classification system in CG190 be immediately abandoned, NICE considers that it is important to be base any changes to its guidance on a process involving review of the relevant evidence by an independent advisory committee and stakeholder engagement. NICE further believes that the approach it has proposed to reviewing the</p>

		<p>babies. This needs to be immediately rectified, even whilst the ‘urgent review’ process is being undertaken because the babies are likely to be harmed due to this serious flaw in the guideline.</p> <p><u>Therefore, we kindly request that that the existing CTG Classification System proposed by NICE 2014 should be immediately abandoned on patient safety grounds, even during the time period when the urgent review is taking place to protect the babies, mothers and the staff. NICE 2007, was less complicated and more user friendly as compared to NICE 2014 and those units who haven’t adopted the FIGO Guidelines on CTG Interpretation can continue to use the old NICE 2007 Guidelines in the interim periods as they are safer than NICE 2014.</u></p> <p>The CTG Guidelines developed by the International Federation of Gynaecology and Obstetrics (FIGO in October 2015 had a 3-member Guideline Development Group who were the representatives of the FIGO and European College of Obstetricians and Gynaecologists, American College of Obstetricians and Gynaecologists and the Royal College of Obstetricians and Gynaecologists, respectively. In addition, there was an International Panel of CTG Experts from 37 countries as well as an additional 13 CTG Experts based on their extensive publications on CTG which included Prof Phil Steer, Prof Sir Arulkumaran and Mr Ugwumadu from the UK.</p> <p>Therefore, the FIGO Guidelines developed with RCOG input and CTG experts from the UK is being implemented in approximately 50 countries and will form the basis for future research, comparison of outcomes and collaboration. In addition to 50 countries, approximately 30 Maternity Units in the UK have implemented the FIGO Guidelines due to its objectivity and ease of use. The Pan London Labour Ward Leads group comprising of approximately 20 maternity units in London has also endorsed the FIGO Guidelines for implementation. During Baby Lifeline CTG Masterclasses, several delegates have highlighted the difficulties in implementing the NICE Guidelines due to its complexity.</p>	<p>guidance on fetal monitoring in CG190 is the quickest way of addressing stakeholder concerns robustly.</p>
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		<p>Therefore, we would like to strongly recommend implementation of the FIGO Guidelines which have already been implemented not only by 50 countries around the world including the European Union, the USA but also by approximately 30 maternity units in the UK and also has had the input of RCOG and as well as eminent CTG experts in the UK who not only have published extensively in the area but also are medico-legal experts to Court in its development.</p> <p>We have inserted the Guideline Table below and have attached the Full Guideline as an appendix (Appendix 1)</p>	
Swansea University	4	<p>Colleagues in practice express continued dissatisfaction with the NICE descriptors for variable decelerations. One expert midwife states that the classification of the CTG is not as straight-forward as Table 10 suggests. In practice it would be helpful if clinicians are able to refer Table 10 to confidently decide whether or not the CTG requires action and / or intervention.</p> <p>Agree to the proposal</p>	Thank you for this comment in support of the proposal to review this question. The additional information provided in the comment will be made available to the Guideline Committee during the review
Norfolk & Norwich University NHS Foundation Trust	4	<p>The NICE classification of CTGs is not fit for purpose.</p> <p>It ought to be replaced by the FIGO classification as soon as possible.</p>	Thank you for this comment. The information provided will be made available to the Guideline Committee during the review
Perinatal Institute	4	<p>1.10.35 – based on an assessment of the most likely underlying cause – mobilisation to be avoided in the case of expected cord prolapse.</p> <p>Agree that the definitions and interpretations of a CTG trace need to be defined in NICE guidance.</p>	Thank you for this comment. The information provided will be made available to the Guideline Committee during the review
British Maternal and Fetal Medicine Society	4	<p>1. Multiple comments that in practice these interpretation guidelines were cumbersome, difficult to remember what you were supposed be doing and changed from the prior tables (which were easy to follow and embedded in practice) without a strong evidence base. Whilst reading them makes ‘sense’, the translated actions from such do not flow and make CTG interpretation more complicated - whilst they may save a few FBS, in practice anything that over complicates CTG interpretation does not seem to improve interpretation.</p>	Thank you for this comment. The information provided will be made available to the Guideline Committee during the review

