National Institute for Health and Care Excellence

Final version

Addendum to Intrapartum care:

Care for healthy women and babies

Clinical Guideline 190.1

Methods, evidence and recommendations

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Final version

Developed by the National Guideline Alliance, hosted by the Royal College of Obstericians and Gynaecologists

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This addendum contains the evidence used to update the fetal monitoring advice in NICE guideline CG190 on interpartum care in 2017. In 2022, the fetal monitoring advice was moved to NICE guideline NG229 on fetal monitoring in labour.

This document has been updated to redact section 4.6 on fetal blood sampling, which has been updated by a 2022 evidence review on this topic.

Disclaimer
Healthcare professionals are expected to take NICE clinical guidelines fully into account when exercising their clinical judgement. However, the guidance does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of each patient, in consultation with the patient and/or their guardian or carer.

Contents

1 Exceptional review of fetal monitoring recommendations in CG190

The National Institute for Health and Care Excellence (NICE) guideline on intrapartum care for healthy women and babies was first published in 2007 (NICE clinical guideline CG55) and updated in 2014 (NICE clinical guideline CG190). Following publication of the 2014 guideline, stakeholder concerns and implementation feedback prompted NICE to commission the National Guideline Alliance (NGA) to undertake an exceptional review of fetal monitoring recommendations contained in the guideline. The review was carried out as a discrete project within an ongoing project to develop a guideline on intrapartum care for high risk women. The evidence related to fetal monitoring was reviewed by the Guideline Committee for the obstetric complications stream of the high risk guideline, augmented by co-opted members with an interest and experience in fetal monitoring. The members of the augmented Committee, including the co-opted members, are listed in Appendix A: and their declarations of interest and associated actions are summarised in Appendix B:. NGA staff who contributed to the exceptional review ('the 2017 NGA technical team') are also listed in Appendix A:. Some of the material presented in this addendum to CG190 was prepared by staff of the former National Collaborating Centre for Women's and Children's Health (NCC-WCH) during the development of the 2014 guideline; their specific contributions to the addendum are documented as the work of 'the 2014 NCC-WCH technical team'.

The areas in CG190 that were included in the 2017 review were:

- cardiotocography (CTG) compared with auscultation on admission in labour
- CTG compared with intermittent auscultation during established labour
- fetal heart rate monitoring for meconium-stained liquor
- interpretation of an electronic fetal heart rate trace
- management of labour based on CTG findings
- predictive value of fetal stimulation
- fetal blood sampling
- women's views and experiences of fetal monitoring
- CTG with fetal electrocardiogram (ECG) analysis compared with CTG alone
- computerised systems versus human interpretation.

2 Summary section

2.1 Recommendations

Initial assessment

Measuring fetal heart rate as part of initial assessment

1. Offer auscultation of the fetal heart rate at first contact with a woman in suspected or established labour, and at each further assessment.
    - Use either a Pinard stethoscope or Doppler ultrasound.
    - Carry out auscultation immediately after a contraction for at least 1 minute and record it as a single rate.
    - Record accelerations and decelerations if heard.
    - Palpate the maternal pulse to differentiate between the maternal and fetal heartbeats. [2017]
2. Be aware that for women at low risk of complications there is insufficient evidence about whether cardiotocography as part of the initial assessment either improves outcomes or results in harm for women and their babies, compared with intermittent auscultation alone. [2017]
3. If a woman at low risk of complications requests cardiotocography as part of the initial assessment:
    - discuss the risks, benefits and limitations of cardiotocography with her, and support her in her choice
    - explain that, if she is in a setting where cardiotocography is not available, she will need to be transferred to obstetric-led care. [2017]
4. Offer continuous cardiotocography if any of the risk factors listed in recommendation 1.4.3 in the NICE guideline are identified on initial assessment, and explain to the woman why this is being offered. (See also section 4.) [2017]
5. Offer cardiotocography if intermittent auscultation indicates possible fetal heart rate abnormalities, and explain to the woman why this is being offered. If the trace is normal (see recommendation table 2 on fetal monitoring) after 20 minutes, return to intermittent auscultation unless the woman asks to stay on continuous cardiotocography. [2017]
6. If fetal death is suspected despite the presence of an apparently recorded fetal heart rate, offer real-time ultrasound assessment to check fetal viability. [2017]

Monitoring during labour

Measuring fetal heart rate

7. Do not offer cardiotocography to women at low risk of complications in established labour. [2017]
8. Offer intermittent auscultation of the fetal heart rate to women at low risk of complications in established first stage of labour:
    - Use either a Pinard stethoscope or Doppler ultrasound.
    - Carry out intermittent auscultation immediately after a contraction for at least 1 minute, at least every 15 minutes, and record it as a single rate.

- Record accelerations and decelerations if heard.
- Palpate the maternal pulse hourly, or more often if there are any concerns, to differentiate between the maternal and fetal heartbeats. [2017]

9. If there is a rising baseline fetal heart rate or decelerations are suspected on intermittent auscultation, actions should include:
   - carrying out intermittent auscultation more frequently, for example after 3 consecutive contractions initially
   - thinking about the whole clinical picture, including the woman's position and hydration, the strength and frequency of contractions and maternal observations.

   If a rising baseline or decelerations are confirmed, further actions should include:
   - summoning help
   - advising continuous cardiotocography, and explaining to the woman and her birth companion(s) why it is needed
   - transferring the woman to obstetric-led care, provided that it is safe and appropriate to do so (follow the general principles for transfer of care described in section 1.6 of the NICE guideline). [2017]
10. Advise continuous cardiotocography if any of the following risk factors are present at initial assessment (see section 1.4 of the NICE guideline) or arise during labour:
    - maternal pulse over 120 beats/minute on 2 occasions 30 minutes apart
    - temperature of 38°C or above on a single reading, or 37.5°C or above on 2 consecutive occasions 1 hour apart
    - suspected chorioamnionitis or sepsis
    - pain reported by the woman that differs from the pain normally associated with contractions
    - the presence of significant meconium (as defined in recommendation 1.5.2 in the NICE guideline)
    - fresh vaginal bleeding that develops in labour
    - severe hypertension: a single reading of either systolic blood pressure of 160 mmHg or more or diastolic blood pressure of 110 mmHg or more, measured between contractions
    - hypertension: either systolic blood pressure of 140 mmHg or more or diastolic blood pressure of 90 mmHg or more on 2 consecutive readings taken 30 minutes apart, measured between contractions
    - a reading of 2+ of protein on urinalysis and a single reading of either raised systolic blood pressure (140 mmHg or more) or raised diastolic blood pressure (90 mmHg or more)
    - confirmed delay in the first or second stage of labour (see recommendations 1.12.14, 1.13.3 and 1.13.4 in the NICE guideline)
    - contractions that last longer than 60 seconds (hypertonus), or more than 5 contractions in 10 minutes (tachysystole)
    - oxytocin use. [2017]
11. Do not offer continuous cardiotocography to women who have non-significant meconium if there are no other risk factors. [2017]

12. Do not regard amniotomy alone for suspected delay in the established first stage of labour as an indication to start continuous cardiotocography. [2007, amended 2014]
13. Address any concerns that the woman has about continuous cardiotocography, and give her and her birth companion(s) the following information:
    - Explain that continuous cardiotocography is used to monitor the baby's heartbeat and the labour contractions.
    - Explain that it may restrict her mobility.
    - Give details of the types of findings that may occur. Explain that a normal trace indicates that the baby is coping well with labour.
    - Explain that changes to the baby's heart rate pattern during labour are common and do not necessarily cause concern.
    - Explain that if the trace is not normal (see recommendation table 2), there will be less certainty about the condition of the baby and so continuous monitoring will be advised.
    - Explain that decisions about her care during labour and birth will be based on an assessment of several factors, including her preferences, her condition and that of her baby, as well as the findings from cardiotocography. [2017]
14. If continuous cardiotocography has been started because of concerns arising from intermittent auscultation, but the trace is normal (see recommendation table 2) after 20 minutes, return to intermittent auscultation unless the woman asks to stay on continuous cardiotocography (see recommendation 3). [2017]

Interpretation of cardiotocograph traces

15. Use recommendation tables 1 and 2 to define and interpret cardiotocograph traces and to guide the management of labour for women who are having continuous cardiotocography. These tables include and summarise individual recommendations about fetal monitoring (16 to 40), fetal scalp stimulation (42 to 43), fetal blood sampling (44 to 59) and intrauterine resuscitation (41, and 1.10.37 in the NICE guideline) in this guideline. [2017]

Recommendation table 1. Description of cardiotocograph trace features

Overall care

- Make a documented systematic assessment of the condition of the woman and unborn baby (including cardiotocography [CTG] findings) every hour, or more frequently if there are concerns.
- Do not make any decision about a woman’s care in labour on the basis of CTG findings alone.
- Take into account the woman's preferences, any antenatal and intrapartum risk factors, the current wellbeing of the woman and unborn baby and the progress of labour.
- Ensure that the focus of care remains on the woman rather than the CTG trace.
- Remain with the woman in order to continue providing one-to-one support.
- Talk to the woman and her birth companion(s) about what is happening and take her preferences into account.

Principles for intrapartum CTG trace interpretation

- When reviewing the CTG trace, assess and document contractions and all 4 features of fetal heart rate: baseline rate; baseline variability; presence or absence of decelerations (and concerning characteristics of variable decelerations* if present); presence of accelerations.
- If there is a stable baseline fetal heart rate between 110 and 160 beats/minute and normal variability, continue usual care as the risk of fetal acidosis is low.

- If it is difficult to categorise or interpret a CTG trace, obtain a review by a senior midwife or a senior obstetrician.

Accelerations

- The presence of fetal heart rate accelerations, even with reduced baseline variability, is generally a sign that the baby is healthy.

Description	Feature		
	Baseline (beats/ minute)	**Baseline variability (beats/minute)**	**Decelerations**
Reassuring	110 to 160	5 to 25	None or early Variable decelerations with no concerning characteristics* for less than 90 minutes
Non-reassuring	100 to 109† OR 161 to 180	Less than 5 for 30 to 50 minutes OR More than 25 for 15 to 25 minutes	Variable decelerations with no concerning characteristics* for 90 minutes or more OR Variable decelerations with any concerning characteristics* in up to 50% of contractions for 30 minutes or more OR Variable decelerations with any concerning characteristics* in over 50% of contractions for less than 30 minutes OR Late decelerations in over 50% of contractions for less than 30 minutes, with no maternal or fetal clinical risk factors such as vaginal bleeding or significant meconium
Abnormal	Below 100 OR Above 180	Less than 5 for more than 50 minutes OR More than 25 for more than 25 minutes OR Sinusoidal	Variable decelerations with any concerning characteristics* in over 50% of contractions for 30 minutes (or less if any maternal or fetal clinical risk factors [see above]) OR Late decelerations for 30 minutes (or less if any maternal or fetal clinical risk factors) OR Acute bradycardia, or a single prolonged deceleration lasting 3 minutes or more

Abbreviation: CTG, cardiotocography.

* Regard the following as concerning characteristics of variable decelerations: lasting more than 60 seconds; reduced baseline variability within the deceleration; failure to return to baseline; biphasic (W) shape; no shouldering.

† Although a baseline fetal heart rate between 100 and 109 beats/minute is a non-reassuring feature, continue usual care if there is normal baseline variability and no variable or late decelerations.

Recommendation table 2. Management based on interpretation of cardiotocograph traces

Category	Definition	Management
Normal	All features are reassuring	• Continue CTG (unless it was started because of concerns arising from intermittent auscultation and there are no ongoing risk factors; see recommendation 14) and usual care • Talk to the woman and her birth companion(s) about what is happening
Suspicious	1 non-reassuring feature AND 2 reassuring features	• Correct any underlying causes, such as hypotension or uterine hyperstimulation • Perform a full set of maternal observations • Start 1 or more conservative measures* • Inform an obstetrician **or** a senior midwife • Document a plan for reviewing the whole clinical picture and the CTG findings • Talk to the woman and her birth companion(s) about what is happening and take her preferences into account
Pathological	1 abnormal feature OR 2 non-reassuring features	• Obtain a review by an obstetrician **and** a senior midwife • Exclude acute events (for example, cord prolapse, suspected placental abruption or suspected uterine rupture) • Correct any underlying causes, such as hypotension or uterine hyperstimulation • Start 1 or more conservative measures* • Talk to the woman and her birth companion(s) about what is happening and take her preferences into account • If the cardiotocograph trace is still pathological after implementing conservative measures: o obtain a further review by an obstetrician **and** a senior midwife o offer digital fetal scalp stimulation (see recommendation 42) and document the outcome • If the cardiotocograph trace is still pathological after fetal scalp stimulation: o consider fetal blood sampling o consider expediting the birth o take the woman's preferences into account
Need for urgent intervention	Acute bradycardia, or a single prolonged deceleration for 3 minutes or more	• Urgently seek obstetric help • If there has been an acute event (for example, cord prolapse, suspected placental abruption or suspected uterine rupture), expedite the birth • Correct any underlying causes, such as hypotension or uterine hyperstimulation • Start 1 or more conservative measures*

Category	Definition	Management
		• Make preparations for an urgent birth • Talk to the woman and her birth companion(s) about what is happening and take her preferences into account • Expedite the birth if the acute bradycardia persists for 9 minutes • If the fetal heart rate recovers at any time up to 9 minutes, reassess any decision to expedite the birth, in discussion with the woman

Abbreviation: CTG, cardiotocography.

* If there are any concerns about the baby's wellbeing, be aware of the possible underlying causes and start one or more of the following conservative measures based on an assessment of the most likely cause(s): encourage the woman to mobilise or adopt an alternative position (and to avoid being supine); offer intravenous fluids if the woman is hypotensive; reduce contraction frequency by reducing or stopping oxytocin if it is being used and/or offering a tocolytic drug (a suggested regimen is subcutaneous terbutaline 0.25 mg).

Overall care

16. When a woman is having continuous cardiotocography:
    - ensure that the focus of care remains on the woman rather than the cardiotocograph trace
    - remain with the woman in order to continue providing one-to-one support
    - encourage and help the woman to be as mobile as possible and to change position as often as she wishes
    - monitor the condition of the woman and the baby, and take prompt action if required
    - differentiate between the maternal and fetal heartbeats hourly, or more often if there are any concerns
    - ensure that the cardiotocograph trace is of high quality, and think about other options if this is not the case
    - if it is difficult to categorise or interpret a cardiotocograph trace, obtain a review by a senior midwife or a senior obstetrician. [2017]
17. When reviewing the cardiotocograph trace, assess and document contractions and all 4 features of fetal heart rate:
    - baseline rate
    - baseline variability
    - presence or absence of decelerations, and concerning characteristics of variable decelerations if present (see recommendation 27)
    - presence of accelerations. [2017]
18. Do not make any decision about a woman's care in labour on the basis of cardiotocography findings alone, but also take into account:
    - her preferences
    - her report of how she is feeling
    - her report of the baby's movements
    - assessment of her wellbeing and behaviour
    - maternal observations, including temperature, blood pressure and pulse
    - whether there is meconium or blood in the amniotic fluid

- any signs of vaginal bleeding
- any medication she is taking
- the frequency of contractions
- the stage and progress of labour
- her parity
- the fetal response to digital scalp stimulation if performed (see recommendations 42 and 43)
- the results of fetal blood sampling if undertaken (see recommendation 52). [2017]

19. Supplement ongoing care with a documented systematic assessment of the condition of the woman and unborn baby (including any cardiotocography findings) every hour. If there are concerns about cardiotocography findings, undertake this assessment more frequently. [2017]

Baseline fetal heart rate

20. Use the following categorisations for baseline fetal heart rate:
    - reassuring:
        - 110 to 160 beats/minute
    - non-reassuring:
        - 100 to 109 beats/minute (but see recommendation 21)
        - 161 to 180 beats/minute
    - abnormal:
        - below 100 beats/minute
        - above 180 beats/minute. [2017]
21. Take the following into account when assessing baseline fetal heart rate:
    - differentiate between fetal and maternal heartbeats
    - baseline fetal heart rate will usually be between 110 and 160 beats/minute
    - although a baseline fetal heart rate between 100 and 109 beats/minute is a non-reassuring feature, continue usual care if there is normal baseline variability and no variable or late decelerations. [2017]

Baseline variability

22. Use the following categorisations for fetal heart rate baseline variability:
    - reassuring:
        - 5 to 25 beats/minute
    - non-reassuring:
        - less than 5 beats/minute for 30 to 50 minutes
        - more than 25 beats/minute for 15 to 25 minutes
    - abnormal:
        - less than 5 beats/minute for more than 50 minutes
        - more than 25 beats/minute for more than 25 minutes
        - sinusoidal. [2017]
23. Take the following into account when assessing fetal heart rate baseline variability:
    - baseline variability will usually be between 5 and 25 beats/minute

- intermittent periods of reduced baseline variability are normal, especially during periods of quiescence ('sleep'). [2017]

Decelerations

24. When describing decelerations in fetal heart rate, specify:
    - their timing in relation to the peaks of the contractions
    - the duration of the individual decelerations
    - whether or not the fetal heart rate returns to baseline
    - how long they have been present for
    - whether they occur with over 50% of contractions
    - the presence or absence of a biphasic (W) shape
    - the presence or absence of shouldering
    - the presence or absence of reduced variability within the deceleration. [2017]
25. Describe decelerations as 'early', 'variable' or 'late'. Do not use the terms 'typical' and 'atypical' because they can cause confusion. [2017]
26. Use the following categorisations for decelerations in fetal heart rate:
    - reassuring:
        - no decelerations
        - early decelerations
        - variable decelerations with no concerning characteristics (see recommendation 27) for less than 90 minutes
    - non-reassuring:
        - variable decelerations with no concerning characteristics for 90 minutes or more
        - variable decelerations with any concerning characteristics in up to 50% of contractions for 30 minutes or more
        - variable decelerations with any concerning characteristics in over 50% of contractions for less than 30 minutes
        - late decelerations in over 50% of contractions for less than 30 minutes, with no maternal or fetal clinical risk factors such as vaginal bleeding or significant meconium
    - abnormal:
        - variable decelerations with any concerning characteristics in over 50% of contractions for 30 minutes (or less if there are any maternal or fetal clinical risk factors)
        - late decelerations for 30 minutes (or less if there are any maternal or fetal clinical risk factors)
        - acute bradycardia, or a single prolonged deceleration lasting 3 minutes or more. [2017]
27. Regard the following as concerning characteristics of variable decelerations:
    - lasting more than 60 seconds
    - reduced baseline variability within the deceleration
    - failure to return to baseline
    - biphasic (W) shape
    - no shouldering. [2017]

28. If variable decelerations with no concerning characteristics (see recommendation 27) are observed:
    - be aware that these are very common, can be a normal feature in an otherwise uncomplicated labour and birth, and are usually a result of cord compression
    - ask the woman to change position or mobilise. [2017]
29. Take the following into account when assessing decelerations in fetal heart rate:
    - early decelerations are uncommon, benign and usually associated with head compression
    - early decelerations with no non-reassuring or abnormal features on the cardiotocograph trace should not prompt further action. [2017]
30. Take into account that the longer and later the individual decelerations, the higher the risk of fetal acidosis (particularly if the decelerations are accompanied by tachycardia or reduced baseline variability). [2017]

Accelerations

31. Take the following into account when assessing accelerations in fetal heart rate:
    - the presence of fetal heart rate accelerations, even with reduced baseline variability, is generally a sign that the baby is healthy
    - the absence of accelerations on an otherwise normal cardiotocograph trace (see recommendation table 2) does not indicate fetal acidosis. [2017]

Categorisation of traces

32. Categorise cardiotocography traces as follows:
    - normal: all features are reassuring (see recommendation table 1)
    - suspicious: 1 non-reassuring feature and 2 reassuring features (but note that if accelerations are present, fetal acidosis is unlikely)
    - pathological:
        - 1 abnormal feature **or**
        - 2 non-reassuring features. [2017]

Management

33. If there is a stable baseline fetal heart rate between 110 and 160 beats/minute and normal variability, continue usual care as the risk of fetal acidosis is low. [2017]
34. If there is an acute bradycardia, or a single prolonged deceleration for 3 minutes or more:
    - urgently seek obstetric help
    - if there has been an acute event (for example, cord prolapse, suspected placental abruption or suspected uterine rupture), expedite the birth (see recommendations 1.13.34 to 1.13.37 in the NICE guideline)
    - correct any underlying causes, such as hypotension or uterine hyperstimulation
    - start one or more conservative measures (see recommendation 39)
    - make preparations for an urgent birth

- talk to the woman and her birth companion(s) about what is happening and take her preferences into account
- expedite the birth if the acute bradycardia persists for 9 minutes.

If the fetal heart rate recovers at any time up to 9 minutes, reassess any decision to expedite the birth, in discussion with the woman. [2017]

35. If the cardiotocograph trace is categorised as pathological (see recommendation 32):
    - obtain a review by an obstetrician and a senior midwife
    - exclude acute events (for example, cord prolapse, suspected placental abruption or suspected uterine rupture)
    - correct any underlying causes, such as hypotension or uterine hyperstimulation
    - start one or more conservative measures (see recommendation 39)
    - talk to the woman and her birth companion(s) about what is happening and take her preferences into account. [2017]
36. If the cardiotocograph trace is still pathological after implementing conservative measures:
    - obtain a further review by an obstetrician and a senior midwife
    - offer digital fetal scalp stimulation (see recommendation 42) and document the outcome.

    If the cardiotocograph trace is still pathological after fetal scalp stimulation, consider:
    - fetal blood sampling (see recommendations 44 to 59)
      or
    - expediting the birth (see recommendations 1.13.34 to 1.13.37 in the NICE guideline).

    Take the woman's preferences into account. [2017]
37. If the cardiotocograph trace is categorised as suspicious (see recommendation 32):
    - correct any underlying causes, such as hypotension or uterine hyperstimulation
    - perform a full set of maternal observations
    - start one or more conservative measures (see recommendation 39)
    - inform an obstetrician or a senior midwife
    - document a plan for reviewing the whole clinical picture and the cardiotocography findings
    - talk to the woman and her birth companion(s) about what is happening and take her preferences into account. [2017]
38. If the cardiotocograph trace is categorised as normal (see recommendation 32):
    - continue cardiotocography (unless it was started because of concerns arising from intermittent auscultation and there are no ongoing risk factors; see recommendation 14) and usual care
    - talk to the woman and her birth companion(s) about what is happening. [2017]

Conservative measures

39. If there are any concerns about the baby's wellbeing, be aware of the possible underlying causes and start one or more of the following conservative measures based on an assessment of the most likely cause(s):
    - encourage the woman to mobilise or adopt an alternative position (and to avoid being supine)
    - offer intravenous fluids if the woman is hypotensive
    - reduce contraction frequency by:
        - reducing or stopping oxytocin if it is being used **and/or**
        - offering a tocolytic drug (a suggested regimen is subcutaneous terbutaline 0.25 mg). [2017]
40. Inform a senior midwife or an obstetrician whenever conservative measures are implemented. [2017]

Intrauterine resuscitation

41. Do not use maternal facial oxygen therapy for intrauterine fetal resuscitation, because it may harm the baby (but it can be used where it is administered for maternal indications such as hypoxia or as part of preoxygenation before a potential anaesthetic). [2014]

Fetal scalp stimulation

42. If the cardiotocograph trace is pathological (see recommendation 32), offer digital fetal scalp stimulation. If this leads to an acceleration in fetal heart rate, only continue with fetal blood sampling if the cardiotocograph trace is still pathological. [2017]
43. If digital fetal scalp stimulation (during vaginal examination) leads to an acceleration in fetal heart rate, regard this as a sign that the baby is healthy. Take this into account when reviewing the whole clinical picture. [2017]

Fetal blood sampling

44. Do not carry out fetal blood sampling if:
    - there is an acute event (for example, cord prolapse, suspected placental abruption or suspected uterine rupture) **or**
    - the whole clinical picture indicates that the birth should be expedited **or**
    - contraindications are present, including risk of maternal-to-fetal transmission of infection or risk of fetal bleeding disorders. [2017]
45. Be aware that for women with sepsis or significant meconium (see recommendation 1.5.2 in the NICE guideline), fetal blood sample results may be falsely reassuring, and always discuss with a consultant obstetrician:
    - whether fetal blood sampling is appropriate
    - any results from the procedure if carried out. [2017]
46. Before carrying out or repeating fetal blood sampling, start conservative measures and offer digital fetal scalp stimulation (see recommendations 39 and 42). Only continue with fetal blood sampling if the cardiotocograph trace remains pathological (see recommendation 32). [2017]
47. When considering fetal blood sampling, take into account the woman's preferences and the whole clinical picture. [2017]

48. When considering fetal blood sampling, explain the following to the woman and her birth companion(s):
    - Why the test is being considered and other options available, including the risks, benefits and limitations of each.
    - The blood sample will be used to measure the level of acid in the baby's blood, which may help to show how well the baby is coping with labour.
    - The procedure will require her to have a vaginal examination using a device similar to a speculum.
    - A sample of blood will be taken from the baby's head by making a small scratch on the baby's scalp. This will heal quickly after birth, but there is a small risk of infection.
    - What the different outcomes of the test may be (normal, borderline and abnormal) and the actions that will follow each result.
    - If a fetal blood sample cannot be obtained but there are fetal heart rate accelerations in response to the procedure, this is encouraging and in these circumstances expediting the birth may not be necessary.
    - If a fetal blood sample cannot be obtained and the cardiotocograph trace has not improved, expediting the birth will be advised.
    - A caesarean section or instrumental birth (forceps or ventouse) may be advised, depending on the results of the procedure. [2017]
49. Do not take a fetal blood sample during or immediately after a prolonged deceleration. [2017]
50. Take fetal blood samples with the woman in the left-lateral position. [2017]
51. Use either pH or lactate when interpreting fetal blood sample results. [2017]
52. Use the following classifications for fetal blood sample results:
    - pH:
        - normal: 7.25 or above
        - borderline: 7.21 to 7.24
        - abnormal: 7.20 or below

    or

    - lactate:
        - normal: 4.1 mmol/l or below
        - borderline: 4.2 to 4.8 mmol/l
        - abnormal: 4.9 mmol/l or above. [2017]
53. Interpret fetal blood sample results taking into account:
    - any previous pH or lactate measurement **and**
    - the clinical features of the woman and baby, such as rate of progress in labour. [2017]
54. If the fetal blood sample result is abnormal:
    - inform a senior obstetrician and the neonatal team **and**
    - talk to the woman and her birth companion(s) about what is happening and take her preferences into account **and**
    - expedite the birth (see recommendations 1.13.34 to 1.13.37 in the NICE guideline). [2017]
55. If the fetal blood sample result is borderline and there are no accelerations in response to fetal scalp stimulation, consider taking a

second fetal blood sample no more than 30 minutes later if this is still indicated by the cardiotocograph trace. [2017]

56. If the fetal blood sample result is normal and there are no accelerations in response to fetal scalp stimulation, consider taking a second fetal blood sample no more than 1 hour later if this is still indicated by the cardiotocograph trace. [2017]
57. Discuss with a consultant obstetrician if a third fetal blood sample is thought to be needed. [2017]

When a fetal blood sample cannot be obtained

58. If fetal blood sampling is attempted and a sample cannot be obtained, but the associated fetal scalp stimulation results in a fetal heart rate acceleration, decide whether to continue the labour or expedite the birth in light of the clinical circumstances and in discussion with the woman and a senior obstetrician. [2017]
59. If fetal blood sampling is attempted but a sample cannot be obtained and there has been no improvement in the cardiotocograph trace, expedite the birth (see recommendations 1.13.34 to 1.13.37 in the NICE guideline). [2017]

2.2 Research recommendations

1. What is the clinical and cost effectiveness of intermittent auscultation versus continuous cardiotocography in otherwise low-risk pregnancies complicated by meconium-stained liquor?
2. What is the clinical and cost effectiveness of fetal blood sampling during labour using pH testing or lactate testing or both?

2.3 Methods

To facilitate rapid development of the review, the process of systematically reviewing the available evidence was conducted in accordance with the methods used in the 2014 guideline (see CG190, Section 1.10 'Guideline development methodology for the 2014 update'). Exceptions to this were where factual inaccuracies were found in the 2014 evidence reviews and corrected by the 2017 NGA technical team, and where dual weeding was undertaken by the 2017 NGA technical team for 2 review questions that had not previously been specified explicitly nor accompanied by a published review protocol or search strategy (see Section 4.4 and Section 4.9).

For each review question considered in the update, the following steps were undertaken:

- specification of a review protocol (see Appendix C:)
- execution of a systematic literature search (see Appendix D:)
- presentation of a summary of identified studies (see Appendix E:)
- presentation of a list of studies excluded after consulting full-text copies of published articles (see Appendix F:)
- description of included studies in the form of evidence tables (see Appendix G:)
- presentation of the results of meta-analysis (where applicable) in forest plots (see Appendix H:)
- quality appraisal and synthesis of evidence from included studies according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (see Appendix I:).

For the question related to automated interpretation of cardiotocograph (CTG) traces (see Section 4.9), a literature search had been conducted for the 2007 guideline (CG55) and 6 studies were identified for inclusion. The original search strategy was not available and so a new search was designed and executed for the 2017 review. This search was run from the time of the original search for CG55 to ensure that the 6 included studies would be identified along with any additional eligible studies published more recently. For the question related to management of labour based on CTG findings (see Section 4.4), no literature search had been conducted for either the 2007 guideline (CG55) or the 2014 guideline (CG190). For this question, a search strategy was, therefore, designed and executed for the 2017 review with no limitation on year of publication. For all other review questions, the literature searches were run from the time of the 2014 guideline (CG190).

Some of the evidence identified for inclusion for the review question about interpretation of CTG traces (see Section 4.3) refers to published fetal heart rate classifications. The relevant classifications are summarised in Appendix J:.

For the question related to automated interpretation of CTG traces (see Section 4.9) where inter-rater agreement was measured using a Kappa statistic, the classifications in Table 1 were used.

Table 1: Kappa statistic classifications

Range	Classification
< 0.4	Poor agreement
0.4 to 0.59	Fair agreement
0.69 to 0.74	Good agreement
> 0.75	Excellent agreement

The 2014 Guideline Committee prioritised a number of review questions considered in CG190 for economic analysis. Two such priority areas were included in the 2017 update and so the relevant economic analyses were updated to take account of new clinical evidence and/or updated costs:

- a cost analysis related to fetal blood sampling (see Section 4.6 and Appendix K:.1)
- a cost effectiveness analysis for electrocardiogram (ECG) analysis with CTG compared with CTG alone (see Section 4.8 and Appendix K:.2).

All other elements involved in developing the update, including recruitment of the 2017 Committee and the process for managing conflicts of interest, were based on the process and methods described in the NICE guidelines manual 2014.

3 Monitoring on admission in labour

3.1 Cardiotocography compared with auscultation on admission in labour

3.1.1 Review question

What is the effectiveness of electronic fetal monitoring compared with intermittent auscultation on admission in labour?

3.1.2 Description of included studies

Five studies were included in this review (Cheyne 2003; Devane 2012; Impey 2003; Mires 2001; Mitchell 2008) reporting data from 4 randomised controlled trials (RCTs).

One study was a systematic review (Devane 2012), which included 4 RCTs conducted in the UK and Ireland. This systematic review was the source for the majority of the outcome data. The other 4 included studies were reports of the same RCTs (Cheyne 2003; Impey 2003; Mires 2001; Mitchell 2008). These trials were incorporated in the published systematic review but were also included as individual articles in the guideline review because the published systematic review did not consistently report how monitoring was conducted during labour, and a relevant outcome reported in 1 trial was not reported in the published systematic review.

Three of the trials included only low-risk women (Cheyne 2003; Impey 2003; Mitchell 2008), of which 1 specifically included only women with clear amniotic fluid following early amniotomy (Impey 2003). In the fourth trial, women at low risk were randomised in the third trimester, and some women developed complications during the interval between randomisation and admission (Mires 2001). However, the authors of the systematic review reported subgroup data for the women who remained at low risk on admission, and these data are reflected below. All of the included studies included both nulliparous and multiparous women but did not report outcomes for these groups separately.

All of the included studies compared the use of electronic fetal monitoring plus electronic monitoring of contractions (admission cardiotocograph [CTG]) with intermittent auscultation alone on admission in established labour. The duration of the CTG use was 20 minutes in 3 trials (Cheyne 2003; Impey 2003; Mires 2001) and 15 minutes in 1 trial (Mitchell 2008).

Auscultation was performed:

- for a minimum of 1 minute, during and immediately following a contraction (Cheyne 2003)
- for 1 minute after a contraction every 15 minutes in the first stage of labour and every 5 minutes in the second stage (Impey 2003; Mitchell 2008)
- during and immediately after at least 1 contraction for an unspecified duration (Mires 2001).

The way in which monitoring was conducted during labour varied between studies. In 3 trials, after the CTG admission test all women were cared for using intermittent auscultation (as described above) provided the fetal heart rate was considered normal (Cheyne 2003; Impey 2003; Mitchell 2008). If the fetal heart rate was considered abnormal, then CTG was used (see the relevant evidence tables in Appendix G: for criteria). In Impey (2003), 58% of women in the CTG arm and 42% of women in the auscultation arm received continuous CTG during labour. In Cheyne (2003), 6% of women in each arm received continuous CTG during labour and a further 80% of women in the CTG arm and 34% of women in the auscultation arm received additional CTG. In Mitchell (2008), no details about the proportion of women receiving continuous CTG in labour were provided. In the fourth trial (Mires 2001), the

protocol for monitoring during labour was not reported but 57% of women in the CTG arm and 47% of women in the auscultation arm ultimately received continuous CTG.

3.1.3 Evidence profile

The effectiveness of cardiotocography compared with auscultation on admission in labour is reported here in 1 GRADE profile (Table 2).

Table 2: Summary GRADE profile for comparison of continuous cardiotocography compared with intermittent auscultation on admission

Number of studies	Design	Number of women or babies		Effect		Quality
		Electronic fetal monitoring	Intermittent auscultation	Relative (95% CI)	Absolute (95% CI) and p-value (if reported)	
Mode of birth: caesarean section						
1 meta-analysis of 4 studies (Devane 2012)	Randomised trials	248/5657 (4.4%)	207/5681 (3.6%)	RR 1.2 (1 to 1.44)	7 more per 1000 (from 0 fewer to 16 more)	Low
Mode of birth: instrumental vaginal birth						
1 meta-analysis of 4 studies (Devane 2012)	Randomised trials	782/5657 (13.8%)	716/5681 (12.6%)	RR 1.1 (0.95 to 1.27)	13 more per 1000 (from 6 fewer to 34 more)	Moderate
Fetal and neonatal deaths						
1 meta-analysis of 4 studies (Devane 2012)	Randomised trials	5/5658 (0.09%)	5/5681 (0.09%)	RR 1.01 (0.3 to 3.47)	0 more per 1000 (from 1 fewer to 2 more)	Low
Neonatal morbidity: hypoxic ischaemic encephalopathy						
1 study (Devane 2012)	Randomised trial	6/1186 (0.51%)	5/1181 (0.42%)	RR 1.19 (0.37 to 3.9)	1 more per 1000 (from 3 fewer to 12 more)	Low
Neonatal morbidity: seizures						
1 study (Devane 2012)	Randomised trial	10/4017 (0.25%)	14/4039 (0.35%)	RR 0.72 (0.32 to 1.61)	1 fewer per 1000 (from 2 fewer to 2 more)	Moderate
Admission to neonatal intensive care unit (NICU)						

Number of studies	Design	Number of women or babies		Effect		Quality
		Electronic fetal monitoring	Intermittent auscultation	Relative (95% CI)	Absolute (95% CI) and p-value (if reported)	
1 meta-analysis of 4 studies (Devane 2012)	Randomised trials	219/5656 (3.9%)	213/5675 (3.8%)	RR 1.03 (0.86 to 1.24)	1 more per 1000 (from 5 fewer to 9 more)	Low
Cord blood gas values at birth: metabolic acidosis (pH<7.20 with a base deficit of >8.0)						
1 study (Mires 2001)	Randomised trial	159/876 (18.2%)	154/860 (17.9%)	RR 1.01 (0.83 to 1.24)	2 more per 1000 (from 30 fewer to 43 more)	Low

CI confidence interval, NICU neonatal intensive care unit, RR relative risk

3.1.4 Evidence statements

There was no definitive evidence of a difference in mode of birth (n=11,339) between women who received CTG and women who received intermittent auscultation, although there was a tendency towards more caesarean sections among women who received CTG. In terms of neonatal outcomes, there was no evidence of a difference in the risk of fetal and neonatal death (n=11,339), hypoxic ischaemic encephalopathy (n=2367), seizures (n=8056), admission to NICU (n=11,331) or metabolic acidosis (n=1736) between the 2 groups. The evidence was of low to moderate quality.

3.1.5 Health economics profile

No published economic evaluations were identified for this review question.

3.1.6 Evidence to recommendations

3.1.6.1 Relative value placed on the outcomes considered

In this review, the Committee hoped to find whether CTG on admission was any more effective than auscultation on admission in identifying babies potentially at greater risk of poor outcomes and who might require additional care. The key outcomes of interest were:

- the rates of caesarean section and instrumental birth
- the rates of fetal and neonatal death
- the rates of both hypoxic ischaemic encephalopathy (HIE) and neonatal seizures.

It was noted that the published meta-analysis was underpowered for the rare findings of adverse neonatal outcomes (mortality and HIE) and so although these were clearly the most important outcomes, the evidence related to them was not useful for informing decision-making.

3.1.6.2 Consideration of clinical benefits and harms

The evidence did not show a statistically significant difference between the intervention and comparison groups for any of the reported outcomes, although the rate of caesarean section was on the borderline of being significantly higher in women receiving CTG on admission. The Committee noted that the rates of caesarean section in both groups were very low compared to current UK rates and thus it might not be possible to extrapolate the difference observed between the groups to current NHS practice.

Although not reported as an outcome in the GRADE table, some of the studies provided information on the number of women in each group who received CTG monitoring in labour. In each study, a greater number of women who had initial continuous CTG monitoring went on to have continuous CTG monitoring throughout labour compared with women in the auscultation arm. Although not necessarily a bad outcome in its own right, taking into account the findings from the review question comparing the effectiveness of continuous CTG and intermittent auscultation during established labour (see Section 4.1), it seemed that continuous CTG monitoring performed on admission and during labour was being used unnecessarily in some cases. The Committee felt that clinicians would sometimes use CTG monitoring for reassurance on admission, rather than for a clear clinical indication, and this could lead to an increase in interventions throughout labour.

From their clinical and personal experience, the Committee members recognised advantages for women in being mobile during labour and not attached to a monitor. On these grounds, and in the absence of complications, auscultation would be preferred.

Given that there is insufficient evidence to suggest either benefits or harms from performing CTG monitoring on admission compared with auscultation, and the need to enable women to be mobile during labour, the Committee agreed that an explanatory recommendation should be made for healthcare professionals to be aware of the current evidence base underpinning their recommendations for fetal heart rate monitoring at initial assessment for women confirmed as being at low risk of developing complications during labour. The Committee considered women's choice and recognised that some women might request CTG monitoring. In such cases it would be important to support the woman in her choice after discussing associated risks, benefits and limitations. The Committee further noted that if the woman were in a setting where CTG monitoring were not available then it should be explained to her that she would need to be transferred to obstetric-led care. The principle of informed choice would be encompassed by offering CTG to women at increased risk of complications (as defined in the recommendations) and as such the need for obstetric-led care would be determined by a requirement for a setting in which CTG monitoring would be available once chosen by the woman.

The Committee agreed that if the findings of auscultation on admission were not normal, it would be appropriate to perform further assessment using CTG for 20 minutes. The Committee agreed that 20 minutes would be sufficient time to identify reassuring features). However, if no further abnormalities were observed during this time then intermittent auscultation should be recommenced. The Committee was concerned that in practice CTG monitoring could affect delivery of one-to-one care and it emphasised in the recommendations that one-to-one care should be continued even if continuous CTG were necessary (see Section 4.3).

Finally, it was noted that none of the studies reported the impact of the different fetal monitoring regimens on the woman's mobility.

3.1.6.3 Consideration of health benefits and resource use

The Committee agreed that performing CTG monitoring on admission might lead to an increase in unnecessary interventions for women during labour with no clear evidence of benefit. As a result, it was agreed that there was a clear health economic benefit in recommending that CTG should not be offered to all women on admission.

3.1.6.4 Quality of evidence

The Committee noted that because the guideline review protocol had only targeted examination of the comparison of CTG versus intermittent auscultation, the assumption was that the fetal heart rate would be measured at initial assessment using one of these techniques, rather than not being measured at all. The evidence included in the guideline review was derived from RCTs and was of low or moderate quality. However, evidence was not available for all the outcomes specified in the review protocol and although, there was a tendency towards more caesarean sections among women who received CTG compared to auscultation, the analysis was underpowered to assess rare adverse neonatal outcomes. The Committee therefore concluded that there was insufficient evidence to definitively judge the benefits and harms of CTG compared to auscultation in women at low risk of complications and made a recommendation to reflect this.

3.1.6.5 Other considerations

The Committee discussed the appropriate method for conducting auscultation. It was agreed that the fetal heart rate should be recorded as a single rate rather than a range. This single rate could then be plotted on a partogram and used as a baseline for future measurements. The Committee decided against recommending auscultation during a contraction because it would be uncomfortable for the woman and technically difficult. The Committee debated the value of auscultation between contractions and more than 1 minute after a contraction and

concluded that was there no support for a change from the 2014 recommendation, which represents current practice.

The Committee agreed that accelerations or decelerations should be recorded (either on the partogram or in the notes) if heard (although it would not be necessary to indicate each time whether or not they were heard). The Committee was of the opinion that while the terms 'acceleration' and 'deceleration' of fetal heart rates detected by intermittent auscultation would be used, these would in fact represent a subjective perception of fetal heart rates by the clinician undertaking the assessment. The Committee recognised that a number of elements are involved in determining the wellbeing of an unborn baby during labour, among which an accelerating or decelerating heart rate is but one. The Committee agreed, however, that it was essential to record any deceleration heard and that the recording of an acceleration would represent good practice as it would provide reassurance (see Section 4.3). The Committee was of the opinion that it would also be important to check that the heart sounds being detected were those of the baby and not the woman and, therefore recommended that the maternal pulse should be palpated at the same time as the fetal heart rate is auscultated in order to differentiate the two.

The Committee was aware of some concern in the clinical and legal community about not performing CTG monitoring routinely on admission and recording the results. The Committee believed there to be a view among some clinicians that continuous CTG monitoring is better than intermittent auscultation at identifying unborn babies at risk of poor outcomes and that the use of CTG would, therefore, be justified, even in women at low risk of developing intrapartum complications. After considering all the evidence identified for inclusion in the guideline review, the Committee was, however, confident that the evidence did not support this view and the Committee agreed that auscultation on admission should be offered to women at low risk of complications at the onset of labour. Further recommendations were added to raise awareness among healthcare professionals that: for women at low risk of complications there is insufficient evidence that CTG on admission either improves outcomes or results in harm for women and their babies, compared with intermittent auscultation alone; and yet if a woman at low risk of complications requests CTG as part of the initial assessment the risks, benefits and limitations of CTG should be discussed with the woman and she should be supported in her choice.

The Committee also recognised that the maternal pulse may be detected by a CTG transducer and mistaken for the fetal pulse. If it is suspected that this is the case, the presence or absence of fetal heart pulsation can be confirmed by ultrasound as reflected in the Committee's final recommendation in this section.

3.1.7 Recommendations

1. **Offer auscultation of the fetal heart rate at first contact with a woman in suspected or established labour, and at each further assessment.**
    - **Use either a Pinard stethoscope or Doppler ultrasound.**
    - **Carry out auscultation immediately after a contraction for at least 1 minute and record it as a single rate.**
    - **Record accelerations and decelerations if heard.**
    - **Palpate the maternal pulse to differentiate between the maternal and fetal heartbeats. [2017]**

2. **Be aware that for women at low risk of complications there is insufficient evidence about whether cardiotocography as part of the initial assessment either improves outcomes or results in harm for women and their babies, compared with intermittent auscultation alone. [2017]**

3. **If a woman at low risk of complications requests cardiotocography as part of the initial assessment:**
    - **discuss the risks, benefits and limitations of cardiotocography with her, and support her in her choice**
    - **explain that, if she is in a setting where cardiotocography is not available, she will need to be transferred to obstetric-led care. [2017]**

4. **Offer continuous cardiotocography if any of the risk factors listed in recommendation 1.4.3 in the NICE guideline are identified on initial assessment, and explain to the woman why this is being offered. (See also section 4.) [2017]**

5. **Offer cardiotocography if intermittent auscultation indicates possible fetal heart rate abnormalities, and explain to the woman why this is being offered. If the trace is normal (see recommendation table 2 on fetal monitoring) after 20 minutes, return to intermittent auscultation unless the woman asks to stay on continuous cardiotocography. [2017]**

6. **If fetal death is suspected despite the presence of an apparently recorded fetal heart rate, offer real-time ultrasound assessment to check fetal viability. [2017]**

4 Monitoring during labour

4.1 Cardiotocography compared with intermittent auscultation during established labour

4.1.1 Review question

What is the effectiveness of electronic fetal monitoring compared with intermittent auscultation during established labour?

4.1.2 Description of included studies

Six studies were included in this review (Grant 1989; Kelso 1978; Leveno 1986; MacDonald 1985; Vintzileos 1993; Wood 1981).

Five of the included studies reported 4 randomised controlled trials (RCTs) that compared continuous electronic fetal monitoring (EFM) using cardiotocography (CTG) with intermittent auscultation during labour (Grant 1989 followed up children whose mothers had participated in the study reported in MacDonald 1985). The sixth included study was a quasi-randomised trial that allocated women to selective or universal CTG in alternating months, and this generated data for the comparison of interest (Leveno 1986).

Two of the included studies included only women with low-risk pregnancies (Wood 1981) or reported data separately for women with low-risk pregnancies (Leveno 1986). In the other 4 studies, the majority of women had low-risk pregnancies, but 20–30% of women were giving birth before term, underwent induction of labour or had antenatal risk factors (more details of specific inclusion and exclusion criteria are presented in the relevant evidence tables in Appendix G:).

In 1 study, EFM was performed externally unless the CTG trace quality became unsatisfactory, in which case monitoring was performed internally using a fetal scalp electrode (Vintzileos 1993) whereas in another study, monitoring was performed externally until membranes ruptured and then internally (Wood 1981). In 3 studies, monitoring was performed internally (Grant 1989; Kelso 1978; MacDonald 1985). One study did not report whether monitoring was performed internally or externally (Leveno 1986).

4.1.3 Evidence profile

A fixed effect model was used for these analyses, with the exception of 2 outcomes (instrumental vaginal birth for any indication and neonatal acidosis), for which random effects models were used due to high heterogeneity ($I^2 > 60\%$).