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		<ol style="list-style-type: none"> <li>2. 1.10.35 – It is unrealistic to think that consultants will or should be asked on when to restart IVO ater stopping it secondary to contraction frequency 1.10.17 and 1.10.20 – as well as IV fluids/paracetamol – should the guidance not be more explicit for looking for risk factors and clinical signs of sepsis and use of antibiotics.</li> <li>3. 1.10.13 – if this a cardiotocograph review (and not a FH tracing review) then a full assessment should include assessment of uterine activity</li> <li>4. 1.10.25 – should the time taken to recover to the baseline be included here</li> <li>5. 1.10.26 – Many comments that the decision to remove the words atypical and typical variable has not felt to have worked in clinical practice and that there was no obvious evidence to support the changes recommended. What may be more effective is advise on what factors would be classed as atypical. Lack of these definitions of variable leaves us practising with different terminology to the other international definitions – is that sensible?</li> <li>6. 1.10.28 – Whilst position change would be supported, mobilisation unless telemetry is in use is unrealistic and the likely scenario is then loss of contact at a time you are trying to achieve good FH monitoring</li> <li>7. 1.10.33 – whilst this statement was agreed with there were concerns that these late decelerations were ‘singled out’ when the very shallow late decelerations may well be more ominous</li> </ol>	
<p>London Labour Ward Leads Group</p>	<p>4</p>	<p>The guideline tables [no 10 &amp; 11] proposed by NICE 2014 is too complex and not user friendly. Many units in London have not implemented it into clinical practice.</p> <p>The guideline needs to be simple for all maternity staff to follow – in order to maximise outcomes for mothers and babies. A complex guideline is prone to misinterpretation.</p> <p>The guideline recommends a single value for baseline variability (&gt;5</p>	<p>Thank you for this comment. The information provided will be made available to the Guideline Committee during the review</p>

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		<p>bpm) as opposed all other international guidelines (5-25 bpm) which could lead to obstetricians and midwives missing the ‘saltatory’ pattern (&gt;25 bpm) associated with an acutely evolving hypoxia leading to hypoxic-ischaemic encephalopathy (HIE) and perinatal deaths.</p> <p>The CTG Guidelines developed by the International Federation of Gynaecology and Obstetrics [FIGO] in October 2015 had a 3-member Guideline Development Group who were the representatives of the FIGO and European College of Obstetricians and Gynaecologists, American College of Obstetricians and Gynaecologists and the Royal College of Obstetricians and Gynaecologists, respectively. In addition, there was an International Panel of CTG Experts from 37 countries as well as an additional 13 CTG Experts based on their extensive publications on CTG, including representation from the UK.</p> <p>Therefore, the FIGO Guidelines developed with RCOG input and CTG experts from the UK is being implemented in approximately 50 countries and will form the basis for future research, comparison of outcomes and collaboration. In addition to 50 countries, approximately 30 Maternity Units in the UK have implemented the FIGO Guidelines due to their objectivity and ease of use.</p> <p>We have considered the NICE &amp; the FIGO guidelines and as a group of over 20 maternity units in London have endorsed the FIGO Guidelines for implementation.</p>	
North Bristol Trust	4	<p>There are changes in the overall classification terminology from the ‘normal, suspicious &amp; pathological’ terms used in the last 2 guidelines, to normal, non-reassuring and abnormal in the new guideline. The justification for the change is unclear when there is little or no new evidence, and it is doubly difficult to understand as ‘non-reassuring’ and ‘abnormal’ were features of a CTG that contributed to the overall classification in the previous NICE guidance.</p> <p>The ‘features’ of a CTG have also now been changed. They were previously as below:</p>	Thank you for this comment. The information provided will be made available to the Guideline Committee during the review



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Feature	Baseline (bpm)	Variability (bpm)	Decelerations	Accelerations
Reassuring	110–160	≥ 5	None	Present
Non-reassuring	100–109 161–180	< 5 for 40–90 minutes	Typical variable decelerations with over 50% of contractions, occurring for over 90 minutes Single prolonged deceleration for up to 3 minutes	The absence of accelerations with otherwise normal trace is of uncertain significance
Abnormal	< 100 > 180 Sinusoidal pattern ≥ 10 minutes	< 5 for 90 minutes	Either atypical variable decelerations with over 50% of contractions or late decelerations, both for over 30 minutes Single prolonged deceleration for more than 3 minutes	

Category	Definition
Normal	An FHR trace in which all four features are classified as reassuring
Suspicious	An FHR trace with one feature classified as non-reassuring and the remaining features classified as reassuring
Pathological	An FHR trace with two or more features classified as non-reassuring or one or more classified as abnormal

These were usefully combined into a CTG sticker that has, and is, being used around the UK (and further abroad) to help staff classify and act on CTGs – see below:

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Intrapartum CTG Proforma	Reassuring (Acceptable)	Non-Reassuring	Abnormal	North Bristol  NHS Trust
<b>Baseline rate (bpm)</b>	110 - 160 Rate:	100 - 109 Rate: 161 - 180 Rate:	Less than 100 Rate: More than 180 Rate: Sinusoidal pattern for 10 minutes or more	Comments:-
<b>N.B Rising baseline rate even within normal range may be of concern if other non-reassuring / abnormal features present.</b>				
<b>Variability (bpm)</b>	5 bpm or more	Less than 5 bpm for 40 - 90 minutes	Less than 5 bpm for 90 minutes	Comments:-
<b>Accelerations</b>	Present	None for 40 minutes	Comments:-	
<b>Decelerations</b>	None	<b>Typical</b> variable decelerations with more than 50% of contractions for more than 90 minutes	<b>Atypical</b> variable decelerations with more than 50% of contractions for more than 30 minutes	Comments:-
	<b>Typical</b> variable decelerations with more than 50% of contractions but for less than 90 minutes	<b>Atypical</b> variable decelerations with more than 50% of contractions for less than 30 minutes	<b>Late</b> decelerations for more than 30 minutes	
	<b>Typical or atypical</b> variable decelerations with less than 50% of contractions	<b>Late</b> decelerations for less than 30 minutes		
	<b>True early</b> decelerations	Single prolonged deceleration for up to 3 minutes	Single prolonged deceleration for more than 3 minutes	
<b>N.B If CTG has any non-reassuring or abnormal features from commencement of monitoring, it may not be appropriate to wait 30 or 90 minutes before requesting review</b>				
<b>Opinion</b> <input type="checkbox"/>	<b>Normal</b> <input type="checkbox"/> <b>CTG</b> (All 4 features reassuring)	<b>Suspicious</b> <input type="checkbox"/> <b>CTG</b> (1 non reassuring feature)	<b>Pathological</b> <input type="checkbox"/> <b>CTG</b> (2 or more non-reassuring or 1 or more abnormal features)	
Cont's: :10	Maternal pulse:	Liquor colour:	Dilatation (cm):	Gestation (wks):
<b>Action:</b>				
RVJ0191 lgd				
Date:	Time:	Signature: .....	Print: .....	Designation: .....
<b>Fresh Eyes opinion</b>   at least 2 hly Agree with the above opinion? YES / NO If different to above opinion please do another sticker.				
Date:	Time:	Signature: .....	Print: .....	Designation: .....

In addition, there are inconsistencies within the guideline: on page 42 of the guideline there is a recommendation to assess all 4 features..... whereas later in the same section, there are only 3 features and in table 11 (P44) only 3 features are recommended.

**Principles for intrapartum CTG trace interpretation**

- When reviewing the CTG trace, assess and document all 4 features (baseline rate, baseline variability, presence or absence of decelerations, presence of accelerations).

See below – only 3 features tabulated

Description	Feature		
	Baseline (beats/ minute)	Baseline variability (beats/ minute)	Decelerations
Normal/ reassuring	100–160	5 or more	None or early

Table 11 recommends using 3 features – see below.

**Table 11 Management based on interpretation of cardiotocograph traces**

Category	Definition	Interpretation	Management
CTG is normal/ reassuring	All 3 features are normal/ reassuring	Normal CTG, no non-reassuring or abnormal features, healthy fetus	<ul style="list-style-type: none"> <li>• Continue CTG and normal care.</li> <li>• If CTG was started because of concerns arising from intermittent auscultation, remove CTG after</li> </ul>

At best, this is inconsistent.

Finally, there is recommendation that seems to obviate all of the above guidance:

- It is not possible to categorise or interpret every CTG trace. **Senior obstetri important in these cases.**

All CTGs will have to be categorized and interpreted at some stage, but we all accept that it can be difficult.

Surely, this should read: ....it can be difficult to categorise or interpret some CTGs and senior input should be sought where this is the case.