Table 3: Summary GRADE profile for comparison of electronic fetal monitoring using cardiotocography compared with intermittent auscultation during established labour

Number of studies	Design	Number of women or babies		Effect		Quality
		Electronic fetal monitoring	Intermittent auscultation	Relative (95% CI)	Absolute (95% CI) and p value (if reported)	
Mode of birth: spontaneous vaginal birth						
1 meta-analysis of 3 studies (Kelso 1978; Vintzileos et al., 1993; Wood et al., 1981)	Randomised trials	1036/1444 (71.7%)	1094/1415 (77.3%)	RR 0.92 (0.89 to 0.97)	62 fewer per 1000 (from 23 fewer to 85 fewer)	Low
Mode of birth: instrumental vaginal birth for any indication						
1 meta-analysis of 4 studies (Kelso 1978; MacDonald 1985; Vintzileos 1993; Wood 1981)	Randomised trials	823/7918 (10.4%)	648/7905 (8.2%)	RR 1.24 (1.04 to 1.48)	20 more per 1000 (from 3 more to 39 more)	Low
Mode of birth: instrumental vaginal birth for fetal distress						
1 study (MacDonald 1985)	Randomised trial	190/6474 (2.9%)	75/6490 (1.2%)	RR 2.54 (1.95 to 3.31)	18 more per 1000 (from 11 more to 27 more)	Moderate
Mode of birth: caesarean section for any indication						
1 meta-analysis of 4 studies (Kelso 1978; MacDonald 1985; Vintzileos 1993; Wood 1981)	Randomised trials	271/7918 (3.4%)	224/7905 (2.8%)	RR 1.19 (1 to 1.41)	5 more per 1000 (from 0 fewer to 12 more)	Moderate
Mode of birth: caesarean section for fetal distress						

Number of studies	Design	Number of women or babies		Effect		Quality
		Electronic fetal monitoring	Intermittent auscultation	Relative (95% CI)	Absolute (95% CI) and p value (if reported)	
1 meta-analysis of 4 studies (Kelso 1978; Leveno 1986; MacDonald 1985; Vintzileos 1993)	Randomised trials	133/14761 (0.9%)	57/14753 (0.39%)	RR 2.28 (1.68 to 3.1)	5 more per 1000 (from 3 more to 8 more)	Low
Intrapartum fetal death						
1 meta-analysis of 3 studies (Leveno 1986; MacDonald 1985; Vintzileos 1993)	Randomised trials	3/14564 (0.02%)	4/14566 (0.03%)	RR 0.76 (0.19 to 3.01)	0 fewer per 1000 (from 0 fewer to 1 more)	Moderate
Neonatal death						
1 meta-analysis of 5 studies (Kelso 1978; Leveno 1986; MacDonald 1985; Vintzileos 1993; Wood 1981)	Randomised trials	18/15262 (0.12%)	25/15299 (0.16%)	RR 0.72 (0.4 to 1.3)	0 fewer per 1000 (from 1 fewer to 0 more)	Moderate
Neonatal morbidity: cerebral palsy						
1 study (Grant 1989)	Randomised trial	12/6527 (0.18%)	10/6552 (0.15%)	RR 1.2 (0.52 to 2.79)	0 more per 1000 (from 1 fewer to 3 more)	Low
Neonatal morbidity: hypoxic ischaemic encephalopathy						
1 study (Vintzileos 1993)	Randomised trial	1/746 (0.13%)	2/682 (0.29%)	RR 0.46 (0.04 to 5.03)	2 fewer per 1000 (from 3 fewer to 12 more)	Low
Neonatal morbidity: seizures						

Number of studies	Design	Number of women or babies		Effect		Quality
		Electronic fetal monitoring	Intermittent auscultation	Relative (95% CI)	Absolute (95% CI) and p value (if reported)	
1 meta-analysis of 3 studies (Leveno 1986; MacDonald 1985; Vintzileos 1993)	Randomised trials	8/13072 (0.06%)	24/13027 (0.18%)	RR 0.34 (0.16 to 0.75)	1 fewer per 1000 (from 0 fewer to 2 fewer)[a]	High
Neonatal morbidity: intraventricular haemorrhage						
1 study (Vintzileos 1993)	Randomised trial	0/746 (0%)	1/682 (0.15%)	RR 0.3 (0.01 to 7.47)	1 fewer per 1000 (from 1 fewer to 9 more)	Low
Neonatal morbidity: respiratory distress						
1 study (Vintzileos 1993)	Randomised trial	55/746 (7.4%)	40/682 (5.9%)	RR 1.26 (0.85 to 1.86)	15 more per 1000 (from 9 fewer to 50 more)	Very low
Neonatal morbidity: abnormal neurologic symptoms or signs						
1 meta-analysis of 3 studies (Kelso 1978; MacDonald 1985; Wood 1981)	Randomised trials	19/5767 (0.33%)	31/5804 (0.53%)	RR 0.62 (0.35 to 1.09)	2 fewer per 1000 (from 3 fewer to 0 more)	Low
Admission to neonatal intensive care unit (NICU) or nursery						
1 meta-analysis of 5 studies (Kelso 1978; Leveno 1986; MacDonald 1985; Vintzileos 1993; Wood 1981)	Randomised trials	780/15200 (5.1%)	753/15291 (4.9%)	RR 1.03 (0.94 to 1.13)	1 more per 1000 (from 3 fewer to 6 more)	Moderate
Cord blood gas values at birth: arterial or venous pH < 7.10						

Number of studies	Design	Number of women or babies		Effect		Quality
		Electronic fetal monitoring	Intermittent auscultation	Relative (95% CI)	Absolute (95% CI) and p value (if reported)	
1 meta-analysis of 2 studies (MacDonald 1985; Vintzileos 1993)	Randomised trials	36/1279 (2.8%)	29/1215 (2.4%)	RR 0.92 (0.27 to 3.11)	2 fewer per 1000 (from 17 fewer to 50 more)	Very low

CI confidence interval, RR relative risk
a When expressed per 10,000 babies, the absolute effect is 12 fewer (from 5 fewer to 15 fewer)

4.1.4 Evidence statements

There was evidence that women monitored with CTG had lower rates of spontaneous vaginal birth (n=2859) and higher rates of instrumental vaginal birth and caesarean section for fetal distress (n=15,823) than women monitored with intermittent auscultation. There was evidence of a higher risk of seizures (n=16,099) in babies born to women monitored with intermittent auscultation, but no evidence of a difference in other neonatal outcomes, including: mortality (n=30,561); cerebral palsy (n=13,079); hypoxic ischaemic encephalopathy (n=1428); intraventricular haemorrhage (n=1428); respiratory distress (n=1428); abnormal neurologic symptoms or signs (n=11,571); admission to neonatal intensive care unit (NICU; n=30,491); and low umbilical artery or venous pH at birth (n=2494). The evidence was of very low to high quality.

4.1.5 Health economics profile

No published economic evaluations were identified for this review question.

4.1.6 Evidence to recommendations

4.1.6.1 Relative value placed on the outcomes considered

In this review, the Guideline Committee hoped to determine whether the use of continuous CTG monitoring during established labour was any more effective than intermittent auscultation in identifying babies at greater risk of poor outcomes due to developing acidosis during labour and who might require additional care or expedited birth. The key outcomes of interest were: mode of birth; rates of fetal and neonatal death; and rates of more serious morbidities such as cerebral palsy and hypoxic ischaemic encephalopathy (HIE).

4.1.6.2 Consideration of clinical benefits and harms

The evidence included in the guideline review showed that there were significantly more spontaneous vaginal births in the group that received intermittent auscultation compared with the group that received continuous CTG monitoring. There was also a significantly greater number of instrumental vaginal births (both for any indication and specifically for fetal distress) in the CTG group. CTG was also associated with a statistically significant increase in the number of caesarean sections for fetal distress (5 more per 1000 births). Similarly, among women with meconium-stained liquor, the evidence indicated that there were significantly increased risks of caesarean section for any indication, caesarean section for abnormal fetal heart rate and/or acidosis, and births other than spontaneous vaginal births in the group that received continuous CTG compared with the group that had intermittent auscultation. These findings seemed to suggest that the use of CTG in labour results in an increase in interventions. However, for the majority of neonatal morbidities, there were no statistically significant findings between the 2 groups of general women in labour. The only statistically significant difference in neonatal morbidity was in seizures, with a lower incidence in the CTG group than the auscultation group; although this was a significant finding, the absolute risk reduction was very low, with a rate of 1 fewer per 1000 babies. In contrast, the risk of NICU admission was significantly reduced (108 fewer per 1000) among women with significant meconium-stained liquor (see Section 4.2).

The Guideline Committee concluded that the use of CTG in labour leads to an increase in the number of interventions without a concomitant increase in positive neonatal outcomes. The Committee noted that major adverse outcomes are rare in a low-risk population, and thus a large number of women would have to undergo CTG monitoring to prevent such outcomes. The Committee did not feel that this was a proven and clinically beneficial trade-off, although the reassurance that women might gain from CTG monitoring was an important

consideration (see Section 4.7). Ultimately, the Committee endorsed the recommendations from the 2007 and 2014 guidelines (CG55 and CG190, respectively) that CTG should not be used in established labour unless there was a specific indication suggesting increased risk to the wellbeing of the unborn baby that would justify switching from intermittent auscultation. At the same time, outcomes following continuous CTG in women with significant meconium showed an increase in intrapartum interventions but fewer admissions to neonatal intensive care (see Section 4.2). As such, the Committee continued to recommend that CTG should be offered when there was significant meconium present. Based on their clinical experience, the Committee felt it appropriate to differentiate between significant and non-significant meconium, with significant meconium being defined (as in CG190) as dark green or black amniotic fluid that is thick or tenacious, or any meconium-stained amniotic fluid containing lumps of meconium. The Committee agreed that non-significant meconium alone would not justify using continuous CTG, but should prompt a full risk assessment. Continuous CTG should be advised if other risk factors were found to be present alongside the careful use of intermittent auscultation.

The Committee discussed the appropriate method for conducting auscultation and agreed that the fetal heart rate should be counted for 1 minute and the result should be written as a single figure, as in the recommendations for auscultation on admission in labour (see Section 3). The need to auscultate the fetal heart for 1 minute immediately after a contraction to detect any late decelerations was noted as important and included in the recommendations. The Committee debated the value of auscultation between contractions and more than 1 minute after a contraction and concluded that was there no support for a change from the 2014 recommendation, which represents current practice.

The Committee noted that the maternal pulse should be palpated to differentiate between the woman's and the unborn baby's heart beats. It was, however, noted that a Pinard stethoscope or Doppler device should not be recommended for differentiation between the maternal and fetal heart beats when continuous CTG is being used (because there was no evidence identified to support such practice).

The Committee was aware that the 2014 (CG190) recommendations were perceived as confusing and difficult to implement. The Committee felt that each risk factor specified in the new (2017) recommendations warranted an offer of CTG in its own right, and a scoring system based on combinations of risk factors (as had been recommended in CG190) lacked an evidence base and was too complex to implement in practice. Based on their clinical expertise and experience, the Committee added as indications for continuous CTG: contractions lasting longer than 60 seconds (hypertonus); and more than 5 contractions in 10 minutes (tachysystole). The Committee's rationale for including these as indications for continuous CTG was that prolonged or frequent contractions can interfere with placental perfusion.

4.1.6.3 Consideration of health benefits and resource use

The clinical evidence suggested that the use of continuous CTG rather than intermittent auscultation during established labour might lead to an increase in interventions such as caesarean section and instrumental vaginal birth (as well as associated morbidities for both the woman and the baby). The perceived benefits from continuous CTG monitoring among women in labour were that there would be fewer babies born with severe fetal acidosis or, at least, the impact of this condition might be ameliorated. However, the Committee did not think that the evidence demonstrated an effect large enough to make continuous CTG cost effective. In the absence of improved neonatal outcomes, the Committee felt that not recommending the use of continuous CTG in women at low risk could lead to health benefits which lead to fewer unnecessary birth interventions. Reducing the use of continuous CTG could also lead to cost savings if less CTG equipment were required in the labour ward, due to reduced maintenance costs and use of ancillary resources such as pH monitoring.

A recommendation in part of CG190 that was not covered by the present update specified indications for transfer to obstetric-led care on initial assessment, and the fetal monitoring recommendations in CG190 that were covered by the update had previously cross-referred to this list of risk factors, stating that the same risk factors should be used as indications for offering CTG during established labour. The 2017 Committee decided to list some specific risk factors associated with transfer to obstetric-led care as indications for offering continuous CTG, rather than using a cross-reference to the recommendation about obstetric-led care that was not part of the update. In doing so, many of the detailed elements of the previous recommendation such as 'pulse over 120 beats/minute on 2 occasions 30 minutes apart' and 'temperature of 38°C or above on a single reading, or 37.5°C or above on 2 consecutive occasions 1 hour apart' were reproduced directly from the recommendation that was not part of the update. Indeed, most of the risk factors leading to an offer of continuous CTG during labour came directly from the recommendation that was not part of the update, but the 2017 Committee narrowed the indications when listing them explicitly (rather than recommending that every indication for transfer to obstetric-led care should be accompanied by an offer of continuous CTG). In particular, the 2017 Committee's view was that observations of the unborn baby listed as risk factors for transfer to obstetric-led care in the recommendation that was not part of the update did not warrant an offer of continuous CTG during labour. This narrowing of the indications for CTG use should result in a reduction in resource use compared with the 2014 guideline (CG190).

4.1.6.4 Quality of evidence

The evidence identified for inclusion in the guideline review was highly relevant to the low-risk population, although the quality of the evidence ranged from very low to high.

The evidence review related to continuous CTG versus intermittent auscultation in women with meconium-stained liquor (see Section 4.2) included only studies involving a significant proportion of women with meconium-stained liquor and so this evidence was regarded as directly applicable to the review question, although again the quality of the evidence ranged from very low to high.

Despite the quality of evidence identified for inclusion, the Committee felt sufficiently confident to make recommendations for women without any increased risk of complications in labour. However, as the evidence for women with meconium-stained liquor was limited and outdated, the Committee recommended that further research was needed that would include an evaluation of significant and non-significant meconium subgroups.

4.1.6.5 Other considerations

The Committee was aware of some concern among clinicians about not using CTG during established labour (this mirrored a concern about monitoring on admission in labour). They felt that too often clinicians used CTG monitoring for reassurance, rather than clinical need. Based on the evidence reviewed, the Committee was confident in recommending that continuous CTG should not be used for women at low risk of complications in established labour.

As with the review for monitoring on admission in labour, the Committee agreed that accelerations or decelerations should be recorded if they were heard on intermittent auscultation.

The Committee felt that the maternal pulse should always be palpated and not only if a fetal heart rate abnormality were suspected. The Committee also noted that healthcare professionals should be alert to the possibility of a gradual increase in the baseline fetal heart rate or decelerations and in such circumstances appropriate actions would include: carrying out intermittent auscultation more frequently (for example after 3 consecutive contractions initially); and thinking about the whole clinical picture, including the woman's position and

hydration, the strength and frequency of contractions and maternal observations. If a rising baseline or decelerations are confirmed then the Committee recommended: summoning help; offering continuous cardiotocography, and explaining to the woman and her birth companion(s) why it is being offered; transferring the woman to obstetric-led care (provided it is safe and appropriate to do so, for example, when birth is not imminent).

The Committee noted limitations in the extent to which the fetal heart rate reflects the risk of fetal hypoxia and acidosis. The fetal heart rate can be affected by factors other than fetal hypoxia, such as fetal behavioural state, maternal analgesia and pyrexia, with the latter constituting an indication for continuous CTG monitoring in its own right.

The 2014 guideline noted that healthcare professionals should not regard amniotomy alone for suspected delay in the established first stage of labour as an indication to start continuous cardiotocography. The corresponding recommendation appears in Section 10.1 of CG190 and is reproduced here although it has not been updated as part of this review.

4.1.7 Recommendations

7. **Do not offer cardiotocography to women at low risk of complications in established labour. [2017]**

8. **Offer intermittent auscultation of the fetal heart rate to women at low risk of complications in established first stage of labour:**
    - **Use either a Pinard stethoscope or Doppler ultrasound.**
    - **Carry out intermittent auscultation immediately after a contraction for at least 1 minute, at least every 15 minutes, and record it as a single rate.**
    - **Record accelerations and decelerations if heard.**
    - **Palpate the maternal pulse hourly, or more often if there are any concerns, to differentiate between the maternal and fetal heartbeats. [2017]**

9. **If there is a rising baseline fetal heart rate or decelerations are suspected on intermittent auscultation, actions should include:**
    - **carrying out intermittent auscultation more frequently, for example after 3 consecutive contractions initially**
    - **thinking about the whole clinical picture, including the woman's position and hydration, the strength and frequency of contractions and maternal observations.**

    If a rising baseline or decelerations are confirmed, further actions should include:
    - **summoning help**
    - **advising continuous cardiotocography, and explaining to the woman and her birth companion(s) why it is needed**
    - **transferring the woman to obstetric-led care, provided that it is safe and appropriate to do so (follow the general principles for transfer of care described in section 1.6 of the NICE guideline). [2017]**

10. **Advise continuous cardiotocography if any of the following risk factors are present at initial assessment (see section 1.4 of the NICE guideline) or arise during labour:**

- **maternal pulse over 120 beats/minute on 2 occasions 30 minutes apart**
- **temperature of 38°C or above on a single reading, or 37.5°C or above on 2 consecutive occasions 1 hour apart**
- **suspected chorioamnionitis or sepsis**
- **pain reported by the woman that differs from the pain normally associated with contractions**
- **the presence of significant meconium (as defined in recommendation 1.5.2 in the NICE guideline)**
- **fresh vaginal bleeding that develops in labour**
- **severe hypertension: a single reading of either systolic blood pressure of 160 mmHg or more or diastolic blood pressure of 110 mmHg or more, measured between contractions**
- **hypertension: either systolic blood pressure of 140 mmHg or more or diastolic blood pressure of 90 mmHg or more on 2 consecutive readings taken 30 minutes apart, measured between contractions**
- **a reading of 2+ of protein on urinalysis and a single reading of either raised systolic blood pressure (140 mmHg or more) or raised diastolic blood pressure (90 mmHg or more)**
- **confirmed delay in the first or second stage of labour (see recommendations 1.12.14, 1.13.3 and 1.13.4 in the NICE guideline)**
- **contractions that last longer than 60 seconds (hypertonus), or more than 5 contractions in 10 minutes (tachysystole)**
- **oxytocin use. [2017]**

11. **Do not offer continuous cardiotocography to women who have non-significant meconium if there are no other risk factors. [2017]**

12. **Do not regard amniotomy alone for suspected delay in the established first stage of labour as an indication to start continuous cardiotocography. [2007, amended 2014]**

13. **Address any concerns that the woman has about continuous cardiotocography, and give her and her birth companion(s) the following information:**
    - **Explain that continuous cardiotocography is used to monitor the baby's heartbeat and the labour contractions.**
    - **Explain that it may restrict her mobility.**
    - **Give details of the types of findings that may occur. Explain that a normal trace indicates that the baby is coping well with labour.**
    - **Explain that changes to the baby's heart rate pattern during labour are common and do not necessarily cause concern.**
    - **Explain that if the trace is not normal (see recommendation table 2), there will be less certainty about the condition of the baby and so continuous monitoring will be advised.**
    - **Explain that decisions about her care during labour and birth will be based on an assessment of several factors, including her preferences, her condition and that of her baby, as well as the findings from cardiotocography. [2017]**

14. **If continuous cardiotocography has been started because of concerns arising from intermittent auscultation, but the trace is normal (see recommendation table 2) after 20 minutes, return to intermittent auscultation unless the woman asks to stay on continuous cardiotocography (see recommendation 3). [2017]**

4.1.8 Research recommendations

1. **What is the clinical and cost effectiveness of intermittent auscultation versus continuous cardiotocography in otherwise low-risk pregnancies complicated by meconium-stained liquor?**

Why this is important

Women at low risk of intrapartum complications have lower rates of intervention (such as caesarean section) and no difference in neonatal outcomes when the fetus is monitored using intermittent auscultation rather than continuous cardiotocography. The studies used to inform this finding required a change in measurement method from intermittent auscultation to cardiotocography if a fetal heart rate abnormality was detected by intermittent auscultation or following development of a risk factor such as meconium-stained liquor. However, it may be that intermittent auscultation in the presence of meconium-stained liquor alone would have been as effective as continuous cardiotocography from the fetal point of view but with the added benefit of a reduced risk of intervention.

A randomised controlled trial is needed that compares continuous cardiotocography with intermittent auscultation in women who are assessed at the onset of labour as being at low risk of developing intrapartum complications and go on to have meconium-stained liquor. The study should include stratified subgroups of significant and non-significant meconium and consider both short- and long-term outcomes such as neonatal mortality, developmental delay at 2 years, caesarean section, woman's experience of labour and birth, neonatal unit admission, requirement for respiratory ventilation, and development of neonatal encephalopathy.

4.2 Fetal heart rate monitoring for meconium-stained liquor

4.2.1 Review question

What is the effectiveness of continuous electronic fetal monitoring compared with intermittent auscultation when there is meconium-stained liquor?

4.2.2 Description of included studies

One study was included in this review (Alfirevic 2013). The study is a systematic review of randomised controlled trials (RCTs) with 12 component trials from a variety of countries. Two of these trials were considered for this review question.

All included trials within the systematic review evaluated the effectiveness of continuous electronic fetal monitoring (EFM) using cardiotocography (CTG) compared with intermittent auscultation of the fetal heart rate. Ten of the included studies within the systematic review included a small proportion of women with meconium stained liquor but no subgroup analyses were reported for this group, and so no evidence from these studies could be included in the guideline review. The 2 remaining studies included a higher percentage of women with meconium stained liquor and are reported for this review question. The studies were conducted in Pakistan and Melbourne. All women in the trial in Pakistan had meconium-stained liquor, but this was true for only 40% of women in the Melbourne trial. Both studies were conducted more than 20 years ago and have substantial limitations.

4.2.3 Evidence profile

The effectiveness of continuous CTG compared with intermittent auscultation when there is meconium-stained liquor is reported here in 1 GRADE profile (Table 4).

Table 4: Summary GRADE profile for comparison of continuous cardiotocography with intermittent auscultation

Number of studies	Design	Number of women		Effect		Quality
		Continuous CTG	Intermittent auscultation (IA)	Relative (95% CI)	Absolute (95% CI)	
Caesarean section						
1 meta-analysis of 2 studies (Alfirevic 2013)	Randomised trials	74/275 (26.9%)	36/275 (13.1%)	RR 2.11 (1.19 to 3.74)	145 more per 1000 (from 25 more to 359 more)	Very low
Caesarean section for abnormal FHR pattern and/or acidosis						
1 meta-analysis of 2 studies (Alfirevic 2013)	Randomised trials	47/275 (17.1%)	21/275 (7.6%)	RR 2.24 (1.38 to 3.64)	95 more per 1000 (from 29 more to 202 more)	Low
Caesarean section for other reason						
1 meta-analysis of 2 studies (Alfirevic 2013)	Randomised trials	27/275 (9.8%)	15/275 (5.5%)	RR 1.80 (0.98 to 3.31)	43 more per 1000 (from 1 fewer to 125 more)	Very low
Instrumental vaginal birth						
1 meta-analysis of 2 studies (Alfirevic 2013)	Randomised trials	108/275 (39.3%)	94/275 (34.2%)	RR 1.16 (0.88 to 1.54)	55 more per 1000 (from 41 fewer to 185 more)	Very low
Spontaneous vaginal birth not achieved						
1 meta-analysis of 2 studies (Alfirevic 2013)	Randomised trials	182/275 (66.2%)	130/275 (47.3%)	RR 1.4 (1.2 to 1.63)	189 more per 1000 (from 95 more to 298 more)	Very low
Perinatal death						
1 meta-analysis of 2 studies (Alfirevic 2013)	Randomised trials	5/275 (1.8%)[a]	6/275 (2.2%)[a]	RR 0.83 (0.26 to 2.67)	4 fewer per 1000 (from 16 fewer to 36 more)	Very low
NICU admissions						

Number of studies	Design	Number of women		Effect		Quality
		Continuous CTG	Intermittent auscultation (IA)	Relative (95% CI)	Absolute (95% CI)	
1 study (Alfirevic 2013)	Randomised trial	11/175 (6.3%)	30/175 (17.1%)	RR 0.37 (0.19 to 0.71)	108 fewer per 1000 (from 50 fewer to 139 fewer)	Moderate
Neonatal seizures						
1 study (Alfirevic 2013)	Randomised trial	0/175 (0%)	4/175 (2.3%)	RR 0.11 (0.01 to 2.05)	20 fewer per 1000 (from 23 fewer to 24 more)	Low
Damage/infection from scalp electrode or scalp sampling						
1 study (Alfirevic 2013)	Randomised trial	1/100 (1%)	0/100 (0%)	RR 3 (0.12 to 72.77)	NC	Low

CI confidence interval, CTG cardiotocography, IA intermittent auscultation, NICU neonatal intensive care unit, RR relative risk

a The rate of mortality was 4.5% (4/100 in CTG group and 5/100 in IA group) in one study (Pakistan 1989) and 0.6% (1/175 in CTG group and 1/175 in IA group) in the other study (Melbourne 1976). 89% of the weight of the meta-analysis is from one study (Pakistan 1989) .The reasons for the perinatal deaths are not reported

4.2.4 Evidence statements

Evidence from 2 studies (n=550) showed that women with meconium-stained liquor who received continuous CTG during labour were less likely to have a spontaneous vaginal birth than those who received intermittent auscultation, with this difference being explained by a higher caesarean section rate among women who revived continuous CTG. In terms of neonatal outcomes, there were no significant differences observed between the 2 groups in perinatal mortality (n=550) and neonatal seizure rate (n=350), but the rate of neonatal intensive care unit (NICU) admission (n=350) was higher in the intermittent auscultation group when compared with the continuous CTG group. The evidence was of very low to moderate quality.

4.2.5 Health economics profile

No published economic evaluations were identified for this review question.

4.2.6 Evidence to recommendations

See Section 4.1 for the evidence to recommendations considerations and recommendations arising from this review question.

4.3 Interpretation of an electronic fetal heart rate trace

4.3.1 Review question

What are the appropriate definitions and interpretation of the features of an electronic fetal heart rate trace?

4.3.2 Introduction

Babies in the uterus derive oxygen from the mother via the placenta and umbilical cord. During contractions of the uterus in labour this oxygen exchange can be interrupted intermittently. During normal labour, babies who are well are not adversely affected by this. However, this is not always the case and fetal hypoxia and then acidosis can occur. Fortunately, these are relatively rare events in normal pregnancies. The Birthplace study (Birthplace in England Collaborative Group 2011), for example, reported that intrapartum stillbirths, early neonatal deaths and cases of neonatal encephalopathy – a proportion of which will have been due to intrapartum fetal hypoxia/acidosis – occurred in less than 4 in 1000 births in women at low risk of intrapartum complications.

Surveillance for fetal hypoxia in labour is undertaken by fetal heart rate monitoring either by intermittent auscultation or by a continuous recording by a cardiotocograph. The aim of using a cardiotocograph is to provide a visual continuous record of fetal heart rate and uterine contractions. There are features that can indicate the baby is well and responding normally to the events of labour (for example, slowing of the fetal heart rate during a contraction). There are other features that may indicate a serious emergency (for example, development of a persistent bradycardia following cord prolapse or placental abruption).

The 4 features of the fetal heart rate that are scrutinised in a cardiotocograph are:

- baseline heart rate
- baseline variability

- presence or absence of decelerations
- presence of accelerations.

All of these have been examined in relation to the development of fetal hypoxia-acidosis.

4.3.3 Description of included studies

Forty-three studies are included in this review (Berkus 1999; Cahill 2013; Cardoso 1995; Cibils 1975; Cibils 1978; Cibils 1980; Cibils 1993; Dellinger 2000; Ellison 1991; Gaffney 1994; Giannubilo 2007; Gilstrap 1984; Gilstrap 1987; Graham 2014; Hadar 2001; Heinrich, 1982; Holzmann 2015; Honjo 2001; Krebs 1982; Larma 2007; Liu 2015; Low 1977; Low 1981; Low 1999; Low 2001; Maso 2012; Menihan 2006; Murphy 1991; Nelson 1996; Ozden 1999; Powell 1979; Roy 2008; Salim 2010; Sameshima 2005; Samueloff 1994; Sharbaf 2014; Sheiner 2001; Soncini 2014; Spencer 1986; Spencer 1997; Williams 2002; Williams 2003; Williams 2004).

Seventeen included studies are from the USA (Berkus 1999; Cahill 2013; Cibils 1975; Cibils 1978; Cibils 1980; Cibils 1993; Dellinger 2000; Gilstrap 1984; Gilstrap 1987; Graham 2014; Krebs 1982; Larma 2007; Liu 2015; Menihan 2006; Nelson 1996; Powell 1979; Samueloff 1994). Seven studies are from Canada (Low 1977; Low 1981; Low 1999; Low 2001; Williams 2002; Williams 2003; Williams 2004), 3 from the UK (Gaffney 1994; Murphy 1991; Spencer 1986), 3 from Israel (Hadar 2001; Salim 2010; Sheiner 2001), 3 from Italy (Giannubilo 2007; Maso 2012; Soncini 2014), 2 from Japan (Honjo 2001; Sameshima 2005) and 1 each from Iran (Sharbaf 2014), Sweden (Holzmann 2015), India (Roy 2008), Australia (Spencer 1997), Germany (Heinrich 1982), Turkey (Ozden 1999), Portugal (Cardoso 1995) and Ireland (Ellison 1991).

All included studies are observational studies (either prospective or retrospective cohort studies, case–control studies or consecutive or non-consecutive case series). All included studies evaluated the predictive value of fetal heart rate features for neonatal adverse outcomes including cerebral palsy, seizure, neonatal acidaemia, encephalopathy, sudden infant death syndrome and birth asphyxia.

The predictive value and association of baseline fetal heart rate (tachycardia and bradycardia) for neonatal adverse outcomes were assessed in 15 studies (Berkus 1999; Ellison 1991; Giannubilo 2007; Gilstrap 1984; Gilstrap 1987; Holzmann 2015; Honjo 2001; Liu 2015; Maso 2012; Nelson 1996; Ozden 1999; Roy 2008; Salim 2010; Sheiner 2001; Williams 2004).

The relation between fetal heart rate baseline variability and neonatal encephalopathy, sudden infant death, seizure and/or metabolic acidosis was evaluated in 14 studies (Berkus 1999; Ellison 1991; Graham 2014; Holzmann 2015; Larma 2007; Liu 2015; Menihan 2006; Murphy 1991; Nelson 1996; Roy 2008; Samueloff 1994; Sheiner 2001; Spencer 1997; Williams 2004).

The predictive value of accelerations and decelerations for neonatal adverse outcomes was assessed in 21 studies (Berkus 1999; Cahill 2013; Cibils 1993; Ellison 1991; Giannubilo 2007; Graham 2014; Hadar 2001; Holzmann 2015; Krebs 1982; Liu 2015; Low 1977; Nelson 1996; Ozden 1999; Powell 1979; Roy 2008; Sameshima 2005; Samueloff 1994; Sheiner 2001; Spencer 1997; Williams 2002; Williams 2003; Williams 2004).

The ability of defined fetal heart rate classification systems (including systems devised by the authors of particular studies included in the guideline review) to predict early adverse neonatal outcomes was assessed in 13 studies (Cardoso 1995; Dellinger 2000; Gaffney 1994; Gilstrap 1987; Graham 2014; Hadar 2001; Heinrich 1982; Low 1999; Low 2001; Ozden

1999; Sharbaf 2014; Sheiner 2001; Spencer 1997). The published classifications for fetal heart rate traces referred to in the evidence are summarised in Appendix J:.

The participants in the included studies were predominantly women at low/mixed-risk populations except in 8 studies involving women at high risk or including stratified analysis for high risk populations (Cibils 1975; Cibils 1978; Cibils 1980; Cibils 1993; Low 1977; Low 1981; Sharbaf 2014; Soncini 2014). The findings for the high risk populations in these 8 studies are reported in separate GRADE profiles.

4.3.4 Evidence profile

Evidence is reported in GRADE profiles (Table 5 to Table 45) for the following fetal heart rate trace features:

- baseline fetal heart rate (tachycardia and bradycardia)
- baseline variability
- accelerations
- decelerations
- categorisation/classification of fetal heart rate traces.

Evidence from prospective comparative observational studies and prospective consecutive case series was initially rated as high quality and was downgraded if any issues were identified that would undermine the trustworthiness of the findings. Evidence from retrospective comparative observational studies and retrospective consecutive case series was initially rated as moderate quality and was downgraded if there were any quality related issues. Evidence from non-consecutive case series was initially rated as low quality and was downgraded if there were any quality related issues.

4.3.4.1 Predictive accuracy and correlation data

In the following tables, predictive accuracy of CTG trace features are reported for different test findings (such as pH and base deficit) and for different neonatal outcomes (such as encephalopathy). The specific CTG feature and the thresholds applied (for example, more than 160 beats per minute (bpm) for tachycardia) are presented in the rows of the GRADE table and the outcomes they predict are detailed in the ‘definition of outcome’ column. The measures of diagnostic test accuracy in each row represent the specific values for that test at the defined threshold in relation to the specified outcome.

4.3.4.2 Summary tables of evidence on low- and mixed-risk populations

4.3.4.2.1 Baseline fetal heart rate (tachycardia and bradycardia)

Table 5: Summary GRADE profile for predictive value of tachycardia and bradycardia for adverse neonatal outcomes

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Tachycardia (> 160 bpm) (FIGO classification 1987)									
1 study (Holzmann 2015)	Cohort	Fetal lactacidaemia (lactate >4.8mmol/l)	NR. 60 minutes prior to first fetal blood sampling.	1070	62.50% (35.87 to 83.72)[a]	67.43% (62.21 to 72.26)[a]	1.92 (1.28 to 2.89)[a]	0.56 (0.29 to 1.05)[a]	Very low
1 study (Holzmann 2015)	Cohort	Fetal lactacidaemia (lactate >4.8mmol/l)	NR. 60 prior to last fetal blood sampling.	888	64.0% (42.6-81.3)[a]	66.4% (60.4-72.0)[a]	1.91 (1.36-2.67)[a]	0.54 (0.32-0.92)[a]	Very low
Tachycardia (> 160 bpm) (duration not reported)									
1 study (Nelson 1996)	Case control	Cerebral palsy	NR	378	28.2% (19.4 to 39)[b]	71.7% (66.3 to 76.5)[b]	0.99 (0.66 to 1.48)[b]	1.0 (0.85 to 1.17)[b]	Low
1 study (Gilstrap, 1984)	Cohort	Umbilical cord arterial pH<7.20	NR	583	47.2% (30.9 to 63.5)[b]	80.4% (76.9 to 83.87)[b]	2.41 (1.63 to 3.55)[b]	0.65 (0.48 to 0.89)[b]	Moderate
Tachycardia (> 180 bpm) (duration not reported)									
1 study (Nelson 1996)	Case control	Cerebral palsy	NR	378	6.4% (2.8 to 14.1)[b]	94.7% (91.5 to 96.7)[b]	1.20 (0.45 to 3.17)[b]	0.98 (0.92 to 1.05)[b]	Low
Bradycardia (< 110 bpm) (NICHD classification) (duration not reported)									

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
1 study (Williams 2004)	Case series	Seizure	1 hour before birth	50	46.7% (30.2 to 63.9)[b]	19.2% (8.5 to 37.9)[b]	0.57 (0.37 to 0.88)[b]	2.77 (1.17 to 6.52)[b]	Low
FHR baseline (< 110 bpm) (NICHD classification) (duration not reported)									
1 study (Larma 2007)	Case control	Moderate hypoxic ischemic encephalopathy (HIE)	Last hour of tracing	214	15.4%	98.9%	7.50	0.86	Very low
Bradycardia ('terminal deceleration')[c]									
1 study (Cahill 2013)	Case control	Umbilical cord arterial pH<7.10	30 minutes before birth	5388	21.0% (11.3 to 33.9)[b]	82.3% (81.3 to 93.4)[b]	1.20 (0.72 to 1.98)[b]	0.96 (0.84 to 1.10)[b]	Low
Bradycardia ('terminal deceleration')[c]									
1 study (Cahill 2013)	Case control	Umbilical cord arterial pH<7.10 and base excess < −8.0	30 minutes before birth	5388	22.0% (11.5 to 36.0)[b]	82.3% (81.3 to 83.4)[b]	1.25 (0.47 to 2.11)[b]	0.95 (0.82 to 1.10)[b]	Low
Bradycardia ('terminal deceleration')[c]									
1 study (Cahill 2013)	Case control	NICU admission	30 minutes before birth	5388	06.67% (1.11 to 32.0)[b]	82.3% (81.2 to 83.3)[b]	0.38 (0.06 to 2.51)[b]	1.13 (0.99 to 1.30)	Low
Prolonged bradycardia (<110 bpm) (≥10 min)[d]									
1 study (Cahill 2013)	Case control	Umbilical cord arterial pH<7.10	30 minutes before birth	951	33.3% (10.13 to 65.5)[b]	97.12% (95.84 to 98.1)[b]	11.6 (4.80 to 28.0)[b]	0.69 (0.46 to 1.02)[b]	Low
Bradycardia (<100 bpm) (duration not reported)									

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
1 study (Nelson 1996)	Case control	Cerebral palsy	NR	378	34.6% (25 to 45.7)[b]	75% (69.8 to 79.6)[b]	1.38 (0.96 to 1.99)[b]	0.87 (0.73 to 1.03)[b]	Low
Mild bradycardia (90–119 bpm) (duration not reported)									
1 study (Gilstrap 1984)	Cohort	Umbilical cord arterial pH<7.20	10 minutes before birth	595	61.2% (47.5 to 74.87)[b]	75.2% (71.6 to 78.8)[b]	2.47 (1.89 to 3.23)[b]	0.51 (0.36 to 0.73)[b]	Very low
Bradycardia (<80 bpm) (duration not reported)									
1 study (Nelson 1996)	Case control	Cerebral palsy	NR	378	16.7% (10 to 26.5)[b]	88.3% (84.2 to 91.5)[b]	1.42 (0.79 to 2.56)[b]	0.94 (0.84 to 1.05)[b]	Low
Moderate/marked bradycardia (60–89 bpm) (duration not reported)									
1 study (Gilstrap 1984)	Cohort	Umbilical cord arterial pH<7.20	NR	551	63.4% (50.3 to 76.5)[b]	82.3% (79 to 85.7)[b]	3.59 (2.71 to 4.76)[b]	0.44 (0.30 to 0.63)[b]	Moderate
Bradycardic episode (<110 bpm as in FIGO classification 1987)									
1 study (Holzmann 2015)	Cohort	Fetal lactacidaemia (lactate >4.8mmol/l)	NR. 60 minutes prior to first fetal blood sampling	1070	62.50% (35.87 to 83.72)[a]	86.76% (82.02 to 90.44)[a]	4.72 (2.90 to 7.68)[a]	0.43 (0.23 to 0.81)[a]	Very low
1 study (Holzmann 2015)	Cohort	Fetal lactacidaemia (lactate >4.8mmol/l)	NR. 60 minutes prior to last fetal blood sampling	888	57.1% (34.4 to 77.4)[a]	88.1% (82.6 to 92.1)[a]	4.81 (2.84 to 8.15)[a]	0.49 (0.30 to 0.80)[a]	Very low

BPM beats per minute; CI confidence interval; FIGO International Federation of Obstetrics and Gynecology; NICHD National Institute of Child Health and Human Development; NICU Neonatal Intensive Care Unit; NR not reported

a Calculated by the 2017 NGA technical team

b Calculated by the 2014 NCC-WCH technical team
c The term 'terminal deceleration' used in the paper for this bradycardia defined as a prolonged deceleration (15 bpm or more below baseline for 2 minutes to 10 minutes)
d Bradycardia <10 minutes compared with prolonged bradycardia >10 minutes

Table 6: Summary GRADE profile for umbilical arterial pH and base excess in babies with intrapartum tachycardia or bradycardia

Number of studies	Design	Stage of labour	Fetal heart rate tracing				Quality
			Normal	Tachycardia[a]	Mild bradycardia[a]	Moderate or severe bradycardia[a]	
Umbilical cord artery pH (mean ± standard deviation)							
1 study (Honjo 2001)	Cohort	2nd stage	pH 7.31±0.05 n=236	pH 7.22±0.11 p<0.001b n=57	pH 7.25±0.06 p<0.01b n=11	pH 7.18±0.06 p<0.001b n=61	Moderate
Base excess							
1 study (Honjo 2001)	Cohort	2nd stage	BE -5.2±2.8 n=236	BE -9.2±4.5 p<0.001b n=57	BE -8.7±4.4 p<0.05b n=11	BE -10.2±3.5 p<0.001b n=61	Moderate

BE base excess

a. Baseline tachycardia and bradycardia were defined as:
Mild bradycardia: baseline FHR between 90 - 109 bpm for ≥10 minutes
Moderate to severe bradycardia: baseline FHR<90 bpm for ≥10 minutes
Tachycardia: baseline FHR of 160 bpm for ≥10 minutes
b. p value when compared with normal FHR tracing

Table 7: Summary GRADE profile for association between fetal heart rate (bradycardia and tachycardia) and umbilical artery blood gas values or adverse neonatal outcomes

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Degree of association or number (percentage) of babies with defined outcome	Quality
'Mild' bradycardia (90–119 bpm) (compared with normal FHR tracing)[a] (duration not reported)						
1 study (Berkus 1999)	Cohort	Immediate adverse neonatal outcome[b]	1st stage	24	No statistically significant association (numerical data not reported)	Very low
1 study (Berkus 1999)	Cohort	Immediate adverse neonatal outcome[b]	2nd stage	24	No statistically significant association (numerical data not reported)	Very low
'Mild' bradycardia (90–119 bpm) (duration not reported)						
1 study (Gilstrap 1987)	Cohort	Umbilical cord arterial pH mean (± SD)	2nd stage before head expulsion	53	7.23±0.07 p<0.05	Very low
Prolonged bradycardia (<110 bpm) (≥10 min)						
1 study (Cahill 2013)	Cohort	Cord pH <7.10	30 minutes before birth	31	OR[c] 18.6 (95% CI 5.0 to 68.9) p=0.01	Low
1 study (Cahill 2013)	Cohort	Cord pH <7.05	30 minutes before birth	31	OR[c] 46.0 (95% CI 5.7 to 373) p=0.01	Low
1 study (Cahill 2013)	Cohort	Cord pH <7.10 and base excess < −8.0	30 minutes before birth	31	OR[c] 3.8 (95% CI 1.4 to 10.7)	Low

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Degree of association or number (percentage) of babies with defined outcome	Quality
					p=0.01	
1 study (Cahill 2013)	Cohort	NICU admission	30 minutes before birth	31	OR[c] 14.2 (95% CI 3.4 to 59.6) p=0.01	Low
'Prolonged' bradycardia (FHR <90 bpm for more than 2.5 minutes) (compared with normal FHR tracing)[a]						
1 study (Berkus 1999)	Cohort	Immediate adverse neonatal outcome[b]	1st stage	129	OR 1.9 (95% CI 1.3 to 3.7)	Very low
1 study (Berkus 1999)	Cohort	Immediate adverse neonatal outcome[b]	2nd stage	129	No statistically significant association (numerical data not reported)	Very low
'Persistent' bradycardia (not defined) (duration not reported)						
1 study (Roy 2008)	Cohort	Umbilical cord pH<7.10	NR	106	n=4 (3.7%)	Low
1 study (Roy 2008)	Cohort	Immediate NICU admission	NR	106	n=16 (15%)	Low
'Moderate to severe' bradycardia (FHR <90 bpm) (mean ± standard deviation)						
1 study (Gilstrap 1987)	Cohort	Umbilical cord arterial pH mean (± SD)	1st stage	63	7.22±0.07 p<0.05	Moderate
Moderate bradycardia (100–109 bpm) (time period of 5 min)						
1 study (Maso 2012)	Case series	pH<7.2	2 hours before birth	17	n=6 (35.3%)	Low
1 study (Maso 2012)	Case series	pH<7.1	2 hours before birth	17	n=0 (0%)	Low

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Degree of association or number (percentage) of babies with defined outcome	Quality
1 study (Maso 2012)	Case series	pH<7.0	2 hours before birth	17	n=0 (0%)	Low
1 study (Maso 2012)	Case series	BD≥12 mmol/l	2 hours before birth	17	n=5 (29.4%)	Low
1 study (Maso 2012)	Case series	Adverse composite neonatal outcome[d]	2 hours before birth	17	n=0 (0%)	Low
Severe bradycardia (<100 bpm) (time period of 10 min)						
1 study (Maso 2012)	Case series	pH<7.2	2 hours before birth	15	n=7 (46.7%)	Low
1 study (Maso 2012)	Case series	pH<7.1	2 hours before birth	15	n=4 (16.7%)	Low
1 study (Maso 2012)	Case series	pH<7.0	2 hours before birth	15	n=1 (6.7%)	Low
1 study (Maso 2012)	Case series	BD≥12 mmol/l	2 hours before birth	15	n=2 (13.3%)	Low
1 study (Maso 2012)	Case series	Adverse composite neonatal outcome[d]	2 hours before birth	15	n=4 (26.7%)	Low
Bradycardia (<70 bpm) (compared with normal FHR tracing - NICHD classification) (duration not reported)						
1 study (Sheiner 2001)	Case series	pH<7.2 and BD ≥12 mmol/l	2nd stage	28	OR 3.4 (95% CI 1.2 to 8.6) p=0.04	Low
1 study (Sheiner 2001)	Case series	pH<7.2	1st stage	57	OR 26.6 (95% CI 5.2 to 150.3) p<0.001	Low
1 study	Case series	pH<7.2	2nd stage	57	OR 2.3	Low