		<p>Classification of decelerations          There is a very clear, but seemingly unjustified sentence to begin with.</p> <p>1.10.26 Describe decelerations as 'early', 'variable' or 'late'. Do not use the terms 'typical' and 'atypical' because they can cause confusion. <b>[new 2014]</b></p> <p>The justification for both of these changes is unclear. There is an observation that <i>'clinicians are confused by the terms typical and atypical variables and therefore these terms should not be used'</i>, but the provenance of this observation is unclear. It would be really useful to understand how and why this decision was reached.</p> <p>We find the difference between typical and atypical decelerations is reasonably simple: typical decelerations are symmetrical through the midline of the deceleration; atypicals are not.</p> <p>The description of variable decelerations has changed from typical and atypical to: variable (1) or variable (2) or late decelerations. Clearly 2 sets of variable decelerations could be considered confusing, at best.</p> <p><b>Variable decelerations:</b></p> <ul style="list-style-type: none"> <li>• dropping from baseline by 60 beats/minute or less and taking 60 seconds or less to recover</li> <li>• present for over 90 minutes</li> <li>• occurring with over 50% of contractions.</li> </ul> <p><b>OR</b></p> <p><b>Variable decelerations:</b></p> <ul style="list-style-type: none"> <li>• dropping from baseline by more than 60 beats/minute or taking over 60 seconds to recover</li> <li>• present for up to 30 minutes</li> <li>• occurring with over 50% of contractions.</li> </ul>	
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		<p>Moreover, the new decelerations classification is very difficult to understand and classify in practice. We have made some additional observations: Is 'dropping' the same as decelerating ? They seemed to be used interchangeably.</p> <p>One type of variable deceleration is: 60 beats/min or less and 60s or less to recover. Is 'recovery' measured from the nadir of the deceleration, or the total duration of the deceleration ? This is unclear.</p> <p>The next type of variable decelerations are basically anything other than the first type of decelerations, but once again there is a very wordy and impenetrable definition. In 1.10.33: there is a confusing further classification of decelerations:</p> <p>1.10.33 Take into account that the longer, the later and the deeper the individual decelerations, the more likely the presence of fetal acidosis (particularly if decelerations are accompanied by tachycardia and/or reduced baseline variability), and take action sooner than 30 minutes if there is concern about fetal wellbeing. <b>[new 2014]</b></p>	
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	<p>Surely the full house of longer, later and deeper is not required and this would be better expressed as longer, later and/or deeper.....</p> <p>Note also that decelerations (of any variety) with a tachycardia and reduced baseline variability would qualify for action on all of the other CTG classifications too.</p> <p>Finally, we are concerned that the new classification may miss shallow, late decelerations that last less than 60s.</p> <p>The new description of variables i.e. the depth and length of decelerations for varying periods of time, is also difficult to implement for local use in a sticker. One unit has contacted us to say that they have gone back to using their DR C BRAVADO stickers as they don't know what else to do: a mnemonic that isn't recommended in NICE at all!</p> <p>The FIGO guidance describes variable as V shaped (typical) and U-shaped with reduce variability within the deceleration (atypical). This description appears to be well understood by our clinical staff</p> <p>Action on CTGs Another issue is the new recommended terminology for actions e.g. <i>'CTG is non-reassuring and suggests need for conservative measures'</i> is the same as the previous 'action' for a 'suspicious' CTG, however, it appears unnecessarily wordy. Using the term 'Conservative measures' rather than 'actions' is confusing and arbitrarily semantic. This is presumably to sound less medical/interventional, however if a woman has sufficient risk factors to justify electronic fetal monitoring, then some intervention or 'action' will be required if the CTG is not Normal. Hopefully we are only performing EFM for those women that really need</p>	
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		<p>it, and it is really important that a full clinical and risk assessment is performed for all women who present in labour (in any birth setting) to jointly identify the most appropriate method of fetal monitoring for their labour.</p> <p>There is also a recommendation in 1.10.35 and Table 11 on P45 for oral fluids in response to a '<i>CTG is non-reassuring and suggests need for conservative measures</i>'. Our concern here, is two-fold: firstly, we have spent along time dispelling the myth that giving women a cold or sugary drink may help to increase fetal movements, and we are concerned that this may indirectly endorse this incorrect action. Secondly, we aim to keep women well hydrated through-out labour, so if dehydration is sufficiently a problem to cause the CTG to become non-reassuring, then it is surely most likely that IV fluids are needed.</p> <p>Furthermore, the actions that should be taken when there are 'non-reassuring' or 'abnormal features' (or a suspicious or pathological CTG) are confusing as once again there are many actions included over several different sections of the guideline (there is a table in the implementation section, but it is 3 pages long, so again this is very difficult to use in practice and make a quick reference guide).</p> <p>Baseline rate          We note that there is a new recommendation that a baseline fetal heart rates of 100-110bpm may be acceptable.          We think that the guideline could, and should, clarify that FH rates of between 100 - 110bpm are only possibly acceptable with EFM, and not IA. We know the authors might think this is clear in the guideline, but again we have had other units contacting us raising the point that their community midwives are now extrapolating from NICE, that it's ok to hear a FH of 100 - 110bpm on IA, which it clearly isn't without further assessment of fetal well-being. However, this is the sort of confusion that has arisen.</p>	
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Furthermore, the table on P42 states that a fetal heart rate of 100 may be acceptable:

Description	Feature		
	Baseline (beats/minute)	Baseline variability (beats/minute)	Decelerations
Normal/reassuring	100-160	5 or more	None or early

On P49 this is finessed further:

- a baseline fetal heart rate between 100 and 109 beats/minute (having confirmed that this is not the maternal heart rate) with normal baseline variability and no variable or late decelerations is normal and should not prompt further action

A baseline of 100 bpm is only normal when all other features are 'normal'. Therefore surely when there is a baseline of 100 bpm with one other non-reassuring feature (as above), then we would expect this to appear in the non-reassuring section of the same table. This does not appear to be the case in the relevant section of the (un-numbered) table below:



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		<table border="1"> <tr> <td data-bbox="613 197 781 555">Non-reassuring</td> <td data-bbox="781 197 909 555">161–180</td> <td data-bbox="909 197 1086 555">Less than 5 for 30–90 minutes</td> <td data-bbox="1086 197 1523 555"> <p>Variable decelerations:</p> <ul style="list-style-type: none"> <li>dropping from baseline by 60 beats/minute or less <b>and</b> taking 60 seconds or less to recover</li> <li>present for over 90 minutes</li> <li>occurring with over 50% of contractions.</li> </ul> <p><b>OR</b></p> <p>Variable decelerations:</p> <ul style="list-style-type: none"> <li>dropping from baseline by more than 60 beats/minute <b>or</b> taking over 60 seconds to recover</li> <li>present for up to 30 minutes</li> <li>occurring with over 50% of contractions.</li> </ul> <p><b>OR</b></p> <p>Late decelerations:</p> <ul style="list-style-type: none"> <li>present for up to 30 minutes</li> <li>occurring with over 50% of contractions.</li> </ul> </td> </tr> </table>	Non-reassuring	161–180	Less than 5 for 30–90 minutes	<p>Variable decelerations:</p> <ul style="list-style-type: none"> <li>dropping from baseline by 60 beats/minute or less <b>and</b> taking 60 seconds or less to recover</li> <li>present for over 90 minutes</li> <li>occurring with over 50% of contractions.</li> </ul> <p><b>OR</b></p> <p>Variable decelerations:</p> <ul style="list-style-type: none"> <li>dropping from baseline by more than 60 beats/minute <b>or</b> taking over 60 seconds to recover</li> <li>present for up to 30 minutes</li> <li>occurring with over 50% of contractions.</li> </ul> <p><b>OR</b></p> <p>Late decelerations:</p> <ul style="list-style-type: none"> <li>present for up to 30 minutes</li> <li>occurring with over 50% of contractions.</li> </ul>	
Non-reassuring	161–180	Less than 5 for 30–90 minutes	<p>Variable decelerations:</p> <ul style="list-style-type: none"> <li>dropping from baseline by 60 beats/minute or less <b>and</b> taking 60 seconds or less to recover</li> <li>present for over 90 minutes</li> <li>occurring with over 50% of contractions.</li> </ul> <p><b>OR</b></p> <p>Variable decelerations:</p> <ul style="list-style-type: none"> <li>dropping from baseline by more than 60 beats/minute <b>or</b> taking over 60 seconds to recover</li> <li>present for up to 30 minutes</li> <li>occurring with over 50% of contractions.</li> </ul> <p><b>OR</b></p> <p>Late decelerations:</p> <ul style="list-style-type: none"> <li>present for up to 30 minutes</li> <li>occurring with over 50% of contractions.</li> </ul>				
National Childbirth Trust	4	<p>Again, this is very confusing. There is also a different table (Table 11) for the ‘management’ of the CTG, which is lengthy, and almost unusable; an algorithm/flow chart may be easier to understand than a table here. Implementation tools: We have reviewed the Implementation Tools and resources included in the Appendix of the NICE guidance, but it appears that these are repeats of the lengthy tables from the main guideline. Clinical staff require simple, easy to use tools at the coal face (making the right way, the easy way), and introducing something that is difficult to understand, could be a significant risk issue.</p> <p>It is unclear why additional questions are being included at this stage. It would be helpful if NICE could explain why these are being reviewed and what new evidence is being considered. Is it being suggested that the original review questions should be changed? We believe that to introduce additional questions at this stage introduces bias to the review process. Please share with us any references that reassure your team that introducing these questions at this point does not introduce bias into the process.</p> <p>NCT acknowledges the complexity of interpreting FHR traces but has concerns about the increasing mechanisation of labour, regardless of the evidence which shows very little difference between IA and CTG.</p>	<p>Thank you for this comment. The published guideline contains recommendations that were formulated by the former guideline development group without making explicit the review question. The intention of the current review is to state a specific review question so that the relevant evidence base can be identified and interpreted. The information</p>				

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		<p>Appendix P is very helpful for this section too, as are the current evidence to recommendations section of chapter 10 CG190. We would be concerned if those parts of CG190 (Appendix P and the evidence to recommendations texts) were substantially amended or deleted insofar as they explain the history and the limitations of CTG use. No discussion of the current evidence or any new evidence can be complete or unbiased without honesty about the context.</p> <p>The statement in the 'Saving Babies' Lives' care bundle from NHS England - that this review is being conducted by RCOG with NICE - has left us concerned about process. Is this review outside normal NICE process in which GDG members work as a multidisciplinary team, including lay members, in equality, which is a safeguard against bias? Does being evidence-based, and current NICE systematic reviewing and interpretation methodology, remain the basis for this process?</p> <p>We are concerned that, if NICE produces alternative recommendations without further evidence and a full transparent review process, this may damage the trust that non-clinical stakeholders have in NICE guidance. It would be good to know more about the rationale for conducting this partial review, and the papers published since 2014 which have triggered it. We have some concern about the ethics of introducing extra questions and therefore bias at this stage. Public money is being spent on this process, so it would be good to have reassurance that it really needs to be spent.</p> <p>1.10.12: We feel this is an important recommendation and should be referenced earlier in the guideline.</p>	<p>provided in the comment will be made available to the Guideline Committee during the review.</p> <p>The comments regarding the Saving Babies Lives care bundle have been highlighted with NICE.</p> <p>Several stakeholders were of the opinion that this question should be reviewed and so it has been decided to proceed with a review. The interpretation of the existing evidence plus any new evidence identified will be considered by the Committee</p> <p>The Guideline Committee will consider how and where to reflect the evidence about women's views in the recommendations</p>
Royal College of Midwives	4	<p>We are surprised with the proposal to review here as the question addressing these definitions and interpretation of features was addressed in the CG190. Changing this level of recommendation will further confuse practitioners.</p>	<p>Thank you for this comment. Several stakeholders were of the opinion that this question should be reviewed and so it</p>