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Degree of association or number (percentage) of babies with defined outcome	Quality
(Sheiner 2001)					(95% CI 0.3 to 17.1) p=0.390	
1 study (Sheiner 2001)	Case series	BD≥12 mmol/l	1st stage	28	OR 5.2 (95% CI 0.8 to 31.9) p=0.007	Low
1 study (Sheiner 2001)	Case series	BD≥12 mmol/l	2nd stage	28	OR 3.8 95% CI 0.3 to 44.2) p=0.282	Low
Bradycardia ('terminal deceleration')[e]						
1 study (Cahill 2013)	Cohort	Cord pH <7.10	30 minutes before birth	951	OR[c] 1.2 (95% CI 0.6 to 2.3) p=0.49	Low
1 study (Cahill 2013)	Cohort	Cord pH <7.05	30 minutes before birth	951	OR[c] 1.4 (95% CI 0.5 to 4.4) p=0.52	Low
1 study (Cahill 2013)	Cohort	Cord pH <7.10 and base excess < −8.0	30 minutes before birth	951	OR[c] 1.3 (95% CI 0.6 to 2.5) p=0.49	Low
1 study (Cahill 2013)	Cohort	NICU admission	30 minutes before birth	951	OR[c] 0.3 (95% CI 0.1 to 2.5) p=0.49	Low
Bradycardia <110 bpm (duration not reported)						
1 study (Liu 2015)	Cohort	Neonatal respiratory morbidity (either	Last 30 minutes before birth	NR (total N=4736)	OR[f] 0.5 (95% CI 0.1 to 3.4)	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Degree of association or number (percentage) of babies with defined outcome	Quality
		any oxygen requirement at or after 6 hours of life or any mechanical ventilation in the first 24 hours).				
FHR <120bpm (duration not reported)						
1 study (Liu 2015)	Cohort	Neonatal respiratory morbidity (either any oxygen requirement at or after 6 hours of life or any mechanical ventilation in the first 24 hours).	Last 30 minutes before birth	NR (total N=4736)	OR[f] 0.7 (95% CI 0.4 to 1.3)	Very low
Tachycardia (>160 bpm) (duration not reported)						
1 study (Berkus 1999)	Cohort	Immediate adverse neonatal outcome[b]	1st stage	126	No statistically significant association (numerical data not reported)	Very low
1 study (Berkus 1999)	Cohort	Immediate adverse neonatal outcome[b]	2nd stage	126	OR 1.9 (95% CI 1.2 to 2.8)	Very low
1 study (Gilstrap 1987)	Cohort	Umbilical cord arterial pH <7.2 Mean (± SD)	2nd stage before head expulsion	32	7.25±0.05	Very low
1 study (Liu 2015)	Cohort	Neonatal respiratory	Last 30 minutes before birth	NR (total N=4736)	OR[f] 2.9 (95% CI 1.9 to 4.4)	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Degree of association or number (percentage) of babies with defined outcome	Quality
		morbidity (either any oxygen requirement at or after 6 hours of life or any mechanical ventilation in the first 24 hours).				
1 study (Liu 2015)	Cohort	Neonatal respiratory morbidity (either any oxygen requirement at or after 6 hours of life or any mechanical ventilation in the first 24 hours).	Last 30 minutes before birth	NR (total N=3994, Caesarean births excluded)	OR[f] 3.0 (95% CI 1.8 to 5.1)	Very low
1 study (Liu 2015)	Cohort	Neonatal respiratory morbidity (either any oxygen requirement at or after 6 hours of life or any mechanical ventilation in the first 24 hours).	Last 30 minutes before birth	NR (total N=4647, cases with maternal fever excluded)	OR[f] 2.9 (95% CI 1.9 to 4.6)	Very low
1 study (Liu 2015)	Cohort	Neonatal mechanical ventilation	Last 30 minutes before birth	NR (total N=4605)	OR[f] 3.1 (95% CI 1.4 to 6.7)	Very low

BD base deficit; BPM beats per minute; CI confidence interval; FHR fetal heart rate; NICHD National Institute of Child Health and Human Development; NICU Neonatal Intensive Care Unit; NR not reported; OR odds ratio; SD standard deviation

a. A normal tracing defined as having a baseline rate of 120 – 160 bpm ; variability ≥5bpm from the baseline during the best one minute of 30 minutes tracing; presence of accelerations >15 bpm at least for 15 seconds; no variable or late decelerations.
b. Neonates were considered to have immediate adverse outcomes if they were admitted to level III, neonatal intensive care unit for >24 hours and required oxygen support (intubation >6 hours, or >24 hours of >40% oxygen supplementation)
c. Adjusted for nulliparity
d. Composite neonatal outcomes: umbilical artery pH<7 and/or APGAR score <7 at 5 minutes and/or neonatal resuscitation in delivery room and admission to neonatal intensive care unit for distress at birth
e. The term 'terminal deceleration' used in the paper for this bradycardia defined as a prolonged deceleration (15 bpm or more below baseline for 2 minutes - 10 minutes)
f. Adjusted for maternal fever, parity, pregestational diabetes mellitus, previous caesarean birth and preeclampsia

Table 8: Summary GRADE profile for baseline fetal heart rate in babies born with umbilical cord blood acidaemia compared with those born without acidaemia

Number of studies	Design	Stage of labour	Outcome		Effect		Quality
			Acidaemia[a]	Control (no acidaemia)	Relative (95% CI) compared to normal	Absolute (95% CI)	
Baseline FHR (bpm)							
1 study (Giannubilo 2007)	Case control	2nd stage	131.25±9.19 n=26	136.25 ±10.14 n=30	NC	MD 5 lower (10.06 lower to 0.06 higher)	Very low

BPM beats per minute; CI confidence interval; FHR fetal heart rate; MD mean difference; NC not calculable

a. pH<7.2, base deficit ≥12mmol/l

Table 9: Summary GRADE profile for correlation of marked tachycardia to neonatal convulsions

Number of studies	Design	Stage of labour	Number of women & baby pairs[a]	Correlation coefficient (p-value)	Quality
'Marked' tachycardia[b]					
1 study (Ellison 1991)	Cohort	1st stage	n=135	r=-0.02 (p=NS)	Low

NS not significant; r correlation coefficient

a. Original cohort from Dublin RCT (MacDonald 1985)
b. No definition of 'marked' tachycardia provided

4.3.4.2.2 *Baseline variability*

Table 10: Summary GRADE profile for predictive value of fetal heart rate baseline variability for neonatal adverse outcomes

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
FHR reduced variability (FIGO classification)									
1 study (Spencer 1997)	Case control	Encephalopathy	First 30 minutes of tracing	73	10.53% (0.77 to 20.28)[a]	94.29% (86.60 to 100)[a]	1.84 (0.35 to 9.44)[a]	0.94 (0.82 to 1.08)[a]	Very low
1 study (Spencer 1997)	Case control	Encephalopathy	Last 30 minutes of tracing	73	38.89% (22.96 to 54.81)[a]	87.10% (75.30 to 98.90)[a]	3.01 (1.10 to 8.20)[a]	0.70 (0.52 to 0.94)[a]	Very low
Reduced variability (FIGO classification 1987)									
1 study (Holzmann 2015)	Cohort	Fetal lactacidaemia (lactate >4.8mmol/l)	NR. 60 minutes prior to first fetal blood sampling	1070	40.00% (13.69 to 72.63)[b]	61.14% (56.06 to 66.00)[b]	1.03 (0.48 to 2.22)[b]	0.98 (0.59 to 1.63)[b]	Low
1 study (Holzmann 2015)	Cohort	Fetal lactacidaemia (lactate >4.8mmol/l)	NR. 60 minutes prior to last fetal blood sampling	888	35.7% (14.1 to 63.9)[b]	62.2% (61.2 to 63.6)[b]	0.95 (0.36 to 1.76)[b]	1.03 (0.57 to 1.40)[b]	Low
Decreased variability (absent or minimal variability according to NIHCD classification 2008)									
1 study (Graham 2014)	Case control	Whole-body hypothermia treatment for suspected moderate to severe encephalopathy.	Last 1 hour tracing before birth	117	33.3% (19.6 to 50.3)[b]	80.8% (70.0 to 88.5)[b]	1.73 (0.92 to 3.27)[b]	0.83 (0.66 to 1.04)[b]	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Baseline variability <5 bpm (NICHD classification)									
1 study (Larma 2007)	Case control	Moderate hypoxic ischemic encephalopathy (HIE)	Last hour of tracing	214	53.8%	79.8%	2.50	0.50	Very low
Baseline variability <5 bpm (NICHD classification)									
1 study (Nelson 1996)	Case control	Cerebral palsy in low and high risk population[c]	NR	378	26.9% (18.3 to 37.7)[a]	90.7% (86.8 to 93.5)[a]	2.88 (1.73 to 4.79)[a]	0.80 (0.70 to 0.92)[a]	Very low
"Minimal absent" variability (NICHD classification)									
1 study (Williams 2004)	Case series	Seizure	1 hour before birth	50	53% (36.2 to 69.5)[a]	64% (44.4 to 79.8)[a]	1.48 (0.79 to 2.75)[a]	0.72 (0.45 to 1.18)[a]	Moderate
Absent variability (FIGO classification 1987)									
1 study (Holzmann 2015)	Cohort	Fetal lactacidaemia (lactate >4.8mmol/l)	NR. 60 minutes prior to first fetal blood sampling	1070	40.00% (13.69 to 72.63)[b]	89.39% (84.88 to 92.72)[b]	3.77 (1.63 to 8.70)[b]	0.67 (0.40 to 1.11)[b]	Very low
1 study (Holzmann 2015)	Cohort	Fetal lactacidaemia (lactate >4.8mmol/l)	NR. 60 minutes prior to last fetal blood sampling	888	43.8% (20.8 to 69.4)[b]	87.7% (82.2 to 91.7)[b]	3.55 (1.83 to 6.91)[b]	0.64 (0.42 to 0.99)[b]	Very low
Non-reactive trace (NICHD classification)									
1 study (Larma 2007)	Case control	Moderate hypoxic ischemic	Last hour of tracing	214	92.3%	61.7%	2.30	0.13	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
		encephalopathy (HIE)							
FHR variability amplitude <3 bpm[d]									
1 study (Samueloff 1994)	Cohort	Umbilical cord artery pH<7.2	2nd stage	1814	10.99%	93.80%	1.40	0.96	Very low
FHR variability amplitude <5 bpm[d]									
1 study (Samueloff 1994)	Cohort	Umbilical cord artery pH<7.2	2nd stage	1814	26.24%	78.93%	1.18	0.94	Very low
FHR variability oscillation <3 bpm[d]									
1 study (Samueloff 1994)	Cohort	Umbilical cord artery pH<7.2	2nd stage	1810	6.78%	95.18%	1.36	0.98	Very low
FHR variability oscillation <5 bpm[d]									
1 study (Samueloff 1994)	Cohort	Umbilical cord artery pH<7.2	2nd stage	1810	25.23%	80.52%	1.25	0.93	Very low
FHR variability ([amplitude[e] + oscillation[f]] ÷ 2) <3 bpm[d]									
1 study (Samueloff 1994)	Cohort	Umbilical cord artery pH<7.2	2nd stage	1913	7.44%	96.30%	1.75	0.96	Very low
1 study (Samueloff 1994)	Cohort	Umbilical cord artery pH<7.2	1st stage (following admission)	1913	2.1%	98.6%	1.50	0.99	Very low
FHR variability oscillation[f] <3bpm[d]									

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
1 study (Samueloff 1994)	Cohort	Umbilical cord artery pH<7.2	1st stage (following admission)	1810	3.16%	98.2%	1.72	0.98	Very low
FHR variability amplitude[e] <3bpm[d]									
1 study (Samueloff 1994)	Cohort	Umbilical cord artery pH<7.2	1st stage (following admission)	1814	3.86%	97.13%	1.31	0.99	Very low
Increased variability (FIGO classification 1987)									
1 study (Holzmann 2015)	Cohort	Fetal lactacidaemia (lactate >4.8mmol/l)	NR. 60 minutes prior to first fetal blood sampling	1070	25.00% (4.45 to 64.42)[b]	96.72% (93.40 to 98.47)[b]	7.63 (1.92 to 30.31)[b]	0.78 (0.52 to 1.16)[b]	Very low
1 study (Holzmann 2015)	Cohort	Fetal lactacidaemia (lactate >4.8mmol/l)	NR. 60 minutes prior to last fetal blood sampling.	888	18.2% (3.2 to 52.2)[b]	97.3% (93.4 to 99.0)[b]	6.65 (1.45 to 30.51)[b]	0.84 (0.64 to 1.11)[b]	Very low
Mild pseudo-sinusoidal pattern[g]									
1 study (Murphy 1991)	Cohort	Umbilical artery pH<7.12	1st stage & 2nd stage	319	80.0% (64.3 to 95.6)[a]	32.3% (26.9 to 37.6)[a]	1.18 (0.95 to 1.46)[a]	0.61 (0.27 to 1.37)[a]	Low
1 study (Murphy 1991)	Cohort	Admission to NICU	1st stage & 2nd stage	319	82.6% (67.1 to 98.1)[a]	32.4% (27.1 to 37.7)[a]	1.22 (0.99 to 1.49)[a]	0.53 (0.21 to 1.32)[a]	Low

BPM beats per minute; CI confidence interval; FHR fetal heart rate; FIGO International Federation of Gynecology and Obstetrics; NICHD National Institute of Child Health and Human Development; NR not reported

a. Calculated by the 2014 NCC-WCH technical team
b. Calculated by the 2017 NGA technical team

c. High risk of cerebral palsy was defined as incidence of bleeding during pregnancy, breech presentation, gestational age of less than 37 weeks at delivery, maternal infection, and the presence of meconium in the amniotic fluid. Low risk was defined as the absence of the five risk factors and high risk as the presence of one or more of them. Positive predictive values were obtained by projection onto the entire population of children born during the three-year study period in four counties. 31% of the population were classified as being 'high risk'

d.Scored using 5 variables:
FHR amplitude ≥3 bpm - high variability, <3 bpm - low variability
FHR amplitude ≥5 bpm - high variability, <5 bpm - low variability
FHR frequency of oscillations ≥3/minutes - high variability, <3/minutes - low variability
FHR frequency of oscillations ≥5/minutes - high variability, <5/minutes - low variability
Combination of (amplitude + frequency) ÷ 2. Value <3 low variability, ≥3 high variability

e.The amplitude was measured as the highest elevation of FHR from the baseline

f. Frequency of oscillations was counted from the number of intersections of oscillations from FHR baseline

g. Pseudo-sinusoidal pattern classification based on amplitude of oscillations and frequency of cycles: Minor when the amplitude of the oscillations was 5 –15 bpm & 2-5 cycles/min; intermediate when amplitude was 16 – 24 bpm & 2-5 cycles/min; major when the amplitude was ≥25 bpm& 1-2 cycles/min

Table 11: Summary GRADE profile for predictive value of fetal heart rate baseline variability for mode of birth

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women and baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Mild pseudo-sinusoidal pattern[a]									
1 study (Murphy 1991)	Cohort	Caesarean birth	1st stage & 2nd stage	319	64.7% (48.6 to 80.7)[b]	30.8% (25.1 to 36.2)[b]	0.93 (0.72 to 1.21)[b]	1.14 (0.70 to 1.86)[b]	Low
1 study (Murphy 1991)	Cohort	Instrumental vaginal birth	1st stage & 2nd stage	319	71.43% (62.1 to 80.7)[b]	32.4% (26.3 to 38.5)[b]	1.05 (0.90 to 1.23)[b]	0.88 (0.60 to 1.28)[b]	Low

a. Pseudo-sinusoidal pattern classification: Minor when the amplitude of the oscillations was 5–15 bpm; intermediate at 16–24 bpm; major when the amplitude was ≥25 bpm
b. Calculated by the 2014 NCC-WCH technical team

Table 12: Summary GRADE profile for association between fetal heart rate variability and adverse neonatal outcomes or umbilical artery blood gas values

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Degree of association or number (percentage) of babies with defined outcome	Quality
Normal variability (> 5 bpm)						
1 study (Maso 2012)	Case series	pH<7.2	2 hours before birth	51	n=3 (5.9%)	Low
1 study (Maso 2012)	Case series	pH<7.1	2 hours before birth	51	0=0 (0%)	Low
1 study (Maso 2012)	Case series	pH<7.0	2 hours before birth	51	0=0 (0%)	Low
1 study (Maso 2012)	Case series	BD≥12 mmol/l	2 hours before birth	51	0=0 (0%)	Low
1 study (Maso 2012)	Case series	Adverse composite neonatal outcome[a]	2 hours before birth	51	0=0 (0%)	Low
Decreased variability (<5 bpm)						
1 study (Berkus 1999)	Cohort	Immediate adverse neonatal outcome[b]	1st stage	77	No statistically significant association (numerical data not reported)	Very low
1 study (Berkus 1999)	Cohort	Immediate adverse neonatal outcome[b]	2nd stage	77	No statistically significant association (numerical data not reported)	Very low
Decreased variability (not defined)						
1 study (Roy 2008)	Cohort	Umbilical cord pH <7.10	NR	17	0%	Low

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Degree of association or number (percentage) of babies with defined outcome	Quality
1 study (Roy 2008)	Cohort	Immediate NICU admission	NR	17	0%	Low
Reduced variability (compared with normal tracing - NICHD classification)						
1 study (Sheiner 2001)	Cohort	pH<7.2	2nd stage	57	OR 2.2 (95% CI 0.3 to 17.1) p=0.728	Low
1 study (Sheiner 2001)	Cohort	BD≥12 mmol/l	2nd stage	28	OR 5.1 (95% CI 0.6 to 46.1) p=0.098	Low
Ever[c] absent or minimal variability (amplitude range undetectable or ≤5bpm, NICHD classification)						
1 study (Liu 2015)	Cohort	Neonatal respiratory morbidity (either any oxygen requirement at or after 6 hours of life or any mechanical ventilation in the first 24 hours)	Last 30 minutes before birth	NR (total N=4736)	OR[d] 1.3 (95% CI 0.9 to 1.8)	Very low
Mostly[e] absent or minimal variability (amplitude range undetectable or ≤5bpm, NICHD classification)						
1 study (Liu 2015)	Cohort	Neonatal respiratory morbidity (either any oxygen requirement at or after 6 hours of life or any mechanical	Last 30 minutes before birth	NR (total N=4736)	OR[d] 1.1 (95% CI 0.8 to 1.6)	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Degree of association or number (percentage) of babies with defined outcome	Quality
		ventilation in the first 24 hours)				
Always[f] absent or minimal variability (amplitude range undetectable or ≤5bpm, NICHD classification)						
1 study (Liu 2015)	Cohort	Neonatal respiratory morbidity (either any oxygen requirement at or after 6 hours of life or any mechanical ventilation in the first 24 hours)	Last 30 minutes before birth	NR (total N=4736)	OR[d] 1.2 (95% CI 0.8 to 1.7)	Very low
Mostly[e] moderate variability (amplitude range 6-25bpm, NICHD classification)						
1 study (Liu 2015)	Cohort	Neonatal respiratory morbidity (either any oxygen requirement at or after 6 hours of life or any mechanical ventilation in the first 24 hours)	Last 30 minutes before birth	NR (total N=4736)	OR[d] 0.7 (95% CI 0.5 to 1.0)	Very low
Always[f] moderate variability (amplitude range 6-25bpm, NICHD classification)						
1 study (Liu 2015)	Cohort	Neonatal respiratory morbidity (either any oxygen requirement at or after 6 hours of life or any mechanical	Last 30 minutes before birth	NR (total N=4736)	OR[d] 0.7 (95% CI 0.5 to 0.9)	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Degree of association or number (percentage) of babies with defined outcome	Quality
		ventilation in the first 24 hours)				
1 study (Liu 2015)	Cohort	Neonatal respiratory morbidity (either any oxygen requirement at or after 6 hours of life or any mechanical ventilation in the first 24 hours)	Last 30 minutes before birth	NR (total N=3997, Caesarean births excluded)	OR[d] 0.7 (95% CI 0.5 to 1.1)	Very low
1 study (Liu 2015)	Cohort	Neonatal respiratory morbidity (either any oxygen requirement at or after 6 hours of life or any mechanical ventilation in the first 24 hours)	Last 30 minutes before birth	NR (total N=4647, cases with maternal fever excluded)	OR[d] 0.7 (95% CI 0.5 to 1.0)	Very low
1 study (Liu 2015)	Cohort	Neonatal mechanical ventilation	Last 30 minutes before birth	NR (total N=4605)	OR[d] 0.8 (95% CI 0.4 to 1.4)	Very low
Ever[c] marked variability (amplitude range >25bpm, NICHD classification)						
1 study (Liu 2015)	Cohort	Neonatal respiratory morbidity (either any oxygen requirement at or after 6 hours of life	Last 30 minutes before birth	NR (total N=4736)	OR[d] 2.7 (95% CI 1.5 to 5.0)	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Degree of association or number (percentage) of babies with defined outcome	Quality
		or any mechanical ventilation in the first 24 hours)				
1 study (Liu 2015)	Cohort	Neonatal respiratory morbidity (either any oxygen requirement at or after 6 hours of life or any mechanical ventilation in the first 24 hours)	Last 30 minutes before birth	NR (total N=3994, Caesarean births excluded)	OR[d] 2.7 (95% CI 1.3 to 5.7)	Very low
1 study (Liu 2015)	Cohort	Neonatal respiratory morbidity (either any oxygen requirement at or after 6 hours of life or any mechanical ventilation in the first 24 hours)	Last 30 minutes before birth	NR (total N=4647, cases with maternal fever excluded)	OR[d] 3.1 (95% CI 1.7 to 5.7)	Very low
1 study (Liu 2015)	Cohort	Neonatal mechanical ventilation	Last 30 minutes before birth	NR (total N=4605)	OR[d] 2.2 (95% CI 0.7 to 7.2)	Very low

BD base deficit; BPM beats per minute; CI confidence interval; FHR fetal heart rate; NICU neonatal intensive care unit; NICHD National Institute of Child Health and Human Development; NR not reported; OR odds ratio

a. Composite neonatal outcomes: umbilical artery pH<7 and/or APGAR score <7 at 5 minutes and/or neonatal resuscitation in delivery room and admission to neonatal intensive care unit for distress at birth
b. Neonates were considered to have immediate adverse outcomes if they were admitted to level III neonatal intensive care unit for >24 hours and required oxygen support (intubation >6 hours, or >24 hours of >40% oxygen supplementation)
c 'Ever' refers to the presence of the EFM feature during any 10-minute segment in the 30-minute period before birth

d. Adjusted for maternal fever, parity, pregestational diabetes mellitus, previous Caesarean birth and preeclampsia
e. 'Mostly' refers to the presence of EFM feature for any ≥15-minute segment in the 30-minute period before birth
f. 'Always' refers to the presence of the EFM feature during the entire 30-minute period before birth.

Table 13: Summary GRADE profile for association between variability (with or without accelerations or decelerations) and umbilical artery blood gas values

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Number (percentage) of babies with defined outcome	Quality
Normal variability (NICHD classification)						
1 study (Williams 2003)	Cohort	pH<7.0	At least 2 hours of tracing[a]	42	n=0 (0%)	Very low
1 study (Williams 2003)	Cohort	pH<7.1	At least 2 hours of tracing[a]	42	n=4 (9.5%)	Very low
1 study (Williams 2003)	Cohort	BD>12 mmol/l	At least 2 hours of tracing[a]	42	n=1 (2.4%)	Very low
Normal variability with late decelerations (NICHD classification)						
1 study (Williams 2003)	Cohort	pH<7.0	At least 2 hours of tracing[a]	173	n=3 (1.7%)	Very low
1 study (Williams 2003)	Cohort	pH<7.1	At least 2 hours of tracing[a]	173	n=23 (13.3%)	Very low
1 study (Williams 2003)	Cohort	BD>12 mmol/l	At least 2 hours of tracing[a]	173	n=8 (4.6%)	Very low
Normal variability with variable decelerations (NICHD classification)						
1 study (Williams 2003)	Cohort	pH<7.0	At least 2 hours of tracing[a]	219	n=50 (23%)	Very low
1 study (Williams 2003)	Cohort	pH<7.1	At least 2 hours of tracing[a]	219	n=20 (9.1%)	Very low
1 study (Williams 2003)	Cohort	BD>12 mmol/l	At least 2 hours of tracing[a]	219	n=12 (5.5%)	Very low
Decreased variability (NICHD classification)						

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Number (percentage) of babies with defined outcome	Quality
1 study (Williams 2003)	Cohort	pH<7.0	At least 2 hours of tracing[a]	13	n=4 (31%)	Very low
1 study (Williams 2003)	Cohort	pH<7.1	At least 2 hours of tracing[a]	13	n=5 (38.5%)	Very low
1 study (Williams 2003)	Cohort	BD>12 mmol/l	At least 2 hours of tracing[a]	13	n=5 (38.5%)	Very low
Decreased variability with late decelerations (NICHD classification)						
1 study (Williams 2003)	Cohort	pH<7.0	At least 2 hours of tracing[a]	25	n=6 (24%)	Very low
1 study (Williams 2003)	Cohort	pH<7.1	At least 2 hours of tracing[a]	25	n=11 (44%)	Very low
1 study (Williams 2003)	Cohort	BD>12 mmol/l	At least 2 hours of tracing[a]	25	n=8 (32%)	Very low
Decreased variability with variable decelerations (NICHD classification)						
1 study (Williams 2003)	Cohort	pH<7.0	At least 2 hours of tracing[a]	16	n=2 (12.5%)	Very low
1 study (Williams 2003)	Cohort	pH<7.1	At least 2 hours of tracing[a]	16	n=3 (18.5%)	Very low
1 study (Williams 2003)	Cohort	BD>12 mmol/l	At least 2 hours of tracing[a]	16	n=2 (12.5%)	Very low
Decreased variability with no accelerations (NICHD classification)						
1 study (Williams 2003)	Cohort	pH<7.0	At least 2 hours of tracing[a]	8	n=5 (62.5%)	Very low
1 study (Williams 2003)	Cohort	pH<7.1	At least 2 hours of tracing[a]	8	n=5 (62.5%)	Very low
1 study (Williams 2003)	Cohort	BD>12 mmol/l	At least 2 hours of tracing[a]	8	n=5 (62.5%)	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Number (percentage) of babies with defined outcome	Quality
Decreased variability with late decelerations + no accelerations (NICHD classification)						
1 study (Williams 2003)	Cohort	pH<7.0	At least 2 hours of tracing[a]	19	n=6 (31.5%)	Very low
1 study (Williams 2003)	Cohort	pH<7.1	At least 2 hours of tracing[a]	19	n=10 (52.6%)	Very low
1 study (Williams 2003)	Cohort	BD>12 mmol/l	At least 2 hours of tracing[a]	19	n=8 (42.1%)	Very low
Decreased variability with variable decelerations + no accelerations (NICHD classification)						
1 study (Williams 2003)	Cohort	pH<7.0	At least 2 hours of tracing[a]	8	n=2 (25%)	Very low
1 study (Williams 2003)	Cohort	pH<7.1	At least 2 hours of tracing[a]	8	n=3 (37.5%)	Very low
1 study (Williams 2003)	Cohort	BD>12 mmol/l	At least 2 hours of tracing[a]	8	n=2 (25%)	Very low
Normal variability and recovery from bradycardia (NICHD classification)						
1 study (Williams 2003)	Cohort	pH<7.0	At least 2 hours of tracing[a]	128	n=2 (2%)	Very low
1 study (Williams 2003)	Cohort	pH<7.1	At least 2 hours of tracing[a]	128	n=28 (22%)	Very low
1 study (Williams 2003)	Cohort	BD>12 mmol/l	At least 2 hours of tracing[a]	128	n=6 (5%)	Very low
Normal variability and no recovery from bradycardia (NICHD classification)						
1 study (Williams 2002)	Cohort	pH<7.0	At least 2 hours of tracing[a]	40	n=7 (18%)	Very low
1 study (Williams 2002)	Cohort	pH<7.1	At least 2 hours of tracing[a]	40	n=13 (33%)	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Number (percentage) of babies with defined outcome	Quality
1 study (Williams 2002)	Cohort	BD>12 mmol/l	At least 2 hours of tracing[a]	40	n=5 (13%)	Very low
Decreased variability and recovery from bradycardia (NICHD classification)						
1 study (Williams 2002)	Cohort	pH<7.0	At least 2 hours of tracing[a]	9	n=4 (44%)	Very low
1 study (Williams 2002)	Cohort	pH<7.1	At least 2 hours of tracing[a]	9	n=5 (56%)	Very low
1 study (Williams 2002)	Cohort	BD>12 mmol/l	At least 2 hours of tracing[a]	9	n=2 (22%)	Very low
Decreased variability and no recovery from bradycardia (NICHD classification)						
1 study (Williams 2002)	Cohort	pH<7.0	At least 2 hours of tracing[a]	9	n=7 (78%)	Very low
1 study (Williams 2002)	Cohort	pH<7.1	At least 2 hours of tracing[a]	9	n=8 (89%)	Very low
1 study (Williams 2002)	Cohort	BD>12 mmol/l	At least 2 hours of tracing[a]	9	n=8 (89%)	Very low

BD base deficit; FHR fetal heart rate; NICHD National Institute of Child Health and Human Development

a. Does not include the last 30 minutes before birth

4.3.4.2.3 Accelerations

Table 14: Summary GRADE profile for predictive value of lack of fetal heart rate accelerations for adverse neonatal outcomes

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Lack of accelerations (Krebs classification)									

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
1 study (Spencer 1997)	Case control	Encephalopathy	First 30 minutes of tracing	73	42.11% (26.41 to 57.80)	77.14% (63.23 to 91)	1.84 (0.9 to 3.76)[b]	0.75 (0.54 to 1.03)[b]	Very low
1 study (Spencer 1997)	Case control	Encephalopathy	Last 30 minutes of tracing	67	72.2% (57.5 to 86.85) [b]	51.61% (34.02 to 69.21) [b]	1.49 (0.98 to 2.26) [b]	0.58 (0.28 to 1.00) [b]	Very low
Lack of accelerations (NICHD classification)									
1 study (Williams 2004)	Case series	Seizure	Last hour before birth	50	24% (11.5 to 43.4) [b]	52% (33.5 to 70) [b]	0.5 (0.22 to 1.12) [b]	1.46 (0.94 to 2.26) [b]	Very low
Lack of accelerations[b]									
1 study (Powell 1979)	Case series	Mortality	NR	50	83.3% (68.4 to 98.2) [b]	57.4% (55 to 59.7) [b]	1.95 (1.6 to 2.36) [b]	0.29 (0.11 to 0.71) [b]	Very low

CI confidence interval; NICHD National Institute of Child Health and Human Development; NR not reported

a. Four accelerations in 30 minutes were needed for inclusion in the normal acceleration category.
b. Calculated by the 2014 NCC-WCH technical team
c. An acceleration was defined as an increase of FHR of 15 bpm above the normal baseline occurring with a contraction. Three accelerations in 15 minutes were needed for inclusion in the acceleration category

Table 15: Summary GRADE profile for association of sporadic accelerations[a] and perinatal mortality

Number of studies	Design	Stage of labour	Number of babies with defined FHR patterns	Number (percentage) of babies who died	Quality
Sporadic accelerations[a] (3 or more accelerations per 30 minutes tracing) (women with no identified risk factors for adverse outcome)					
1 study (Krebs 1982)	Cohort	First 30 minutes of tracing	811	n=2 (0.2%)	Low
Sporadic accelerations[a] (fewer than 3 accelerations per 30 minutes tracing) (women with identified risk factors for adverse outcome)					

Number of studies	Design	Stage of labour	Number of babies with defined FHR patterns	Number (percentage) of babies who died	Quality
1 study (Krebs 1982)	Cohort	First 30 minutes of tracing	122	n=12 (9.8%)	Very low
Sporadic accelerations[a] (3 or more accelerations per 30 minutes tracing) (women with identified risk factors for adverse outcome)					
1 study (Krebs 1982)	Cohort	First 30 minutes of tracing	955	n=4 (0.4%)	Very low
Sporadic accelerations[a] (fewer than 3 accelerations per 30 minutes tracing) (women with no identified risk factors for adverse outcome)					
1 study (Krebs 1982)	Cohort	First 30 minutes of tracing	108	n=3 (2.8%)	Very low

FHR fetal heart rate

a. Sporadic accelerations occur independently from uterine contractions

Table 16: Summary GRADE profile for association of presence of accelerations and adverse neonatal outcomes

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
Accelerations present (NICHD classification 2008)						
1 study (Liu 2015)	Cohort	Neonatal respiratory morbidity (either any oxygen requirement at or after 6 hours of life or any mechanical ventilation in the first 24 hours).	Last 30 minutes before birth	NR (total N=4736)	OR 0.6a (95% CI 0.4 to 0.9)	Very low
1 study (Liu 2015)	Cohort	Neonatal respiratory morbidity (either any oxygen requirement at or after 6 hours of life or any mechanical	Last 30 minutes before birth	NR (total N=3994, Caesarean births excluded)	OR 0.8a (95% CI 0.5 to 1.2)	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
		ventilation in the first 24 hours).				
1 study (Liu 2015)	Cohort	Neonatal respiratory morbidity (either any oxygen requirement at or after 6 hours of life or any mechanical ventilation in the first 24 hours).	Last 30 minutes before birth	NR (total N=4647, cases with maternal fever excluded)	OR 0.6a (95% CI 0.4 to 0.9)	Very low
1 study (Liu 2015)	Cohort	Neonatal mechanical ventilation.	Last 30 minutes before birth	NR (total N=4605)	OR 0.4a (95% CI 0.2 to 0.9)	Very low

CI confidence interval; NR not reported; OR odds ratio

a. Adjusted for maternal fever, parity, pregestational diabetes mellitus, previous Caesarean birth and preeclampsia

Table 17: Summary GRADE profile for predictive value of a reactive trace for adverse neonatal outcomes

					Measure of diagnostic accuracy (95% CI)				
Number of studies	**Design**	**Definition of outcome**	**Stage of labour**	**Total number of women and baby pairs**	**Sensitivity**	**Specificity**	**Positive likelihood ratio**	**Negative likelihood ratio**	**Quality**
Reactivity (presence of at least 2 accelerations [NICHD classification 2008] within a 20-minute period)									
1 study (Graham 2014)	Case control	Whole-body hypothermia treatment for suspected moderate to severe encephalopathy	Last 1 hour tracing before birth	117	41.0% (26.0 to 57.8)[a]	38.5% (27.9 to 50.2)[a]	0.67 (0.44 to 1.01)[a]	1.53 (1.13 to 2.07)[a]	Very low

CI confidence interval; NICHD National Institute of Child Health and Human Development

a. Calculated by the 2017 NGA technical team

Table 18: Summary GRADE profile for association between reactive trace and neonatal adverse outcomes

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Degree of association or number (percentage) of babies with defined outcome	Quality
Reactive trace (presence of at least two accelerations [NICHD classification 2008] within a 20-minute period)						
1 study (Graham 2014)	Case control	Whole-body hypothermia treatment for suspected moderate to severe encephalopathy	Last 1 hour tracing before birth	64	OR[a] 0.50 (0.22 to 1.12)	Very low

CI confidence interval; NICHD National Institute of Child Health and Human Development; OR odds ratio

a. Adjusted for chorioamnionitis

4.3.4.2.4 Decelerations

Table 19: Summary GRADE profile for predictive value of fetal heart rate early decelerations for adverse neonatal outcomes

Number of studies	Design	Definition of outcome	Stage of labour	Number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Early decelerations (NICHD classification 2008)									
1 study (Graham 2014)	Case control	Whole-body hypothermia treatment for suspected moderate to severe	Last 1 hour tracing before birth	117	23.1% (11.7 to 39.7)	94.9% (86.7 to 98.3)	4.53[a]	0.81[a]	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
		encephalopathy							

CI confidence interval; NICHD National Institute of Child Health and Human Development

a. Calculated by the 2017 NGA technical team

Table 20: Summary GRADE profile for association between decelerations (in general), early decelerations and prolonged decelerations and adverse neonatal outcomes

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
Decelerations present (NICHD classification 2008)						
1 study (Liu 2015)	Cohort	Neonatal respiratory morbidity (either any oxygen requirement at or after 6 hours of life, or any mechanical ventilation in the first 24 hours)	Last 30 minutes before birth	NR (total N=4736)	OR[a] 0.8 (95% CI 0.5 to 1.2)	Very low
Early decelerations (NICHD classification 2008)						
1 study (Liu 2015)	Cohort	Neonatal respiratory morbidity (either any oxygen requirement at or after 6 hours of life, or any mechanical ventilation in the first 24 hours)	Last 30 minutes before birth	NR (total N=4736)	OR[a] 0.4 (95% CI 0.1 to 1.1)	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
Early decelerations (NICHD classification 2008)						
1 study (Graham 2014)	Case control	Whole-body hypothermia treatment for suspected moderate to severe encephalopathy	Last 1 hour tracing before birth	NR	OR[b] 0.58 (95% CI 0.35 to 0.94)	Very low
Prolonged decelerations (NICHD classification 2008)						
1 study (Liu 2015)	Cohort	Neonatal respiratory morbidity (either any oxygen requirement at or after 6 hours of life, or any mechanical ventilation in the first 24 hours)	Last 30 minutes before birth	NR (total N=4736)	OR[a] 1.7 (95% CI 1.3 to 2.4)	Very low
1 study (Liu 2015)	Cohort	Neonatal respiratory morbidity (either any oxygen requirement at or after 6 hours of life, or any mechanical ventilation in the first 24 hours)	Last 30 minutes before birth	NR (total N=3994, Caesarean births excluded)	OR[a] 1.8 (95% CI 1.2 to 2.8)	Very low
1 study (Liu 2015)	Cohort	Neonatal respiratory morbidity (either any oxygen requirement at or after 6 hours of life,	Last 30 minutes before birth	NR (total N=4647, cases with maternal fever excluded)	OR[a] 1.8 (95% CI 1.3 to 2.5)	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
		or any mechanical ventilation in the first 24 hours)				
1 study (Liu 2015)	Cohort	Neonatal mechanical ventilation	Last 30 minutes before birth	NR (total N=4605)	OR[a] 2.6 (95% CI 1.4 to 4.7)	Very low

CI confidence interval; NICHD National Institute for Child Health and Human Development; NR not reported; OR odds ratio

a. Adjusted for maternal fever, parity, pregestational diabetes mellitus, previous Caesarean birth and preeclampsia
b. Adjusted for chorioamnionitis

Table 21: Summary GRADE profile for correlation of fetal heart rate early decelerations with neonatal convulsions

Number of studies	Design	Stage of labour	Number of women & baby pairs	Correlation coefficient (p value)	Quality
Early decelerations[a]					
1 study (Ellison 1991)	Case series	1st stage	135	r: 0.01 (p=ns)	Low
1 study (Ellison 1991)	Case series	2nd stage	135	r: - 0.14 (p<0.05)	Low

NS not significant

a. Original cohort from Dublin RCT (MacDonald 1985), no definition of 'deceleration' provided

Table 22: Summary GRADE profile for predictive value of fetal heart rate late decelerations for adverse neonatal outcomes

Number of studies	Design	Definition of outcome	Stage of labour	Number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Late decelerations (Krebs classification)									
1 study (Spencer 1997)	Case control	Encephalopathy	First 30 minutes of tracing	73	5.26% (1.48 to 12.36)[a]	100% (100 to 100)[a]	NC	0.95 (0.87 to 1.02)[a]	Low
1 study (Spencer 1997)	Case control	Encephalopathy	Last 30 minutes of tracing	73	47.2% (30.91 to 63.53)[a]	74.19% (58.79 to 89.60)[a]	1.82 (0.91 to 3.64)[a]	0.71 (0.49 to 1.03)[a]	Low
Late decelerations (FIGO classification 1987)									
1 study (Holzmann 2015)	Cohort	Fetal lactacidaemia (lactate >4.8mmol/l)	NR. 60 minutes prior to first fetal blood sampling	1070	57.14% (29.65 to 81.19)[b]	82.52% (77.50 to 86.64)[b]	3.27 (1.95 to 5.49)[b]	0.52 (0.28 to 0.95)[b]	Very low
1 study (Holzmann 2015)	Cohort	Fetal lactacidaemia (lactate >4.8mmol/l)	NR. 60 minutes prior to last fetal blood sampling	888	55.0% (32.0 to 76.2)[b]	82.4% (76.5 to 87.1)[b]	3.13 (1.91 to 5.10)[b]	0.55 (0.34 to 0.89)[b]	Very low
Late decelerations (NICHD classification)									
1 study (Williams 2004)	Case series	Seizure	1 hour before birth	50	32% (17.2 to 51.5)[a]	48% (30 to 56.5)[a]	0.61 (0.31 to 1.22)[a]	1.41 (0.86 to 2.30)[a]	Very low

CI confidence interval; FIGO International Federation of Gynecology and Obstetrics; NC not calculable; NICHD National Institute of Child Health and Human Development, NR not reported

a. Calculated by the 2014 NCC-WCH technical team
[b]. Calculated by the 2017 NGA technical team

Table 23: Summary GRADE profile for association between fetal heart rate late decelerations and adverse neonatal outcome

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Degree of association or number (percentage) of babies with defined outcome	Quality
Recurrent late decelerations						
1 study (Roy 2008)	Cohort	Umbilical cord artery pH<7.10	NR	56	n=5 (9%)	Low
1 study (Roy 2008)	Cohort	Admission to NICU	NR	56	n=10 (19%)	Low
Late decelerations (compared with normal tracing - NICHD classification)						
1 study (Hadar 2001)	Cohort	Umbilical cord artery pH<7.2 and BD≥12	1st stage	45	OR 17.5 (95% CI 1.6 to 185.7) p=0.01	Moderate
1 study (Sheiner 2001)	Case series	pH< 7.2 and BD≥12	2nd stage	28	OR 3.9 (95% CI 1.1 to 13.1) p=0.02	Low
1 study (Sheiner 2001)	Case series	pH<7.2	2nd stage	57	OR 15.2 (95% CI 2.8 to 91.4) p<0.001	Low
1 study (Sheiner 2001)	Case series	BD≥12 mmol/l	2nd stage	28	OR 17.3 (95% CI 2.9 to 101.9) p=0.002	Low
Late decelerations (compared with normal tracing - NICHD classification 2008)						
1 study (Graham 2014)	Case control	Whole-body hypothermia treatment for suspected moderate to severe encephalopathy	Last 1 hour tracing before birth	NR	OR[a] 1.10 (95% CI 1.00 to 1.21)	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR pattern	Degree of association or number (percentage) of babies with defined outcome	Quality
1 study (Liu 2015)	Cohort	Neonatal respiratory morbidity (either any oxygen requirement at or after 6 hours of life or any mechanical ventilation in the first 24 hours)	Last 30 minutes before birth	NR (total N=4736)	OR[b] 0.8 (95% CI 0.6 to 1.1)	Very low
Late decelerations						
1 study (Berkus 1999)	Case series	Immediate adverse neonatal outcome[c]	1st stage	90	No statistically significant association (numerical data not reported)	Very low

BD base deficit; CI confidence interval; FHR fetal heart rate; NICHD National institute of Child Health and Human Development; NICU neonatal intensive care unit; OR odds ratio

a. Adjusted for chorioamnionitis
b. Adjusted for maternal fever, parity, pregestational diabetes mellitus, previous Caesarean birth and preeclampsia
c. Neonates were considered to have immediate adverse outcomes if they were admitted to a level III neonatal intensive care unit for >24 hours and required oxygen support (intubation >6 hours, or >24 hours of >40% oxygen supplementation)

Table 24: Summary GRADE profile for correlation of fetal heart rate late decelerations with neonatal convulsions

Number of studies	Design	Stage of labour	Number of women & baby pairs	Correlation coefficient (p value)	Quality
Late decelerations[a]					
1 study (Ellison 1991)	case series	1st stage	135	r: 0.38 (p<0.001)	Low
1 study (Ellison 1991	case series	2nd stage	135	r: -0.32 (p<0.001)	Low

a. Original cohort from Dublin RCT (MacDonald 1985), no definition of 'deceleration' provided

Table 25: Summary GRADE profile for predictive value of variable fetal heart rate decelerations for adverse neonatal outcome

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Variable decelerations (NICHD classification)									
1 study (Williams 2004)	Case series	Seizure	1 hour before birth	50	36% (20.2 to 55.5)[a]	40% (23.4 to 59.3)[a]	0.6 (0.32 to 1.10)[a]	1.6 (0.91 to 2.80)[a]	Low
Severe variable decelerations (FIGO classification 1987)									
1 study (Holzmann 2015)	Cohort	Fetal lactacidaemia (lactate >4.8mmol/l)	NR. 60 minutes prior to first fetal blood sampling.	1070	75.00% (52.95 to 89.40)[b]	68.41% (63.17 to 73.22)[b]	2.37 (1.80 to 3.14)[b]	0.37 (0.18 to 0.73)[b]	Very low
1 study (Holzmann 2015)	Cohort	Fetal lactacidaemia (lactate >4.8mmol/l)	NR. 60 minutes prior to last fetal blood sampling.	888	70.0% (50.4 to 84.6)[b]	70.1% (64.0 to 75.6)[b]	2.34 (1.73 to 3.16)[b]	0.43 (0.25 to 0.74)[b]	Very low
Loss of variability during decelerations									
1 study (Ozden 1999	Cohort	Umbilical cord arterial pH<7.20	NR	37	63.9%	65%	1.80	0.56	Moderate
Slow return to baseline from decelerations									
1 study (Ozden 1999	Cohort	Umbilical cord arterial pH<7.20	NR	17	27.8%	82.5%	1.50	0.89	Moderate
Loss of primary accelerations[c]									

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
1 study (Ozden 1999)	Cohort	Umbilical cord arterial pH<7.20	NR	24	47.2%	82.5%	2.60	0.64	Moderate
Loss of secondary accelerations[d]									
1 study (Ozden 1999	Cohort	Umbilical cord arterial pH<7.20	NR	23	38.9%	77.5%	1.60	0.80	Moderate
Biphasic decelerations[e]									
1 study (Ozden 1999)	Cohort	Umbilical cord arterial pH<7.20	NR	13	22.2%	90.0%	2.22	0.86	Moderate

CI confidence interval; FIGO International Federation of Gynecology and Obstetrics; NICHD National Institute of Child Health and Human Development; NR not reported

a. Calculated by the 2014 NCC-WCH technical team
b. Calculated by the 2017 NGA technical team
c. Loss of primary accelerations: an initial acceleration followed by a W deceleration component.
d. Loss of secondary accelerations: acceleration after a W deceleration component
e. Variable deceleration classified into 7 subtypes according to poor prognostic features (PPFs):
    Loss of primary acceleration
    Loss of secondary acceleration
    Loss of variability during deceleration
    Slow return to baseline
    Biphasic deceleration
    Prolonged secondary acceleration
    Prolonged deceleration

Table 26: Summary GRADE profile for association between variable fetal heart rate decelerations and adverse neonatal outcome

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
'Mild or moderate' variable decelerations (Krebs classification)						
1 study (Berkus 1999)	Case series	Immediate adverse neonatal outcome[a]	1st stage	1098	No statistically significant association (numerical data not reported)	Very low
1 study (Berkus 1999)	Case series	Immediate adverse neonatal outcome[a]	2nd stage	1098	No statistically significant association (numerical data not reported)	Very low
Variable decelerations						
1 study (Roy 2008)	Cohort	Cord pH<7.10	NR	38	n=4 (10.5%)	Low
1 study (Roy 2008)	Cohort	Admission to NICU	NR	38	n=7 (18.4%)	Low
Variable decelerations (compared with normal FHR trace - NICHD classification)						
1 study (Hadar 2001)	Cohort	Umbilical cord artery pH<7.2 and BD≥12	1st stage	301	OR 3.9 (95% CI 1.3 to 11.7) p=0.01	Moderate
1 study (Liu 2015)	Cohort	Neonatal respiratory morbidity (either any oxygen requirement at or after 6 hours of life	Last 30 minutes before birth	NR (total N=4736)	OR[b] 0.8 (95% CI 0.5 to 1.1)	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
		or any mechanical ventilation in the first 24 hours)				
1 study (Liu 2015)	Cohort	Neonatal respiratory morbidity (either any oxygen requirement at or after 6 hours of life or any mechanical ventilation in the first 24 hours)	Last 30 minutes before birth	NR (total N=3994, Caesarean births excluded)	OR[b] 3.4 (95% CI 1.2 to 9.5)	Very low
Variable decelerations (nadir <70 bpm)[c] (compared with normal tracing - NICHD classification)						
1 study (Sheiner 2001)	Case series	pH<7.2	1st stage	57	OR 16.3 (95% CI 3.8 to 80.5) p<0.001	Low
1 study (Sheiner 2001)	Case series	BD≥12 mmol/l	2nd stage	28	OR 10.5 (95% CI 1.9 to 56.4) p=0.06	Low
Variable decelerations (nadir ≥70 bpm)[d] (compared with normal tracing - NICHD classification)						
1 study (Sheiner 2001)	Case series	pH<7.2	1st stage	57	OR 5.1 (95% CI 1.4 to 21.4) p=0.08	Low
1 study (Sheiner 2001)	Case series	BD≥12 mmol/l	2nd stage	28	OR 3.5	Low