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			has been decided to proceed with a review. The interpretation of the existing evidence plus any new evidence identified will be considered by the Committee
Baby Lifeline	5	<p>This is wholly illogical and does not make any sense as scientific studies have shown that digital scalp stimulation reduces the need for FBS (Elimian A, Figueroa R, Tejani N. Intrapartum assessment of fetal well-being: a comparison of scalp stimulation with scalp blood pH sampling. <i>Obstet Gynecol</i> 1997;89:373–6).</p> <p>Digital Scalp Stimulation is a non-invasive test and therefore, it should be recommend as the first secondary test of fetal wellbeing if there are concerns on the CTG Trace (i.e. not following FBS but without FBS).</p> <p>FBS has no scientific evidence of benefit but has only complications including delay in delivery, contamination with alkaline amniotic fluid leading to a falsely reassuring result as well as increase in instrumental vaginal births or caesarean sections without improving long term neurological outcomes. In addition, it may cause rare but potentially serious complications such as leakage of cerebrospinal fluid, meningitis, fatal fetal haemorrhage. It does not fulfil the principle of first do no harm as the risks outweigh the benefits (none) and therefore, it should not be recommended in the Modern Day Obstetric Practice.</p> <p>Unlike what was believed by some very senior obstetricians in the past, current evidence does not support previous erroneous assumption that FBS reduced caesarean sections.</p>	Thank you for this comment. The information provided will be made available to the Guideline Committee during the review
Swansea University	5	Disagree – unless there is significant new high quality evidence to inform a change in practice	Thank you for this comment. Several stakeholders were of the opinion that this question should be reviewed and so it has been decided to proceed with a review. The interpretation

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			of the existing evidence plus any new evidence identified will be considered by the Committee
London Labour Ward Leads Group	5	Digital Scalp Stimulation is a non-invasive test and therefore, it should be recommended as the first secondary test of fetal wellbeing if there are concerns on the CTG Trace (i.e. not following FBS but without FBS).	Thank you for this comment. The information provided will be made available to the Guideline Committee during the review
North Bristol Trust	5	The FIGO Guidance provides some very helpful additional information on the use of fetal scalp stimulation (FSS). It stresses that only if FSS leads to the appearance of an acceleration, followed by subsequent normalisation of the fetal heart pattern, can it be regarded as a reassuring feature. If FSS does not elicit an acceleration and/or reduced variability continues, then further tests are required such as FBS.  It also mentions that some studies have indicated that FSS (if correctly interpreted) can reduce the need for FBS by up to 50 %.	Thank you for this comment. The information provided will be made available to the Guideline Committee during the review
National Childbirth Trust	5	We are not aware of any new evidence in this area and are therefore unable to support this proposal. Our understanding, from reading the full guideline (Evidence to Recommendations) is that this recommendation was arrived at via a combination of evidence and expert opinion. We would appreciate NICE sharing the process which has led to this recommendation being put up for review?	Thank you for this comment. Several stakeholders were of the opinion that this question should be reviewed and so it has been decided to proceed with a review. The interpretation of the existing evidence plus any new evidence identified will be considered by the Committee
Royal College of Midwives	5	We agree with the proposal to review.	Thank you for this comment in support of the proposal to review this question
Baby Lifeline	6	FBS has no scientific evidence of benefit but has only complications including delay in delivery, contamination with alkaline amniotic fluid leading to a falsely reassuring result as well as increase in instrumental vaginal births or caesarean sections without improving long term	Thank you for this comment. The information provided will be made available to the Guideline Committee during the review.

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	<p>neurological outcomes. In addition, it may cause rare but potentially serious complications such as leakage of cerebrospinal fluid, meningitis, fatal fetal haemorrhage. It does not fulfil the principle of first do no harm as the risks outweigh the benefits (none) and therefore, it should not be recommended in the Modern Day Obstetric Practice (Appendix 2 &amp; Appendix 3).</p> <p>In the Draft Guideline (March 2014) the NICE GDG stated erroneously and falsely stated that the FBS <i>reduced</i> operative vaginal births. We strongly protested against this misleading statement as the Cochrane Systematic Review had concluded in 2008 and 2013 that FBS did not reduce caesarean section rate and in fact increased the operative vaginal births. In addition, FBS did not improve long term neurological outcomes (Appendix 4, Pages 180-185).</p> <p>The NICE GDG finally conceded and changed their statement in the Final Version (December 2014) and accepted the evidence that FBS actually <i>increased</i> the number of instrumental births and caesarean sections. However, very bizarrely, they continued to recommend FBS, but also, very unfortunately forced the obstetricians to lie to their patients by stating that prior to performing FBS, obstetricians should inform women that ‘the procedure will <i>reduce</i> the need for further interventions’.</p> <p>This is not compatible with ‘Duty of Candour’ as the obstetricians are forced to <i>lie</i> to their patients by their National Guideline development Group because the current scientific evidence suggests that FBS <i>increases</i> the C sections and operative vaginal births. Therefore, telling women that ‘it may prevent further more serious interventions’ not only amounts to lying to patients but also, it would expose obstetricians, especially our trainees who are forced to do majority of FBS, medico-legal claims as well as being reported to the GMC for lying to patients.</p> <p>We very kindly request you to immediately remove the recommendation even whilst this ‘Urgent Review’ is being carried out in the interest of</p>	<p>The request to remove the recommendation while the review is ongoing has been highlighted with NICE</p>
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	<p>Duty of Candour and to protect our trainees from being reported to the GMC.</p> <p>The NICE GDG very strangely used a population-based study from Germany in 1990s to justify the role of FBS in reducing neonatal acidosis. This study was a retrospective study analysing the population registry in Germany and therefore, scientifically very weak. The authors of the study have themselves highlighted several flaws in their study and have stated that the different classification systems were used by several hospitals in Germany and therefore, it cannot be concluded that FBS improved neonatal outcomes.</p> <p>It is very regrettable that our National Guideline Development Group chose to use such a flawed scientific study to recommend FBS in the UK, which is not only associated with increased risk of caesarean sections and operative vaginal births but also my cause serious neonatal complications by delaying delivery (approximately 18 minutes), risk of fetal haemorrhage and sepsis as well as rate but potentially very serious complications such as leakage of cerebrospinal fluid) without any potential benefit to the mother or her fetus.</p> <p>Despite our concerns expressed during the last consultation process, the GDG has very unfortunately, had chosen to ignore our concerns and constructive suggestions in 2014 (Appendix 4, Pages 6&amp;7- highlighted).</p> <p>National Guidelines are aimed at improving patient care and outcomes and they should be based on robust scientific evidence to have the credibility amongst its users and not on personal opinions contrary to existing scientific evidence. Current systematic review on FBS confirms that FBS actually <i>increases</i> caesarean sections and operative vaginal births and also, it does not improve long term outcomes. A paper from Sweden published last year confirms that repetitive fetal scalp blood sampling actually doubles the caesarean section rate (Holzmann M, Wretler S, Cnatingius S, Nordström L. Neonatal outcome and delivery mode in labors with repetitive fetal scalp blood sampling. Eur J Obstet</p>	
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		<p>Gynecol Reprod Biol. 2015 Jan;184:97-102.</p> <p>We have attached two recent commentaries analysing the anatomical, physiological basis as well as scientific evidence on FBS (Appendix 2 &amp; Appendix 3).</p> <p>Therefore, we strongly recommend that the NICE GDG should be honest and truthful and simply state the fact “According to current scientific evidence, the use of FBS is associated with an increase in the number of caesarean sections and instrumental vaginal births with no improvement in the long term neurological outcomes.</p>	
Swansea University	6	<p>Agree to the first review question.</p> <p>Disagree to the second and third review questions– unless there is significant new high quality evidence to inform a change in practice</p>	<p>Thank you for this comment in partial support of the proposal to review these questions. Several stakeholders were of the opinion that the questions should be reviewed and so it has been decided to proceed with a review. The methodology used in the published guideline is such that it is necessary to review all three questions together because the terminology and content of the recommendations is inter-related</p>
British Maternal and Fetal Medicine Society	6	<p>1.10.52 – many concerns with regard to this comment that how long should you leave it without a further sample if the CTG remains unchanged but still pathological – it was felt there was no robust evidence base for this.</p> <p>- it would be helpful to have base excess ranges in table 12 as that can aid with interpretation on pH, when/if to perform another sample, how quickly the pH may start dropping, aid interpretation in sepsis cases</p>	<p>Thank you for this comment. The information provided will be made available to the Guideline Committee during the review</p>
London Labour	6	<p>FBS has no scientific evidence of benefit but has only complications including delay in delivery, contamination with alkaline amniotic fluid</p>	<p>Thank you for this comment. The information provided will be</p>

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Ward Leads Group		<p>leading to a falsely reassuring result as well as increase in instrumental vaginal births or caesarean sections without improving long term neurological outcomes.</p> <p>In addition, it may cause rare but potentially serious complications such as leakage of cerebrospinal fluid, meningitis and fetal haemorrhage. It does not fulfil the principle of first do no harm as the risks outweigh the benefits (none) and therefore, it should not be recommended by National Guidelines.</p> <p>Current evidence does not support that FBS reduces the caesarean section rate. The Cochrane Systematic Review concluded in 2008 and 2013 that FBS did not reduce caesarean section rate and in fact increased the operative vaginal births. In addition, FBS did not improve long term neurological outcomes.</p>	made available to the Guideline Committee during the review
North Bristol Trust	6	The opinions in the literature on fetal blood sampling appear to be conflicting: there are a number of reviews, inc Cochrane, that conclude that FBS does not reduce the CS rate. More clarity on the advantages would be useful.	Thank you for this comment. The information provided will be made available to the Guideline Committee during the review
National Childbirth Trust	6	<p>1.10.41: We believe it is important to retain this recommendation as information provided to women is crucial. We are unclear why this should be reviewed and so do not support this.</p> <p>1.10.42 This seems to be sensible information about contraindications and it is again unclear why this needs to be reviewed. For the remainder - what new evidence has been published?</p>	Thank you for this comment. Several stakeholders were of the opinion that the questions should be reviewed and so it has been decided to proceed with a review. The interpretation of the existing evidence plus any new evidence identified will be considered by the Committee
British HIV Association (BHIVA)	6	The data regarding fetal blood sampling and the use of scalp electrodes as a risk for mother to child transmission of HIV originate from the pre-cART era and have yielded conflicting results. The Writing Group of the British HIV Association acknowledges a lack of data from the cART era, but concluded	Thank you for this comment. The information provided will be made available to the Guideline Committee during the review