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
					(95% CI 0.8 to 15.8) p=0.101	
Typical variable decelerations[e]						
1 study (Maso 2012)	Case series	pH<7.2	2 hours before birth	63	n=18 (28.6%)	Low
1 study (Maso 2012)	Case series	pH<7.1	2 hours before birth	63	n=6 (9.5%)	Low
1 study (Maso 2012)	Case series	pH<7.0	2 hours before birth	63	n=1 (1.6%)	Low
1 study (Maso 2012)	Case series	BD≥12 mmol/l	2 hours before birth	63	n=5 (7.9%)	Low
1 study (Maso 2012)	Case series	Adverse composite neonatal outcome[e]	2 hours before birth	63	n=6 (9.5%)	Low
Atypical variable decelerations[g]						
1 study (Maso 2012)	Case series	pH<7.2	2 hours before birth	27	n=13 (48.2%)	Low
1 study (Maso 2012)	Case series	pH<7.1	2 hours before birth	27	n=2 (7.4%)	Low
1 study (Maso 2012)	Case series	pH<7.0	2 hours before birth	27	n=0 (0%)	Low
1 study (Maso 2012)	Case series	BD≥12 mmol/l	2 hours before birth	27	n=0 (0%)	Low
1 study (Maso 2012)	Case series	Adverse composite neonatal outcome[e]	2 hours before birth	27	n=3 (11.1%)	Low
'Severe' variable decelerations (Krebs classification)						

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
1 study (Berkus 1999)	Case series	Immediate adverse neonatal outcome[a]	1st stage	148	No statistically significant association (numerical data not reported)	Very low
1 study (Berkus 1999)	Case series	Immediate adverse neonatal outcome[a]	2nd stage	148	No statistically significant association (numerical data not reported)	Very low

BD base deficit; CI confidence interval; FHR fetal heart rate; NICHD National Institute of Child Health and Human Development; NICU neonatal intensive care unit; NR not reported; OR odds ratio

a. Neonates were considered to have immediate adverse outcomes if they were admitted to level III, neonatal intensive care unit for >24 hours and required oxygen support (intubation >6 hours, or >24 hours of >40% oxygen supplementation)
b. Adjusted for maternal fever, parity, pregestational diabetes mellitus, previous Caesarean birth and preeclampsia
c. Lowest point of the deceleration is below a FHR of 70 bpm
d. Lowest point of the deceleration is at or above a FHR of 70 bpm
e. Normal FHR baseline, normal variability and the presence of typical variable decelerations, without bradycardia. No definition for typical variable provided.
f. Composite neonatal outcomes: umbilical artery pH<7 and/or APGAR score <7 at 5 minutes and/or neonatal resuscitation in delivery room and admission to neonatal intensive care unit for distress at birth.
g. Normal FHR baseline, normal variability and the presence of atypical variable decelerations, without bradycardia. Atypical variable defined in the presence of at least one of the following conditions: loss of primary or secondary rise in the baseline rate; slow return to baseline FHR after the contraction; prolonged secondary rise in the baseline rate; biphasic deceleration; loss of variability during deceleration; continuation of baseline rate at lower level

Table 27: Summary GRADE profile for association between variable fetal heart rate decelerations and maternal outcome

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of women with defined outcome	Quality
'Non-significant' variable decelerations (compared with normal FHR trace - NICHD classification)						
1 study (Salim 2010)	Cohort	Caesarean birth	1st stage	12	OR 2.25 (95% CI 0.80 to 6.87) p=0.1	Moderate
'Severe' variable decelerations (compared with normal FHR trace - NICHD classification)						
1 study (Salim 2010)	Cohort	Caesarean birth	1st stage	25	OR 17.9 (95% CI 6.65 to 48.78) p=0.0001	Moderate
'Non-significant' variable decelerations (compared with normal FHR trace - NICHD classification)						
1 study (Salim 2010)	Cohort	Vacuum birth	1st stage	8	OR 1.84 (95% CI 0.55 to 6.53) p=0.3	Moderate
'Severe' variable decelerations (compared with normal FHR trace - NICHD classification)						
1 study (Salim 2010)	Cohort	Vacuum birth	1st stage	11	OR 6.91 (2.23 to 23.47) p=0.001	Moderate

CI confidence interval; FHR fetal heart rate; NICHD National Institute of Child Health and Human Development; OR odds ratio

Table 28: Summary GRADE profile for number of fetal heart rate decelerations (>15 bpm/15 seconds) and association with fetal acidaemia

Number of studies	Design	Stage of labour	Outcome		Effect		Quality
			Acidaemia[a]	No acidaemia	Relative (95% CI) compared to normal	Absolute (95% CI)	
Number of decelerations (>15 bpm/15 sec) (mean ± SD)							
1 study (Giannubilo 2006)	Case control	2nd stage	8.03±3.77 n=26	4.64±3.84 n=30	NC	24 more per 1000 (from 8 fewer to 58 more)	Very low

BPM beats per minute; CI confidence interval; NC not calculable; SD standard deviation

a. Acidaemia defined as umbilical artery cord pH<7.2

Table 29: Summary GRADE profile for correlation of fetal heart rate decelerations and neonatal convulsions

Number of studies	Design	Stage of labour	Number of women & baby pairs	Correlation coefficient (p-value)	Quality
Normal baseline and variability (no decelerations)					
1 study (Ellison 1991)	Case series	1st stage	135	r= −0.05 (p=NS)	Low
Moderate variable decelerations[a]					
1 study (Ellison 1991	Case series	1st stage	135	r: −0.02 (p=NS)	Low
Severe variable decelerations[a]					
1 study (Ellison 1991)	Case series	1st stage	135	r: −0.04 (p=NS)	Low

NS not significant

a. Original cohort from Dublin RCT (MacDonald 1985), no definition of decelerations provided

4.3.4.2.5 *Combinations of fetal heart rate trace features*

Table 30: Summary GRADE profile for predictive value of combinations of features

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Tachycardia and reduced variability (FIGO classification 1987)									
1 study (Holzmann 2015)	Cohort	Fetal lactacidaemia (lactate >4.8mmol/l)	NR. 60 minutes prior to first fetal blood sampling.	1070	60.00% (32.89 to 82.54)[a]	62.76% (57.64 to 67.63)[a]	1.61 (1.04 to 2.49)[a]	0.64 (0.34 to 1.19)[a]	Very low
1 study (Holzmann 2015)	Cohort	Fetal lactacidaemia (lactate >4.8mmol/l)	NR. 60 minutes prior to last fetal blood sampling.	888	43.8% (20.8 to 69.4)[a]	59.3% (53.7 to 65.1)[a]	1.08 (0.61 to 1.92)[a]	0.94 (0.61 to 1.46)[a]	Very low
Multiple late decelerations, decreased variability or both									
1 study (Nelson 1996)	Cohort	Cerebral palsy in low risk population	NR	378	13.8%	91.3%	1.40	0.95	Very low
"Recurrent" late decelerations with no acceleration (NICHD classification)									
1 study (Sameshima 2005)	Cohort	Umbilical artery pH <7.1	2 hours before birth	301	68.7% (46 to 91.4)[b]	74.7% (65.3 to 84)[b]	2.71 (1.65 to 4.46)[b]	0.41 (0.20 to 0.87)[b]	Very low
"Recurrent" late decelerations with decreased variability (NICHD classification)									
1 study (Sameshima 2005)	Cohort	Umbilical artery pH <7.1	2 hours before birth	301	62.5% (38.7 to 86.2)[b]	89.1% (82.4 to 95.8)[b]	5.76 (2.79 to 11.8)[b]	0.42 (0.22 to 0.79)[b]	Very low
Late decelerations and reduced variability (FIGO classification 1987)									

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
1 study (Holzmann 2015)	Cohort	Fetal lactacidaemia (lactate >4.8mmol/l)	NR. 60 minutes prior to first fetal blood sampling.	1070	33.33% (9.04 to 69.08)[a]	91.47% (87.20 to 94.46)[a]	3.91 (1.43 to 10.70)[a]	0.73 (0.46 to 1.16)[a]	Very low
1 study (Holzmann 2015)	Cohort	Fetal lactacidaemia (lactate >4.8mmol/l)	NR. 60 minutes prior to last fetal blood sampling.	888	52.6% (29.5 to 74.8)[a]	88.1% (82.6 to 92.1)[a]	4.43 (2.51 to 7.82)[a]	0.54 (0.33 to 0.86)[a]	Very low
Severe variable decelerations and reduced variability (FIGO classification 1987)									
1 study (Holzmann 2015)	Cohort	Fetal lactacidaemia (lactate >4.8mmol/l)	NR. 60 minutes prior to first fetal blood sampling.	1070	40.00% 13.69 to 72.63)[a]	90.77% (86.41 to 93.88)[a]	4.33 (1.85 to 10.13)[a]	0.66 (0.40 to 1.10)[a]	Very low
1 study (Holzmann 2015)	Cohort	Fetal lactacidaemia (lactate >4.8mmol/l)	NR. 60 minutes prior to last fetal blood sampling.	888	47.1% (23.9 to 71.5)[a]	89.9% (84.6 to 93.6)[a]	4.66 (2.42 to 8.95)[a]	0.59 (0.38 to 0.92)[a]	Very low
Severe variable decelerations and tachycardia (FIGO classification 1987)									
1 study (Holzmann 2015)	Cohort	Fetal lactacidaemia (lactate >4.8mmol/l)	NR. 60 minutes prior to first fetal blood sampling.	1070	57.14% (29.65 to 81.19)[a]	90.77% (86.41 to 93.88)[a]	6.19 (3.42 to 11.20)[a]	0.47 (0.26 to 0.87)[a]	Very low
1 study (Holzmann 2015)	Cohort	Fetal lactacidaemia (lactate >4.8mmol/l)	NR. 60 minutes prior to last fetal	888	64.0% (42.6 to 81.3)[a]	91.3% (86.2 to 94.7)[a]	7.34 (4.27 to 12.61)[a]	0.39 (0.23 to 0.67)[a]	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
			blood sampling.						

CI confidence interval; FIGO International Federation of Gynecology and Obstetrics; NICHD National Institute of Child Health and Human Development; NR not reported
a. Calculated by the 2017 NGA technical team
b. Calculated by the 2014 NCC-WCH technical team

4.3.4.2.6 Categorisation/classification of fetal heart rate traces

Table 31: Summary GRADE profile for predictive value of published categorisation of fetal heart rate traces for adverse neonatal outcomes

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Krebs score (abnormal versus normal)									
1 study (Spencer 1997)	Case control	Encephalopathy	First 30 minutes of tracing	73	5.71% (1.98 to 13.40)[a]	96.97% (96.97 to 100)[a]	1.80 (0.11 to 7.74)[a]	0.97 (0.90 to 1.17)[a]	Very low
FIGO classification (abnormal versus normal)									
1 study (Spencer 1997)	Case control	Encephalopathy	First 30 minutes of tracing	73	50% (34.10 to 65.90)[a]	74.29% (59.81 to 88.77)[a]	1.94 (1.01 to 3.71)[a]	0.67 (0.46 to 0.97)[a]	Very low
Krebs score (abnormal versus normal)									
1 study (Spencer 1997)	Case control	Encephalopathy	Last 30 minutes of tracing	54	41.38% (23.45 to 59.30)	84% (69.63 to 98.37)	2.58 (0.95 to 7.01)[a]	0.69 (0.49 to 0.99)[a]	Very low
FIGO classification (abnormal versus normal)									
1 study	Case control	Encephalopathy	Last 30 minutes of tracing	67	88.89%	48.39%	1.72	0.22	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
(Spencer 1997)					(78.2 to 99.16)[a]	(30.79 to 65.98)[a]	(1.20 to 2.46)[a]	(0.08 to 0.61)[a]	
'Ominous' first stage CTG (No definition provided)									
1 study (Gaffney 1994)	Cohort	Encephalopathy	1st stage	96	32.50% (17.98 to 47.02)[a]	92.31% (85.06 to 99.55)[a]	4.22 (1.49 to 11.91)[a]	0.73 (0.58 to 0.9)[a]	Low
'Ominous' second stage CTG (No definition provided)									
1 study (Gaffney 1994)	Cohort	Encephalopathy	2nd stage	96	45.65% (31.26 to 60.05)[a]	70.31% (59.12 to 81.51)[a]	1.53 (0.94 to 2.51)[a]	0.77 (0.56 to 1.05)[a]	Low
Pattern 1 (absent baseline variability [≥ 1 cycle] usually with late and/or prolonged deceleration)[b]									
1 study (Low 1999)	Case control	Asphyxia	NR	142	17%	98%	8.50	0.84	Very low
Pattern 2 (minimal baseline variability [≥ 2 cycles] and late and/or prolonged deceleration [≥ 2 cycles])[b]									
1 study (Low 1999)	Case control	Asphyxia	NR	142	46%	89%	4.18	0.60	Very low
Pattern 3 (minimal baseline variability [≥ 2 cycles] or late and/or prolonged deceleration [≥ 2 cycles])[b]									
1 study (Low 1999)	Case control	Asphyxia	NR	142	75%	57%	1.70	0.43	Very low
Pattern 4 (minimal baseline variability [1 cycles] and/or late and/or prolonged deceleration [1 cycle])[b]									
1 study (Low 1999)	Case control	Asphyxia	NR	142	93%	29%	1.30	0.29	Very low
Fetal sleep pattern ≥50% of the tracing (NICHD classification) (fetal sleep pattern not defined)									
1 study (Menihan 2006)	Case control	Sudden infant death	NR	142	40% (21.9 to 61.3)[a]	45.7% (34.6 to 57.3)[a]	0.70 (0.41 to 1.31)[a]	1.31 (0.84 to 2.03)[a]	Very low
'Abnormal' FHR pattern (NICHD classification)									

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
1 study (Hadar 2001)	Cohort	Umbilical artery pH 7.1, 7.2 + Base deficit > 12	1st stage	601	78.3% (70.4 to 86.1)[a]	55.9% (51.5 to 60.3)[a]	1.77 (1.54 to 2.04)[a]	0.38 (0.26 to 0.56)[a]	Moderate
Category III (versus Category I) (NICHD classification 2008)									
1 study (Graham 2014)	Case control	Whole-body hypothermia treatment for suspected moderate to severe encephalopathy	Last 1 hour tracing before birth	117	55.6% (22.7 to 84.7)[c]	87.5% (46.7 to 99.3)[c]	4.44 (0.65 to 30.44)[c]	0.51 (0.24 to 1.09)[c]	Very low
Category II (versus Category I) (NICHD classification 2008)									
1 study (Graham 2014)	Case control	Whole-body hypothermia treatment for suspected moderate to severe encephalopathy	Last 1 hour tracing before birth	117	88.2% (71.6 to 96.2)[c]	9.1% (4.0 to 18.4)[c]	0.97 (0.84 to 1.12)[c]	1.29 (0.40 to 4.19)[c]	Very low
Indeterminate FHR pattern (Category II, NICHD classification 2008)									
1 study (Sharbaf 2014)	Cohort	Umbilical artery pH ≤7.2	In early labour during a 20-40 minute period	Mixed population of both low- and high-risk pregnancies. N=818 (normal n=659,	40.6% (24.2 to 59.2)	69.8% (62.5 to 76.2)	1.34 (0.84 to 2.16)[c]	0.85 (0.64 to 1.14)[c]	Low

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
				indeterminate n=159)					
1 study (Sharbaf 2014)	Cohort	NICU admission	In early labour during a 20-40 minute period	Mixed population of both low- and high-risk pregnancies. N=818 (normal n=659, indeterminate n=159)	35.7% (22.0 to 52.0)	81.4% (78.5 to 84.1)	1.92 (1.25 to 2.96)[c]	0.79 (0.63 to 1.00)[c]	Low
1 study (Sharbaf 2014)	Cohort	NICU admission excluding preterm birth	In early labour during a 20-40 minute period	Mixed population of both low- and high-risk pregnancies. N=818 (normal n=659, indeterminate n=159)	31.3%	81.9%	1.73c	0.84c	Low
1 study (Sharbaf 2014)	Cohort	Neonatal death	In early labour during a 20-40 minute period	Mixed population of both low- and high-risk pregnancies. N=818 (normal n=659, indeterminate n=159)	100% (19.8 to 100)	80.8% (77.8 to 83.4)	5.2 (4.52 to 5.98)[c]	0 (NC)[c]	Low

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
1 study (Sharbaf 2014)	Cohort	Umbilical artery pH ≤7.2	In early labour during a 20-40 minute period	Low-risk population only N=492 (normal n=410, indeterminate n=82)	26.7% (8.9 to 55.2)	83.7% (80.0 to 86.8)	1.63 (0.69 to 3.87)[c]	0.88 (0.65 to 1.19)[c]	Low
1 study (Sharbaf 2014)	Cohort	NICU admission	In early labour during a 20-40 minute period	Low-risk population only N=492 (normal n=410, indeterminate n=82)	16.7% (4.4 to 42.4)	83.3% (79.6 to 86.5)	1.00 (0.35 to 2.86)[c]	1.00 (0.81 to 1.23)[c]	Low
1 study (Sharbaf 2014)	Cohort	NICU admission excluding preterm birth	In early labour during a 20-40 minute period	Low-risk population only N=492 (normal n=410, indeterminate n=82)	12.5%	83.2%	0.74[c]	1.05[c]	Low
1 study (Sharbaf 2014)	Cohort	Neonatal death	In early labour during a 20-40 minute period	Low-risk population only N=492 (normal n=410, indeterminate n=82)	NA (no cases of neonatal death)	83.3% (79.7 to 86.4)	0[c](NA)	1.20[c](NA)	Low
'Stressed' or 'distressed' FHR patterns (Dellinger classification)									
1 study (Dellinger 2000)	Cohort	NICU admission	1 hour before birth	898 (normal=627, stressed	46%	72%	1.64	0.75	Low

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
				n=263, distressed n=8)					
1 study (Dellinger 2000)	Cohort	Umbilical artery pH<7	1 hour before birth	898 (normal=627, stressed n=263, distressed n=8)	100%	66%	2.9	0	Low
1 study (Dellinger 2000)	Cohort	BE< −11	1 hour before birth	898 (normal=627, stressed n=263, distressed n=8)	100%	66%	2.9	0	Low
'Distressed' FHR patterns (Dellinger classification)									
1 study (Dellinger 2000)	Cohort	NICU admission	1 hour before birth	635 (normal=627, distressed n=8)	9%	99%	9.0	0.91	Low
1 study (Dellinger 2000)	Cohort	Umbilical artery pH<7	1 hour before birth	635 (normal=627, distressed n=8)	100%	98%	50	0	Low
1 study (Dellinger 2000)	Cohort	BE< −11	1 hour before birth	635 (normal=627, distressed n=8)	100%	98%	50	0	Low
Presence of 1 poor prognostic featured									

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
1 study (Ozden 1999)	Cohort	Umbilical cord arterial pH<7.20	NR	13	75%	55%	1.60	0.45	Moderate
Presence of 2 poor prognostic features)[d]									
1 study (Ozden 1999)	Cohort	Umbilical cord arterial pH<7.20	NR	12	55.6%	70.0%	1.83	0.64	Moderate
Presence of 3 poor prognostic features)[d]									
1 study (Ozden 1999)	Cohort	Umbilical cord arterial pH<7.20	NR	8	36.1%	82.5%	2.06	0.77	Moderate
Presence of 4 poor prognostic features[d]									
1 study (Ozden 1999)	Cohort	Umbilical cord arterial pH<7.20	NR	12	22.2%	90%	2.22	0.86	Moderate
FHR baseline <110 bpm, baseline variability <5 bpm and non-reactive trace (NICHD classification)									
1 study (Larma 2007)	Case control	Moderate hypoxic ischemic encephalopathy (HIE)	Last hour of tracing	214	7.7%	98.9%	6.36	0.94	Very low

BE base excess; CI confidence interval; CTG cardiotocography; FHR fetal heart rate; FIGO International Federation of Obstetrics and Gynaecology; NICHD National Institute of Child Health and Human Development; NA not applicable; NC not calculable; NICU neonatal intensive care unit; NR not reported

a. Calculated by the 2014 NCC-WCH technical team
b. Fetal asphyxia was classified as mild, moderate, or severe on the basis of umbilical artery base deficit (cut off >12 mmol/l) and neonatal encephalopathy and other organ system complications
FHR criteria predictive of fetal asphyxia:
Absent or minimal baseline variability and late or prolong decelerations
The FHR patterns are based on the findings in six 10 minute cycles of FHR recording
Absent baseline variability, usually with repeat cycles (≥ 2) of the late or prolonged decelerations

Repeat cycles (≥ 2) of both minimal baseline variability and late or prolonged decelerations
Repeat cycles (≥ 2) of either minimal baseline variability or late or prolonged decelerations
One cycle of either minimal baseline variability or late or prolong decelerations
No cycle of either minimal baseline variability or late or prolonged decelerations

c. Calculated by the 2017 NGA technical team

d. Variable deceleration classified into 7 subtypes according to poor prognostic features (PPFs):
Loss of primary acceleration
Loss of secondary acceleration
Loss of variability during deceleration
Slow return to baseline
Biphasic deceleration
Prolonged secondary acceleration
Prolonged deceleration

Table 32: Summary GRADE profile for predictive value of published categorisations of fetal heart rate traces for mode of birth

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
'Pathological' FHR pattern (NICHD classification)									
1 study (Hadar 2001)	Cohort	Spontaneous vaginal birth	2nd stage	301	45.31% (40.9 to 49.7)[a]	28.8% (20.4 to 37.26)[a]	0.63 (0.54 to 0.74)[a]	1.89 (1.40 to 2.56)[a]	Moderate
'Pathological' FHR pattern (NICHD classification)									
1 study (Hadar 2001)	Cohort	Vacuum birth	2nd stage	301	73.33% (60.41 to 86.25)[a]	51.8% (47.6 to 55.9)[a]	1.52 (1.25 to 1.85)[a]	0.51 (0.31 to 0.84)[a]	Moderate
'Pathological' FHR pattern (NICHD classification)									
1 study (Hadar 2001)	Cohort	Caesarean birth	2nd stage	301	69.70% (58.61 to 80.78)[a]	52.34% (48.10 to 56.57)[b]	1.46 (1.21 to 1.75)[a]	0.57 (0.39 to 0.84)[a]	Moderate
'Stressed' or 'distressed' FHR patterns (Dellinger classification)									
1 study (Dellinger 2000)	Cohort	Caesarean birth	1 hour before birth	898 (normal=627, stressed n=263,	35%	71%	1.20	0.91	Low

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
				distressed n=8)					
'Distressed' FHR patterns (Dellinger classification)									
1 study (Dellinger 2000)	Cohort	Caesarean birth	1 hour before birth	635 (normal=627, distressed n=8)	5%	99%	5.0	0.95	Low
Indeterminate FHR pattern (Category II, NICHD classification 2008)									
1 study (Sharbaf 2015)	Cohort	Caesarean birth	In early labour during a 20-40 minute period	Mixed population of both low- and high-risk pregnancies N=818 (normal n=659, indeterminate n=159)	30.9%	86.3%	2.26[b]	0.80[b]	Low
Indeterminate FHR pattern (Category II, NICHD classification 2008)									
1 study (Sharbaf 2015)	Cohort	Caesarean birth	In early labour during a 20-40 minute period	Low-risk population only N=492 (normal n=410, indeterminate n=82)	28.6%	87.7%	2.33[b]	0.81[b]	Low

CI confidence interval; FHR fetal heart rate; NICHD National Institute of Child Health and Human Development; NR not reported

a. Calculated by the 2014 NCC-WCH technical team
[b]. Calculated by the 2017 NGA technical team

Table 33: Summary GRADE profile for association between categorisation of fetal heart rate traces and adverse neonatal outcomes

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
'Pathological' FHR pattern (NICHD classification)						
1 study (Hadar 2001)	Cohort	Umbilical cord artery pH<7.2 and BD≥12	2nd stage	301	OR 2.86 (95% CI 0.3 to 24.4) p=0.33	Moderate
'Predictive' FHR pattern[a]						
1 study (Low 2001)	Case series	Moderate or severe asphyxia (BD>12 at birth, encephalopathy and cardiovascular, respiratory and renal complications)	NR	23	n=13 (56%)	Low
'Suspect' FHR pattern[a]						
1 study (Low 2001)	Case series	Moderate or severe asphyxia (BD>12 at birth, encephalopathy and cardiovascular, respiratory and renal complications)	NR	23	n=7 (30%)	Low
'Non-predictive' FHR pattern[a]						
1 study (Low 2001)	Case series	Moderate or severe asphyxia (BD>12 at birth, encephalopathy	NR	26	n=3 (11.5%)	Low

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
		and cardiovascular, respiratory and renal complications)				
'Abnormal' FHR tracing (compared with normal tracing - NICHD classification)						
1 study (Sheiner 2001)	Case series	pH< 7.2 and BD≥12	1st stage	28	OR 3.4 (95% CI 1.3 to 8.7) p=0.01	Low
Type 0 FHR tracing[b]						
1 study (Cardoso 1995)	Case series	Umbilical cord arterial pH (mean ± SD)	2nd stage	103	7.24±0.06	Low
Type 1a FHR tracing[b]						
1 study (Cardoso 1995)	Case series	Umbilical cord arterial pH (mean ± SD)	2nd stage	93	7.24±0.07 p=ns	Very low
Type 1b FHR tracing[b]						
1 study (Cardoso 1995)	Case series	Umbilical cord arterial pH (mean ± SD)	2nd stage	19	7.15±0.07 p=0.0001	Low
Type 2a FHR tracing[b]						
1 study (Cardoso 1995)	Case series	Umbilical cord arterial pH (mean ± SD)	2nd stage	34	7.19±0.06 p=0.0001	Low
Type 2b FHR tracing[b]						
1 study (Cardoso 1995)	Case series	Umbilical cord arterial pH	2nd stage	13	7.06±0.07 p=0.0001	Low

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
		(mean ± SD)				
Type 3 FHR tracing[b]						
1 study (Cardoso 1995)	Case series	Umbilical cord arterial pH (mean ± SD)	2nd stage	14	7.09±0.06 p=0.0001	Low
Type 4 FHR tracing[b]						
1 study (Cardoso 1995)	Case series	Umbilical cord arterial pH (mean ± SD)	2nd stage	15	7.19±0.07 p=0.01	Low
'Normal' FHR tracing[b]						
1 study (Gilstrap 1987)	Cohort	Umbilical cord arterial pH (mean ± SD)	1st stage	129	7.29±0.6	Very low
Indeterminate FHR pattern (Category II, NICHD classification 2008)						
1 study (Sharbaf 2014)	Cohort	Umbilical artery pH ≤7.2	"Early labour"	Mixed population of both low- and high-risk pregnancies N=159	RR 1.5 (95% CI 0.8 to 2.8)	Very low
1 study (Sharbaf 2014)	Cohort	NICU admission	"Early labour"	Mixed population of both low- and high-risk pregnancies N=159	RR 2.3 (95% CI 1.2 to 4.2)	Very low
1 study (Sharbaf 2014)	Cohort	NICU admission after excluding preterm births	"Early labour"	Mixed population of both low- and high-risk pregnancies N=159	RR 2.0 (95% CI 1.0 to 4.1)	Very low
1 study (Sharbaf 2014)	Cohort	Umbilical artery pH ≤7.2	"Early labour"	Low-risk population only N=82	RR 1.05 (95% CI 0.4 to 3.0)	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
1 study (Sharbaf 2014)	Cohort	NICU admission	"Early labour"	Low-risk population only N=82	RR 1.0 (95% CI 0.3 to 3.4)	Very low
1 study (Sharbaf 2014)	Cohort	NICU admission after excluding preterm births	"Early labour"	Low-risk population only N=82	RR 0.7 (95% CI 0.2 to 3.1)	Very low

BD base deficit; CI confidence interval; FHR fetal heart rate; NICHD National Institute for Child Health and Human Development; NR not reported; OR odds ratio; RR risk ratio; SD standard deviation

a. Criteria for classification of FHR as predictive, suspect, and non-predictive of fetal asphyxia on the basis of a 10 minute cycle of FHR tracing
Predictive: Absent baseline variability (repetitive cycle) ≥1 and presence of late or prolonged decelerations ≥2 or presence of minimal baseline variability (repetitive cycle) ≥2 and presence of late or prolonged decelerations ≥2
Suspect: Presence of minimal baseline variability (repetitive cycle ≥2) and late or prolonged decelerations (repetitive cycle ≥0/1) or presence of minimal baseline variability (repetitive cycle ≥0/1) and late or prolonged decelerations ≥2 repetitive cycle
Non-predictive: Minimal baseline variability (repetitive cycle 1) and no late or prolonged decelerations

b. No definition for "Normal" FHR tracing provided. Abnormal FHR defined as:
Mild bradycardia (FHR 90 – 119 bpm)
Moderate bradycardia (FHR 60 – 89 bpm)
Marked or severe bradycardia (FHR below 60 bpm)
Tachycardia (FHR ≥160 bpm)

Table 34: Summary GRADE profile for association between categorisation of fetal heart rate traces and mode of birth

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
Indeterminate FHR pattern (Category II, NICHD classification 2008)						
1 study (Sharbaf 2014)	Cohort	Caesarean birth due to non-reassuring FHR pattern	"Early labour"	Mixed population of both low- and high-risk pregnancies N=159	RR 3.8 (95% CI 2.5 to 5.6)	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
1 study (Sharbaf 2014)	Cohort	Caesarean birth due to non-reassuring FHR pattern	"Early labour"	Low-risk population only N=82	RR 3.7 (95% CI 2.1 to 6.9)	Very low

CI confidence interval; FHR fetal heart rate; NICHD National Institute of Child Health and Human Development; RR risk ratio

Table 35: Summary GRADE profile for umbilical cord arterial pH in women with 'normal' and 'abnormal' fetal heart rate tracing

Number of studies	Design	Stage of labour	Percentage and number of babies in each FHR tracing category				Quality
			'Normal'[a]	'Warning symptoms'[a]	'Severe functional hemodynamic'[a]	'Hypoxia'[a]	
Umbilical cord artery pH>7.20							
1 study (Heinrich 1982)	Cohort	2nd stage (30 minutes prior to birth)	96.6% n=1043	96.7% n=1095	83% n=357	60% n=30	Low
Umbilical cord artery pH 7.25 – 7.20							
1 study (Heinrich 1982)	Cohort	2nd stage (30 minutes prior to birth)	2.5% n=27	2.4% n=48	11% n=48	22% n=11	Low
Umbilical cord artery pH <7.20							
1 study (Heinrich 1982)	Cohort	2nd stage (30 minutes prior to birth)	0.9% n=10	0.9% n=11	6.0% n=26	18% n=9	Low

FHR fetal heart rate

a. Categorisation:
Normal: Baseline 120 – 160 bpm, variability 10 – 25 bpm, sporadic variable accelerations, no variable or late decelerations
Warning: Tachycardia, variability <10 bpm or >25 bpm, periodic accelerations, moderate variable decelerations, early decelerations
Severe: Transient bradycardia, severe variable decelerations, prolonged decelerations

Hypoxia: Final bradycardia, variability 0 – 5 bpm, typical late decelerations

4.3.4.3 Summary tables of evidence from high risk populations

4.3.4.3.1 Accelerations

Table 36: Summary GRADE profile for association between absence of, or decreased, fetal heart rate accelerations and fetal metabolic acidosis

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
Absence or decreased FHR accelerations						
1 study (Low 1981)	Cohort	Fetal metabolic acidosis[a]	Last 4 hours prior to birth	280	Absence of, or decreased, FHR accelerations was not associated with fetal acidosis[b]	Moderate

FHR fetal heart rate

a. Fetal metabolic acidosis is defined as an umbilical artery buffer base of <36.1 mEq/l
b. There was no statistical significant difference between the two groups (babies with metabolic acidosis and babies with no metabolic acidosis) in regard to decrease frequency or absence of FHR accelerations in the 12 FHR trace cycles (4 hours before birth) (no synthesis of statistical data provided).

4.3.4.3.2 Decelerations

Table 37: Summary GRADE profile for association between no decelerations/early decelerations and adverse neonatal outcomes

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
Early decelerations[a]						
1 study (Cibils 1980)	Cohort	Fetal distress[b]	1st stage	247	Early decelerations group: 5% with fetal distress	Low

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
					No decelerations groups: 4% with fetal distress	
Early decelerations[a]						
1 study (Cibils 1980)	Cohort	Neonatal death[c]	1st stage	247	Early deceleration group: n=1[d] No decelerations groups: n=1[d]	Low

FHR fetal heart rate

a. Early deceleration defined as a decrease of FHR of at least 10 bpm coinciding with a uterine contraction
b. Fetal distress defined as presence of meconium stained liquor, sustained fetal tachycardia, markedly irregular heart beat
c. Fetal metabolic acidosis is defined as an umbilical artery buffer base of <36.1 mEq/L
d. Reason for neonatal death was congenital malformation in "no deceleration" group and congenital heart disease in "early deceleration" group

Table 38: Summary GRADE profile for association between no decelerations/variable decelerations[a] and adverse neonatal outcomes

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
Variable decelerations						
1 study (Cibils 1978)	Cohort	Fetal distress[b]	1st stage	312	No deceleration: 4% with fetal distress Variable decelerations: 23% with fetal distress p<0.0005	Low

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
Variable decelerations						
1 study (Cibils 1978)	Cohort	Neonatal death	1st stage	312	No deceleration: 0.2% Variable decelerations: 2.2% p<0.0005	Low
Variable decelerations with late component						
1 study (Cibils 1978)	Cohort	Fetal distress[b]	1st stage	312	Variable deceleration with late component: 78% with fetal distress Variable decelerations without late component: 23% with fetal distress p<0.0005	Low
Variable decelerations with late component						
1 study (Cibils 1978)	Cohort	Neonatal death	1st stage	312	Variable deceleration with late component: 11% Variable decelerations without late component: 2.2% p=NS	Low
Variable decelerations						

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
(Low 1981)	Cohort	Fetal metabolic acidosis[c]	Last 20 minutes prior to birth	68	Variable decelerations were significantly associated with fetal metabolic acidosis[d]	Moderate

NS not significant

a. Variable deceleration defined as starts usually in the early part of the rise of contraction, FHR falling to between 60 and 90 bpm, sustained for 10 to 50 seconds and the recovery is rapid
b. Fetal distress defined as presence of meconium stained liquor, sustained fetal tachycardia, markedly irregular heart beat
c. Fetal metabolic acidosis is defined as an umbilical artery buffer base of <36.1 mEq/l
d. See evidence table for more information (no synthesis of statistical data provided).

Table 39: Summary GRADE profile for association between no decelerations/late decelerations[a] and adverse neonatal outcomes

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
Late decelerations						
1 study (Cibils 1975)	Cohort	Neonatal morbidity or death[b]	60 minutes recording prior to 2nd stage or caesarean section	147	Late deceleration group: 7% No deceleration group: 0.5% p<0.0001	Low
Late decelerations						
1 study (Cibils 1975)	Cohort	Neonatal morbidity or death in low	60 minutes recording prior to	147	Late deceleration group: 15%	Low

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
		birthweight babies <2500 g	2nd stage or caesarean section		No deceleration group: 5% p=NS	
Late decelerations						
1 study (Cibils 1975)	Cohort	Fetal distress during labour and after birth[c]	60 minutes recordings prior to 2nd stage or caesarean section	147	Distressed during labour: 50% Born 'depressed': 33%	Low
Late decelerations						
(Low 1981)	Cohort	Fetal metabolic acidosis[d]	Last hour prior to birth	101	Late decelerations were significantly associated with acidosis[e]	Moderate

FHR fetal heart rate, NS not significant

a. Late deceleration defined: the beginning of the fall in FHR starts when the contraction reaches its apex or slightly later (usually >20 seconds after the contraction began its relaxation). The recovery is slow the total duration of the deceleration is close to 60 seconds
b. The only neonatal death in the "no deceleration" group was due to severe congenital heart disease. No more details on neonatal death reported
c. Fetal distress defined as presence of meconium stained liquor, sustained fetal tachycardia, markedly irregular heart beat
d. Fetal metabolic acidosis is defined as an umbilical artery buffer base of <36.1 mEq/l
e. See evidence table for more information (no synthesis of statistical data provided).

Table 40: Summary GRADE profile for association between marked patterns of total decelerations[a], moderate/marked pattern of late decelerations[b] and fetal asphyxia

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
FHR deceleration patterns						
1 study (Low 1977)	Cohort	Fetal asphyxia[c]	Four hours prior to birth	122	FHR deceleration patterns was not associated with fetal asphyxia	Low
FHR deceleration patterns						
1 study (Low 1977)	Cohort	Fetal asphyxia[c]	Last two hours/last one hour to birth	122	An increased incidence of marked patterns of total deceleration and marked pattern of late decelerations	Low
FHR deceleration patterns						
1 study (Low 1977)	Cohort	Fetal asphyxia[c]	Last two hours prior to birth	122	An increased incidence of marked patterns of total deceleration and moderate plus marked pattern of late decelerations	Low

FHR fetal heart rate

a. Total decelerations defined as percentage of contractions associated with a deceleration in each two-hour period. It is classified as moderate (5% to 29% of contractions were associated with a deceleration) and marked (>30% of contractions were associated with a deceleration)
b. Late decelerations defined as percentage of contractions associated with a late deceleration in each two-hour period. It is classified as moderate (<10% of contractions were associated with a late deceleration) and marked (≥10% of contractions were associated with a late deceleration)
c. The fetal asphyxia group included n=122 women in whom their baby had umbilical artery buffer base of <2 SD below the mean, i.e. <36.1 mEq/l.

Table 41: Summary GRADE profile for predictive value of fetal heart rate decelerations for adverse neonatal outcomes in prolonged pregnancy (>42 gestational weeks)

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Late decelerations									
1 study (Cibils 1993)	Case series	Umbilical cord arterial pH<7.20	1st stage	707	39.1% (25 to 53.2)	67.7% (58.7 to 76.4)	1.20 (0.76 to 1.89)	0.90 (0.69 to 1.17)	Low
Variable decelerations									
1 study (Cibils 1993)	Case series	Umbilical cord arterial pH<7.20	1st stage	707	36.4% (23.8 to 50.1)	55.7% (46.5 to 64.7)	0.83 (0.53 to 1.28)	1.13 (0.85 to 1.53)	Low
No or early decelerations									
1 study (Cibils 1993)	Case series	Umbilical cord arterial pH<7.20	1st stage	707	23.7% (11.2 to 35.9)	76.2% (68.5 to 84.9)	1.01 (0.54 to 1.88)	0.99 (0.82 to 1.20)	Low

CI confidence interval

4.3.4.3.3 Categorisation/classification of fetal heart rate traces

Table 42: Summary GRADE profile for predictive value of published categorisations of fetal heart rate traces on adverse neonatal outcomes among high risk group

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Indeterminate FHR tracing (NICHD classification 2008)									
1 study (Sharbaf 2014)	Cohort	Umbilical artery pH ≤7.2	In early labour during a 20-40	326	52.9% (28.5 to 76.1)[a]	80.0% (72.9 to 82.4)[a]	2.41 (1.47 to 3.95)[b]	0.60 (0.36 to 1.00)[b]	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
			minute period						
1 study (Sharbaf 2014)	Cohort	NICU admission	In early labour during a 20-40 minute period	326	50.0% (29.6 to 70.4)[a]	78.5% (73.3 to 82.9)[a]	2.32 (1.47 to 3.66)[b]	0.64 (0.43 to 0.95)[b]	Very low
1 study (Sharbaf 2014)	Cohort	NICU admission excluding preterm birth	In early labour during a 20-40 minute period	NR	50.0%[c]	79.9%[c]	2.49b,[c]	0.63b,[c]	Low
1 study (Sharbaf 2014)	Cohort	Neonatal death	In early labour during a 20-40 minute period	326	100% (19.8 to 100)[a]	76.9% (71.8 to 81.3)[a]	4.32 (3.54 to 5.27)[b]	0 (NA)	Very low
"Abnormal" FHR pattern (Category III, NICHD classification 2008)									
1 study (Soncini 2014)	Cohort	NICU admission	At least 1 hour and up to 5 hours before birth	314 (normal n=108, category III n=31, category IIA n=118, category IIB n=57)	100% (69.9 to 100)[b]	85.0% (77.4 to 90.5)[b]	6.68 (4.42 to 10.12)[b]	0 (NA)[b]	Very low
1 study (Soncini 2014)	Cohort	Encephalopathy	At least 1 hour and up to 5 hours before birth	314 (normal n=108, category III	100% (59.8 to 100)[b]	82.4% (74.6 to 88.3)[b]	5.70 (3.93 to 8.25)[b]	0 (NA)[b]	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
				n=31, category IIA n=118, category IIB n=57)					
1 study (Soncini 2014)	Cohort	Moderate-severe neonatal encephalopathy	At least 1 hour and up to 5 hours before birth	314 (normal n=108, category III n=31, category IIA n=118, category IIB n=57)	100% (39.6 to 100)[b]	80.0% (72.1 to 86.2)[b]	5.00 (3.57 to 7.01)[b]	0 (NA)[b]	Very low
1 study (Soncini 2014)	Cohort	Death before NICU discharge	At least 1 hour and up to 5 hours before birth	314 (normal n=108, category III n=31, category IIA n=118, category IIB n=57)	100% (31.0 to 100)[b]	79.4% (71.4 to 85.7)[b]	4.86 (3.49 to 6.76)[b]	0 (NA)[b]	Very low
1 study (Soncini 2014)	Cohort	Umbilical artery pH<7	At least 1 hour and up to 5 hours before birth	314 (normal n=108, category III n=31, category IIA n=118, category IIB n=57)	100% (77.1 to 100)[b]	88.5% (81.2 to 93.3)[b]	8.71 (5.32 to 14.27)[b]	0 (NA)[b]	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
1 study (Soncini 2014)	Cohort	Umbilical artery BE ≤ -12 mmol/l	At least 1 hour and up to 5 hours before birth	314 (normal n=108, category III n=31, category IIA n=118, category IIB n=57)	86.4% (64.0 to 96.4)[b]	89.7% (82.4 to 94.4)[b]	8.42 (4.80 to 14.76)[b]	0.15 (0.05 to 0.44)[b]	Very low
1 study (Soncini 2014)	Cohort	Umbilical artery pH <7 and BE ≤ -12 mmol/l	At least 1 hour and up to 5 hours before birth	314 (normal n=108, category III n=31, category IIA n=118, category IIB n=57)	100% (73.2 to 100)[b]	86.4% (78.8 to 91.6)[b]	7.35 (4.73 to 11.44)[b]	0 (NA)[b]	Very low
"Indeterminate" FHR pattern with minimal/absent baseline FHR variability and no FHR accelerations (Category IIB, NICHD classification2008 with subcategorization according to ACOG guidelines)									
1 study (Soncini 2014)	Cohort	NICU admission	At least 1 hour and up to 5 hours before birth	314 (normal n=108, category III n=31, category IIA n=118, category IIB n=57)	100% (62.9 to 100)[b]	69.2% (61.3 to 76.2)[b]	3.25 (2.57 to 4.11)[b]	0 (NA)[b]	Very low
1 study	Cohort	Encephalopathy	At least 1 hour and up	314	100%	66.7%	3.00	0 (NA)[b]	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
(Soncini 2014)			to 5 hours before birth	(normal n=108, category III n=31, category IIA n=118, category IIB n=57)	(31.0 to 100)[b]	(58.8 to 73.8)[b]	(2.41 to 3.73)[b]		
1 study (Soncini 2014)	Cohort	Moderate-severe neonatal encephalopathy	At least 1 hour and up to 5 hours before birth	314 (normal n=108, category III n=31, category IIA n=118, category IIB n=57)	100% (5.5 to 100)[b]	65.9% (58.0 to 73.0)[b]	2.93 (2.37 to 3.62)[b]	0 (NA)[b]	Very low
1 study (Soncini 2014)	Cohort	Death before NICU discharge	At least 1 hour and up to 5 hours before birth	314 (normal n=108, category III n=31, category IIA n=118, category IIB n=57)	NA	65.5% (57.6 to 72.6)[b]	NA	1.53 (NA)[b]	Very low
1 study (Soncini 2014)	Cohort	Umbilical artery pH <7	At least 1 hour and up to 5 hours before birth	314 (normal n=108, category III n=31, category IIA	100% (56.1 to 100)[b]	68.4% (60.4 to 75.4)[b]	3.16 (2.51 to 3.97)[b]	0 (NA)[b]	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
				n=118, category IIB n=57)					
1 study (Soncini 2014)	Cohort	Umbilical artery BE ≤ -12 mmol/l	At least 1 hour and up to 5 hours before birth	314 (normal n=108, category III n=31, category IIA n=118, category IIB n=57)	82.4% (55.8 to 95.3)[b]	71.0% (62.8 to 78.0)[b]	2.83 (2.03 to 3.96)[b]	0.25 (0.09 to 0.70)[b]	Very low
1 study (Soncini 2014)	Cohort	Umbilical artery pH <7 and BE ≤ -12 mmol/l	At least 1 hour and up to 5 hours before birth	314 (normal n=108, category III n=31, category IIA n=118, category IIB n=57)	100% (39.6 to 100)[b]	67.1% (59.2 to 74.2)[b]	3.04 (2.44 to 3.79)[b]	0 (NA)[b]	Very low
"Indeterminate" FHR pattern with moderate FHR variability or FHR accelerations (Category IIA, NICHD classification 2008 with subcategorisation according to ACOG guidelines)									
1 study (Soncini 2014)	Cohort	NICU admission	At least 1 hour and up to 5 hours before birth	314 (normal n=108, category III n=31, category IIA n=118, category IIB n=57)	100% (31.0 to 100)[b]	48.4% (41.7 to 55.2)[b]	1.94 (1.71 to 2.20)[b]	0 (NA)[b]	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
1 study (Soncini 2014)	Cohort	Encephalopathy	At least 1 hour and up to 5 hours before birth	314 (normal n=108, category III n=31, category IIA n=118, category IIB n=57)	NA	47.8% (41.1 to 54.5)[b]	0 (NA)[b]	2.09 (NA)[b]	Very low
1 study (Soncini 2014)	Cohort	Moderate-severe neonatal encephalopathy	At least 1 hour and up to 5 hours before birth	314 (normal n=108, category III n=31, category IIA n=118, category IIB n=57)	NA	47.8% (41.1 to 54.5)[b]	0 (NA)[b]	2.09 (NA)[b]	Very low
1 study (Soncini 2014)	Cohort	Death before NICU discharge	At least 1 hour and up to 5 hours before birth	314 (normal n=108, category III n=31, category IIA n=118, category IIB n=57)	NA	47.8% (41.1 to 54.5)[b]	0 (NA)[b]	2.09 (NA)[b]	Very low
1 study (Soncini 2014)	Cohort	Umbilical artery pH <7	At least 1 hour and up to 5 hours before birth	314 (normal n=108, category III n=31,	NA	47.8% (41.1 to 54.5)[b]	0 (NA)[b]	2.09 (NA)[b]	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
				category IIA n=118, category IIB n=57)					
1 study (Soncini 2014)	Cohort	Umbilical artery BE ≤ -12 mmol/l	At least 1 hour and up to 5 hours before birth	314 (normal n=108, category III n=31, category IIA n=118, category IIB n=57)	40.0% (7.3 to 83.0)[b]	47.5% (40.8 to 54.3)[b]	0.76 (0.26 to 2.25)[b]	1.26 (0.61 to 2.61)[b]	Very low
1 study (Soncini 2014)	Cohort	Umbilical artery pH <7 and BE ≤ -12 mmol/l	At least 1 hour and up to 5 hours before birth	314 (normal n=108, category III n=31, category IIA n=118, category IIB n=57)	NA	47.8% (41.1 to 54.5)[b]	0 (NA)[b]	2.09 (NA)[b]	Very low