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		that it is unlikely that the use of fetal scalp electrodes or fetal blood sampling confers increased risk of HIV transmission in a woman with an undetectable viral load although this cannot be proven from the current evidence. Electronic fetal monitoring should be performed therefore according to national guidelines. HIV infection <i>per se</i> is not an indication for continuous fetal monitoring as there is no increased risk of intrapartum hypoxia or sepsis.	
Royal College of Midwives	6	We agreed with the proposal to review	Thank you for this comment in support of the proposal to review this question
Swansea University	7	Agree to proposal	Thank you for this comment in support of the proposal not to review this question
Perinatal Institute	7	With increasing women using water for labour analgesia telemetry is very useful in the situation that a woman requires CTG who is in the pool. It also enables much more mobilisation, improving woman's experience and labour progress. Agree that this does not need to be reviewed.	Thank you for this comment in support of the proposal not to review this question
British Maternal and Fetal Medicine Society	7	Agree a review is not required	Thank you for this comment in support of the proposal not to review this question
London Labour Ward Leads Group	7	In agreement	Thank you for this comment in support of the proposal not to review this question
National Childbirth Trust	7	We agree with this recommendation (1.10.8) and see no reason for reviewing it. Anecdotal evidence from our contacts with pregnant women indicate that telemetry is seen as a superior option to conventional CTG as it is less likely to negatively affect their mobility and options for pain relief such as using a birth pool.	Thank you for this comment in support of the proposal not to review this question
Royal College of Midwives	7	We agree with the proposal not to review here	Thank you for this comment in support of the proposal not to review this question
Swansea	8	Agree to proposal	Thank you for this comment in support of the proposal to

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University			review this question
National Childbirth Trust	8	We welcome this proposal and look forward to seeing any additional evidence on this issue.	Thank you for this comment in support of the proposal to review this question. The interpretation of the existing evidence plus any new evidence identified will be considered by the Committee
Royal College of Midwives	8	We agree with the proposal to review here.	Thank you for this comment in support of the proposal to review this question
Baby Lifeline	9	<p>The latest Systematic Review (January 2016) which incorporates the American Randomised Controlled Trial confirms that STAN (Fetal ECG) reduces the incidence of neonatal metabolic acidosis rate by 36% and operative vaginal delivery rate by 8% (Blix E, Brurberg KG, Reierth E, Reinar LM, Øian P. ST waveform analysis versus cardiotocography alone for intrapartum fetal monitoring: a systematic review and meta-analysis of randomized trials. Acta Obstet Gynecol Scand. 2016 Jan;95(1):16-27), despite the flaws of the largest randomised controlled US Trial which used the wrong criteria, which reduced the positive effect on the outcomes (Bhide A, Chandraharan E, Acharya G. Fetal monitoring in labor: Implications of evidence generated by new systematic review. Acta Obstet Gynecol Scand. 2016 Jan;95(1):5-8). Therefore, if the US Trial was conducted robustly, the magnitude of benefit of STAN would have been even greater.</p> <p>Therefore, according to the current meta-analysis including 6 randomised controlled trials with approximately 26,000 patients, there is clear evidence to confirm that Fetal ECG (STAN) reduces neonatal metabolic acidosis rate and operative vaginal delivery rates. At George's Maternity Unit which has been using STAN in combination with an intensive training on fetal physiology and competency testing, the reported emergency caesarean section rate has been between 6-8% (half of any other Teaching Hospital in London with similar number of births and complexity) and our HIE Rate is half the nationally</p>	Thank you for this comment. The information provided will be made available to the Guideline Committee during the review

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		<p>reported rate.</p> <p>Therefore, we would like the GDG to recommend STAN (Fetal ECG) based on the latest systematic review.</p> <p>Thank you very much for kindly considering our comments aimed at improving outcomes for women and babies in the UK and we are very grateful to you and applaud your decision to conduct an urgent review of this guideline to protect women and babies from avoidable harm.</p>	
Swansea University	9	Agree to proposal	Thank you for this comment in support of the proposal to review this question
Perinatal Institute	9	Cannot comment.	No response required
National Childbirth Trust	9	The main guideline informs us that there was no recommendation made here because of a large trial about to be published. So we agree this should be reviewed, assuming this trial is now published or maybe there is other new evidence.	Thank you for this comment in support of the proposal to review this question
Royal College of Midwives	9	We agree with the proposal to review.	Thank you for this comment in support of the proposal not to review this question
Royal College of Paediatrics and Child Health	General	No comments	No response required