ACOG American College of Obstetricians and Gynecologists, BE base excess; CI confidence interval; FHR fetal heart rate; NA not applicable; NICHD National Institute of Child Health and Human Disease; NICU neonatal intensive care unit; NR not reported

a. 95% CI calculated by the 2017 NGA technical team
b. Calculated by the 2017 NGA technical team
c. 95% CI not calculable from the data reported in the article

Table 43: Summary GRADE profile for predictive value of published categorisations of fetal heart rate traces on mode of birth among high risk group

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
"Indeterminate" FHR tracing (NICHD classification 2008)									
1 study (Sharbaf 2014)	Cohort	Caesarean birth	In early labour during a 20-40 minute period	326	33.1%[a]	83.4%[a]	1.99a,[b]	0.80a,[b]	Low
"Abnormal" FHR pattern (Category III, NICHD classification 2008)									
1 study (Soncini 2014)	Cohort	Instrumental birth	At least 1 hour and up to 5 hours before birth	314 (normal n=108, category II n=31, category IIA n=118, category IIB n=57)	20.4% (13.0 to 30.3)[b]	73.9% (58.6 to 85.2)[b]	0.78 (0.42 to 1.47)[b]	1.08 (0.96 to 1.21)[b]	Very low
1 study (Soncini 2014)	Cohort	Instrumental birth for suspected fetal distress	At least 1 hour and up to 5 hours before birth	314 (normal n=108, category II n=31, category IIA n=118, category IIB n=57)	42.9% (28.1 to 58.9)[b]	86.6% (77.8 to 92.4)[b]	3.20 (1.73 to 5.91)[b]	0.66 (0.51 to 0.86)[b]	Very low
"Indeterminate" FHR pattern with minimal/absent baseline FHR variability and no FHR accelerations (Category IIB, NICHD classification 2008 with subcategorisation according to ACOG guidelines)									
1 study	Cohort	Instrumental birth	At least 1 hour and up	314	28.9%	55.7%	0.65	1.28	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
(Soncini 2014)			to 5 hours before birth	(normal n=108, category II n=31, category IIA n=118, category IIB n=57)	(20.6 to 38.7)[b]	(42.5 to 68.2)[b]	(0.43 to 0.98)[b]	(1.10 to 1.48)[b]	
1 study (Soncini 2014)	Cohort	Instrumental birth for suspected fetal distress	At least 1 hour and up to 5 hours before birth	314 (normal n=108, category II n=31, category IIA n=118, category IIB n=57)	54.7% (40.6 to 68.2)[b]	75.0% (65.8 to 82.5)[b]	2.19 (1.46 to 3.28)[b]	0.60 (0.45 to 0.82)[b]	Very low
"Indeterminate" FHR pattern with moderate FHR variability or FHR accelerations (Category IIA, NICHD classification 2008 with subcategorisation according to ACOG guidelines)									
1 study (Soncini 2014)	Cohort	Instrumental birth	At least 1 hour and up to 5 hours before birth	314 (normal n=108, category II n=31, category IIA n=118, category IIB n=57)	49.7% (41.4 to 58.0)[b]	43.0% (32.1 to 54.6)[b]	0.87 (0.68 to 1.12)[b]	1.17 (0.96 to 1.42)[b]	Very low
1 study (Soncini 2014)	Cohort	Instrumental birth for suspected fetal distress	At least 1 hour and up to 5 hours before birth	314 (normal n=108, category II	67.6% (55.6 to 77.7)[b]	55.3% (47.0 to 63.3)[b]	1.51 (1.19 to 1.91)[b]	0.59 (0.42 to 0.82)[b]	Very low

Number of studies	Design	Definition of outcome	Stage of labour	Total number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
				n=31, category IIA n=118, category IIB n=57)					

ACOG American College of Obstetricians and Gynecologists, CI confidence interval; FHR fetal heart rate; NICHD National Institute of Child Health and Human Development

a. Confidence intervals not calculable from data reported in the article
b. Calculated by the 2017 NGA technical team

Table 44: Summary GRADE profile for association between published categorisations of fetal heart rate traces and adverse neonatal outcomes

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
Indeterminate FHR tracing (NICHD classification 2008)						
1 study (Sharbaf 2014)	Cohort	Umbilical artery pH ≤7.2	Early labour during a 20-40 minute period	818	RR 1.9 (95% CI 0.8 to 4.5)[a]	Very low
1 study (Sharbaf 2014)	Cohort	NICU admission	Early labour during a 20-40 minute period	818	RR 3.2 (95% CI 1.5 to 6.9)[a]	Very low
1 study (Sharbaf 2014)	Cohort	NICU admission after excluding preterm birth	Early labour during a 20-40 minute period	752	RR 3.6 (95% CI 1.4 to 9.2)[a]	Very low

CI confidence interval; FHR fetal heart rate; NICHD National Institute of Child Health and Human Development; NICU neonatal intensive care unit; RR risk ratio

a. Presumably unadjusted (adjustments not reported)

Table 45: Summary GRADE profile for association between published categorisation of fetal heart rate traces and mode of birth

Number of studies	Design	Definition of outcome	Stage of labour	Number of babies with defined FHR patterns	Degree of association or number (percentage) of babies with defined outcome	Quality
Indeterminate FHR tracing (NICHD classification 2008)						
1 study (Sharbaf 2014)	Cohort	Caesarean birth due to non-reassuring fetal heart rate pattern	Early labour during a 20-40 minute period	77	RR 3.4 (95% CI 2.0 to 5.7)[a]	Very low

CI confidence interval; FHR fetal heart rate; NICHD National Institute of Child Health and Human Development; RR risk ratio

a. Presumably unadjusted (adjustments not reported)

4.3.5 Evidence statements

4.3.5.1 Evidence from low- and mixed-risk populations

4.3.5.1.1 Baseline fetal heart rate (tachycardia and bradycardia)

Tachycardia

Three studies (n=2031) showed that fetal tachycardia was not useful in predicting fetal lactacidaemia, acidosis or cerebral palsy. Some of the findings from these studies showed moderate to high specificity for adverse neonatal outcomes. The evidence for this finding was of very low to moderate quality. Three studies (n=7769) showed that tachycardia in the second stage of labour increased the likelihood of adverse neonatal outcomes, mainly neonatal respiratory morbidity. The evidence for this finding was of very low quality.

Bradycardia

Six studies (n=7695) showed that fetal bradycardia was mostly not useful in predicting adverse neonatal outcomes. The evidence for this finding was of very low to moderate quality. One of the studies (n=5388) showed that prolonged bradycardia (< 110 bpm for ≥ 10 minutes) in the last 30 minutes before birth was very useful in predicting umbilical cord pH of < 7.10. This finding was based on low quality evidence. Another study (n=214) showed bradycardia (< 110 bpm) in the last hour of tracing to be moderately useful in predicting moderate hypoxic ischaemic encephalopathy. This finding was based on very low quality evidence.

Many of the studies showed moderate to high specificity of absence of bradycardia for predicting neonatal adverse outcomes. Two studies (n=1621) showed that absence of bradycardia was moderately useful in predicting absence of fetal lactacidaemia and acidosis. This finding was based on very low to moderate quality evidence.

There was some evidence that fetal bradycardia increased the likelihood of adverse neonatal outcomes, although most findings showed no clinically significant association. One study (n=5388) showed that prolonged bradycardia (< 110 bpm for ≥ 10 minutes) in the last 30 minutes before birth increased the likelihood of fetal acidosis and admission to a neonatal intensive care unit (NICU). This finding was based on low quality evidence. Another study (n=2200) showed that prolonged bradycardia (< 90 bpm for > 2.5 minutes) in the first stage of labour increased the likelihood of an immediate adverse neonatal outcome. This finding was based on very low quality evidence. A further study (n=601) showed that fetal bradycardia (< 70 bpm) increased the likelihood of cord pH < 7.2 during the first stage of labour and cord pH < 7.2 combined with base deficit ≥ 12 mmol/l during the second stage of labour. This finding was based on low quality evidence.

4.3.5.1.2 Baseline variability

Seven studies (n=1331) showed that reduced or absent baseline variability was not useful in predicting adverse neonatal outcomes. Most of the findings from these studies showed moderate to high specificity for adverse neonatal outcomes. These findings were based on very low to low quality evidence. Three studies (n=7537) found no clinically significant association between reduced or absent variability and adverse neonatal outcomes. This finding was based on very low to low quality evidence.

One study (n=1070) showed that increased baseline variability (amplitude > 25 bpm) was moderately useful in predicting fetal lactacidaemia and had high specificity for this outcome.

This finding was based on very low quality evidence. Another study (n=4736) showed that increased baseline variability (amplitude > 25 bpm) increased the odds of neonatal respiratory morbidity. This finding was based on very low quality evidence.

One study (n=319) showed that a mild pseudo-sinusoidal pattern was not useful in predicting umbilical artery pH < 7.12 or admission to NICU. The same study showed moderate sensitivity of this pattern for both outcomes. The study also showed that a mild pseudo-sinusoidal pattern was not useful in predicting caesarean section or instrumental vaginal birth. The evidence for all of these findings was of low quality.

4.3.5.1.3 Accelerations

Three studies (n=173) showed that a lack of fetal heart rate accelerations was not useful in predicting adverse neonatal outcomes. The evidence for this finding was of very low quality. One of these studies (n=50) showed accelerations to be moderately useful in ruling out neonatal mortality. This finding was based on very low quality evidence. Some of the evidence from these 3 studies showed moderate specificity for detecting adverse neonatal outcomes. A different study (n=4736) showed that the presence of accelerations in the fetal heart rate tracing lowered the likelihood of neonatal respiratory morbidity and neonatal mechanical ventilation. This finding was based on very low quality evidence.

One study (n=117) did not show a reactive trace to be associated with or useful in predicting whole-body hypothermia treatment for suspected moderate to severe neonatal encephalopathy. This finding was based on very low quality evidence.

4.3.5.1.4 Decelerations

Early decelerations

One study (n=117) showed that early decelerations were not useful in predicting whole-body hypothermia treatment for suspected moderate to severe neonatal encephalopathy, but showed high specificity. This finding was based on very low quality evidence.

Findings on the association between early decelerations and adverse neonatal outcomes were somewhat mixed. One study (n=4736) found no clinically significant association between early decelerations in the last 30 minutes before birth and neonatal respiratory morbidity. This finding was based on very low quality evidence. However, another study (n=117) found that early decelerations in the last hour before birth lowered the likelihood of whole-body hypothermia treatment for suspected moderate to severe neonatal encephalopathy. This finding was also based on very low quality evidence.

Prolonged decelerations

One study (n=4736) showed that prolonged decelerations in the last 30 minutes before birth increased the likelihood of neonatal respiratory morbidity and neonatal mechanical ventilation. This finding was based on very low quality evidence.

Late decelerations

Three studies (n=1193) showed that late decelerations were not useful in predicting adverse neonatal outcomes, although some outcomes showed moderate to high specificity. The evidence for these findings was of very low to low quality. Findings on the association between late decelerations and adverse neonatal outcomes were mixed. Two publications from the same study (n=601) found that late decelerations increased the likelihood of neonatal acidosis in both the first and second stages of labour. These findings were based on low to moderate quality evidence. However, three other studies (n=7053) showed no

clinically significant association between late decelerations and other adverse neonatal outcomes. This finding was based on very low quality evidence.

Variable decelerations

Three studies (n=1157) showed that variable decelerations were not useful in predicting adverse neonatal outcomes. This finding was based on very low to moderate quality evidence. One of the studies (n=1070) showed that the absence of severe variable decelerations was moderately useful in predicting the absence of fetal lactacidaemia. This finding was based on very low quality evidence. Findings on the association between variable decelerations and adverse neonatal outcomes were mixed. Two publications from the same study (n=601) showed that variable decelerations increased the likelihood of fetal acidosis in both the first and second stages of labour. These findings were based on low to moderate quality evidence. Another study (n=3994) showed that variable decelerations increased the likelihood of neonatal respiratory morbidity when caesarean births were excluded. This finding was based on very low quality evidence. However, a third study (n=2200) found no clinically significant association between variable decelerations and immediate adverse neonatal outcome. This finding was also based on very low quality evidence. Another study (n=513) showed that severe variable decelerations increased the likelihood of caesarean birth and vacuum birth. This finding was based on moderate quality evidence. No clinically significant association was found between non-significant variable decelerations and mode of birth. One study (n=167) showed that biphasic decelerations were not useful in predicting umbilical cord arterial pH < 7.20. The same evidence showed high specificity of biphasic decelerations in predicting umbilical cord arterial pH < 7.20. These findings were based on moderate quality evidence.

4.3.5.1.5 Combinations of fetal heart rate trace features

Three studies (n=1749) looked at different combinations of fetal heart rate trace features on adverse neonatal outcomes. One study (n=1070) showed that tachycardia in combination with reduced baseline variability, late decelerations in combination with reduced baseline variability, and severe variable decelerations in combination with reduced baseline variability were not useful in predicting fetal lactacidaemia. However, evidence from the same study showed that severe variable decelerations in combination with tachycardia were moderately useful in predicting fetal lactacidaemia and absence of the above features was moderately useful in predicting the absence of fetal lactacidaemia. Another study (n=301) showed that recurrent late decelerations with decreased variability were moderately useful in predicting cord artery pH <7.10. The third study (n=378) showed that multiple late decelerations, decreased variability, or both were not useful in predicting cerebral palsy. The second study (n=301) showed that the absence of recurrent late decelerations in combination with no accelerations was moderately useful in predicting the absence of cord artery pH < 7.10. All of these findings were based on very low quality evidence.

4.3.5.1.6 Categorisation/classification of fetal heart rate traces

Ten studies (n=3268) on the predictive value of different categorisations of fetal heart rate traces showed that fetal heart rate patterns were mostly not useful in predicting adverse neonatal outcomes. These findings were based on very low to moderate quality evidence. Three studies (n=2017) showed that fetal heart rate patterns were mostly not useful in predicting mode of birth. This finding was based on low to moderate quality evidence.

Krebs score and FIGO classification

One study (n=73) showed that an abnormal Krebs score was not useful in predicting encephalopathy. The same study showed that an abnormal pattern (International Federation

of Obstetrics and Gynecology (FIGO) 1987 classification) was not useful in predicting encephalopathy, however it showed that the absence of an abnormal pattern in the last 30 minutes of tracing was moderately useful in predicting the absence of encephalopathy. The study also showed that depending on the timing of the tracing, specificity of an abnormal Krebs score for encephalopathy ranged from moderate to high and sensitivity of an abnormal pattern (FIGO classification) for encephalopathy ranged from low to moderate. All of these findings were based on very low quality evidence.

Ominous cardiotocograph trace

One study (n=96) showed that an 'ominous' CTG trace (no definition reported) was not useful in predicting encephalopathy. The same evidence showed that specificity of an ominous CTG trace for encephalopathy ranged from low to high depending on the stage of labour. This finding was based on low quality evidence.

NICHD classification

Five studies (n=1892) mostly showed that fetal heart rate patterns as defined by the National Institute of Child Health and Human Development (NICHD) classification were not useful in predicting adverse neonatal outcomes. These findings were based on very low to low quality evidence.

- One study (n=601) showed that an 'abnormal' fetal heart rate pattern (NICHD classification) was not useful in predicting fetal acidosis, however it showed that the absence of the pattern was moderately useful in predicting the absence of this outcome. These findings were based on moderate quality evidence.
- The second study (n=117) showed that category II or category III (NICHD classification 2008) were not useful in predicting whole-body hypothermia treatment for suspected moderate to severe neonatal encephalopathy. This finding was based on very low quality evidence.
- The third study showed that an indeterminate fetal heart rate pattern (category II, NICHD classification 2008) was not useful in predicting umbilical cord artery pH ≤ 7.2, or NICU admission, or NICU admission excluding preterm birth in either a mixed-risk population of both low- and high-risk pregnancies (n=818) or in a low-risk population only (n=492). This finding was based on low quality evidence. The same study showed that an indeterminate fetal heart rate pattern was moderately useful in predicting neonatal death in the mixed-risk population although not useful in predicting the same outcome in the low-risk population; moreover, absence of an indeterminate fetal heart rate pattern was very useful in predicting absence of neonatal death in the mixed-risk population, although it was not useful for this purpose in the low-risk population. However, the predictive values for neonatal death were based on a very small number of cases in the study and should be interpreted with caution. These findings were based on very low to low quality evidence.
- The fourth study (n=214) showed that a combination of fetal heart rate baseline < 110 bpm, baseline variability < 5 bpm and a non-reactive trace (NICHD classification) was moderately useful in predicting moderate hypoxic ischaemic encephalopathy. This finding was based on very low quality evidence.
- The firth study (n=142) showed that a fetal sleep pattern for ≥ 50% of the tracing (NICHD classification – fetal sleep pattern not defined) was not useful in predicting sudden infant death. This finding was based on very low quality evidence.

The same five studies (n=1892) showed that sensitivity of fetal heart rate patterns as defined by the NICHD classification was often low for adverse neonatal outcomes whereas specificity

was often moderate, but overall there were mixed results and both sensitivity and specificity ranged from low to high. These findings were based on very low to low quality evidence.

Three studies (n=2020) reported relative risks and odds ratios in relation to adverse neonatal outcomes and fetal heart rate patterns as defined by the NICHD classification. Overall this evidence was of very low to moderate quality. One study (n=601) found no clinically significant association between a pathological fetal heart rate pattern (NICHD classification) and umbilical cord artery pH < 7.2 plus base deficit ≥ 12. This finding was based on moderate quality evidence. However, another study (n=601) found that an abnormal fetal heart rate tracing (NICHD classification) increased the odds of pH < 7.2 and base deficit ≥ 12 compared to a normal tracing. This finding was based on low quality evidence. The third study found that an indeterminate fetal heart rate pattern (category II, NICHD classification 2008) increased the likelihood of NICU admission in a mixed population of both low- and high-risk pregnancies (n=818), although there was no clinically significant association between the indeterminate pattern and NICU admission in the low-risk population (n=492). Moreover, there was no clinically significant association between an indeterminate fetal heart rate pattern and umbilical cord artery pH ≤ 7.2 or NICU admission excluding preterm birth either in a mixed- or low-risk population only. These findings were based on very low quality evidence.

Two studies (n=1119) showed that fetal heart rate patterns as defined by the NICHD classification were not useful in predicting mode of birth. These findings were based on very low to low quality evidence. One study (n=301) showed that a 'pathological' fetal heart rate pattern (NICHD classification) was not useful in predicting spontaneous vaginal birth, vacuum birth or caesarean birth. These findings were based on moderate quality evidence. Another study showed that an indeterminate fetal heart rate pattern (category II, NICHD classification 2008) was not useful in predicting caesarean birth amongst a mixed population of both low- and high-risk pregnancies (n=818) nor amongst the low-risk population only (n=492). These findings were based on low quality evidence. The same study showed high specificity of an indeterminate fetal heart rate pattern for caesarean section amongst both the mixed- and low-risk population. These findings were based on low quality evidence. The same study found that an indeterminate fetal heart rate pattern increased the likelihood of caesarean section due to a non-reassuring fetal heart rate pattern amongst both the mixed- and low-risk population only. These findings were based on very low quality evidence.

Pattern 1, 2, 3 or 4

One study (n=142) showed that 'pattern 1' (absent variability for at least 1 cycle, usually with late or prolonged decelerations) was moderately useful in predicting asphyxia, however the absence of this pattern was not useful in predicting the absence of asphyxia. These findings were based on very low quality evidence. The same study showed that none of the following patterns were useful in predicting asphyxia: 'pattern 2' (minimal baseline variability for at least 2 cycles and late or prolonged decelerations for at least 2 cycles); 'pattern 3' (minimal baseline variability for at least 2 cycles] or late or prolonged decelerations for at least 2 cycles); 'pattern 4' (minimal baseline variability for 1 cycle or late or prolonged deceleration for 1 cycle). However, the absence of pattern 3 or pattern 4 was moderately useful in predicting the absence of asphyxia. These findings were based on very low quality evidence. The evidence also showed high specificity of pattern 1, moderate specificity of pattern 2, moderate sensitivity of pattern 3 and high sensitivity of pattern 4 in predicting asphyxia.

Dellinger classification

One study (n=898) showed that 'stressed' or 'distressed' fetal heart rate patterns (Dellinger classification) were not useful in predicting NICU admission, umbilical artery pH < 7 or base

excess < -11, when 'stressed' and 'distressed' patterns were considered together in the analysis. However, the same study showed that the absence of the patterns was very useful in predicting the absence of umbilical artery pH < 7 or the absence of base excess < -11. Sensitivity of the patterns for the two latter outcomes was high. When 'distressed' fetal heart rate patterns were considered separately in the same study (n=635), these patterns were moderately useful in predicting NICU admission and very useful in predicting umbilical artery pH < 7 and base excess < -11. Moreover, the absence of the patterns was very useful in predicting the absence of umbilical artery pH < 7 or the absence of base excess < -11. Specificity of 'distressed' patterns was high for all three outcomes and sensitivity was high for the two latter outcomes. All of these findings were based on low quality evidence.

The same study (n=898) showed that 'stressed' or 'distressed' fetal heart rate patterns were not useful in predicting caesarean birth when 'stressed' and 'distressed' patterns were considered together in the analysis. However, when the predictive value of' 'distressed' fetal heart rate patterns was assessed separately in the same study (n=635), the presence of 'distressed' patterns was moderately useful in predicting caesarean birth, although the absence of the patterns was not useful in predicting absence of caesarean birth. The study also showed high specificity of 'distressed' fetal heart rate patterns for caesarean birth. All of these findings were based on low quality evidence.

Presence of 1 to 4 poor prognostic features

One study (n=167) showed that the presence of 1, 2, 3 or 4 prognostic features was not useful in predicting umbilical cord arterial pH < 7.20. However, the absence of 1 poor prognostic feature was moderately useful in predicting the absence of umbilical cord arterial pH < 7.20. The same study showed moderate sensitivity of the presence of 1 poor prognostic feature, moderate specificity of the presence of 3 poor prognostic features and high specificity of the presence of 4 prognostic features in predicting umbilical cord arterial pH < 7.20. All of these findings were based on moderate quality evidence.

4.3.5.2 Evidence from high risk populations

4.3.5.2.1 Decelerations

One study (n=707) showed that late decelerations, variable decelerations or no or early decelerations were not useful in predicting umbilical cord pH < 7.20 amongst prolonged pregnancies (> 42 gestational weeks). These findings were based on low quality evidence.

4.3.5.2.2 Categorisation/classification of fetal heart rate traces

Two studies (n=640) investigated the predictive value of published categorisations of fetal heart rate traces on adverse neonatal outcomes and mode of birth amongst women at high risk. The evidence was of very low to low quality.

NICHD classification

Two studies (n=640) mostly showed that an indeterminate fetal heart rate pattern (NICHD classification 2008) was not useful in predicting adverse neonatal outcomes amongst women at high risk. These findings were based on very low to low quality evidence. However, one of these studies (n=314) mostly showed that an abnormal fetal heart rate pattern (NICHD classification 2008) was useful in predicting adverse neonatal outcomes amongst women at high risk. These findings were based on very low quality evidence.

One study (n=326) showed that an indeterminate fetal heart rate tracing (NICHD classification 2008) was not useful in predicting umbilical artery pH ≤ 7.2, NICU admission,

NICU admission excluding preterm birth, or neonatal death. The same study showed that the absence of an indeterminate fetal heart rate tracing was very useful in predicting the absence of neonatal death, however this predictive value was based on a very small number of cases and should be interpreted with caution. These findings were based on very low to low quality evidence.

The second study (n=314) showed that an indeterminate fetal heart rate pattern with minimal or absent baseline fetal heart rate variability and no fetal heart rate accelerations (category IIB, NICHD classification 2008 with subcategorisation according to American College of Obstetricians and Gynecologists (ACOG) guidelines) was not useful in predicting NICU admission, encephalopathy, moderate to severe neonatal encephalopathy, death before NICU discharge, umbilical artery pH < 7, umbilical artery base excess ≤ - 12 mmol/l, or umbilical artery pH < 7 plus base excess ≤ -12 mmol/l. The same evidence showed that the absence of the pattern was very useful in predicting the absence of most of these outcomes. These findings were based on very low quality evidence.

The same study (n=314) showed that an indeterminate fetal heart rate pattern with moderate fetal heart rate variability or fetal heart rate accelerations (category IIA, NICHD classification 2008 with subcategorisation according to ACOG guidelines) was not useful in predicting adverse neonatal outcomes. These findings were based on very low quality evidence.

The same study (n=314) showed that an abnormal fetal heart rate pattern (category III, NICHD classification 2008) was moderately useful in predicting NICU admission, encephalopathy, moderate to severe neonatal encephalopathy, umbilical artery pH < 7, umbilical artery base excess ≤ - 12 mmol/l, or umbilical artery pH < 7 plus base excess ≤ -12 mmol/l. However, the pattern was not useful in predicting death before NICU discharge. The same evidence mostly showed that the absence of an abnormal pattern (category III, NICHD classification 2008) was very useful in predicting the absence of the above-mentioned outcomes. These findings were based on very low quality evidence.

The evidence from the 2 studies was mixed with regard to sensitivity and specificity of an indeterminate fetal heart rate pattern. One study (n=314) showed that specificity of an abnormal fetal heart rate pattern (NICHD classification 2008) was moderate and sensitivity was mostly high for adverse neonatal outcomes. These findings were based on very low quality evidence. The other study (n=326) found no clinically significant association between an indeterminate fetal heart rate tracing (NICHD classification 2008) and umbilical artery pH ≤ 7.2 however it found that this pattern increased the likelihood of NICU admission and the likelihood of NICU admission after excluding preterm birth.

The 2 studies (n=640) showed that an indeterminate or abnormal fetal heart rate pattern (NICHD classification 2008) was not useful in predicting mode of birth. Overall the evidence for these findings was of very low to low quality. One study (n=326) showed that an indeterminate fetal heart rate tracing (NICHD classification 2008) was not useful in predicting caesarean section. The evidence for this finding was of low quality. The other study (n=314) showed that an indeterminate fetal heart rate pattern with minimal or absent baseline fetal heart rate variability and no fetal heart rate accelerations (category IIB, NICHD classification 2008 with subcategorisation according to ACOG guidelines) or an indeterminate fetal heart rate pattern with moderate fetal heart rate variability or fetal heart rate accelerations (category IIA, NICHD classification 2008 with subcategorisation according to ACOG guidelines) or an abnormal fetal heart rate pattern (category III, NICHD classification 2008) was not useful in predicting instrumental birth generally or instrumental birth specifically for suspected fetal distress. The evidence for these findings was of very low quality.

The 2 studies referred to above showed that specificity of an indeterminate or abnormal fetal heart rate pattern (NICHD classification 2008) ranged from low to moderate for mode of birth,

while sensitivity was low. One of the studies (n=326) found that an indeterminate fetal heart rate tracing (NICHD classification 2008) increased the likelihood of caesarean section due to a non-reassuring fetal heart rate pattern. The evidence for this finding was of very low quality.

4.3.6 Health economics profile

No published economic evaluations were identified for this review question.

4.3.7 Evidence to recommendations

4.3.7.1 Relative value placed on the outcomes considered

The Guideline Committee agreed that the consequences of intrapartum fetal acidosis should be the main outcomes for this question. However, the fetal heart rate is only a surrogate for fetal oxygenation and potential associated acidosis. Furthermore, other factors can influence the fetal heart rate (for example, maternal temperature). Therefore the Committee felt it was important to assess how effective CTG is at identifying babies with fetal hypoxia that may lead to acidosis, both in terms of identifying true positives and ruling out false negatives.

4.3.7.2 Consideration of clinical benefits and harms

There are two types of hypoxia in labour – acute and chronic.

Acute hypoxia develops because there is a sudden, almost total, interruption of the oxygenation of the baby. This can be caused by maternal collapse, complete placental abruption, uterine rupture, cord prolapse or complete cord compression. Acute profound hypoxia can occasionally occur as an end-stage event following chronic compromise. These are sudden events and require immediate action if prolonged severe acidosis leading to irreparable fetal injury is to be avoided.

Chronic partial hypoxia leading to acidosis develops over a period of hours rather than minutes. While most babies benefit from the normal intermittent relative hypoxia of labour associated with uterine contractions, chronic hypoxia followed by acidosis may develop in some, for example, as a result of long labours, where there is repeated cord compression with contractions, or where there are excessive contractions (either spontaneous or stimulated). In these cases, a more gradual change occurs in the characteristics of fetal heart rate.

CTG records only 2 parameters: the fetal heart rate and uterine contractions. The continuous monitoring allows a number of features to be considered simultaneously which can also be examined for trends over a period of time. In contrast, intermittent auscultation is used to record the fetal heart rate over a period of 1 minute immediately after a contraction once every 15 minutes during the first stage of labour, and after every contraction in the second stage. It can be used to detect decelerations that occur during that minute but it does not identify decelerations at other times or baseline variability. For this reason, CTG is used when there are factors present that indicate an increased risk of developing fetal hypoxia, including abnormalities detected using intermittent auscultation.

Disadvantages of CTG use include the increased likelihood that the woman may be left alone, mobility may be reduced and the woman may be frightened by hearing changes in the fetal heart rate. Clinicians may focus on the recording rather than the woman and this may translate into a lack of support for the woman. Clinicians may also derive a false sense of reassurance and fail to act promptly in the event of an abnormality, or over-react in the face

of normal physiological fetal heart rate changes which may in turn lead to an increase in the rate of interventions. CTG is sometimes incorrectly used in place of continuous supportive one-to-one care. The Committee noted that it is crucial that the focus remains on the woman rather than the CTG trace. The whole clinical picture, as well as the woman's preferences, should always guide decision making. Therefore, it is important that the clinician remains with the woman to provide one-to-one care and support. The Committee emphasised that the woman should be provided with clear information about the benefits and harms of performing electronic fetal monitoring as well as the interpretation of the CTG trace.

CTG is currently used in practice to monitor the fetal heart rate when there is a concern that fetal hypoxia may develop and lead to acidosis, although there is no high quality evidence about the extent of the risks and benefits derived from CTG use. There are no alternative forms of monitoring that could replace CTG, although there are adjuncts to CTG that are discussed elsewhere in this guideline (see, for example, Section 4.8).

It is important to remember that CTG monitoring acts as a screening tool, and not a diagnostic test or a treatment. The Committee noted that abnormal CTG trace features are common in clinical practice and that most abnormal trace features are not associated with abnormal outcomes; the Committee also noted that CTG trace features may return to normal after some time. Interventions undertaken following observation of abnormalities in the CTG trace during labour occur in 10–20% of monitored labours. Although severe perinatal asphyxia (causing death or severe neurological impairment) is very rare (see Section 4.3.2), it is difficult to identify what proportion is 'avoidable'. While the incidence of avoidable death or brain damage that is caused, or exacerbated by, aspects of labour and birth in higher risk labours is not known, neither is the number of interventions (operative births) required to avoid 1 poor outcome. However, it is likely that the number is high. Nevertheless, the Committee agreed that, because the incidence of avoidable death or brain damage is greater in higher risk labours than in the whole population, CTG should be a more effective screening test than intermittent auscultation in such labours for 2 reasons: first, it records the fetal heart rate continuously rather than intermittently; and second, it provides more information about the fetal heart rate than is possible to determine with intermittent auscultation.

The Committee felt that current practice assumes CTG has greater accuracy than the evidence suggests. CTG was often not useful in predicting poor neonatal outcomes due to its high false-positive rate, although this demonstrates that the randomised studies (see Section 4.1) were underpowered to show an effect on this outcome. There was limited evidence that, in some instances, the use of CTG is useful in predicting adverse neonatal outcomes. This is considered in more detail under 'Other considerations' below. It is likely that individual parameters are interpreted with an impression of precision that is not supported by the evidence. For example, clinicians may think that reduced variability for more than 50 minutes (that is, an 'abnormal' feature according to the 2017 update of the guideline) is associated with acidosis. However, there is no evidence of such an association, and this feature was classified as abnormal based on the Committee's clinical expertise and experience (see references to baseline variability in the 'Other considerations' subsection below). As such, it is tempting to suggest that each parameter can be defined in terms of its severity and subsequently classified, but the available evidence does not support the assumption that a CTG trace can be interpreted so precisely.

The 2014 guideline (CG190) noted that the classification presented in the 2007 guideline (CG55) took no account of the stage or progress of labour, the presence or absence of meconium or signs of infection, and little account of uterine contractions or the woman's condition. This could have an adverse effect on care provided. For example, the use of an arbitrary time period may lead to demonstrably 'abnormal' trace features not being considered to reach the threshold for action when in fact action would be required.

Conversely, an unnecessary intervention may be initiated in response to an 'abnormal' CTG patterns in a second stage of labour that is progressing normally. In a rapidly progressing labour, fetal heart rate changes are common and do not necessarily cause concern. The 2014 guideline emphasised that the inclusion in the classification in the 2007 guideline of both 'suspicious' and 'pathological' led to the view that there were 2 distinct categories of an 'abnormal' CTG trace. By definition, a 'suspicious' CTG trace is intended to be one that requires examination for the presence of risk factors and consideration of whether a change in management might avoid a future worsening of condition, rather than indicating the baby is at risk of compromise in that immediate moment. It is for these reasons that the 2014 guideline concluded that the classification should be less complex and less rigid than the 2007 classification. However, the 2014 guideline used the same terms to define the individual features of the CTG trace and the overall classification of the trace. The 2017 Committee concluded that an overall categorisation of CTG traces with different terminology to the individual trace features should be developed to avoid confusion.

The 2017 Committee recognised that a change in guidance would require re-training of clinical staff, which could delay adoption. This may, in turn, lead to inconsistency in care and confusion about terminology. Any ambivalence or difficulty in terminology could cause safety concerns, especially in an emergency situation. It was, therefore, important that any changes to terminology and cut-off values in the 2014 guidance were carefully considered. The Committee discussed the potential benefits and harms of different terminology for the categorisation of CTG traces overall, and of individual trace features, taking into account women's experiences and views of concerning language used by clinicians during labour and birth. After careful consideration, the Committee decided that 'reassuring', 'non-reassuring' and 'abnormal' were appropriate terms for classifying individual trace features and should be used in the 2017 update of guideline. The term 'normal/reassuring' used in the 2014 guideline was changed to 'reassuring' in order to simplify the description and because the term 'normal' was adopted for the overall classification of the CTG trace in the 2017 update. Moreover, the Committee agreed that in the absence of specific evidence to support a particular classification or terminology there were advantages in the NICE guidance being more closely aligned with the well-recognised FIGO consensus guidelines on intrapartum fetal monitoring using cardiotocography (Ayres-de-Campos 2015).

The Committee discussed at length the terminology for the overall classification of the CTG trace. The main reason to monitor the fetal heart rate is to assess the risk of fetal acidosis, and as such the Committee discussed the use of the level of risk of fetal acidosis to define the categories for CTG traces. The Committee discussed a classification comprising three categories: low risk of fetal acidosis; medium risk of fetal acidosis; and high risk of fetal acidosis. However it was concluded that there is uncertainty about the risk of acidosis in relation to a CTG trace and therefore it would not be possible to provide an accurate definition of low, medium or high risk of acidosis. After considering some alternative options, the Committee decided to adopt the terms 'normal', 'suspicious' and 'pathological', which were already used in the 2007 NICE guideline (and the FIGO consensus guidelines; Ayres-de-Campos 2015). The Committee noted that many healthcare professionals are already familiar with these terms, which should facilitate uptake of the 2017 NICE guidance. The Committee recognised that there are differences between the 2017 NICE guideline and the 2015 FIGO consensus guidelines. Therefore, the same terms have different meanings in the NICE and FIGO guidelines, which might cause confusion. However, the Committee also agreed that there are many similarities and a few differences between the 2017 NICE guideline and the FIGO consensus guidelines in relation to the classification of a CTG as 'normal', 'suspicious' or 'pathological', therefore it is less confusing to use the same terms than to use different terms in the two guidelines. Moreover, the Committee noted that the key to avoiding confusion is adequate training (although detailed consideration of training is beyond the scope of the guideline). The Committee also noted that the term 'pathological'

suggests that there is a pathology, which is incorrect because a so-called pathological CTG would often appear in the absence of pathology, however it was preferred to use the term 'pathological' over 'abnormal' because the latter is used to describe the individual features of a trace. A fourth category describing a CTG tracing that indicates the need for urgent intervention was defined as the presence of an acute bradycardia (defined as a bradycardia of sudden onset from a previously normal baseline rate), or a single prolonged deceleration, persisting for 3 minutes or more. The Committee discussed how some women might find particular terminology alarming which might unnecessarily negatively affect their birth experience. However they concluded that women generally accepted the use of clinically relevant phrases if used in a sensitive manner.

4.3.7.3 Consideration of health benefits and resource use

As this question looked at the diagnostic accuracy of different features of fetal heart rate traces, there were no resource use issues to consider.

4.3.7.4 Quality of evidence

The quality of the evidence reviewed varied from very low to moderate. The Committee noted several factors that limited the usefulness of the research findings, as described below.

First, the incidence of outcomes of importance are rare so that a large numbers of cases would be needed to show a difference, if one existed, especially in terms of long-term neurodevelopment. Second, there is likely to be a 'treatment effect'. Because of prior knowledge and experience, many clinicians would feel it inappropriate not to act in the presence of a significant CTG 'abnormality' because it has previously been associated with a poor outcome. The low threshold for intervention makes it difficult to establish which cases are true 'false positives', leading to a situation where CTG is being widely used without good evidence of benefit.

Third, the characteristics of the fetal heart rate trace act only as a surrogate for fetal hypoxia and arguably not a very good one. Fetal heart rate is influenced by other factors. In an analogous intensive care setting after birth, no one would rely exclusively on the woman's pulse to assess her condition.

Fourth, this guideline recommends the use of CTG only in high-risk labours (see Section 4.1). However, the majority of the studies included in the guideline review were conducted in low mixed-risk populations.

Finally, the CTG trace is analysed clinically taking into account multiple factors. It is not just the fetal heart rate that is considered but underlying risk factors including fetal clinical risk factors and other relevant information, such as the progress of labour and/or maternal complications. This means that the performance of individual parameters may not reflect the risks and benefits of using CTG in a clinical setting. Complex tasks of pattern recognition together with clinical evaluation may not be captured in simple algorithms and not reflected in the research reviewed for the guideline.

The evidence base to support the use of CTG alone to monitor high-risk labours is not strong. The Committee noted that there are no randomised trials in higher risk women to measure the advantages and harms of CTG monitoring in terms of long-term child health outcomes and so a research recommendation was formulated (see Section 4.1) to evaluate such outcomes in the context of meconium-stained liquor, including a requirement for subgroup analysis according to significant or non-significant meconium. The present rationale for the use of CTG in high-risk labours is based on both the association of certain abnormal CTG features with adverse neonatal outcomes and the theoretical reasoning that it

provides more information than is available from intermittent auscultation. In addition, no better alternative is available.

4.3.7.5 Other considerations

The Committee was aware that the reliability of interpretation of CTG recordings, both between different users and when carried out by the same person, has been shown to be variable (see Section 4.9). This suggests that there will be differences between clinicians regarding interpretation of CTG traces, including baseline variability and categorisation of decelerations. Care should, therefore, be taken when interpreting CTG traces so that appropriate action will be taken when there are signs that cause concern, and so that unnecessary actions and interventions will be avoided. Moreover, the Committee noted that it would be important to ensure that each CTG trace is of high quality.

The Committee recognised that CTG traces can be difficult to interpret and that guidance on interpretation should be as straightforward as possible. Moreover, the Committee concluded that when it is difficult to interpret or categorise a CTG trace, a senior midwife or a senior obstetrician should be consulted.

Differentiating between maternal and fetal heart beats was added to the guidance to reduce the risk of false interpretation of the fetal heart beats.

The Committee noted that medico-legal claims have been associated with very rare but serious adverse outcomes. These cases may subsequently affect custom and practice in clinical care because, for example, it is difficult to defend a case of intrapartum fetal hypoxia leading to acidosis if a CTG has not been used in the management of a high-risk labour. However, the Committee agreed that defensible practice should be evidence-based practice and so did not feel that it was appropriate to base a recommendation on medico-legal experience.

Although the Committee considered it would be appropriate to establish principles of interpretation, they appreciated that practical and implementable guidance would be needed to influence clinical practice. In developing the recommendations for definition and interpretation of CTG traces, and those for care based on the result of a CTG trace, the Committee relied on the evidence as far as practicable, but informal consensus was also needed because of the wide variation in definitions used in studies included in the guideline review. The Committee emphasised that the combination of evidence and expert opinion was a feature of all CTG scoring systems.

Baseline fetal heart rate: tachycardia

Amongst low/mixed-risk populations, there was evidence that fetal tachycardia is not useful for predicting adverse neonatal outcomes. However, there was also some evidence that fetal tachycardia with values above 160 bpm in the second stage of labour increased the odds of adverse neonatal outcomes. There was no evidence identified in relation to fetal tachycardia amongst high-risk populations. Therefore the Committee recommended that the upper limit of the normal baseline heart rate should be 160 bpm.

Empirically the Committee felt that if fetal acidosis was associated with a fetal tachycardia then the risk would be greater at values above 180 bpm than values between 161 bpm and 180 bpm, although there was no direct evidence to confirm this. The Committee therefore distinguished 2 categories of fetal tachycardia: 161–180 bpm (non-reassuring) and more than 180 bpm (abnormal).

Baseline fetal heart rate: bradycardia

Although there was limited evidence that fetal bradycardia (< 110 bpm) was useful in predicting adverse neonatal outcomes, and many of the studies included in the guideline review showed moderate to high specificity of fetal bradycardia for adverse outcomes, the evidence mostly showed that fetal bradycardia was not useful in predicting adverse outcomes amongst low/mixed-risk populations. There was no evidence identified in relation to fetal bradycardia amongst high-risk populations. Based on the Committee's clinical expertise, it was decided that a fetal baseline heart rate of 110–160 bpm should be classified as reassuring; this is aligned with the FIGO consensus guidelines on intrapartum fetal monitoring using cardiotocography (Ayres-de-Campos 2015). This decision represented a change from the 2014 guideline (CG190), in which 100–160 bpm was classified as 'normal'. In the absence of evidence to direct a recommendation, the Committee discussed that a baseline fetal heart rate of 100–109 bpm should be considered non-reassuring because it is uncommon. However, the Committee recognised that a baseline fetal heart rate of 100–109 bpm could be regarded as normal if were associated with normal baseline variability and no variable or late decelerations.

Baseline variability

Amongst low/mixed-risk populations, the evidence included in the guideline review showed that reduced or absent variability was not useful in predicting adverse neonatal outcomes, although specificity of reduced or absent variability was mostly moderate to high for adverse neonatal outcomes. There was no evidence identified in relation to women at high risk. Based on their clinical expertise and experience, the Committee decided that baseline variability of less than 5 bpm for 30–50 minutes should be considered non-reassuring and for more than 50 minutes it should be considered abnormal. In the 2014 guideline (CG190), baseline variability of less than 5 bpm for more than 90 minutes was considered abnormal. The 2017 Committee decided that it would be unrealistic to wait for 90 minutes without obtaining a review from a senior midwife and an obstetrician and, therefore, agreed that baseline variability of less than 5 bpm for more than 50 minutes (rather than 90 minutes) should be considered abnormal. This decision was based on the recognised normal fetal sleep-wake cycle of 40–50 minutes. The Committee agreed that intermittent periods of reduced baseline variability are normal, especially during periods of quiescence ('sleep').

New evidence related to low/mixed-risk populations became available after the 2014 guideline (CG190) was published that showed a baseline variability amplitude range of more than 25 bpm increased the odds of neonatal respiratory morbidity. The same evidence showed that baseline variability range of more than 25 bpm is moderately useful in predicting fetal lactacidaemia (fetal lactate > 4.8 mmol/l). The duration of the feature in the CTG trace in relation to neonatal outcomes was not reported in the evidence. Considering the available evidence, the Committee decided that reassuring baseline variability would be 5–25 bpm. The Committee noted that in their experience increased variability is a rare feature, however, when it is present it is useful to detect a high risk of adverse outcomes. In the absence of evidence on the duration of increased baseline variability, the Committee made a consensus recommendation that baseline variability of more than 25 bpm for 15 to 25 minutes should be considered non-reassuring, and when this occurs for more than 25 minutes it should be considered abnormal. The minimum time interval of 15 minutes for the non-reassuring category was introduced to avoid unnecessary interventions based on the presence of a single feature which would most often change back to normal after some time. The Committee discussed whether the time cut-off between the non-reassuring and abnormal category should be 25 minutes or 30 minutes and decided on 25 minutes because a baseline variability range of more than 25 bpm for more than 25 minutes would be easier for clinicians to remember. The Committee noted that these time intervals refer to a repeated sporadic

saltatory feature rather than to a continuous feature, but did not specify this in the recommendations because this should be covered by routine training on CTG interpretation.

There was limited evidence that mild (’pseudo’) sinusoidal patterns (oscillations of 5–15 bpm) were not useful in predicting adverse neonatal outcomes, but there was no evidence identified in relation to other sinusoidal patterns and fetal/neonatal outcomes. The Committee decided that a sinusoidal pattern should be considered as an example of abnormal baseline variability. The Committee’s view was that a sinusoidal pattern represents a sign of fetal anaemia or hypoxia and, therefore, an abnormal feature that needs immediate consideration.

Early decelerations

Amongst low/mixed-risk populations, there was some evidence that early decelerations were not useful in predicting adverse neonatal outcomes, although specificity was high. Findings in relation to the association between early decelerations and adverse neonatal outcomes were mixed. Amongst high-risk populations, there was some evidence that early decelerations were not useful in predicting umbilical cord pH < 7.20 in prolonged pregnancies. Based on their clinical expertise and experience, the Committee decided that no decelerations at all, or early decelerations (defined as a fall in baseline rate coinciding in timing with a uterine contraction), should be regarded as a reassuring feature.

Variable and late decelerations

The 2014 guideline recommended that decelerations be described as 'early', 'variable' or 'late', and that the terms 'typical' and 'atypical' should not be used because they could cause confusion. The 2017 Committee agreed with this and retained the recommendation from CG190.

Amongst low/mixed-risk populations, the evidence included in the guideline review showed that variable decelerations were mostly not useful in predicting adverse neonatal outcomes. Findings related to the association between variable decelerations and adverse neonatal outcomes were mixed. Amongst high-risk populations, there was some evidence that variable decelerations were not useful in predicting umbilical cord pH < 7.20 in prolonged pregnancies.

The 2017 Committee introduced a distinction between variable decelerations with concerning characteristics and those without such characteristics. The Committee chose this distinction as opposed to the 2007 (CG55) distinction between ‘typical’ and ‘atypical’ decelerations because there had been lack of clarity and confusion in clinical practice over the meaning of these terms. Therefore, the 2017 Committee chose to focus attention on the specific characteristics of variable decelerations that determined whether their presence would be classified as reassuring, non-reassuring or abnormal. The Committee agreed what would constitute concerning characteristics based on their clinical expertise and experience. It was agreed that the risk of fetal acidosis would be greater when the time to recovery of the variable deceleration was greater and when variable decelerations were present for longer. The Committee discussed whether it would be useful to have 2 thresholds to distinguish severe variable decelerations from the less severe; namely 60 bpm for the depth and 60 seconds for the duration, as in CG190. However, the Committee emphasised the importance of the guideline making the interpretation of CTG traces as straightforward as possible. The Committee discussed that depth of the deceleration is not important because a non-reassuring deceleration can be shallow too and it was, therefore, agreed that the depth of the deceleration would not be referred to in the recommendations. With regard to time to recovery, the Committee believed that the distinction made in CG190 between variable decelerations ‘taking 60 seconds or less to recover’ and ‘taking over 60 seconds to recover’

was too complex to implement when interpreting the CTG trace and that this previous distinction was not implemented in practice. For example, there was confusion amongst clinicians about whether the time to recovery should be calculated from baseline or from nadir. Instead, the 2017 Committee decided to use the phrase 'failure to return to baseline' that seemed more practical and intuitive for defining a concerning characteristic of a variable decelerations. Moreover, the Committee concluded that a duration longer than 60 seconds would constitute a concerning characteristic of a variable deceleration because it means that the deceleration lasts longer than a contraction (a contraction usually lasts about 60 seconds). The Committee discussed whether to include a gradual return to baseline among the concerning characteristics, however concluded that this would be covered under variable decelerations lasting longer than 60 seconds. Based on their experience, the Committee also agreed that a biphasic shape or reduced variability within the decelerations should be regarded as concerning characteristics of variable decelerations. Moreover, 'shouldering' is a useful reassuring trace feature to avoid unnecessary intervention, and the absence of shouldering should be regarded as concerning characteristic in the presence of variable decelerations. The Committee considered the possibility of confusing shouldering with a true acceleration, but felt that healthcare professionals should be able to distinguish between the two.

Amongst low/mixed-risk populations, there was evidence that late decelerations were not useful in predicting adverse neonatal outcomes, although some outcomes showed moderate to high specificity. Findings in relation to the association between late decelerations and adverse neonatal outcomes were mixed. Amongst high-risk populations, there was some evidence that late decelerations were not useful in predicting umbilical cord pH < 7.20 in prolonged pregnancies. Based on their clinical expertise and experience, the Committee decided that late decelerations are an abnormal feature of the CTG trace.

The Committee felt that there should be an upper limit for the duration of variable or late decelerations that would prompt intervention. Although there was very limited evidence about the relationship between the duration, or number, of variable or late decelerations with adverse outcomes, the Committee was aware that in practice many interventions occur unnecessarily early, perhaps after only 2 or 3 decelerations. The Committee reasoned that the longer the duration of late decelerations, the greater the risk of fetal acidosis, although there was no evidence to directly support this view. The Committee decided that variable decelerations without any concerning characteristics for 90 minutes should be considered non-reassuring. A consensus recommendation was made to use 90 minutes as the cut-off based on the Committee's clinical expertise and experience and in the light of a lack of evidence of need for an earlier intervention. The Committee decided that variable decelerations with concerning characteristics should be considered abnormal if these features occurred for 30 minutes in over 50% of contractions, or in less than 50% of contractions for more than 30 minutes. These thresholds (30 minutes and 50% of contractions) were based on the Committee's clinical expertise and experience, as it was felt important that such decelerations should be regarded as significant only if they occurred with the majority of contractions or for a considerable amount of time These thresholds were also aligned with the cut-off points for late or prolonged decelerations in the FIGO consensus guidelines on intrapartum fetal monitoring using cardiotocography (Ayres-de-Campos 2015). Moreover, late decelerations should be considered abnormal if these features occur for 30 minutes. By definition, late decelerations occur in over 50% of contractions and so there was no need to mention this frequency (percentage) in the recommendations.

Prolonged decelerations

There was some evidence included in the guideline review that prolonged decelerations in the last 30 minutes before birth are associated with adverse neonatal outcomes. The

Committee noted that a prolonged deceleration would be distinguishable from an acute bradycardia only if recovery occurred. In practice, irrespective of the terminology, a persistent fall in the fetal heart rate would inevitably be associated with fetal hypoxia and acidosis. The Committee chose 3 minutes as the upper limit of duration of a prolonged deceleration at which action should be taken. This took into consideration the Committee's expert opinion that a fetus can possibly withstand up to 10 minutes of absolute hypoxia without sustaining irreversible neurodevelopmental injury.

Accelerations

Amongst low/mixed-risk populations, a lack of fetal heart rate accelerations was not useful in predicting adverse neonatal outcomes, although in 1 study the presence of accelerations was moderately useful in ruling out neonatal mortality. There was also some evidence that the presence of accelerations reduced the likelihood of adverse neonatal outcomes. There was limited evidence showing that a reactive trace was not associated with or useful in predicting adverse neonatal outcomes. There was no evidence on accelerations amongst high-risk populations. Based on the evidence and on their clinical expertise and experience, the Committee decided that the presence of fetal heart rate accelerations was generally a sign that the unborn baby would be healthy, although the absence of accelerations in an otherwise normal CTG trace would not indicate fetal acidosis.

Combinations of features and categorisation/classification of fetal heart rate traces

Amongst low/mixed-risk populations, findings were mixed with regards to the usefulness of combinations of trace features in predicting adverse neonatal outcomes. Moreover, the evidence included in the guideline review showed that fetal heart rate patterns (as defined by categorisation systems of fetal heart rate traces) were mostly not useful in predicting adverse neonatal outcomes amongst low-risk or mixed populations, although some studies found some useful (see definition in Section 1.10.7 of the CG190 full guideline) positive or negative likelihood ratios. Amongst high-risk populations, there was some evidence that an indeterminate fetal heart rate pattern (NICHD classification 2008) was mostly not useful in predicting adverse neonatal outcomes. Findings were mixed with regard to the usefulness of the absence of an indeterminate pattern in predicting the absence of adverse neonatal outcomes. Moreover, there was evidence that an abnormal fetal heart rate pattern (NICHD classification 2008) was mostly moderately useful in predicting adverse neonatal outcomes amongst high-risk populations. There was also evidence that the absence of an abnormal pattern was mostly very useful in predicting the absence of adverse neonatal outcomes. In light of the evidence and their clinical expertise and experience, the Committee agreed that considering all 4 features of the fetal heart rate would provide a more comprehensive picture than any single feature considered alone. The Committee recommended, therefore, that all 4 features of the fetal heart rate should be assessed to predict fetal health.

4.3.7.6 Key conclusions

The best available evidence to guide interpretation of CTG traces is limited for the following reasons.

- The adverse outcomes of greatest interest are rare, especially in low- or moderate-risk populations.
- One principle of the use of CTG in practice is for it to be used for monitoring fetuses in high-risk pregnancies. However, only a minority of the studies identified in the guideline review involved women with high-risk pregnancies. The predictive values of baseline fetal heart rate, baseline variability and accelerations were assessed only in low/mixed-risk

populations. Moreover, evidence on the predictive value of decelerations amongst high-risk populations was limited to a study on prolonged pregnancies.

- There is a 'treatment paradox' that intervention will have occurred before the clinically significant adverse outcome arises – this is the very aim of intrapartum fetal surveillance. The effect might be offset, however, by the assertion that without proper testing, beneficial outcomes associated with an intervention might be wrongly attributed to it and any harm it is causing may go unnoticed.
- The fetal heart rate is not a good surrogate for hypoxia and acidosis – it can be affected by a number of other factors and may be unaffected with some types of hypoxia.
- Looking at the CTG trace in isolation is too simplistic and does not take account of the whole clinical picture.

Despite these serious limitations, the Committee felt that, on balance, the potential benefits of continuous CTG probably outweighed the risks and limitations and that the use of continuous CTG in high-risk labours should be recommended in the absence of a more effective alternative.

The 2017 Committee endorsed the 2014 Committee's reasoning below in terms of making recommendations for the interpretation of CTGs.

- In certain pregnancies there is an increased risk of intrapartum fetal acidosis ('high-risk' or 'at risk' labours; see CG190 Section 3.4, 'Assessment for choosing place of birth').
- The fetal heart rate is the only parameter by which the fetal condition can be continuously assessed and monitored. The role of fetal electrocardiogram (ECG) monitoring has been evaluated and it was not recommended for use in practice (see Section 4.8).
- There is some evidence that the likelihood of adverse outcome from intrapartum fetal acidosis is greater with certain abnormal features of CTG, although the risk of false positives is high when many features are considered.
- Given that abnormalities of fetal heart rate are not only due to fetal hypoxia, various conservative actions are recommended in the first instance which will ameliorate some of the non-hypoxic and hypoxic factors (see CG190, Section 11.7, 'Intrauterine resuscitation').
- Fetal blood sampling is the only single assessment which directly assesses whether an observed fetal heart rate abnormality is due to hypoxia severe enough to cause acidosis. This form of testing is discussed in Section 4.6. The value of fetal stimulation as an adjunctive test of fetal health in labour is discussed in Section 4.5.

The recommendations arising from the review question about management of labour based on CTG findings are also presented in this section. See Section 4.4 for the evidence to recommendations section for these recommendations.

4.3.8 Recommendations

15. Use recommendation tables 1 and 2 to define and interpret cardiotocograph traces and to guide the management of labour for women who are having continuous cardiotocography. These tables include and summarise individual recommendations about fetal monitoring (16 to 40), fetal scalp stimulation (42 to 43), fetal blood sampling (44 to 59) and intrauterine resuscitation (41, and 1.10.37 in the NICE guideline) in this guideline. [2017]

Recommendation table 1. Description of cardiotocograph trace features

Overall care

- Make a documented systematic assessment of the condition of the woman and unborn baby (including cardiotocography [CTG] findings) every hour, or more frequently if there are concerns.
- Do not make any decision about a woman's care in labour on the basis of CTG findings alone.
- Take into account the woman's preferences, any antenatal and intrapartum risk factors, the current wellbeing of the woman and unborn baby and the progress of labour.
- Ensure that the focus of care remains on the woman rather than the CTG trace.
- Remain with the woman in order to continue providing one-to-one support.

  Talk to the woman and her birth companion(s) about what is happening and take her preferences into account.

Principles for intrapartum CTG trace interpretation

- When reviewing the CTG trace, assess and document contractions and all 4 features of fetal heart rate: baseline rate; baseline variability; presence or absence of decelerations (and concerning characteristics of variable decelerations* if present); presence of accelerations.
- If there is a stable baseline fetal heart rate between 110 and 160 beats/minute and normal variability, continue usual care as the risk of fetal acidosis is low.
- If it is difficult to categorise or interpret a CTG trace, obtain a review by a senior midwife or a senior obstetrician.

Accelerations

- The presence of fetal heart rate accelerations, even with reduced baseline variability, is generally a sign that the baby is healthy.

Description	Feature		
	Baseline (beats/ minute)	**Baseline variability (beats/minute)**	**Decelerations**
Reassuring	110 to 160	5 to 25	None or early Variable decelerations with no concerning characteristics* for less than 90 minutes
Non-reassuring	100 to 109† OR 161 to 180	Less than 5 for 30 to 50 minutes OR More than 25 for 15 to 25 minutes	Variable decelerations with no concerning characteristics* for 90 minutes or more OR Variable decelerations with any concerning characteristics* in up to 50% of contractions for 30 minutes or more OR Variable decelerations with any concerning characteristics* in over 50% of contractions for less than 30 minutes OR Late decelerations in over 50% of contractions for less than 30 minutes, with no maternal or fetal clinical risk factors such as vaginal

			bleeding or significant meconium
Abnormal	Below 100 OR Above 180	Less than 5 for more than 50 minutes OR More than 25 for more than 25 minutes OR Sinusoidal	Variable decelerations with any concerning characteristics* in over 50% of contractions for 30 minutes (or less if any maternal or fetal clinical risk factors [see above]) OR Late decelerations for 30 minutes (or less if any maternal or fetal clinical risk factors) OR Acute bradycardia, or a single prolonged deceleration lasting 3 minutes or more

Abbreviation: CTG, cardiotocography.

* Regard the following as concerning characteristics of variable decelerations: lasting more than 60 seconds; reduced baseline variability within the deceleration; failure to return to baseline; biphasic (W) shape; no shouldering.

† Although a baseline fetal heart rate between 100 and 109 beats/minute is a non-reassuring feature, continue usual care if there is normal baseline variability and no variable or late decelerations.

Recommendation table 2. Management based on interpretation of cardiotocograph traces

Category	Definition	Management
Normal	All features are reassuring	• Continue CTG (unless it was started because of concerns arising from intermittent auscultation and there are no ongoing risk factors; see recommendation 14) and usual care • Talk to the woman and her birth companion(s) about what is happening
Suspicious	1 non-reassuring feature AND 2 reassuring features	• Correct any underlying causes, such as hypotension or uterine hyperstimulation • Perform a full set of maternal observations • Start 1 or more conservative measures* • Inform an obstetrician **or** a senior midwife • Document a plan for reviewing the whole clinical picture and the CTG findings • Talk to the woman and her birth companion(s) about what is happening and take her preferences into account
Pathological	1 abnormal feature OR 2 non-reassuring features	• Obtain a review by an obstetrician **and** a senior midwife • Exclude acute events (for example, cord prolapse, suspected placental abruption or suspected uterine rupture) • Correct any underlying causes, such as hypotension or uterine hyperstimulation

Category	Definition	Management

		• Start 1 or more conservative measures*
		• Talk to the woman and her birth companion(s) about what is happening and take her preferences into account
		• If the cardiotocograph trace is still pathological after implementing conservative measures:
		  ○ obtain a further review by an obstetrician **and** a senior midwife
		  ○ offer digital fetal scalp stimulation (see recommendation 42) and document the outcome
		• If the cardiotocograph trace is still pathological after fetal scalp stimulation:
		  ○ consider fetal blood sampling
		  ○ consider expediting the birth
		  ○ take the woman's preferences into account

Need for urgent intervention	Acute bradycardia, or a single prolonged deceleration for 3 minutes or more	• Urgently seek obstetric help • If there has been an acute event (for example, cord prolapse, suspected placental abruption or suspected uterine rupture), expedite the birth • Correct any underlying causes, such as hypotension or uterine hyperstimulation • Start 1 or more conservative measures* • Make preparations for an urgent birth • Talk to the woman and her birth companion(s) about what is happening and take her preferences into account • Expedite the birth if the acute bradycardia persists for 9 minutes • If the fetal heart rate recovers at any time up to 9 minutes, reassess any decision to expedite the birth, in discussion with the woman

Abbreviation: CTG, cardiotocography.

* If there are any concerns about the baby's wellbeing, be aware of the possible underlying causes and start one or more of the following conservative measures based on an assessment of the most likely cause(s): encourage the woman to mobilise or adopt an alternative position (and to avoid being supine); offer intravenous fluids if the woman is hypotensive; reduce contraction frequency by reducing or stopping oxytocin if it is being used and/or offering a tocolytic drug (a suggested regimen is subcutaneous terbutaline 0.25 mg).

16. When a woman is having continuous cardiotocography:

- **ensure that the focus of care remains on the woman rather than the cardiotocograph trace**
- **remain with the woman in order to continue providing one-to-one support**
- **encourage and help the woman to be as mobile as possible and to change position as often as she wishes**
- **monitor the condition of the woman and the baby, and take prompt action if required**
- **differentiate between the maternal and fetal heartbeats hourly, or more often if there are any concerns**

- **ensure that the cardiotocograph trace is of high quality, and think about other options if this is not the case**
- **if it is difficult to categorise or interpret a cardiotocograph trace, obtain a review by a senior midwife or a senior obstetrician. [2017]**

17. **When reviewing the cardiotocograph trace, assess and document contractions and all 4 features of fetal heart rate:**
    - **baseline rate**
    - **baseline variability**
    - **presence or absence of decelerations, and concerning characteristics of variable decelerations if present (see recommendation 27)**
    - **presence of accelerations. [2017]**

18. **Do not make any decision about a woman's care in labour on the basis of cardiotocography findings alone, but also take into account:**
    - **her preferences**
    - **her report of how she is feeling**
    - **her report of the baby's movements**
    - **assessment of her wellbeing and behaviour**
    - **maternal observations, including temperature, blood pressure and pulse**
    - **whether there is meconium or blood in the amniotic fluid**
    - **any signs of vaginal bleeding**
    - **any medication she is taking**
    - **the frequency of contractions**
    - **the stage and progress of labour**
    - **her parity**
    - **the fetal response to digital scalp stimulation if performed (see recommendations 42 and 43)**
    - **the results of fetal blood sampling if undertaken (see recommendation 52). [2017]**

19. **Supplement ongoing care with a documented systematic assessment of the condition of the woman and unborn baby (including any cardiotocography findings) every hour. If there are concerns about cardiotocography findings, undertake this assessment more frequently. [2017]**

20. **Use the following categorisations for baseline fetal heart rate:**
    - **reassuring:**
        - **110 to 160 beats/minute**
    - **non-reassuring:**
        - **100 to 109 beats/minute (but see recommendation 21)**
        - **161 to 180 beats/minute**
    - **abnormal:**

  - **below 100 beats/minute**
  - **above 180 beats/minute. [2017]**

21. **Take the following into account when assessing baseline fetal heart rate:**
    - **differentiate between fetal and maternal heartbeats**
    - **baseline fetal heart rate will usually be between 110 and 160 beats/minute**
    - **although a baseline fetal heart rate between 100 and 109 beats/minute is a non-reassuring feature, continue usual care if there is normal baseline variability and no variable or late decelerations. [2017]**

22. **Use the following categorisations for fetal heart rate baseline variability:**
    - **reassuring:**
      - **5 to 25 beats/minute**
    - **non-reassuring:**
      - **less than 5 beats/minute for 30 to 50 minutes**
      - **more than 25 beats/minute for 15 to 25 minutes**
    - **abnormal:**
      - **less than 5 beats/minute for more than 50 minutes**
      - **more than 25 beats/minute for more than 25 minutes**
      - **sinusoidal. [2017]**

23. **Take the following into account when assessing fetal heart rate baseline variability:**
    - **baseline variability will usually be between 5 and 25 beats/minute**
    - **intermittent periods of reduced baseline variability are normal, especially during periods of quiescence ('sleep'). [2017]**

24. **When describing decelerations in fetal heart rate, specify:**
    - **their timing in relation to the peaks of the contractions**
    - **the duration of the individual decelerations**
    - **whether or not the fetal heart rate returns to baseline**
    - **how long they have been present for**
    - **whether they occur with over 50% of contractions**
    - **the presence or absence of a biphasic (W) shape**
    - **the presence or absence of shouldering**
    - **the presence or absence of reduced variability within the deceleration. [2017]**

25. **Describe decelerations as 'early', 'variable' or 'late'. Do not use the terms 'typical' and 'atypical' because they can cause confusion. [2017]**

26. **Use the following categorisations for decelerations in fetal heart rate:**
    - **reassuring:**

    - **no decelerations**
    - **early decelerations**
    - **variable decelerations with no concerning characteristics (see recommendation 27) for less than 90 minutes**
  - **non-reassuring:**
    - **variable decelerations with no concerning characteristics for 90 minutes or more**
    - **variable decelerations with any concerning characteristics in up to 50% of contractions for 30 minutes or more**
    - **variable decelerations with any concerning characteristics in over 50% of contractions for less than 30 minutes**
    - **late decelerations in over 50% of contractions for less than 30 minutes, with no maternal or fetal clinical risk factors such as vaginal bleeding or significant meconium**
  - **abnormal:**
    - **variable decelerations with any concerning characteristics in over 50% of contractions for 30 minutes (or less if there are any maternal or fetal clinical risk factors)**
    - **late decelerations for 30 minutes (or less if there are any maternal or fetal clinical risk factors)**
    - **acute bradycardia, or a single prolonged deceleration lasting 3 minutes or more. [2017]**

27. **Regard the following as concerning characteristics of variable decelerations:**
    - **lasting more than 60 seconds**
    - **reduced baseline variability within the deceleration**
    - **failure to return to baseline**
    - **biphasic (W) shape**
    - **no shouldering. [2017]**

28. **If variable decelerations with no concerning characteristics (see recommendation 27) are observed:**
    - **be aware that these are very common, can be a normal feature in an otherwise uncomplicated labour and birth, and are usually a result of cord compression**
    - **ask the woman to change position or mobilise. [2017]**

29. **Take the following into account when assessing decelerations in fetal heart rate:**
    - **early decelerations are uncommon, benign and usually associated with head compression**
    - **early decelerations with no non-reassuring or abnormal features on the cardiotocograph trace should not prompt further action. [2017]**

30. **Take into account that the longer and later the individual decelerations, the higher the risk of fetal acidosis (particularly if the decelerations are accompanied by tachycardia or reduced baseline variability). [2017]**

31. **Take the following into account when assessing accelerations in fetal heart rate:**
    - **the presence of fetal heart rate accelerations, even with reduced baseline variability, is generally a sign that the baby is healthy**
    - **the absence of accelerations on an otherwise normal cardiotocograph trace (see recommendation table 2) does not indicate fetal acidosis. [2017]**

32. **Categorise cardiotocography traces as follows:**
    - **normal: all features are reassuring (see recommendation table 1)**
    - **suspicious: 1 non-reassuring feature and 2 reassuring features (but note that if accelerations are present, fetal acidosis is unlikely)**
    - **pathological:**
        - **1 abnormal feature or**
        - **2 non-reassuring features. [2017]**

33. **If there is a stable baseline fetal heart rate between 110 and 160 beats/minute and normal variability, continue usual care as the risk of fetal acidosis is low. [2017]**

34. **If there is an acute bradycardia, or a single prolonged deceleration for 3 minutes or more:**
    - **urgently seek obstetric help**
    - **if there has been an acute event (for example, cord prolapse, suspected placental abruption or suspected uterine rupture), expedite the birth (see recommendations 1.13.34 to 1.13.37 in the NICE guideline)**
    - **correct any underlying causes, such as hypotension or uterine hyperstimulation**
    - **start one or more conservative measures (see recommendation 39)**
    - **make preparations for an urgent birth**
    - **talk to the woman and her birth companion(s) about what is happening and take her preferences into account**
    - **expedite the birth if the acute bradycardia persists for 9 minutes.**

    If the fetal heart rate recovers at any time up to 9 minutes, reassess any decision to expedite the birth, in discussion with the woman. [2017]

35. **If the cardiotocograph trace is categorised as pathological (see recommendation 32):**
    - **obtain a review by an obstetrician and a senior midwife**
    - **exclude acute events (for example, cord prolapse, suspected placental abruption or suspected uterine rupture)**
    - **correct any underlying causes, such as hypotension or uterine hyperstimulation**
    - **start one or more conservative measures (see recommendation 39)**
    - **talk to the woman and her birth companion(s) about what is happening and take her preferences into account. [2017]**

36. **If the cardiotocograph trace is still pathological after implementing conservative measures:**
    - **obtain a further review by an obstetrician and a senior midwife**
    - **offer digital fetal scalp stimulation (see recommendation 42) and document the outcome.**

    If the cardiotocograph trace is still pathological after fetal scalp stimulation, consider:
    - **fetal blood sampling (see recommendations 44 to 59)**
      or
    - **expediting the birth (see recommendations 1.13.34 to 1.13.37 in the NICE guideline).**

    Take the woman's preferences into account. [2017]

37. **If the cardiotocograph trace is categorised as suspicious (see recommendation 32):**
    - **correct any underlying causes, such as hypotension or uterine hyperstimulation**
    - **perform a full set of maternal observations**
    - **start one or more conservative measures (see recommendation 39)**
    - **inform an obstetrician or a senior midwife**
    - **document a plan for reviewing the whole clinical picture and the cardiotocography findings**
    - **talk to the woman and her birth companion(s) about what is happening and take her preferences into account. [2017]**

38. **If the cardiotocograph trace is categorised as normal (see recommendation 32):**
    - **continue cardiotocography (unless it was started because of concerns arising from intermittent auscultation and there are no ongoing risk factors; see recommendation 14) and usual care**
    - **talk to the woman and her birth companion(s) about what is happening. [2017]**

39. **If there are any concerns about the baby's wellbeing, be aware of the possible underlying causes and start one or more of the following conservative measures based on an assessment of the most likely cause(s):**
    - **encourage the woman to mobilise or adopt an alternative position (and to avoid being supine)**
    - **offer intravenous fluids if the woman is hypotensive**
    - **reduce contraction frequency by:**
      - **reducing or stopping oxytocin if it is being used and/or**
      - **offering a tocolytic drug (a suggested regimen is subcutaneous terbutaline 0.25 mg). [2017]**

40. **Inform a senior midwife or an obstetrician whenever conservative measures are implemented. [2017]**

41. **Do not use maternal facial oxygen therapy for intrauterine fetal resuscitation, because it may harm the baby (but it can be used where it is administered for maternal indications such as hypoxia or as part of preoxygenation before a potential anaesthetic). [2014]**

4.4 Management of labour based on cardiotocograph findings

4.4.1 Review question

How should care in labour be modified as a result of cardiotocograph findings?

4.4.2 Description of included studies

Three studies were included in this review (Clark 2015; Katsuragi 2015; Lowe 2016).

One study was from the United States (Clark 2015), 1 from Japan (Katsuragi 2015), and 1 from Australia (Lowe 2016).

In the first study (Clark 2015), the population consisted of women with term, singleton pregnancies undergoing induction of labour. In the second study (Katsuragi 2015), the population consisted of women with mainly low-risk pregnancies, excluding women with planned caesarean sections. In the remaining study (Lowe 2016), the population consisted of women with term, singleton pregnancies, excluding fetal death in utero and known congenital abnormality, who had continuous cardiotocography (CTG) in labour.

The first study (Clark 2015) examined the effect of reducing or stopping oxytocin in the presence of abnormal fetal heart rate tracing on primary caesarean section and neonatal intensive care unit (NICU) admission. The second study (Katsuragi 2015) examined the effect of introducing training related to a 5-tier, colour-coded fetal heart rate management system in a single centre on cord artery pH and base excess levels. The final study (Lowe 2016) examined the effect of introducing a consultant obstetrician review of every abnormal CTG tracing prior to making a decision about performing fetal scalp lactate testing on mode of birth, umbilical artery gas levels, fetal scalp lactate level and admission to neonatal nursery.

4.4.3 Evidence profile

Table 46: Summary GRADE profile for comparison of reducing or stopping oxytocin and not reducing or stopping oxytocin in the presence of an abnormal fetal heart rate tracing

Quality assessment		Number of women or babies		Effect		
Number of studies	Design	Reducing or stopping oxytocin	Not reducing or stopping oxytocin	Relative (95% CI)	Absolute (95% CI) and p-value (if reported)	Quality
Neonatal intensive care unit admission						
1 study (Clark 2015)	Prospective nonrandomised comparative study	91/2364 (3.8%)	276/5272 (5.2%)	RR 0.74 (0.58 to 0.93)	14 fewer per 1000 (from 4 fewer to 22 fewer)	Very low
Primary caesarean section						
1 study (Clark 2015)	Prospective nonrandomised comparative study	630/2364 (26.6%)	923/5272 (17.5%)	RR 1.52 (1.39 to 1.66)	91 more per 1000 (from 68 more to 116 more)	Very low

CI confidence interval, RR relative risk

Table 47: Summary GRADE profile for comparison of outcomes before and after introduction of a 5-tier colour-coded fetal heart rate management system

Quality assessment		Number of women or babies		Effect		
Number of studies	Design	After introduction of 5-tier colour-coded FHR management system	Before introduction of 5-tier colour-coded FHR management system	Relative (95% CI)	Absolute (95% CI) and p-value (if reported)	Quality
Cord artery pH < 7.15						
1 study (Katsuragi 2015)	Comparative observational study	2/744 (0.27%)	11/688 (1.6%)	RR 0.17 (0.04 to 0.76)	13 fewer per 1000 (from 4 fewer to 15 fewer)	Very low

Quality assessment		Number of women or babies		Effect		
Number of studies	Design	After introduction of 5-tier colour-coded FHR management system	Before introduction of 5-tier colour-coded FHR management system	Relative (95% CI)	Absolute (95% CI) and p-value (if reported)	Quality
Cord artery BE < - 2 mmol/l						
1 study (Katsuragi 2015)	Comparative observational study	2/744 (0.27%)	11/688 (1.6%)	RR 0.17 (0.04 to 0.76)	13 fewer per 1000 (from 4 fewer to 15 fewer)	Very low

BE base excess; CI confidence interval; FHR fetal heart rate; RR relative risk

Table 48: Summary GRADE profile for comparison of outcomes before and after introduction of consult-led (obstetric) review of abnormal cardiotocograph traces prior to decision to measure fetal scalp lactate

Quality assessment		Number of women or babies		Effect		
Number of studies	Design	Consultant-led	No consultant	Relative (95% CI)	Absolute (95% CI) and p-value (if reported)	Quality
Emergency caesarean section (any)						
1 study (Lowe 2016)	Retrospective cohort study	547/2487 (22%)	537/2225 (24.1%)	RR 0.93 (0.84 to 1.03)	17 fewer per 1000 (from 39 fewer to 7 more)	Very low
Emergency caesarean section (for fetal distress)						
1 study (Lowe 2016)	Retrospective cohort study	165/2487 (6.6%)	181/2225 (8.1%)	RR 0.82 (0.67 to 1)	15 fewer per 1000 (from 27 fewer to 0 more)	Very low
Emergency caesarean section (for failure to progress)						
1 study (Lowe 2016)	Retrospective cohort study	253/2487 (10.2%)	230/2225 (10.3%)	RR 0.98 (0.83 to 1.17)	2 fewer per 1000 (from 18 fewer to 18 more)	Very low
Emergency caesarean section (for reasons other than fetal distress or failure to progress)						
1 study (Lowe 2016)	Retrospective cohort study	141/2487 (5.7%)	126/2225 (5.7%)	RR 1 (0.79 to 1.26)	0 fewer per 1000 (from 12 fewer to 15 more)	Very low
Instumental birth						

Quality assessment		Number of women or babies		Effect		
Number of studies	**Design**	**Consultant-led**	**No consultant**	**Relative (95% CI)**	**Absolute (95% CI) and p-value (if reported)**	**Quality**
1 study (Lowe 2016)	Retrospective cohort study	439/2487 (17.7%)	445/2225 (20%)	RR 0.88 (0.78 to 0.99)	24 fewer per 1000 (from 2 fewer to 44 fewer)	Very low
Normal vaginal birth						
1 study (Lowe 2016)	Retrospective cohort study	1460/2487 (58.7%)	1231/2225 (55.3%)	RR 1.06 (1.01 to 1.12)	33 more per 1000 (from 6 more to 66 more)	Very low
Cord pH < 7.1						
1 study (Lowe 2016)	Retrospective cohort study	20/2487 (0.8%)	49/2225 (2.2%)	RR 0.37 (0.22 to 0.61)	14 fewer per 1000 (from 9 fewer to 17 fewer)	Very low
Fetal scalp lactate > 4.8 mmol/l						
1 study (Lowe 2016)	Retrospective cohort study	36/2487 (1.4%)	56/2225 (2.5%)	RR 0.58 (0.38 to 0.87)	11 fewer per 1000 (from 3 fewer to 16 fewer)	Very low
Admission to neonatal nursery						
1 study (Lowe 2016)	Retrospective cohort study	106/2487 (4.3%)	98/2225 (4.4%)	RR 0.97 (0.74 to 1.27)	1 fewer per 1000 (from 11 fewer to 12 more)	Very low
Fetal blood sampling performed						
1 study (Lowe 2016)	Retrospective cohort study	43/2487 (1.7%)	79/2225 (3.6%)	RR 0.49 (0.34 to 0.7)	18 fewer per 1000 (from 11 fewer to 23 fewer)	Very low

4.4.4 Evidence statements

One study (n=7363) among women with singleton, term pregnancies who had an induced labour showed a clinically significant lower risk of neonatal intensive care unit (NICU) admission when oxytocin infusion was reduced or stopped because of an abnormal fetal heart rate (FHR) tracing compared to not stopping or reducing oxytocin. The same study showed a clinically significant higher risk of primary caesarean section when oxytocin infusion was reduced or stopped because of an abnormal FHR tracing compared to not stopping or reducing the oxytocin. The evidence for these findings was of very low quality.

One study (n=1432) among women with mainly low risk pregnancies (excluding planned caesarean sections) showed a clinically significant decreased risk of cord artery pH <7.15 and cord artery base excess less than -12 mmol/l after a 5-tier, colour-coded FHR management system was adopted in the study facility. The evidence for this finding was of very low quality.

One study (n=4712) among women with singleton, term pregnancies (excluding fetal death in utero and congenital abnormality) showed no difference in overall emergency caesarean section rates, emergency caesarean section due to fetal distress, emergency caesarean section due to failure to progress, emergency caesarean section due to other reasons or admission to neonatal nursery after a new policy was introduced where a consultant obstetrician reviewed all abnormal CTG tracings prior to decision making of whether or not to perform fetal scalp lactate measurement (Lowe 2016). The same study found no clinically significant difference in rates of instrumental birth or normal vaginal birth after the policy was introduced. The study also showed a clinically significant lowered risk of fetal scalp lactate more than 4.8 mmol/l, a clinically significant lower risk of cord pH less than 7.1 and a clinically significant lowered risk of performing fetal blood sampling. The evidence for these findings was of very low quality.

4.4.5 Health economics profile

No published economic evaluations were identified for this review question.

4.4.6 Evidence to recommendations

4.4.6.1 Relative value placed on the outcomes considered

The aim of this review was to assess how care in labour should be modified according to CTG trace findings. The Guideline Committee considered the safety of the baby and the woman, and woman's satisfaction with and experience of labour and birth to be the most important outcomes for consideration.

4.4.6.2 Consideration of clinical benefits and harms

Limited evidence was identified for this review to inform decision making (despite the literature search being performed with no restriction on date of publication of articles for consideration), therefore, the recommendations on how management of labour should be modified according to CTG trace findings were derived mostly from the collective experience and knowledge of the Guideline Committee while taking account of the 2014 (CG190) recommendations that had been quite detailed in the specification of these aspects of care.

The Committee felt that it was important that the recommendations: ensured consistency and safety of care; enhanced women's experiences; and prevented unnecessary interventions. The Committee agreed that the recommendations needed to be clear and easily understood in order to standardise care and ensure safety. At the same time, the Committee

acknowledged that each woman's labour and any associated clinical situations are unique and that no guideline could consider all possible scenarios. The agreed intention was, therefore, that the recommendations should not be too prescriptive.

The Committee felt that the 2014 (CG190) recommendations, including the accompanying tabular presentation, should be simplified and made less wordy. Rather than focusing on individual CTG features, the Committee discussed that it is more important to focus on the overall categorisation of the CTG trace in order to encourage clinicians to evaluate the CTG findings as a whole. At the same time, the Committee sought to emphasise in the recommendations the importance of assessing the whole clinical picture, of which the CTG trace and findings form but a part, and so this concept was included in several recommendations. An acute bradycardia, or a single prolonged deceleration lasting 3 minutes or more, indicating fetal hypoxia, was considered an exception as in this case immediate action is required regardless of the whole clinical picture.

The Committee agreed that CTG traces should be categorised as 'normal', 'suspicious' or 'pathological' and that each category should be accompanied by recommended actions for clinical care. The Committee agreed that when a CTG trace is suspicious or pathological, the potential underlying cause could, for example, be hypotension or hyperstimulation. The phrase 'such as infection' that had been included in the 2014 (CG190) recommendation about being aware of underlying causes was removed. For the same reason, in addition to measuring maternal temperature and pulse it is important to measure maternal respiratory rate and blood pressure, and so the recommendation was amended to specify that a full set of maternal observations should be performed.

The Committee agreed that having a summary table that captured the main messages of the recommendations could be helpful in clinical practice and therefore the tabular presentation was retained and refined. In particular, the Committee felt that the table needed to be simplified while the recommendations that underpinned it would provide further details.

The Committee recognised the importance of keeping the woman (and her birth companion(s)) continuously informed about the situation and therefore added to several recommendations a phrase about talking to the woman (and her birth companion(s)) about what is happening and taking her preferences into account.

The Committee revised the content of recommendations about conservative measures. For example, it was agreed that mobilisation is very important and rather than recommending changing position only to the left-lateral position, changing to any position (other than supine) in which the woman feels comfortable should be encouraged. The Committee recognised that most units have technology for electronic fetal monitoring that allows the woman to mobilise to some extent (CTG with telemetry). The Committee clarified that intravenous fluids should be offered if the woman is hypotensive. The Committee did not include a reference to offering oral fluids among the conservative measures because oral fluids are part of routine care and should already be in use. The Committee considered that reducing oxytocin, as an alternative to stopping its administration completely, should be part of the measures to reduce the frequency of uterine contractions. Also, the Committee concluded that a decision to restart oxytocin could be taken by a senior member of staff other than a consultant obstetrician and the recommendation was amended accordingly. The Committee agreed that it would not always be necessary to inform both a senior midwife and an obstetrician when conservative measures were to be taken up, therefore, the Committee changed the recommendation to state that a senior midwife or an obstetrician should be informed.

4.4.6.3 Consideration of health benefits and resource use

The Committee considered that there would be a high cost associated with a serious adverse outcome for the baby if an increased risk of fetal hypoxia/acidosis was either not recognised or not accompanied by an intervention to mitigate the risk. Conversely, too low a threshold

for intervention to mitigate the risks associated with fetal hypoxia/acidosis could result in unnecessary intervention that would incur avoidable costs. However, none of the interventions recommended by the Committee represented a change from current NHS practice and so no detailed economic analysis was undertaken. As noted above, the 2014 (CG190) recommendations had been quite specific in their content and the 2017 Committee retained much of the specific content when no evidence was identified to direct a change in practice. Examples include:

- supplementing ongoing care with a documented systematic assessment of the condition of the woman and unborn baby every hour
- specification of the numbers, types and combinations of CTG trace features to be used for overall classification of the trace
- expediting the birth if bradycardia persists for 9 minutes
- offering a tocolytic drug such as terbutaline as part of conservative measures.

In retaining these aspects of the 2014 (CG190) recommendations, the 2017 Committee addressed the safety of the woman and the baby with no concomitant uplift in resource use.

4.4.6.4 Quality of evidence

The evidence identified for inclusion in the review was of very low quality. Moreover, the Committee agreed that the available evidence was not particularly useful for making recommendations as it did not evaluate the important types of interventions that the Committee had sought to evaluate. The evidence reported on three types of interventions: the effect of reducing or stopping oxytocin in the presence of an abnormal fetal heart rate tracing; the effect of introducing a 5-tier, colour-coded fetal heart rate management system; and the effect of having a consultant obstetrician review all abnormal CTG traces before making a decision about performing fetal blood sampling. The Committee found these to be of limited use in guiding the recommendations and relied instead on their collective experience and knowledge to review and refine the recommendations related to care based on CTG results that had been included in CG190.

4.4.6.5 Other considerations

Some of the recommendations included in CG190 referred to using paracetamol to treat raised maternal temperature (pyrexia). Management of pyrexia during labour and birth is included in the scope for the forthcoming guideline on intrapartum care for high risk women (see www.nice.org.uk/guidance/indevelopment/gid-cgwave0613 [accessed 12/10/2016]) and so references to paracetamol were removed from the recommendations in this guideline pending development of the high risk guideline.

The 2014 guideline noted that units should not be stopped from using oxygen for maternal indications but agreed that it would be appropriate to recommend against the use of maternal facial oxygen therapy specifically for the purposes of intrauterine resuscitation, given the lack of evidence and the concern over possible risk (see Section 11.7 of CG190). The corresponding recommendation appears in Section 10.3 of CG190 and is reproduced here although it has not been updated as part of this review.

See Section 4.3 for the recommendations arising from this review question.

4.5 Predictive value of fetal stimulation

4.5.1 Review question

Does the use of fetal stimulation as an adjunct to electronic fetal monitoring improve the predictive value of monitoring and clinical outcomes when compared with:

- electronic fetal monitoring alone
- electronic fetal monitoring plus electrocardiogram (ECG)?

4.5.2 Description of included studies

Nineteen studies are included in this review (Anyaegbunam 1994; Arulkumaran 1987; Bartelsmeyer 1995; Chauhan 1999; Clark 1982; Clark 1984; Edersheim 1987; Elimian 1997; Ingemarsson 1989; Irion 1996; Lazebnik 1992; Lin 2001; Polzin 1988; Sarno 1990; Smith 1986; Spencer 1991; Tannirandorn 1993; Trochez 2005; Umstad 1992). One of the included studies was a randomised controlled trial (RCT; Anyaegbunam 1994), 2 of the studies were prospective comparative observational studies (Smith 1986; Tannirandorn 1993) and the remaining studies were case series. Six of the case series were consecutive, of which 4 were prospective (Elimian 1997; Irion 1996; Sarno 1990; Umstad 1992), and 2 were retrospective (Spencer 1991; Trochez 2005). Two studies were specifically reported as being non-consecutive case series (Chauhan 1999; Polzin 1988), and the remaining 8 studies did not reported clearly whether they were prospective or retrospective.

Seven studies investigated fetal scalp stimulation (Arulkumaran 1987; Clark 1982; Clark 1984; Elimian 1997; Lazebnik 1992; Spencer 1991; Trochez 2005), 10 studied vibroacoustic stimulation (Anyaegbunam 1994; Bartelsmeyer 1995; Chauhan 1999; Ingemarsson 1989; Irion 1996; Lin 2001; Polzin 1988; Sarno 1990; Smith 1986; Tannirandorn 1993) and 2 studied vibroacoustic stimulation followed by fetal scalp stimulation (Edersheim ; Umstad 1992). In the studies where fetal scalp stimulation was performed, 2 used digital stimulation (Elimian 1997; Trochez 2005), 2 used Allis clamp stimulation (Arulkumaran 1987; Clark 1984) and 3 used scalp puncture as the stimulation (Clark 1982; Lazebnik 1992; Spencer 1991).

Studies reported the predictive value of fetal scalp stimulation or vibroacoustic stimulation for the following:

- fetal scalp pH less than 7.20
- fetal scalp pH less than 7.25
- cord pH less than 7.20
- caesarean section and Apgar score less than 7 at 5 minutes.

All studies defined an acceleration as an increase in fetal heart rate over baseline of at least 15 bpm for at least 15 seconds (apart from Lazebnik 1992, which defined it as a net difference in heart rate of more than 15 bpm).

No study reported the time elapsed between fetal stimulation and birth. All studies except 1 (Anyaegbunam 1994) involved women whose unborn babies had a cardiotocograph recording which was interpreted as being indicative of the need for a fetal scalp blood sample to be tested for acidaemia.

4.5.3 Evidence profile

Data are reported in GRADE profiles below for the following tests:

- fetal scalp stimulation
  - fetal scalp blood sampling puncture as stimulus
  - digital massage as stimulus
  - Allis clamp as stimulus
- vibroacoustic stimulation.

The majority of included studies used absence of an acceleration following stimulation as a positive test result in order to calculate predictive values. For those studies that used presence of an acceleration as a positive test result, this is reported in the relevant evidence

table (see Appendix G:) and the 2014 NCC-WCH technical team calculated predictive values using no acceleration as a positive test result to provide consistency of interpretation across studies.

Similarly, where fetal blood sample pH was the reference test, the majority of included studies defined a positive test result as acidosis (either pH less than 7.20 or pH less than 7.25). For those studies that used no acidosis (either pH greater than or equal to 7.20 or pH greater than or equal to 7.25) as a positive test result, this is reported in the relevant evidence table (see Appendix G:) and the 2014 NCC-WCH technical team converted these to predictive values using acidosis as a positive reference test result.

Evidence from RCTs, prospective comparative observational studies and prospective consecutive case series was initially rated as high quality and was downgraded if any issues were identified that would undermine the trustworthiness of the findings. Evidence from retrospective comparative observational studies and retrospective consecutive case series was initially rated as moderate quality and was downgraded if there were any quality-related issues. Evidence from non-consecutive case series was initially rated as low quality and was downgraded if there were any quality-related issues.

Table 49: Summary GRADE profile for predictive accuracy of no fetal heart rate acceleration following fetal scalp blood sampling puncture as stimulus

Number. of studies	Design	Other considerations	Number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
				Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Fetal scalp pH < 7.20								
1 study (Edersheim 1987)	Case series	pH < 7.20 = 6/188 (3% of samples)	188 samples; 127 women & baby pairs	100% (NC)[a]	43.41% (36.21 to 50.61)[a]	1.77 (1.56 to 2.01)[a]	0 (NC)[a]	Very low
1 study (Elimian 1997)	Case series	pH < 7.20 = 15/108 (14%)	108	100% (NC)[b]	53.76% (43.63 to 63.9)[b]	2.16 (1.73 to 2.69)[a]	0 (NC)[a] Useful	Low
1 study (Lazebnik 1992)	Case series	pH < 7.20 = 15/104 (14%)	104	73% (50.95 to 95.71)[b]	17% (9.08 to 24.63)[b]	0.88 (0.64 to 1.21)[a]	1.58 (0.61 to 4.12)[a]	Very low
1 study (Spencer 1991)	Case series	pH < 7.20 = 6/138 (4%)	138	100% (NC)[a]	52.27% (43.75 to 60.79)[a]	2.10 (1.75 to 2.50)[a]	0 (NC)[a]	Very low
1 study (Umstad 1992)	Case series	pH < 7.20 = 8/60 (13%)	60	62.5% (28.95 to 96.05)[b]	67.3% (54.56 to 80.06)[b]	1.91 (0.98 to 3.71)[a]	0.56 (0.22 to 1.39)[a]	Moderate
Fetal scalp pH < 7.21								
1 study (Clark 1982)	Case series	pH < 7.21 = 19/200 (10%)	200	100% (NC)[a]	93.37% (89.75 to 96.99)[a]	15.08 (8.73 to 26.06)[a]	0 (NC)[a] Useful	Very low
Fetal scalp pH < 7.25								
1 study (Spencer 1991)	Case series	pH < 7.25 = 17/138 (5%)	138	65.38% (47.10 to 83.67)[a]	53.57% (44.33 to 62.81)[a]	1.41 (1.00 to 1.96)[a]	0.87 (0.79 to 0.95)[a]	Very low
1 study (Umstad 1992)	Case series	pH < 7.25 = 23/60 (38%)	60	82.6%	91.9% (83.10 to 100)[b]	10.19	0.19 (0.08 to 0.46)[a]	Moderate

Number. of studies	Design	Other considerations	Number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
				Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
				(67.12 to 98.10)[b]		(3,39 to 30.63)[a]		
Apgar score < 7 at 5 minutes								
1 study (Spencer 1991)	Case series	Apgar < 7 = 1/138 (0.7%)	138	100% (NC)[a]	50.36% (41.99 to 58.74)[a]	2.01 (1.70 to 2.38)[a]	0 (NC)[a]	Very low

CI confidence interval, NC not calculable

a Calculated by the 2014 NCC-WCH technical team
b As reported in study, confidence intervals calculated by the 2014 NCC-WCH technical team

Table 50: Summary GRADE profile for predictive accuracy of no fetal heart rate acceleration following digital massage as stimulus

Number. of studies	Design	Other considerations	Number of women & baby pairs	Measure of diagnostic accuracy				Quality
				Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Fetal scalp pH < 7.20								
1 study (Elimian 1997)	Case series	pH < 7.20 = 15/108 (14%) 15 sec of stimulation	108	100% (NC)[a]	54.84% (44.72 to 64.95)[a]	2.21 (1.77 to 2.77)[b]	0 (NC)[b]	Low
Fetal scalp pH ≤ 7.20								
1 study (Trochez 2005)	Case series	pH < 7.20 = 5/70 (7% of samples) VE acting as stimulus	70 samples; 54 women & baby pairs	40% (7.26 to 82.96)[a]	69.23% (56.4 to 79.76)[a]	1.3 (0.27 to 6.24)[a]	0.87 (0.44 to 1.70)[a]	Very low
Umbilical cord pH ≤ 7.20								

Number. of studies	Design	Other considerations	Number of women & baby pairs	Measure of diagnostic accuracy				Quality
				Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
1 study (Trochez 2005)	Case series	pH < 7.20 = 5/70 (7% of samples) VE acting as stimulus	34 women & baby pairs	40% (0 to 82.94)[b]	75.86% (60.29 to 91.44)[b]	1.66 (0.47 to 5.80)[b]	0.79 (0.38 to 1.67)[b]	Very low
Apgar score < 7 at 5 minutes								
1 study (Trochez 2005)	Case series	Apgar < 7 = 4/50 (8%) VE acting as stimulus	50	50% (1 to 99)[b]	69.57% (56.27 to 82.66)[b]	1.64 (0.56 to 4.80)[b]	0.72 (0.26 to 1.95)[b]	Very low

NC not calculable, VE vaginal examination

a As reported in study, confidence intervals calculated by the 2014 NCC-WCH technical team
b Calculated by the 2014 NCC-WCH technical team

Table 51: Summary GRADE profile for predictive accuracy of no fetal heart rate acceleration following Allis clamp as stimulus

Number. of studies	Design	Other considerations	Number of women & baby pairs	Measure of diagnostic accuracy				Quality
				Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Fetal scalp pH < 7.20								
1 study (Arulkumaran 1987)	Case series	pH < 7.20 = 2/50 (4%)	50	100% (not calculable [NC])[a]	83.33% (72.79 to 93.88)[a]	6.0 (3.19 to 11.30)[a]	0 (NC)[a]	Very low
1 study (Clark 1984)	Case series	pH < 7.20 = 19/64 (30%)	64	100% (NC)[a]	33.33% (19.56 to 47.11)[a]	1.5 (1.22 to 1.84)[a]	0 (NC)[a]	Very low
Caesarean section								

Number. of studies	Design	Other considerations	Number of women & baby pairs	Measure of diagnostic accuracy				Quality
				Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
1 study (Arulkumaran 1987)	Case series	Caesarean sections = 10/50 (20%)	50	60% (29.64 to 90.36)[a]	90% (80.70 to 99.30)[a]	6.0 (2.08 to 17.29)[a]	0.44 (0.21 to 0.96)[a]	Very low

NC not calculable

a Calculated by the 2014 NCC-WCH technical team

Table 52: Summary GRADE profile for predictive accuracy of no fetal heart rate acceleration following 3 or 5 seconds of vibroacoustic stimulation (VAS)

Number. of studies	Design	Other considerations	Number of women & baby pairs	Measure of diagnostic accuracy				Quality
				Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Fetal scalp pH < 7.20								
1 study (Edersheim 1987)	Case series	pH < 7.20 = 6/188 (3%) 3-sec VAS	188 samples; 127 woman & baby pairs	100% (NC)[a]	63.74% (56.75 to 70.72)[a]	2.76 (2.27 to 3.24)[a]	0 (NC)[a]	Very low
1 study (Lin 2001)	Case series	pH < 7.20 = 31/113 (27%) 3-sec VAS	113	39% (21.56 to 55.86)[b]	93% (87.05 to 98.32)[b]	5.29 (2.18 to 12.86)[a]	0.66 (0.50 to 0.88)[a]	Very low
1 stud (Umstad 1992)	Case series	pH < 7.20 = 8/60 (13%) 3-sec VAS	60	100% (NC)[b]	59.6% (46.28 to 72.95)[b]	2.48 (1.78 to 3.45)[a]	0 (NC)[a]	Moderate
1 study (Bartelsmeyer 1995)	Case series	pH < 7.20 = 14/104 (13%) 5-sec VAS	104	79% (57.08 to 100)[a]	52.22% (41.9 to 62.54)[a]	1.64 (1.12 to 2.33)[a]	0.41 (0.15 to 1.14)[a]	Low
1 study (Ingermarsson 1989)	Case series	pH < 7.20 = 4/51 (8%) 5-sec VAS	51	50% (1 to 99)[a]	68.97% (52.13 to 85.80)[a]	1.61 (0.53 to 4.94)[a]	0.73 (0.26 to 1.99)[a]	Very low

Number. of studies	Design	Other considerations	Number of women & baby pairs	Measure of diagnostic accuracy				Quality
				Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
1 study (Irion 1996)	Case series	pH < 7.20 = 31/421 (7.4%) 5-sec VAS	421 samples; 253 woman & baby pairs	77.42% (62.70 to 92.14)[a]	51.54% (46.58 to 56.50)[a]	1.60 (1.29 to 1.98)[a]	0.44 (0.23 to 0.85)[a]	Moderate
1 study (Polzin 1988)	Case series	pH < 7.20 = 10/100 (10%) 5-second VAS	100	90% (71.41 to – 100)[a]	84.44% (76.96 to 91.93)[a]	5.79 (3.43 to 9.77)[a]	0.11 (0.02 to 0.76)[a]	Very low
Fetal scalp pH < 7.25								
1 study (Smith 1986)	Case series	pH < 7.25 = 18/64 (28%) < 3 second VAS	64	100% (NC)[a]	65.22% (51.45 to 78.98)[a]	2.88 (1.94 to 4.27)[a]	0 (NC)[a]	Very low
1 study (Umstad 1992)	Case series	pH < 7.20 = 8/60 (13%) 3-second VAS	60	100% (NC)[b]	83.8% (71.91 to 95.66)[b]	6.17 (2.96 to 12.83)[a]	0 (NC)[a]	Moderate
1 study (Irion 1996)	Case series	pH < 7.25 = 130/421 (31%) 5-second VAS	421 samples; 253 women & baby pairs	65.38% (57.21 to 73.56)[a]	56.01% (50.31 to 61.72)[a]	1.49 (1.24 to 1.78)[a]	0.62 (0.48 to 0.80)[a]	Moderate
1 study (Polzin 1988)	Case series	pH < 7.25 = 22/100 (22%) 5-second VAS	100	45.45% (24.65 to 66.26)[a]	83.33% (75.06 to 91.60)[a]	2.73 (1.39 to 5.36)[a]	0.65 (0.44 to 0.97)[a]	Very low
Umbilical cord pH < 7.10								
1 study (Chauhan 1999)	Case series	pH < 7.10 = 8/271 (3%) 3-second VAS	271	44% (11.98 to 76.91)[b]	91% (87.79 to 94.65)[b]	5.06 (2.21 to 11.59)[a]	0.61 (0.34 to 1.09)[a]	Low
Umbilical cord pH < 7.00								
1 study (Chauhan 1999)	Case series	pH < 7.00 = 4/271 (1.5%) 3-second VAS	271	50% (1 to 99)[b]	91% (87.14 to 94.13)[b]	5.34 (1.87 to 15.24)[a]	0.55 (0.21 to 1.47)[a]	Low

Number. of studies	Design	Other considerations	Number of women & baby pairs	Measure of diagnostic accuracy				Quality
				Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
1 study (Anyaegbunam 1994)	Case series[c]	pH < 7.20 = 18/316 (6%) 5-second VAS	316	22.2% (3.02 to 41.43)[a]	77.18% (72.42 to 81.95)[a]	0.97 (0.40 to 2.37)[a]	1.00 (0.78 to 1.30)[a]	Low
Caesarean section								
1 study (Chauhan 1999)	Case series	Caesarean sections = 8/271 (3%) 3-second VAS	271	37% (3.95 to 71.05)[b]	92% (87.39 to 94.35)[b]	4.11 (1.55 to 10.87)[a]	0.69 (0.40 to 1.18)[a]	Low
1 study (Sarno 1990)	Case series	Caesarean sections = 16/201 (8%) 3-second VAS	201	31.2% (8.54 to 53.96)[b]	95.1% (92.04 to 98.24)[b]	6.42 (2.44 to 16.89)[a]	0.72 (0.52 to 1.01)[a]	Low
Apgar score < 7 at 5 minutes								
1 study (Lin 2001)	Case series	Apgar <7 = 3/113 (3%) 3-second VAS	113	100% (NC)[b]	86% (79.95 to 92.78)[b]	7.33 (4.58 to 11.74)[a]	0 (NC)[a]	Very low
1 study (Sarno 1990)	Case series	Apgar <7 = 6/201 (3%) 3-second VAS	201	33.3% (0 to 71.50)[b]	93.8% (90.47 to 97.22)[b]	5.42 (1.54 to 19.05)[a]	0.71 (0.40 to 1.25)[a]	Moderate
1 study (Anyaegbunam 1994)	Case series	Apgar <7 = 10/316 (3%) 5-second VAS	316	30% (1.60 to 58.40)[a]	77.45% (72.77 to 82.13)[a]	1.33 (0.50 to 3.51)[a]	0.90 (0.60 to 1.36)[a]	Low
1 study (Bartelsmeyer 1995)	Case series	Apgar <7 = 6/104 (6%) 5-second VAS	104	83.33% (53.51 to 100)[a]	52.04% (42.15 to 61.93)[a]	1.74 (1.15 to 2.62)[a]	0.32 (0.05 to 1.93)[a]	Low
1 study (Polzin 1988)	Case series	Apgar <7 = 6/100 (6%) 5-second VAS	100	50% (9.99 to 90.01)[a]	57.45% (47.45 to 67.44)[a]	1.18 (0.51 to 2.71)[a]	0.87 (0.38 to 1.97)[a]	Very low
Poor perinatal outcome[d]								

Number. of studies	Design	Other considerations	Number of women & baby pairs	Measure of diagnostic accuracy				Quality
				Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
1 study (Tannirandorn 1993)	Case series	Poor perinatal outcome = 7/140 (5%) 3-second VAS	140	71.4% (37.96 to 100)[b]	99.2% (97.78 to 100)[b]	95 (12.75 to 707.63)[a]	0.29 (0.09 to 0.93)[a]	Very low

NC not calculable, VAS vibroacoustic stimulation

a Calculated by the 2014 NCC-WCH technical team
b As reported in study, confidence intervals calculated by the 2014 NCC-WCH technical team
c Study reported only data for those receiving VAS intervention (cases) in a randomised controlled trial
d Poor perinatal outcome comprises perinatal death, 5 minute Apgar score < 7, fetal distress requiring caesarean section, thick meconium stained amniotic fluid, NICU admission

4.5.4 Evidence statements

4.5.4.1 Fetal scalp stimulation

4.5.4.1.1 Neonatal outcomes

Evidence from 5 studies (n=537) indicated that the lack of an acceleration in fetal heart rate following fetal scalp stimulation (by fetal blood sampling puncture, digital stimulation or Allis clamp) has varied (low to high) sensitivities for fetal scalp pH of 7.20 or less or umbilical cord pH of 7.20 or less, with more studies showing high sensitivity than moderate or low. Most studies also showed a useful negative likelihood ratio. Other diagnostic parameters (specificity and positive likelihood ratio) were low. The evidence was of very low to moderate quality.

The lack of fetal heart rate acceleration following fetal scalp stimulation (by fetal blood sampling puncture) has low to moderate sensitivity and specificity for fetal scalp pH less than 7.25, with 1 study (n=60) showing high specificity. Findings for positive and negative likelihood ratios are conflicting. One study (n=200) showed that a lack of fetal heart rate acceleration had high sensitivity and specificity for fetal scalp pH less than 7.21. This study also showed useful positive and negative likelihood ratios. The evidence was of very low to moderate quality.

The lack of fetal heart rate acceleration following fetal scalp stimulation (by fetal blood sampling puncture or digital stimulation) has low to high sensitivity but low specificity for Apgar score less than 7 at 5 minutes (n=50). The positive likelihood ratio is not useful, but 1 study showed a useful negative likelihood ratio. The evidence was of very low quality.

4.5.4.1.2 Maternal outcomes

Evidence from 2 studies (n=272) indicated that the lack of fetal heart rate acceleration following fetal scalp stimulation (by Allis clamp) has high specificity and low sensitivity for caesarean section. Positive and negative likelihood ratios are moderately useful. The evidence was of very low quality.

4.5.4.2 Vibroacoustic stimulation

4.5.4.2.1 Neonatal outcomes

Evidence from 7 studies (n=808) indicated that the lack of a fetal heart rate acceleration following vibroacoustic stimulation (for 3 or 5 seconds) has varied (low to high) sensitivity and specificity for fetal scalp pH of 7.20 or less, with more studies showing high sensitivity than moderate or low, and more studies showing low specificity than moderate or high. The values for negative likelihood ratio are conflicting, but the values for positive likelihood ratios are consistently low. One study (n=271) showed low sensitivity and high specificity for umbilical cord pH less than 7.10 and less than 7.00. Positive likelihood ratios were moderately useful and negative likelihood ratios were not useful. The evidence was of moderate to very low quality.

Evidence from 4 studies (n=477) showed that the lack of a fetal heart rate acceleration following vibroacoustic stimulation (for 3 or 5 seconds) has varied findings for sensitivity and low to moderate specificity for fetal scalp pH less than 7.25. Two out of 4 studies (n=124) showed a useful negative likelihood ratio. The values for positive likelihood ratio ranged from moderate to low. The evidence was of moderate to very low quality.

Evidence from 5 studies (n=834) showed that the lack of fetal heart rate acceleration following vibroacoustic stimulation (for 3 or 5 seconds) has low to high sensitivity and

specificity for Apgar score less than 7 at 5 minutes, with more studies showing low and moderate sensitivity and specificity than high sensitivity and specificity. The positive likelihood ratio is not useful, but 1 study showed a useful negative likelihood ratio. The evidence was of moderate to very low quality.

4.5.4.2.2 Maternal outcomes

One study (n=471) found the lack of a fetal heart rate acceleration following vibroacoustic stimulation (for 3 seconds) has high specificity but low sensitivity for caesarean section. The positive and negative likelihood ratios are not useful. The evidence was of low quality.

4.5.5 Health economics profile

No published economic evaluations were identified for this review question.

4.5.6 Evidence to recommendations

4.5.6.1 Relative value placed on the outcomes considered

The purpose of fetal stimulation is to prompt a fetal heart rate acceleration (which the majority of studies included in the guideline review defined as an increase in fetal heart rate over baseline by 15 beats per minute for at least 15 seconds). The aim of this review was to determine the predictive value of fetal stimulation (either by using some form of scalp stimulation or by using vibroacoustic stimulation) for neonatal outcomes when used as an adjunctive test to CTG. The Guideline Committee agreed that it was useful to consider both sensitivity and specificity, and positive and negative likelihood ratios when considering the evidence findings.

The Committee had hoped that the reported evidence would include both maternal and neonatal 'patient-important outcomes', including major morbidities such as neonatal seizures and cerebral palsy. However, the majority of the reported outcomes related to fetal scalp pH values and so the Committee used these primarily in its decision-making.

4.5.6.2 Consideration of clinical benefits and harms

The evidence included in the guideline review varied in terms of the usefulness of fetal stimulation for predicting low pH values. Negative likelihood ratios for fetal stimulation ranged from not useful to useful, with no clear pattern in the evidence one way or the other. Similarly, there was no consistent finding for sensitivity and specificity. This means that if an acceleration is observed upon fetal stimulation it may indicate that the fetal pH value is not low (a reassuring finding) but this is not a certain finding. Positive likelihood ratios were more often than not found to be not useful for predicting low pH values. This means that if an acceleration is not observed upon fetal stimulation it cannot be relied upon as an indicator of a low fetal pH value. The Committee recognised that the act of fetal scalp blood sampling was simultaneously an act of scalp stimulation, and thus even if it were not possible to obtain a blood sampling result from a scalp sample (for example, because insufficient blood was obtained), if an acceleration were observed it should still be treated as a potentially reassuring feature and this should be taken into account when considering the whole clinical picture. The Committee recognised that no evidence was identified to guide on the ideal frequency of performing fetal scalp stimulation. The Committee therefore recommended that the CTG trace should be reviewed by a senior obstetrician 30 minutes after fetal scalp stimulation unless the CTG trace had normalised. The interval of 30 minutes was chosen to align with the interval for reassessment after fetal blood sampling.

4.5.6.3 Consideration of health benefits and resource use

There were no specific resource use issues addressed for this question because fetal scalp stimulation would be carried out during a vaginal examination or when taking a fetal blood sample and so there are unlikely to be any additional resources required. Given the usefulness of the test in providing potential reassurance about babies that are well, the Guideline Committee felt confident in recommending the use of the test.

4.5.6.4 Quality of evidence

The available evidence was of mixed quality, ranging from very low to moderate (with the majority of the evidence rated as very low or low). The Guideline Committee was concerned about the poor quality of the evidence and noted that the results of the different studies varied greatly. Moreover, many of the results had wide or very wide confidence intervals (CIs).

4.5.6.5 Other considerations

CG190 describes how the available evidence did not provide a clear indication of either the effectiveness of fetal scalp stimulation per se or when fetal scalp stimulation should be used as an adjunct to CTG monitoring. As a result, the 2014 guideline did not recommend fetal scalp stimulation in its own right but recognised that there are occasions when the baby's scalp will be stimulated anyway (such as when performing a vaginal examination or taking a fetal blood sample); on these occasions clinicians should be alert to accelerations as a potential indication of fetal wellbeing. The 2017 Committee considered the evidence available as part of the update of CG190 in conjunction with the 2014 guideline Committee's interpretation of the evidence. Additionally, the 2017 Committee agreed to move away from the view that fetal blood sampling should be 'offered' in the presence of non-reassuring variable decelerations (see Section 4.6) and instead recommended that fetal blood sampling be 'considered' in such circumstances. In the light of this decision, the 2017 Committee also amended the recommendations about fetal scalp stimulation to emphasise that (conservative measures and) digital fetal scalp stimulation should be offered before performing and/or repeating fetal blood sampling (because then the latter might not be needed). The Committee's specific recommendation was to offer digital fetal scalp stimulation and if this leads to an acceleration in fetal heart rate, only continue with fetal blood sampling if the CTG trace is still pathological (see Section 4.3 for further recommendations about offering fetal scalp stimulation before performing and/or repeating fetal blood sampling).

Although the available evidence included outcomes associated with vibroacoustic stimulation, the Committee felt that this was not relevant unless performed vaginally and it was noted that this practice was not in routine clinical use. This prompted the Committee to clarify in the recommendations that fetal scalp stimulation is performed digitally as part of a vaginal examination.

4.5.7 Recommendations

42. If the cardiotocograph trace is pathological (see recommendation 32), offer digital fetal scalp stimulation. If this leads to an acceleration in fetal heart rate, only continue with fetal blood sampling if the cardiotocograph trace is still pathological. [2017]

43. If digital fetal scalp stimulation (during vaginal examination) leads to an acceleration in fetal heart rate, regard this as a sign that the baby is healthy. Take this into account when reviewing the whole clinical picture. [2017]

4.6 Fetal blood sampling

4.6.1 Fetal blood sampling as an adjunct to electronic fetal monitoring

4.6.1.1 Review question

Does the use of fetal blood sampling as an adjunct to electronic fetal monitoring (EFM) improve outcomes, when compared to:

- electronic fetal monitoring alone
- electronic fetal monitoring plus electrocardiogram (ECG)?

4.6.1.2 Description of included studies

Four studies (Alfirevic 2013; Becker 2011; Noren 2007; Stein 2006) are included in this review. Two studies (Alfirevic 2013; Stein 2006) evaluated the use of fetal blood sampling as an adjunct to CTG when compared to CTG alone or intermittent auscultation. Two studies (Becker 2011; Noren 2007) examined the use of fetal blood sampling as an adjunct to CTG plus ECG.

Of the 2 studies that evaluated the use of fetal blood sampling as an adjunct to CTG compared with CTG alone or intermittent auscultation, 1 was a systematic review (Alfirevic 2013) with 13 component trials from a variety of locations. None of the included trials reported evidence for fetal blood sampling as an adjunct to CTG compared with CTG alone. Eight of the included trials reported subgroup analyses for women who had fetal blood sampling as an adjunct to CTG compared with intermittent auscultation. An additional observational study conducted in Germany (Stein 2006) compared the impact of CTG alone versus CTG with additional fetal blood sampling in vaginal births complicated by pathologic fetal heart rate.

Of the 2 studies that evaluated the use of fetal blood sampling as an adjunct to CTG plus ECG (Becker 2011; Noren 2007), 1 was conducted in Norway and 1 in the Netherlands. Both studies provided secondary analyses of subgroups of data from large multicentre studies. One study (Becker 2011) used data from the experimental arm of a multicentre randomised trial and evaluated recommendations for additional fetal blood sampling when using ST analysis of the fetal ECG. The other study (Noren 2007) also used data from a European multicentre study and assessed the relationship between fetal blood sampling and ST analysis in the presence of acidosis. In this case–control study, out of 911 participants with fetal blood sampling results, 97 cases were identified of whom 53 had a cord artery pH less than 7.06 and 44 had a cord artery pH ranging from 7.06 to 7.09, categorised as marked acidosis and moderate acidaemia respectively. These cases were analysed with 97 controls with a cord artery pH of 7.20 or more.

4.6.1.3 Evidence profile

The findings for the effect of fetal blood sampling as an adjunct to CTG are reported in 5 GRADE profiles. The following comparisons were considered based on whether fetal blood sampling was used as an adjunct to CTG and compared to CTG alone or intermittent auscultation, or fetal blood sampling used as an adjunct to CTG plus ECG (ST waveform analysis).

- Fetal blood sampling as an adjunct to CTG compared with CTG or intermittent auscultation alone:
  - CTG plus fetal blood sampling versus CTG alone or intermittent auscultation in labour.
- Fetal blood sampling as an adjunct to CTG plus ECG:

- distribution of fetal blood sampling and an ECG guideline (ST waveform analysis) indication to intervene; marked acidosis (cord artery pH < 7.06) versus control
- distribution of fetal blood sampling and an ST guideline indication to intervene; moderate acidosis (cord artery pH 7.06–7.09) versus control
- cases with abnormal CTG and their relation to normal and abnormal fetal blood sampling and ST waveform analysis
- additional fetal blood sampling when using ST analysis of fetal ECG.

4.6.1.3.1 Fetal blood sampling as an adjunct to cardiotocography compared with cardiotocography alone or intermittent auscultation

Table 53: Summary GRADE profile for comparison of cardiotocography plus fetal blood sampling with intermittent auscultation (Alfirevic 2013) or cardiotocography alone in labour (Stein 2006)

Number of studies	Design	Other considerations: CTG or IA	Number of women		Effect		Quality
			Continuous CTG and FBS	IA or CTG with no FBS	Relative (95% CI)	Absolute (95% CI)	
Instrumental vaginal birth							
1 meta-analysis of 5 studies (Alfirevic 2013)	Randomised trials	IA	775/7460 (10.4%)	592/7368 (8.0%)	RR 1.25 (1.13 to 1.38)	20 more per 1000 (from 10 more to 31 more)	Low
1 study (Stein 2006)	Observational study	CTG	4790/12893 (37.2%)	15015/36667 (40.9%)	RR 0.91 (0.88 to 0.93)	37 fewer per 1000 (from 29 fewer to 49 fewer)	Very low
Caesarean section							
1 meta-analysis of 6 studies (Alfirevic 2013)	Randomised trials	IA	305/7582 (4.0%)	224/7492 (3.0%)	RR 1.50 (1.10 to 2.06)	15 more per 1000 (from 3 more to 32 more)	Very low
Cord blood acidosis (pH < 7.0)							
1 study (Alfirevic 2013)	Randomised trial	IA	5/540 (0.93%)	11/535 (2.1%)	RR 0.45 (0.16 to 1.29)	11 fewer per 1000 (from 17 fewer to 6 more)	Low
1 study (Stein 2006)	Observational study	CTG	64/12893 (0.5%)	307/36667 (0.8%)	RR 0.59 (0.45 to 0.78)	3 fewer per 1000 (from 2 fewer to 5 fewer)	Very low
Cerebral palsy							
1 meta-analysis of 2 studies (Alfirevic 2013)	Randomised trials	IA	28/6609 (0.42%)	17/6643 (0.26%)	RR 1.74 (0.97 to 3.11)	2 more per 1000 (from 0 fewer to 5 more)	Very low
Neonatal resuscitation							

Number of studies	Design	Other considerations: CTG or IA	Number of women		Effect		Quality
			Continuous CTG and FBS	IA or CTG with no FBS	Relative (95% CI)	Absolute (95% CI)	
1 study (Stein 2006)	Observational study	CTG	652/12893 (5.1%)	2273/36667 (6.2%)	RR 0.82 (0.75 to 0.89)	11 fewer per 1000 (from 7 fewer to 15 fewer)	Very low
Neonatal seizures							
1 meta-analysis of 5 studies (Alfirevic 2013)	Randomised trials	IA	19/7542 (0.25%)	39/7462 (0.52%)	RR 0.49 (0.29 to 0.84)	3 fewer per 1000 (from 1 fewer to 4 fewer)	Low
Apgar score < 7 at 5 minutes							
1 study (Stein 2006)	Observational study	CTG	78/12893 (0.6%)	314/36667 (0.86%)	RR 0.71 (0.55 to 0.9)	2 fewer per 1000 (from 1 fewer to 4 fewer)	Very low

CI confidence interval, CTG cardiotocography, FBS fetal blood sampling, IA intermittent auscultation, RR relative risk

4.6.1.3.2 Fetal blood sampling as an adjunct to cardiotocography plus electrocardiogram

The evidence presented in the following GRADE profiles is from articles reporting secondary analyses of subgroups taken from larger studies to investigate the role of fetal blood sampling as an adjunct to CTG plus ECG analysis. These studies were not designed as intervention studies comparing CTG with ECG analysis plus fetal blood sampling versus CTG with ECG analysis without fetal blood sampling.

The first 3 tables present findings from Noren (2007) which is a case–control study. Cases were defined as babies born with marked acidosis (cord artery pH less than 7.06; n=53) or moderate acidaemia (cord artery pH 7.06 to 7.09; n=44); controls were babies with cord artery pH of 7.20 or more.

Table 54: Summary GRADE profile for distribution of fetal blood sampling findings and ST guideline indication to intervene[a]: marked academia (cord artery pH < 7.06)

Number of studies	Design	Number of babies / number of fetal scalp blood samples		Effect		Quality
		Marked acidaemia	Control	Relative (95% CI)	Absolute (95% CI)	
Women with abnormal FBS (pH<7.20)						

Number of studies	Design	Number of babies / number of fetal scalp blood samples		Effect		Quality
		Marked acidaemia	Control	Relative (95% CI)	Absolute (95% CI)	
1 study (Noren 2007)	Observational study	24/53 (45.3%)	4/53 (7.5%)	RR 6 (2.23 to 16.11)	377 more per 1000 (from 93 more to 1000 more)	Very low
ST indication to intervene[a]						
1 study (Noren 2007)	Observational study	41/53 (77.4%)	20/53 (37.7%)	RR 2.05 (1.41 to 2.98)	396 more per 1000 (from 155 more to 747 more)	Very low
No ST indication to intervene (adequately monitored)						
1 study (Noren 2007)	Observational study	5/46 (10.9%)	22/42 (52.4%)	RR 0.21 (0.09 to 0.5)	414 fewer per 1000 (from 262 fewer to 477 fewer)	Very low

CI confidence interval, FBS fetal blood sampling, RR relative risk

a The ST log automatically notified the staff if any ST events occurred and intervention was required in case of combined CTG and ST changes. Intervention was also indicated by occurrence of preterminal CTG (complete loss of variability and reactivity). No intervention was recommended if CTG was normal, irrespective of the ST wave analysis.

Table 55: Summary GRADE profile for distribution of fetal blood sampling and ST guideline indication to intervene[a]; moderate acidaemia (cord artery pH 7.06 – 7.09)

Number of studies	Design	Number of women		Effect		Quality
		Moderate acidaemia	Control	Relative (95% CI)	Absolute (95% CI)	
Women with abnormal FBS (pH<7.20)						
1 study (Noren 2007)	Observational study	15/44 (34.1%)	0/44 (0%)	RR 31 (1.91 to 502.54)	NC	Very low
ST indication to intervene[a]						
1 study (Noren 2007)	Observational study	24/44 (54.5%)	10/44 (22.7%)	RR 2.4 (1.31 to 4.41)	318 more per 1000 (from 70 more to 775 more)	Very low

Number of studies	Design	Number of women		Effect		Quality
		Moderate acidaemia	Control	Relative (95% CI)	Absolute (95% CI)	
No ST indication to intervene (adequately monitored)						
1 study (Noren 2007)	Observational study	16b/40 (40%)	22/32 (68.8%)	RR 0.58 (0.37 to 0.91)	289 fewer per 1000 (from 62 fewer to 433 fewer)	Very low

CI confidence interval, RR relative risk

a The ST log automatically notified the staff if any ST events occurred and intervention was required in case of combined CTG and ST changes. Intervention was also indicated by occurrence of preterminal CTG (complete loss of variability and reactivity). No intervention was recommended if CTG was normal, irrespective of the ST wave analysis.
b All newborns had Apgar score > 7 at 5 minutes apart from one baby born by ventouse who recovered quickly and did not require special care.

Table 56: Summary GRADE profile for participants with abnormal or intermediary cardiotocography[a] noted at start of ST analysis recording

Number of studies	Design	Number of women		Effect		Quality
		Moderate acidaemia + marked acidosis	Control	Relative (95% CI)	Absolute (95% CI)	
Normal FBS and normal ST analysis						
1 study (Noren 2007)	Observational study	20/37 (54.1%)	23/24 (95.8%)	RR 0.56 (0.41 to 0.77)	422 fewer per 1000 (from 220 fewer to 565 fewer)	Very low
Normal FBS and abnormal ST analysis						
1 study (Noren 2007)	Observational study	1/37 (2.7%)	0/24 (0%)	RR 1.97 (0.08 to 46.55)	NC	Very low
Abnormal FBS and normal ST analysis						
1 study (Noren 2007)	Observational study	3/37 (8.1%)	0/24 (0%)	RR 1.97 (0.08 to 46.55)	NC	Very low
Abnormal FBS and abnormal ST analysis						

Number of studies	Design	Number of women		Effect		Quality
		Moderate acidaemia + marked acidosis	Control	Relative (95% CI)	Absolute (95% CI)	
1 study (Noren 2007)	Observational study	13/37 (35.1%)	1/24 (4.2%)	RR 8.43 (1.18 to 60.35)	310 more per 1000 (from 7 more to 1000 more)	Very low

CI confidence interval, FBS fetal blood sampling, RR relative risk

a Out of 121 cases with abnormal CTG (with normal and abnormal ST analysis) n = 84 (69%) showed a cord pH < 7.10. ST analysis indicated the need to intervene in 70/84 (83%)

The following GRADE table presents data from Becker et al. (2011) which represents a secondary analysis of fetal blood sampling findings within the experimental arm of an ST analysis trial. A comparison is made between findings for fetal blood samples taken according to the ST analysis trial protocol with those taken based on clinical judgement not according to the protocol.

Table 57: Summary GRADE profile for additional fetal blood sampling when using ST analysis of fetal electrocardiogram

Number of studies	Design	Number of women		Effect		Quality
		According to trial protocol[a]	Not according to trial protocol[a]	Relative (95% CI)	Absolute (95% CI)	
FBS pH > 7.25[b]						
1 study (Becker 2011)	Observational study	112/171 (65.5%)	96[c]/126 (76.2%)	RR 0.86 (0.74 to 0.99)	107 fewer per 1000 (from 8 fewer to 198 fewer)	Very low
FBS pH 7.20 to 7.25[b]						
1 study (Becker 2011)	Observational study	33/171 (19.3%)	15[d]/126 (11.9%)	RR 1.62 (0.92 to 2.85)	74 more per 1000 (from 10 fewer to 220 more)	Very low
FBS pH < 7.20[b]						
1 study (Becker 2011)	Observational study	17/171 (9.9%)	10[e]/126 (7.9%)	RR 1.25 (0.59 to 2.64)	20 more per 1000 (from 33 fewer to 130 more)	Very low
1 study (Becker 2011)	Observational study	17/171 (9.9%)	10[e]/126 (7.9%)	RR 1.25 (0.59 to 2.64)	20 more per 1000 (from 33 fewer to 130 more)	Very low

CI confidence interval, FBS fetal blood sampling, RR relative risk

a In the trial protocol FBS was recommended in three situations:
(1) Start of ST analysis registration with an intermediary or abnormal CTG trace
(2) Abnormal CTG trace for more than 60 minutes without ST events
(3) Poor ECG signal quality in the presence of an intermediary or abnormal CTG trace.
b Classification at sample level not at participant level
c n = 19/96 had at least one ST event, n = 77/96 had no ST indication to intervene
d n = 5/15 had at least one ST event, n = 10/15 had no ST indication to intervene
e n = 8/10 had at least one ST event, n = 2/10 had no ST indication to intervene

Some neonatal outcomes were reported by Becker (2011). Among women where fetal blood samples were obtained according to the trial protocol, 3 out of 123 babies were born with metabolic acidosis (cord artery pH less than 7.05 and base deficit in extracellular fluid more than 12 mmol/l). Fetal blood sample findings for these babies were pH 7.19 (time interval to birth not reported), pH 7.24 (20 minutes before birth) and pH 7.32 (9 hours before birth). Among women where a fetal blood sample was performed outside the trial protocol, 3 out of 101 babies were born with metabolic acidosis (no difference between groups; p=0.81). In all 3 cases, ST events (abnormality of the ST segment of the fetal ECG) were present. Fetal blood sample findings were reported for only 1 of these babies, where multiple samples were obtained with recordings of pH 7.38, 7.33, 7.31, 7.28 and 7.28. Time before the final fetal blood sample and birth was 114 minutes (caesarean section following failed ventouse). Umbilical cord artery pH was 6.96 and the baby died of severe asphyxia and encephalopathy.

4.6.1.4 Evidence statements

4.6.1.4.1 Fetal blood sampling as an adjunct to cardiotocography compared with cardiotocography alone or intermittent auscultation

Evidence from 6 studies showed that the rates of caesarean section (n=16,001) and instrumental vaginal birth (n=65,315) were higher in women who received CTG plus fetal blood sampling compared with women who received intermittent auscultation only. The rates of resuscitation (n=49,560), neonatal seizure (n=15,004) and Apgar score less than 7 at 5 minutes (n=49,560) were lower in babies born to women who received cardiotocography plus fetal blood sampling compared with babies born to women who received intermittent auscultation or cardiotocography only. The rate of cord blood acidosis (n=50,635) was lower in women who received cardiotocography plus fetal blood sampling compared with women who received cardiotocography alone, but there was no difference when compared with women who received intermittent auscultation. No difference was found between the 2 groups in the incidence of cerebral palsy (n=13,252). The evidence was of very low to low quality.

4.6.1.4.2 Fetal blood sampling as an adjunct to cardiotocography plus fetal electrocardiogram

Distribution of fetal blood sampling findings and ST analysis guideline indication to intervene (marked acidosis: cord artery pH less than 7.06)

Evidence from 1 study (n=106) showed that a higher number of babies with marked cord artery acidosis (pH less than 7.06) had abnormal fetal blood sampling and ST analysis indications to intervene compared with the control group (babies with cord artery pH of 7.20 or more). A lower number of babies with marked acidosis (who were adequately monitored) had no ST analysis indications to intervene compared with the control group. The evidence was of very low quality.

Distribution of fetal blood sampling and ST analysis guideline indication to intervene (moderate acidemia: cord artery pH less than 7.06–7.09)

Evidence from 1 study (n=88) showed that a higher number of babies with moderate cord artery acidaemia had abnormal fetal blood sampling or ST analysis indications to intervene compared with the control group (babies with cord artery pH of 7.20 or more). A lower number of babies with cord artery moderate acidaemia (who were adequately monitored) had no ST analysis indications to intervene compared with the control group. The evidence was of very low quality.

Cases with abnormal cardiotocography noted at start of fetal electrocardiogram recording

Evidence from 1 study (n=61) showed that a lower number of babies with marked acidosis and moderate acidaemia had normal fetal blood sampling with normal ST analysis compared with the control group (babies with cord artery pH of 7.20 or more). However, a higher number of babies with marked acidosis and moderate acidaemia had abnormal fetal blood sampling with abnormal ST analysis compared with the control group. No differences were found in the number of babies with marked acidosis and moderate acidaemia who had normal fetal blood sampling results with abnormal ST analysis or abnormal fetal blood sampling results with normal ST analysis compared with the control group. The evidence was of very low to moderate quality.

ST analysis of fetal electrocardiogram plus fetal blood sampling

Evidence from 1 study (n=297) showed that the number of women with a fetal blood sample pH of more than 7.25 was lower where fetal blood samples were performed according to the ST analysis trial protocol compared with women where fetal blood sampling was not performed according to the ST analysis trial protocol. However, this difference was not observed for women with a fetal blood sample pH of 7.25 or less. The evidence was of very low quality.

4.6.1.5 Health economics profile

No published economic evaluations were identified for this review question.

4.6.1.6 Evidence to recommendations

4.6.1.6.1 Relative value placed on the outcomes considered

For this review, the main maternal outcomes of interest were rates of caesarean section and instrumental birth. The main neonatal outcome of interest was cerebral palsy. These were felt to be clinically relevant, with caesarean section and instrumental birth an important component of the woman's experience of birth.

4.6.1.6.2 Consideration of clinical benefits and harms

One observational study which considered the specific comparison of interest showed that there was a statistically significant reduction in the number of instrumental vaginal births in the group that received fetal blood sampling in addition to CTG compared with the group that did not receive fetal blood sampling. The study also showed a statistically significant reduction in the rate of cord blood acidosis, neonatal resuscitation and 5-minute Apgar score of less than 7.

The Committee recognised that the quality of the evidence for all of these outcomes was very low. However, it was agreed that fetal blood sampling as an adjunctive test may help clinicians to identify those babies for whom additional intervention may be required, and thereby reduce the rates of adverse neonatal outcomes. The Committee also recognised that differences exist in the use of fetal blood sampling in UK NHS practice. There was insufficient evidence to support a strong recommendation to 'offer' fetal blood sampling or to justify abandoning the widespread UK practice of carrying out fetal blood sampling and so a weak recommendation was made to 'consider' fetal blood sampling if the CTG trace is still pathological after implementing conservative measures and fetal scalp stimulation.

As indicated above, the Committee felt it was important that a full clinical assessment, conservative measures and fetal scalp stimulation were employed before considering fetal blood sampling. Conservative measures to correct possible underlying causes may improve the fetal heart rate and provide reassurance about the condition of the baby which may negate the need for fetal blood sampling. Full clinical assessment and conservative measures were felt to help avoid invasive interventions that would consequently improve the woman's experience of labour and birth. The Committee considered that fetal blood sampling was not a prerequisite to making a decision about expediting birth in the context of the clinical picture, although there may be advantages to using fetal blood sampling when considering the timing of birth. To support a reduction in routine fetal blood sampling in clinical practice, recommendations were made to emphasise that fetal blood sampling would not always be necessary and that interpretation of results should be in the context of other available information (for example, any previous pH or lactate measurement) and of the whole clinical picture. Consideration of the previous pH (or lactate) measurement would allow

healthcare professionals to address any concerns related to a rapid fall in pH, for example, while consideration of the clinical features of the woman and baby would cover any concerns related to rate of progress in labour etc.

It was noted that in certain circumstances risks associated with performing fetal blood sampling would outweigh any potential benefits, for example, where there is an increased risk of passing infection to the baby. The Committee was aware that for some women with a bloodborne infection it may be safe to perform fetal blood sampling, however, this clinical scenario should have been discussed antenatally and an individualised plan made. The Committee did not review the evidence in this area and, therefore, felt it inappropriate to make specific recommendations.

There are some clinical scenarios in which fetal blood sampling would not be appropriate because the birth should be expedited, for example, the occurrence of an acute event such as uterine rupture, suspected cord prolapse, or suspected placental abruption. The Committee also considered clinical scenarios where fetal blood sampling results may be misleading (in the presence of sepsis or significant meconium, and when sampling has been performed immediately after prolonged decelerations, for example, after an epidural top-up). The Committee recommended, therefore, that healthcare professionals should be aware that for women with sepsis or significant meconium, fetal blood sample results may be falsely reassuring, and they should always discuss with a consultant obstetrician whether fetal blood sampling is appropriate and any results from the.

The Committee further agreed that if fetal scalp stimulation resulted in accelerations then fetal blood sampling would not be necessary because the accelerations would provide reassurance about the condition of the baby, avoiding further more invasive intervention and labour could be allowed to continue.

4.6.1.6.3 Consideration of health benefits and resource use

No formal cost effectiveness analysis was performed for this review question. However, it was agreed that as fetal blood sampling is not an expensive test and does not require a large additional investment in clinicians' time, its use is likely to be cost effective, given that there may be gains in quality adjusted life years (QALYs) and some 'downstream' savings to be made by avoiding poor neonatal outcomes and unnecessary interventions.

The 2017 Committee was aware that the 2014 (CG190) recommendations included references to offering repeat sampling if this was still indicated by the CTG trace:

- no more than 30 minutes later if the fetal blood sample result was borderline
- no more than 1 hour later if the fetal blood sample result was normal.

The 2017 Committee retained the specific content of the recommendations about these timings of repeat sampling because no evidence was identified to direct a change in practice. As there was no associated change in recommended practice it is expected that there would also be no uplift in resource use.

4.6.1.6.4 Quality of evidence

Although the comparison of interest was fetal blood sampling as an adjunct to CTG compared with CTG alone (or CTG plus ECG), only 1 study was identified that investigated this specific comparison. This study was observational in design and the quality of its evidence for each relevant outcome was very low. The decision was made to include a large systematic review that compared CTG plus fetal blood sampling with intermittent auscultation, as it was felt that the published systematic review might contain relevant information for the Guideline Committee to consider. However, none of the 13 trials included

in the published systematic review reported data for fetal blood sampling as an adjunct to CTG monitoring compared with CTG alone, which was the primary focus of the guideline review question. Eight of the included trials reported a subgroup analysis for women who had received fetal blood sampling as an adjunct to CTG compared with intermittent auscultation. The Committee was aware that the majority of the women who participated in the trials included in the published systematic review had a high-risk pregnancy. In addition, women with preterm labour or multiple pregnancy were included. Because of the way the data were reported in the individual studies, it was not possible to perform a subgroup analysis for women with a low-risk pregnancy, term pregnancy or singleton pregnancy. Given these issues, the Committee did not feel it was appropriate to consider the findings of the published systematic review when developing its recommendations. The recommendations were, therefore, made on the basis of the 1 (observational) study that suggested that fetal blood sampling was associated with improved maternal and neonatal outcomes.

One further case-control study was identified which took findings from the experimental arm of a randomised controlled trial (RCT) in which women received fetal blood sampling as an adjunct to CTG plus ECG, and compared them with findings from a group of controls. This was not the most appropriate study design and the Committee noted that the number of women included in the study was very small, making it difficult to extrapolate from the study's findings. Again, the Committee did not feel it was appropriate to consider the findings from this study when developing its recommendations.

4.6.1.6.5 Other considerations

The Committee felt that it was important for women to be informed fully about the nature of the procedure required to obtain a fetal blood sample and associated risks, benefits and limitations, particularly the risk of a 'failed' sample and actions that might be considered once a result were obtained. The Committee also recognised the importance of informing the woman that if a fetal blood sample cannot be obtained but there are fetal heart accelerations in response to the procedure, this is encouraging and in these circumstances expediting the birth may not be necessary.

See Section 4.3 for further recommendations about considering fetal blood sampling when a CTG trace is pathological. See Section 4.6.3 for all other recommendations arising from the review questions related to fetal blood sampling.

4.6.2 Time from decision to take a fetal blood sample to result

4.6.2.1 Review question

What is the optimum time from the decision to perform a fetal blood sample to having the blood result?

4.6.2.2 Description of included studies

Three studies are included in this review (Annappa 2008; Rimmer 2016; Tuffnell 2006). Two studies (Annappa 2008; Tuffnell 2006) were prospective and the other (Rimmer 2016) was retrospective. All studies were conducted in the UK. Two of them (Annappa 2008; Tuffnell 2006) documented consecutive attempts at fetal blood sampling, and the other (Rimmer 2016) selected a random sample of women for fetal blood sampling.

4.6.2.3 Evidence profile

Table 58: Summary GRADE profile for the time from the decision to perform a fetal blood sample to having the scalp pH result

Number of studies	Design	Number of women (number of samples)	Median / minutes (IQR) or number of events/total (%)	Quality
Time from decision to result of fetal blood sample				
1 study (Tuffnell 2006)	Case series	74 (100)	18 (12 to 25)	Very low
1 study (Annappa 2008)	Case series	72 (107)	17 (11 to 22)	Very low
1 study (Rimmer 2016)	Case series	112 (199)	10 (NR)[a]	Very low
Proportion of samples where the time from decision to result of fetal blood sample was longer than 30 minutes				
1 study (Tuffnell 2006)	Case series	74 (100)	8/89b (9.0%)	Very low
1 study (Annappa 2008)	Case series	72 (107)	5/107 (4.7%)	Very low
Proportion of samples where the time from decision to result of fetal blood sample was ≥ 20 minutes				
1 study (Rimmer 2016)	Case series	112 (199)	15/199 (7.5%)	Very low

IQR interquartile range; NR not reported

a IQR not reported; range reported as 2 to 39
b 11 out of the 100 samples were not adequate for analysis

4.6.2.4 Evidence statements

One study (n=74) reported that the median time from the decision to perform a fetal blood sample to obtaining the result was 18 minutes and that in 9% of cases the time interval was longer than 30 minutes. Another study (n=72) reported that the median time from the decision to perform a fetal blood sample to obtaining the result was 17 minutes and that in 5% of cases the time interval was longer than 30 minutes. A third study reported that the median time from the decision to perform a fetal blood sample to obtaining the result was 10 minutes and that in 7.5% of cases the time interval was longer than 10 minutes. The evidence from all studies was of very low quality.

4.6.2.5 Health economics profile

No published economic evaluations were identified for this review question.

4.6.2.6 Evidence to recommendations

4.6.2.6.1 Relative value placed on the outcomes considered

The Guideline Committee felt that the most important outcome for this review question was the average time from the decision to perform a fetal blood sample to having the result (which was reported as a median in the available evidence). The Committee agreed that it would be useful to have supplementary information about the proportion of samples where the time from decision to result was longer than 30 minutes. However, the Committee was of the view that the minimum time (2 minutes) reported in one study (Rimmer 2016) was very short if it really referred to time to obtain the result of fetal blood sampling and not the time to performing the test. Note that this study differed from the other included studies in that it reported the full range of times taken to obtain the result, whereas the others reported the (narrower) interquartile range for the corresponding measurements. The Committee commented that it can take a long time to perform fetal blood sampling and that obtaining a sufficient sample may be difficult.

4.6.2.6.2 Consideration of clinical benefits and harms

The aim of this review was to identify the average time taken from the decision to perform a fetal blood sample to having the result. This was in order that clinicians considering whether or not to perform fetal blood sampling could take into account the time required to obtain the results (which in terms of the median time was longer than 20 minutes in all of the included studies). The Committee also felt that continuous risk assessment would be of greater importance than the precise duration from taking the decision to obtaining the result. In instances where a clinician was concerned about a baby's condition on the basis of the whole clinical picture, the birth ought to be expedited.

The Committee felt that the CG190 recommendation about taking into account the time needed to take a fetal blood sample when planning repeat sampling was ambiguous. Instead the 2017 Committee made a recommendation to consider the whole clinical picture and actions that would stem from this, such as implementing conservative measures or expediting the birth, and this encompasses the intention of the CG190 recommendation.

4.6.2.6.3 Consideration of health benefits and resource use

This review addresses the time taken from the decision to perform a fetal blood sample to having the result available to clinicians. As this does not involve a comparison of alternative strategies, no economic analysis was conducted. The review of the clinical evidence

provided information on timing only, and so there were no associated health benefit or resource implications.

4.6.2.6.4 Quality of evidence

The quality of the evidence available for this review question was very low as it was derived from case series. However, the Committee felt that this was an appropriate study design for this question.

4.6.2.6.5 Other considerations

There were no other considerations.

See Section 4.3 and Section 4.6.3 for the recommendations arising from the review questions related to fetal blood sampling.

4.6.3 Predictive value of fetal blood sampling

4.6.3.1 Review question

What is the predictive value of the following measures, for maternal and neonatal outcomes:

- fetal blood pH analysis
- fetal blood lactate analysis
- fetal acid-base status
- fetal base deficit?

4.6.3.2 Description of included studies

Nine studies are included in this review (Bakr 2005; Brandt-Niebelschutz 1994; East 2011; Hon 1969; Kerenyi 1970; Khazin 1969; Kubli, 1968; Wiberg-Itzel 2008; Young 1980).

One of the included studies was a systematic review which included 2 randomised controlled trials (RCTs), both from Sweden (East 2011). One of the other included studies was a further report of 1 of the trials included in the published systematic review, which was included as an individual article in the guideline review because additional evidence were reported (Wiberg-Itzel 2008). One of the included studies was a prospective comparative observational study from Egypt (Bakr 2005). Two of the included studies were retrospective consecutive case series from Germany (Brandt-Niebelschutz 1994) and Canada (Young 1980), respectively. The remaining 4 included studies were case series from the USA which did not report clearly whether or not the cases were consecutive (Hon 1969; Kerenyi 1970; Khazin 1969; Kubli 1968).

The published systematic review (East 2011) incorporated trials which randomised women to have either the lactate level or the pH of the fetal blood sample measured. Clinical outcomes for both the woman and the baby were reported for this comparison. The remaining included studies evaluated the predictive value of fetal blood pH, lactate, base deficit or base excess values for neonatal outcomes. For predictive value data, only studies reporting data for samples taken within 1 hour of birth were included. The time interval between fetal blood sampling and birth was up to 60 minutes in 6 studies (Bakr 2005; Brandt-Niebelschutz 1994; Hon 1969; Kerenyi 1970; Wiberg-Itzel 2008; Young 1980) and up to 30 minutes in 2 studies (Khazin 1969; Kubli 1968).

One study (Wiberg-Itzel 2008) reported excluding women with multiple pregnancy or who were in labour before 34 weeks' gestation. In the remaining studies inclusion/exclusion

criteria and characteristics of the study populations were poorly reported and so it is not possible to judge whether women would have been classified as low risk prior to the onset of labour.

4.6.3.3 Evidence profile

Evidence is reported in GRADE profiles below for the following tests and outcomes:

- comparative clinical outcome data for women randomised to fetal blood lactate or pH testing
- predictive accuracy and correlation data:
  - composite neonatal outcomes – predictive value of fetal blood pH at different thresholds
  - 5 minute Apgar score – predictive value of fetal blood pH, lactate and base deficit at different thresholds and correlation of fetal blood pH and base deficit measurements with Apgar score
  - umbilical arterial pH at birth - predictive value of fetal blood pH, lactate and base deficit at different thresholds and correlation of fetal blood pH and base-excess measurements with umbilical arterial measurements.

Evidence from RCTs, prospective comparative observational studies and prospective consecutive case series was initially rated as high quality and was downgraded if there were any issues identified that would undermine the trustworthiness of the findings. Evidence from retrospective comparative observational studies and retrospective consecutive case series was initially rated as moderate quality and was downgraded if there were any quality-related issues. Evidence from non-consecutive case series was initially rated as low quality and was downgraded if there were any quality-related issues.

4.6.3.3.1 *Comparative clinical outcome data*

Table 59: Summary GRADE profile for lactate compared with pH for fetal blood sampling

Number of studies	Design	Number of women		Effect		Quality
		Lactate	pH	Relative (95% CI)	Absolute (95% CI)	
Mode of birth: spontaneous vaginal birth						
1 meta-analysis of 2 studies (East 2011)	Randomised trials	709/1667 (42.5%)	709/1652 (42.9%)	RR 0.91 (0.67 to 1.24)	39 fewer per 1000 (from 142 fewer to 103 more)	Very low
Mode of birth: assisted vaginal birth						
1 meta-analysis of 2 studies (East 2011)	Randomised trials	415/1667 (24.9%)	455/1652 (27.5%)	RR 0.9 (0.81 to 1.01)	28 fewer per 1000 (from 52 fewer to 3 more)	Moderate
Mode of birth: caesarean section						
1 meta-analysis of 2 studies (East 2011)	Randomised trials	472/1667 (28.3%)	432/1652 (26.2%)	RR 1.09 (0.97 to 1.22)	24 more per 1000 (from 8 fewer to 58 more)	Moderate
Mode of birth: operative birth for non-reassuring fetal status						
1 study (East 2011)	Randomised trials	580/1496 (38.8%)	571/1496 (38.2%)	RR 1.02 (0.93 to 1.11)	8 more per 1000 (from 27 fewer to 42 more)	Moderate
Neonatal death						
1 study (East 2011)	Randomised trial	0/1496 (0%)	3/1496a (0.2%)	RR 0.14 (0.01 to 2.76)	2 fewer per 1000 (from 2 fewer to 4 more)	Moderate
Neonatal encephalopathy						
1 study (East 2011)	Randomised trial	6/1496 (0.4%)	6/1496 (0.4%)	RR 1 (0.32 to 3.09)	0 fewer per 1000 (from 3 fewer to 8 more)	Moderate
Admission to neonatal intensive care unit						

Number of studies	Design	Number of women		Effect		Quality
		Lactate	pH	Relative (95% CI)	Absolute (95% CI)	
1 study (East 2011)	Randomised trial	167/1496 (11.2%)	164/1496 (11%)	RR 1.02 (0.83 to 1.25)	2 more per 1000 (from 19 fewer to 27 more)	Moderate
Apgar score < 7 at 5 minutes						
1 meta-analysis of 2 studies (East 2011)	Randomised trials	50/1667 (3%)	44/1652 (2.7%)	RR 1.13 (0.76 to 1.68)	3 more per 1000 (from 6 fewer to 18 more)	Moderate
Metabolic acidaemia (arterial pH < 7.05 and base deficit > 12 mmol/l)						
1 study (East 2011)	Randomised trial	44/1360 (3.2%)	47/1315 (3.6%)	RR 0.91 (0.6 to 1.36)	3 fewer per 1000 (from 14 fewer to 13 more)	Low
Umbilical arterial pH < 6.98[b]						
1 study (East 2011)	Randomised trial	4/171 (2.3%)	8/156 (5.1%)	RR 0.46 (0.14 to 1.49)	28 fewer per 1000 (from 44 fewer to 25 more)	Very low
Umbilical arterial pH < 7.00						
1 study (East 2011)	Randomised trial	21/1376 (1.5%)	24/1322 (1.8%)	RR 0.84 (0.47 to 1.5)	3 fewer per 1000 (from 10 fewer to 9 more)	Low
Umbilical arterial pH < 7.10						
1 study (East 2011)	Randomised trial	121/1376 (8.8%)	131/1322 (9.9%)	RR 0.89 (0.7 to 1.12)	11 fewer per 1000 (from 30 fewer to 12 more)	Low
Umbilical arterial lactate > 4.68 mmol/l[b]						
1 study (East 2011)	Randomised trial	20/171 (11.7%)	29/156 (18.6%)	RR 0.63 (0.37 to 1.07)	69 fewer per 1000 (from 117 fewer to 13 more)	Very low
Umbilical arterial base deficit > 19.2[b]						

Number of studies	Design	Number of women		Effect		Quality
		Lactate	pH	Relative (95% CI)	Absolute (95% CI)	
1 study (East 2011)	Randomised trial	1/171 (0.58%)	3/156 (1.9%)	RR 0.3 (0.03 to 2.89)	13 fewer per 1000 (from 19 fewer to 36 more)	Very low

CI confidence interval, RR relative risk

a These three deaths occurred in babies with diaphragmatic hernias (n = 2) or congenital cardiac fibrosis. None of the babies was acidaemic at birth.
b These thresholds were chosen by the trial authors according to the 1st or 99th centiles of normal values, which are reported in another of their studies

4.6.3.3.2 *Predictive accuracy and correlation data*

In the following tables, predictive accuracy is reported for different tests (such as pH or lactate) and for different outcomes (such as Apgar score). The specific tests and thresholds used (for example, fetal scalp pH less than 7.25) are listed in the rows of the GRADE table and the outcomes that they predict are listed in the 'definition of outcome' column. The measures of diagnostic accuracy in each row represent the specific values for that test and threshold for that outcome.

Table 60: Summary GRADE profile for predictive accuracy of fetal blood sampling for composite neonatal outcomes

Number of studies	Design	Definition of outcome	Maximum interval between sample and birth (minutes)	Number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Fetal scalp pH < 7.25									
1 study (Young 1980)	Case series	Either 5 minute Apgar < 7 or 1 minute Apgar < 7 plus the need for positive pressure resuscitation	60	96	50.00% (15.35 to 84.65)a	81.82% (73.76 to 89.88)a	2.75 (1.21 to 6.26)a	0.61 (0.30 to 1.23)a	Low

Number of studies	Design	Definition of outcome	Maximum interval between sample and birth (minutes)	Number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Fetal scalp pH ≤ 7.21									
1 study (Bakr 2005)	Prospective observational study	Any of the following: - Apgar < 7 at 5 minutes - secondary respiratory distress - transfer to NICU - arterial pH ≤ 7.15 - neonatal death	Unknown	150	82% (65 to 91)	52% (42 to 61)	1.69 (1.33 to 2.16)[a]	0.36 (0.18 to 0.71)[a]	Low
Fetal scalp pH < 7.20									
1 study (Young 1980)	Case series	Either 5 minute Apgar < 7 or 1 minute Apgar < 7 plus the need for positive pressure resuscitation	60	96	37.50% (3.95 to 71.05)[a]	96.59% (92.80 to 100)[a]	11.00 (2.64 to 45.8)[a]	0.65 (0.38 to 1.11)[a]	Very low

CI confidence interval, NICU neonatal intensive care unit

a Calculated by the 2014 NCC-WCH technical team

Table 61: Summary GRADE profile for predictive accuracy of fetal blood sampling for Apgar score at 5 minutes

Number of studies	Design	Definition of outcome	Maximum interval between sample and birth (minutes)	Number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Fetal scalp pH ≤ 7.25									
1 study (Wiberg-Itzel 2008)	Randomised trial	Apgar score < 7	60	508	57.14% (35.98 to 78.31)[a]	55.85% (51.44 to 60.26)[a]	1.29 (0.88 to 1.90)[a]	0.77 (0.47 to 1.27)[a]	Moderate
1 study (Kerenyi 1970)	Case series	Apgar score < 7	60	23	66.67% (13.32 to 100)[a]	15.00% (0 to 30.65)[a]	0.78 (0.35 to 1.78)[a]	2.22 (0.33 to 15.01)[a]	Very low
Fetal scalp pH < 7.21									
1 study (Wiberg-Itzel 2008)	Randomised trial	Apgar score < 7	60	508	47.62% (26.26 to 68.98)	74.33% (70.45 to 78.21)	1.86 (1.16 to 2.98)	0.70 (0.47 to 1.06)	Moderate
1 study (Kerenyi 1970)	Case series	Apgar score < 7	60	23	66.67% (13.32 to 100)[a]	60.00% (38.53 to 81.47)[a]	1.67 (0.64 to 4.37)[a]	0.56 (0.11 to 2.86)[a]	Very low
Fetal scalp pH < 7.10									
1 study (Kerenyi 1970)	Case series	Apgar score < 7	60	23	66.67% (13.32 to 100)[a]	95.00% (85.45 to 100)[a]	13.33 (1.68 to 105.79)[a]	0.35 (0.07 to 1.74)[a]	Very low
Fetal scalp lactate ≥ 4.2 mmol/l									
1 study (Wiberg-Itzel 2008)	Randomised trial	Apgar score < 7	60	684	85.71% (72.75 to 98.68)[a]	51.83% (48.01 to 55.65)[a]	1.78 (1.50 to 2.11)[a]	0.28 (0.11 to 0.69)[a]	Moderate
Fetal scalp lactate > 4.8 mmol/l									
1 study (Wiberg-Itzel 2008)	Randomised trial	Apgar score < 7	60	684	82.14% (67.96 to 96.33)[a]	62.80% (59.11 to 66.50)[a]	2.21 (1.81 to 2.70)[a]	0.28 (0.13 to 0.63)[a]	Moderate

Number of studies	Design	Definition of outcome	Maximum interval between sample and birth (minutes)	Number of women & baby pairs	Measure of diagnostic accuracy (95% CI				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Base deficit > 10 mEq/l									
1 study (Kerenyi 1970)	Case series	Apgar score < 7	60	19	0a (NC)	83.33% (66.12 to 100)[a]	0a (NC)	1.20 (0.98 to 1.48)[a]	Very low
Base deficit >12.5 mEq/l									
1 study (Kerenyi 1970)	Case series	Apgar score < 7	60	19	0a (NC)	94.44% (83.86 to 100)[a]	0a (NC)	1.06 (0.95 to 1.18)[a]	Very low
1 study (Kerenyi 1970)	Case series	Apgar score < 7	30	130	42.86% (6.20 to 79.52)[a]	90.24% (85.00 to 95.49)[a]	4.39 (1.60 to 12.06)[a]	0.63 (0.33 to 1.21)[a]	Very low

CI confidence interval, NC not calculable, NR not reported

a Calculated by the 2014 NCC-WCH technical team

Table 62: Summary GRADE profile for correlation of fetal blood sampling with high and low Apgar scores at 5 minutes

Number of studies	Design	Definition of outcome	Maximum interval between sample and birth (minutes)	Number of women & baby pairs	Correlation coefficient (p-value)	Quality
Correlation of fetal scalp pH with low Apgar scores						
1 study (Hon 1969)	Case series	Apgar score of 1–6	60	41	r: 0.3880 (p<0.01)	Very low
1 study (Hon 1969)	Case series	Apgar score of 1–6	45	41	r: 0.3880 (p<0.01)	Very low
1 study	Case series	Apgar score of 1–6	30	40	r: 0.3591	Very low

Number of studies	Design	Definition of outcome	Maximum interval between sample and birth (minutes)	Number of women & baby pairs	Correlation coefficient (p-value)	Quality
(Hon 1969)					(p<0.05)	
1 study (Hon 1969)	Case series	Apgar score of 1–6	15	24	r: 0.4261 (p<0.05)	Very low
1 study (Hon 1969)	Case series	Apgar score of 1–6	5	8	r: 0.6171 (p<0.05)	Very low
Correlation of fetal scalp base deficit with low Apgar scores						
1 study (Khazin 1969)	Case series	Apgar score of 1–6	60	13	r: −0.8362 (p<0.005)	Very low
1 study (Khazin 1969)	Case series	Apgar score of 1–6	45	13	r: −0.8362 (p<0.005)	Very low
1 study (Khazin 1969)	Case series	Apgar score of 1–6	30	12	r: −0.8359 (p<0.005)	Very low
1 study (Khazin 1969)	Case series	Apgar score of 1–6	15	6	r: −0.9366 (p<0.005)	Very low
1 study (Khazin 1969)	Case series	Apgar score of 1–6	5	1	r: NA (p-value: NA)	Very low
Correlation of fetal scalp pH with high Apgar scores						
1 study (Hon 1969)	Case series	Apgar score of 7–10	60	595	r: 0.0607 (p>0.05)	Very low
1 study (Hon 1969)	Case series	Apgar score of 7–10	45	555	r: 0.0019 (p>0.05)	Very low
1 study (Hon 1969)	Case series	Apgar score of 7–10	30	503	r: 0.0044 (p>0.05)	Very low
1 study (Hon 1969)	Case series	Apgar score of 7–10	15	400	r: −0.0120 (p>0.05)	Very low
1 study (Hon 1969)	Case series	Apgar score of 7–10	5	151	r: −0.0534 (p>0.05)	Very low

Number of studies	Design	Definition of outcome	Maximum interval between sample and birth (minutes)	Number of women & baby pairs	Correlation coefficient (p-value)	Quality
Correlation of fetal scalp base deficit with high Apgar scores						
1 study (Khazin 1969)	Case series	Apgar score of 7–10	60	309	r: −0.0960 (p>0.05)	Very low
1 study (Khazin 1969)	Case series	Apgar score of 7–10	45	287	r: −0.0663 (p>0.05)	Very low
1 study (Khazin 1969)	Case series	Apgar score of 7–10	30	253	r: −0.1383 (p<0.05)	Very low
1 study (Khazin 1969)	Case series	Apgar score of 7–10	15	197	r: −0.1454 (p>0.05)	Very low
1 study (Khazin 1969)	Case series	Apgar score of 7–10	5	84	r: −0.1517 (p>0.05)	Very low

NA not applicable

Table 63: Summary GRADE profile for predictive accuracy of fetal blood sampling for arterial pH at birth

Number of studies	Design	Definition of outcome	Maximum interval between sample and birth (minutes)	Number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
Fetal scalp pH ≤ 7.25									
1 study (Wiberg-Itzel 2008)	Randomised trial	Metabolic acidaemia, defined as pH < 7.05 and base deficit > 12 mmol/l	60	508	65.00% (44.10 to 85.90)[a]	56.15% (51.74 to 60.55)[a]	1.48 (1.06 to 2.08)[a]	0.62 (0.34 to 1.14)[a]	Moderate

Number of studies	Design	Definition of outcome	Maximum interval between sample and birth (minutes)	Number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
1 study (Kerenyi 1970)	Case series	pH < 7.10	60	21	100%[a] (NC)	22.22% (3.02 to 41.43)[a]	1.29 (1.00 to 1.65)[a]	0a (NC)	Very low
1 study (Wiberg-Itzel 2008)	Randomised trial	pH < 7.00	60	508	63.64% (35.21 to 92.06)[a]	55.73% (51.37 to 60.10)[a]	1.44 (0.91 to 2.27)[a]	0.65 (0.30 to 1.43)[a]	Moderate
Fetal scalp pH<7.21									
1 study (Wiberg-Itzel 2008)	Randomised trial	Metabolic acidaemia, defined as pH < 7.05 and base deficit > 12 mmol/l	60	508	50.00% (28.09 to 71.91)[a]	74.39% (70.51 to 78.26)[a]	1.95 (1.23 to 3.10)[a]	0.67 (0.43 to 1.05)[a]	Moderate
1 study (Bakr 2005)	Prospective observational study	pH ≤ 7.15	Unknown	150	72% (58 to 82)	53% (42 to 63)	1.54 (1.17 to 2.02)[a]	0.53 (0.34 to 0.83)[a]	Low
1 study (Kerenyi 1970)	Case series	pH < 7.10	60	21	100%[a] (NC)	66.67% (44.89 to 88.44)[a]	3.00 (1.56 to 5.77)[a]	0.00a (NC)	Very low
1 study (Wiberg-Itzel 2008)	Randomised trial	pH < 7.00	60	508	45.45% (16.03 to 74.88)[a]	73.84% (69.98 to 77.71)[a]	1.74 (0.89 to 3.38)[a]	0.74 (0.43 to 1.27)[a]	Moderate
Fetal scalp pH < 7.10									
1 study (Kerenyi 1970)	Case series	pH < 7.10	60	21	33.33% (0 to 86.68)[a]	94.44% (83.86 to 100)[a]	6.00 (0.50 to 72.21)[a]	0.71 (0.31 to 1.58)[a]	Very low
Fetal scalp lactate ≥ 4.2 mmol/l									

Number of studies	Design	Definition of outcome	Maximum interval between sample and birth (minutes)	Number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
1 study (Wiberg-Itzel 2008)	Randomised trial	Metabolic acidaemia, defined as pH < 7.05 and base deficit > 12 mmol/l	60	684	100%[a] (NC)	51.04% (47.26 to 54.81)[a]	2.04 (1.89 to 2.21)[a]	0.00a (NC)	Moderate
1 study (Wiberg-Itzel 2008)	Randomised trial	pH<7.00	60	684	76.00% (59.26 to 92.74)[a]	51.29% (47.47 to 55.11)[a]	1.56 (1.24 to 1.97)[a]	0.47 (0.23 to 0.94)[a]	Moderate
Fetal scalp lactate > 4.8 mmol/l									
1 study (Wiberg-Itzel 2008)	Randomised trial	Metabolic acidaemia, defined as pH < 7.05 and base deficit > 12 mmol/l	60	684	76.00% (59.26 to 92.74)[a]	62.37% (58.67 to 66.07)[a]	2.02 (1.59 to 2.57)[a]	0.38 (0.19 to 0.78)[a]	Moderate
1 study (Wiberg-Itzel 2008)	Randomised trial	pH < 7.00	60	684	100%[a] (NC)	61.87% (58.20 to 65.54)[a]	2.62 (2.38 to 2.89)[a]	0.00[a] (NC)	Moderate
Fetal scalp base deficit > 10 mEq/l									
1 study (Kerenyi 1970)	Case series	pH < 7.10	60	18	0%[a] (NC)	81.25% (62.12 to 100)[a]	0a (NC)	1.23 (0.97 to 1.56)[a]	Very low
Fetal scalp base deficit > 12.5 mEq/l									
1 study	Case series	pH < 7.10	60	18	0%[a] (NC)	93.75%	0a (NC)	1.07	Very low

Number of studies	Design	Definition of outcome	Maximum interval between sample and birth (minutes)	Number of women & baby pairs	Measure of diagnostic accuracy (95% CI)				Quality
					Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	
(Kerenyi 1970)						(81.89 to 100)[a]		(0.94 to 1.21)[a]	

CI confidence interval, NC not calculable, NR not reported

a Calculated by the 2014 NCC-WCH technical team
b Values reported in the table are as reported in the study; however, they do not match the 2x2 data reported, therefore the 2014 NCC-WCH technical team calculations have also been quoted

Table 64: Summary GRADE profile for correlation of fetal scalp blood sample values with umbilical artery values at time of birth

Number of studies	Design	Definition of outcome	Maximum interval between sample and birth (minutes)	Number of women & baby pairs	Correlation coefficient	Quality
Correlation of fetal scalp pH						
1 study (Kubli 1968)	Case series	Artery pH at time of birth	5	31	r: 0.76	Very low
Correlation of fetal scalp base excess						
1 study (Kubli 1968)	Case series	Artery pH at time of birth	5	31	r: 0.90	Very low

4.6.3.4 Evidence statements

4.6.3.4.1 Comparative clinical outcome data

There was no evidence of a difference in mode of birth (n=3319) for women whose labour was managed with fetal blood sample lactate measurements and women whose labour was managed with pH measurements. There was also no evidence of a difference in risk of the neonatal outcomes reported, including death (n=2992), encephalopathy (n=2992), admission to neonatal intensive care unit (n=2992), Apgar score less than 7 at 5 minutes (n=3319) and various cord blood gas measurements (pH, lactate and base deficit; n=3348). The evidence was of very low to moderate quality.

4.6.3.4.2 Predictive accuracy of fetal blood sampling for composite neonatal outcomes

A pH of less than 7.25 was found to have a moderate specificity for the composite neonatal outcome (n=96), but all other diagnostic accuracy parameters were low or not useful. There was conflicting evidence around the accuracy of a threshold of 7.20 or 7.21: 1 study using a threshold of pH of 7.21 of less (n=150) reported a moderate sensitivity and moderately useful negative likelihood ratio with other parameters classed as low or not useful, whereas another study using a threshold of pH less than 7.20 (n=96) reported a high specificity and very useful positive likelihood ratio with low sensitivity and not useful negative likelihood ratio. The quality of the evidence ranged from very low to moderate.

4.6.3.4.3 Predictive accuracy of fetal blood sampling for Apgar score at 5 minutes

There was consistent evidence from 2 studies (n=531) that a pH threshold of 7.25 or less or less than 7.21 had low sensitivity, low specificity and not useful likelihood ratios for predicting a low 5 minute Apgar score. A pH threshold of less than 7.10 was found to have high specificity and a very useful positive likelihood ratio for predicting low Apgar score at 5 minutes, but the sample size was very small (n=23) which limited the validity of the findings.

Lactate measurements (using a threshold of 4.2 mmol/l or more, or more than 4.8 mmol/l) were found to have a moderate sensitivity and moderately useful negative likelihood ratio for predicting low 5 minute Apgar score (n=684), with other diagnostic accuracy parameters low or not useful.

The use of base deficit measurements (using thresholds of more than 10 mEq/l or more than 12.5 mEq/l) was found to have moderate to high specificity, but other diagnostic accuracy parameters were low or not useful. However, most of this evidence came from 1 study with a very small sample size (n=19). The evidence across all outcomes was of very low to moderate quality.

4.6.3.4.4 Correlation of fetal blood sampling findings with Apgar score at 5 minutes

Evidence from 1 study (n=41) showed that the correlation of fetal blood sample pH and low Apgar score at 5 minutes was low between 60 and 15 minutes of birth, becoming moderately positively correlated for pH measurements taken within 15 minutes of birth and highly positively correlated for pH measurements taken within 5 minutes of birth. However, the sample size was small, particularly for the group with fetal blood samples taken within 5 minutes of birth (n=8). There was very low or no correlation between pH and high Apgar score at 5 minutes, regardless of the point at which the measurement was taken.

Evidence from 1 study (n=13) showed that base deficit taken within 60 minutes of birth was highly negatively correlated with low Apgar at 5 minutes, regardless of at what point the

measurement was taken. However, the study sample size was very small. In contrast, there was very low or no correlation between base excess and high Apgar score at 5 minutes. The quality of the evidence was very low.

4.6.3.4.5 Predictive accuracy of fetal blood sampling for arterial pH at birth

There was evidence from 1 study (n=508) that a pH threshold of either 7.25 or less, or less than 7.21 had a low or not useful level of diagnostic accuracy for poor arterial cord blood gas values at birth, as measured either by a pH of less than 7.00 at birth or the diagnosis of metabolic acidaemia (pH less than 7.05 and base deficit more than 12 mmol/l). Evidence from another study (n=21) was that these same pH thresholds also had a high sensitivity and very useful negative likelihood ratio, but the sample size was very small.

There was evidence from 1 study (n=684) that a lactate threshold of 4.2 mmol/l or more, or more than 4.8 mmol/l had a high sensitivity and moderate negative likelihood ratios, with specificity and positive likelihood ratios all low or not useful.

Base deficit thresholds of more than 10 mEq/l or more than 12.5 mEq/l were found to have a moderate to high specificity, but again the sample size was very small (n=18). The evidence was of very low to moderate quality.

4.6.3.4.6 Correlation of fetal blood sampling with umbilical artery values at birth

There was evidence from 1 study (n=31) that pH and base excess measured within 5 minutes of birth have high correlation with umbilical artery pH at birth, but this evidence was from 1 small study. The evidence was of very low quality.

4.6.3.5 Health economics profile

No published economic evaluations were identified for this review question.

A cost analysis was developed in Excel – further details of the cost inputs can be found in Appendix K.1.

Lactate levels can be measured on some blood gas analysers, but not all. Therefore it is likely that new lactate test meters would be needed if fetal blood sampling using lactate were recommended. The blood gas analyser is a standard device in obstetric units and it is estimated that fetal blood sampling would represent approximately one-tenth of the use of the machine. Therefore the analyser would still be needed even if it was not used for fetal blood sampling. The costs of purchasing a lactate meter and the associated consumables (£2.06 per sample taken) were compared to the consumable costs corresponding to using a blood gas analyser for pH measurements (£0.75 per sample taken).

A capillary sample of the baby's blood is taken from the scalp. The technique is the same regardless of whether lactate or pH is measured. The costs for staff to take a sample were estimated (£14 to £20 for 20 minutes of a specialty trainee or registrar's time).

The success rates reported in the review of clinical evidence were used to calculate the mean staff costs for taking a sample (97.8% for lactate tests compared to 89.6% for pH tests). For the base-case analysis it was assumed that successful tests would have only 1 sample taken, whereas unsuccessful tests would require 2 samples. This was a conservative assumption as sometimes a successful test can require 2 or more attempts to obtain a sample. This rate will depend on the experience of staff.

Under these assumptions the cost per test was lower for the pH sample when using a blood gas analyser, but as the success rates were lower than for taking a lactate sample this

analysis showed lactate testing was slightly less expensive than pH testing. The difference in cost per test was small (£0.36 less for lactate).

4.6.3.6 Evidence to recommendations

4.6.3.6.1 Relative value placed on the outcomes considered

The aim of this review was to determine the value of various fetal blood sampling measures in predicting neonatal outcomes. Clinically, the aim of performing fetal blood sampling is to identify those babies who are acidotic and whose birth needs to be expedited by either caesarean section or instrumental intervention.

In the study that compared clinical outcome data for pH and lactate measurements, the key outcomes of interest were mode of birth, neonatal encephalopathy and Apgar score less than 7 at 5 minutes.

In the studies that evaluated the diagnostic test accuracy of various fetal blood sampling tests and thresholds for identifying either low Apgar scores or composites of poor neonatal outcomes, the Committee agreed the most important measures were specificity and negative likelihood ratio (as these indicate that a particular test is effective at identifying babies who are not at risk, thus minimising unnecessary intervention). The Committee considered that this was appropriate as clinically fetal blood sampling would be performed as an adjunctive test to electronic fetal monitoring which generally has a high sensitivity and low specificity (that is, it has a high false positive rate). The results of the 2 tests would thus be considered together.

The Committee recognised that there were reasons to treat all of the diagnostic test accuracy measures with caution. The first issue was that in some of the included studies there was a delay of up to 60 minutes between the blood sample being obtained and the baby being born. During this time, the baby could develop a new complication or go through a traumatic birth, and therefore be born in poor condition despite having an apparently normal fetal blood sampling result. This would have the effect of lowering the sensitivity and generating worse negative likelihood ratio findings, since it would appear that the test had failed to identify a baby at risk.

A further issue for the Committee when considering the diagnostic test accuracy measures reported in the guideline review was that the studies were designed so that if the result of a fetal blood sample were regarded as concerning then action was taken by the clinicians to resolve the problem. Consequently, even though a large number of the babies who had a concerning fetal blood sample result were born without poor outcomes, it was not possible to determine whether this was because the particular test gave a false positive result or because the clinical intervention avoided a poor neonatal outcome.

The Committee did not place great value on correlation findings reported in the evidence review, except to note that these confirmed their clinical experience that there was an increasingly high correlation between a poor fetal blood sample result and a poor outcome when the interval between the sample being taken and the birth was shortened.

4.6.3.6.2 Consideration of clinical benefits and harms

With regard to fetal blood sampling, the Committee wished to strike a balance between ensuring that babies genuinely at risk would be identified and treated accordingly, and ensuring that women were not unnecessarily offered an intervention such as caesarean section. Although the Committee recognised that it could be difficult for women to form a balanced opinion of treatment options whilst experiencing pain during labour, they believed

that the woman should be fully supported to make decisions about whether to proceed with fetal blood sampling. This should ensure that the woman is well informed about alternative management strategies, including caesarean section. The Committee considered that good antenatal information provision might help pregnant women understand about fetal blood sampling and alternatives well in advance of labour and birth. A recommendation was, therefore, made to take account of the whole clinical picture as well as the woman's preferences when considering fetal blood sampling.

The Committee noted that the published systematic review (which combined evidence from 2 trials) reported a direct comparison between pH and lactate measurements that showed no statistically significant difference between the measurements for any of the clinical outcomes considered. In other words, the choice of test strategy did not make a significant difference to the numbers of babies experiencing poor outcomes in either arm of the study. Given the equivalence of the 2 test strategies, the Committee considered that it was appropriate to reference pH and lactate measurements in its recommendations. The Committee considered the evidence comparing the diagnostic accuracy of the tests and noted that although the measures were similar for pH and lactate, lactate appeared to be associated with a slightly higher negative likelihood ratio. In addition, in a study that evaluated both tests (Wiberg-Itzel 2008), the use of lactate was associated with higher sensitivities for both low Apgar score and arterial pH. The Committee members were aware from their clinical experience that the use of lactate could potentially reduce the time for a sample to be obtained because less blood would need to be taken and fewer repeat samples would be required (although not included in the evidence review as one of the priority outcomes, the published systematic review [East 2011] reported that lactate had a statistically significantly higher success rate than pH [95% compared with 89%]). As the process of taking a fetal blood sample is invasive, the Committee felt that it would be a positive step if the time required for this could be reduced and noted that the availability of bedside testing kits might save time to perform testing and would not require the clinician to leave the woman alone in the room.

Ultimately, the Committee did not feel that they could recommend that lactate be used in preference to pH as a diagnostic test. They did not feel that there was strong enough evidence in its favour and, as noted above, what was available was not associated with an improvement in clinical outcomes. Furthermore, the Committee recognised that pH is the standard test used in the UK for this indication. Although the Committee was aware of potential advantages to women and babies of lactate testing, they felt there was insufficient experience of the use of lactate testing compared to the relative merits of pH testing to allow them to make a firm recommendation to use one in preference to the other or both together. The Committee made a research recommendation to evaluate the clinical and cost effectiveness of fetal blood sampling using pH or lactate or both. The Committee discussed the possibility of pH and lactate being used together to interpret fetal blood sampling results and concluded that until the recommended research had been undertaken it was not advisable to comment on this on the recommendations. The Committee envisaged that individual units would use either pH or lactate (and not both) consistently.

The Committee noted that there was evidence available for the use of base deficit. Although the findings were comparable to those of the other tests, the Committee did not feel that it was appropriate to recommend its routine use. From their clinical experience, the Committee members were aware that there can sometimes be difficulty with taking a base deficit sample as the results can be affected by exposure to air while the blood sample is being taken. In addition, they noted that the majority of the evidence for base-deficit was based on a small sample of less than 20 women in 1 study (Kerenyi 1970).

The Committee discussed the practicalities of performing fetal blood sampling and agreed that the procedure should be performed with the woman in the left-lateral position because this would reduce the risk of aorto-caval compression. The Committee recognised that this

might not always be possible, but this would be their general recommendation. They also recognised that the procedure was more likely to be successful if the woman's cervix was dilated to 4 cm or more.

The Committee discussed the required actions following failed sampling or a finding of fetal acidosis. A finding of fetal acidosis should prompt the clinician to offer expediting the birth but the Committee noted that there would be situations when there would a necessary delay due to the maternal condition (for example, when a woman cannot receive anaesthesia and a consultant's opinion is needed). The Committee agreed that the consultant obstetrician and neonatal team should be informed simultaneously, while talking to the woman (and her birth companion(s)) about what is happening and taking her preferences into account would also be important. The Committee also agreed that the consultant obstetrician needed to be involved in decision making when a fetal blood sample could not be obtained and there were no accelerations in response to fetal scalp stimulation.

The guideline review protocol from CG190 did not specify inclusion of studies evaluating repeat samples, yet the Committee felt that they formed a key part of standard clinical practice. The Committee was made aware through the stakeholder comments on the draft mini-scope of a recent study from Sweden that examined neonatal outcome and mode of birth in labours with repetitive fetal scalp blood sampling (Holzmann 2015). While the study did not meet the inclusion criteria for the review, the Committee wished to give due consideration to the stakeholder comments. The study reported that the risk of caesarean section was almost doubled if fetal blood sampling was undertaken more than twice. The indication in the study for fetal blood sampling based on CTG results was not directly applicable to the UK setting. The Committee acknowledged that sampling is an invasive procedure, but they agreed that performing further samples when indicated by the CTG was preferable to offering or performing unnecessary instrumental or caesarean births. The Committee was cautious about the risks associated with repeated sampling and recommended discussion with a consultant obstetrician if a third sample was needed. The particular thresholds that the Committee chose for repeat sampling and the associated timings of the samples were derived from their clinical practice and experience.

The Committee appreciated that digital fetal scalp stimulation was a less invasive procedure for the woman and the baby relative to fetal blood sampling to predict fetal acidaemia. Thus, the Committee considered that digital fetal scalp stimulation should precede fetal blood sampling and emphasised that fetal scalp stimulation should be performed only with the fingers and not with any other instrument (for example, forceps).

4.6.3.6.3 Consideration of health benefits and resource use

A cost analysis was performed for this review in place of formal cost effectiveness modelling. The Committee considered the likely cost impact of its recommendations and agreed that it would be minimal. Although lactate was recommended as an option for testing, this would occur only in units where the equipment and training were already available. Otherwise, there would not necessarily be a large change in practice. The Committee felt that it would be possible to have a clearer understanding of the likely cost impact of using lactate rather than pH measurements once better quality outcome data were available from UK studies.

4.6.3.6.4 Quality of evidence

The evidence was of mixed quality, ranging from very low to moderate for the various outcomes considered. The evidence supporting the change in the recommendations in CG190 in favour of lactate was drawn from a study of moderate quality. However, as the study was from a setting other than the UK NHS (the study was conducted in Sweden) and was not particularly large, the Committee did not feel it was sufficient to make a stronger

recommendation. The 2017 Committee additionally felt that as pH is still used more frequently than lactate in the NHS then pH should appear ahead of lactate in the recommendations, although in reality either form of measurement could be used. The Committee felt that it would be confusing to use both pH and lactate because in some situations there may be conflicting results, and so the recommendations were phrased to ensure that one or other of pH and lactate (but not both) should be used to interpret the results of fetal blood sampling pending further research.

4.6.3.6.5 Other considerations

The Guideline Committee discussed appropriate thresholds for interpreting the findings of fetal blood samples. They did not feel there was any evidence to suggest changing the extant thresholds for pH, and agreed that they should recommend the use of the lactate thresholds as reported in the studies.

The Committee felt it important that women be fully informed of the nature of the procedure required to obtain a fetal blood sample and its risks, benefits and limitations, particularly the risk of a 'failed' sample and the possible actions that may be considered once a result is obtained. The Committee also recognised the importance of informing the woman that if a fetal blood sample cannot be obtained but there are fetal heart accelerations in response to the procedure, this is encouraging and in these circumstances expediting the birth may not be necessary.

4.6.3.6.6 Key conclusions

The Committee concluded that there was extensive evidence of benefits to the baby, notably lower incidences of cord blood acidosis, need for neonatal resuscitation, neonatal seizures and low Apgar scores. Also the predictive accuracy statistics for fetal blood sample values showed very good positive predictive values for adverse neonatal outcome with a pH less than 7.20 and very good positive predictive values and moderately good negative predictive values for a fetal blood sampling pH threshold of 7.10. Finally, there was excellent correlation between fetal blood sample pH values and cord arterial pH values. The Committee noted that there was evidence from one published meta-analysis that showed that the use of fetal blood sampling as an adjunct to CTG was associated with significantly more instrumental vaginal births and caesarean sections than was CTG monitoring alone. However, this was not the comparison of interest and they also noted that the majority of the study participants were women with a high-risk pregnancy. On balance, the Committee felt that the evidence of benefit to the baby from using CTG supported by fetal blood sampling outweighed the increased likelihood of an operative birth.

The Committee also concluded that when interpreting fetal blood sampling results individual units should use either pH or lactate consistently (but not both together) because in some situations there may be conflicting results when using both.

The recommendations below reflect the Committee's conclusions from the 3 review questions related to fetal blood sampling. See also Section 4.3 for an overarching recommendation to consider fetal blood sampling when the CTG trace is pathological.

4.6.4 Recommendations

44. Do not carry out fetal blood sampling if:

- **there is an acute event (for example, cord prolapse, suspected placental abruption or suspected uterine rupture) or**

- **the whole clinical picture indicates that the birth should be expedited or**
- **contraindications are present, including risk of maternal-to-fetal transmission of infection or risk of fetal bleeding disorders. [2017]**

45. **Be aware that for women with sepsis or significant meconium (see recommendation 1.5.2 in the NICE guideline), fetal blood sample results may be falsely reassuring, and always discuss with a consultant obstetrician:**
    - **whether fetal blood sampling is appropriate**
    - **any results from the procedure if carried out. [2017]**

46. **Before carrying out or repeating fetal blood sampling, start conservative measures and offer digital fetal scalp stimulation (see recommendations 39 and 42). Only continue with fetal blood sampling if the cardiotocograph trace remains pathological (see recommendation 32). [2017]**

47. **When considering fetal blood sampling, take into account the woman's preferences and the whole clinical picture. [2017]**

48. **When considering fetal blood sampling, explain the following to the woman and her birth companion(s):**
    - **Why the test is being considered and other options available, including the risks, benefits and limitations of each.**
    - **The blood sample will be used to measure the level of acid in the baby's blood, which may help to show how well the baby is coping with labour.**
    - **The procedure will require her to have a vaginal examination using a device similar to a speculum.**
    - **A sample of blood will be taken from the baby's head by making a small scratch on the baby's scalp. This will heal quickly after birth, but there is a small risk of infection.**
    - **What the different outcomes of the test may be (normal, borderline and abnormal) and the actions that will follow each result.**
    - **If a fetal blood sample cannot be obtained but there are fetal heart rate accelerations in response to the procedure, this is encouraging and in these circumstances expediting the birth may not be necessary.**
    - **If a fetal blood sample cannot be obtained and the cardiotocograph trace has not improved, expediting the birth will be advised.**
    - **A caesarean section or instrumental birth (forceps or ventouse) may be advised, depending on the results of the procedure. [2017]**

49. **Do not take a fetal blood sample during or immediately after a prolonged deceleration. [2017]**

50. **Take fetal blood samples with the woman in the left-lateral position. [2017]**

51. **Use either pH or lactate when interpreting fetal blood sample results. [2017]**

52. Use the following classifications for fetal blood sample results:

- **pH:**
  - **normal: 7.25 or above**
  - **borderline: 7.21 to 7.24**
  - **abnormal: 7.20 or below**

or

- **lactate:**
  - **normal: 4.1 mmol/l or below**
  - **borderline: 4.2 to 4.8 mmol/l**
  - **abnormal: 4.9 mmol/l or above. [2017]**

53. Interpret fetal blood sample results taking into account:

- **any previous pH or lactate measurement and**
- **the clinical features of the woman and baby, such as rate of progress in labour. [2017]**

54. If the fetal blood sample result is abnormal:

- **inform a senior obstetrician and the neonatal team and**
- **talk to the woman and her birth companion(s) about what is happening and take her preferences into account and**
- **expedite the birth (see recommendations 1.13.34 to 1.13.37 in the NICE guideline). [2017]**

55. If the fetal blood sample result is borderline and there are no accelerations in response to fetal scalp stimulation, consider taking a second fetal blood sample no more than 30 minutes later if this is still indicated by the cardiotocograph trace. [2017]

56. If the fetal blood sample result is normal and there are no accelerations in response to fetal scalp stimulation, consider taking a second fetal blood sample no more than 1 hour later if this is still indicated by the cardiotocograph trace. [2017]

57. Discuss with a consultant obstetrician if a third fetal blood sample is thought to be needed. [2017]

58. If fetal blood sampling is attempted and a sample cannot be obtained, but the associated fetal scalp stimulation results in a fetal heart rate acceleration, decide whether to continue the labour or expedite the birth in light of the clinical circumstances and in discussion with the woman and a senior obstetrician. [2017]

59. If fetal blood sampling is attempted but a sample cannot be obtained and there has been no improvement in the cardiotocograph trace, expedite the birth (see recommendations 1.13.34 to 1.13.37 in the NICE guideline). [2017]

4.6.5 Research recommendations

2. What is the clinical and cost effectiveness of fetal blood sampling during labour using pH testing or lactate testing or both?

Why this is important

Fetal blood sampling is a common but invasive and uncomfortable procedure that is used to help determine whether a baby is acidotic. Two kinds of tests are available to assess for acidosis: measurement of fetal blood pH (currently in common use in the UK) and measurement of fetal blood lactate. While lactate testing is associated with improved practical benefits such as a small blood sample and quick processing time compared with pH testing, there was insufficient evidence identified in the guideline review to support a recommendation that lactate testing be used in preference to pH testing. The efficient use of fetal blood sampling during labour is expected to improve outcomes for women and their babies and lead to a net saving for the NHS by avoiding unnecessary duplicate testing and expedited/assisted births.

A study is needed to evaluate the clinical and cost effectiveness of fetal blood sampling during labour using pH testing and/or lactate testing in singleton term pregnant women in labour who have a concerning CTG trace. The mixed-method design should include a randomised controlled trial comparing decision rules after testing, or alternatively a prospective cohort study evaluating decisions taken after conflicting results, in conjunction with a qualitative study of women's views and experiences. Data should be obtained on clinical outcomes such as success rates (that is, the need for repeat sampling), as well as technology (such as a bedside testing facility for measuring one or both parameters) and training requirements.

4.7 Women's views and experiences of fetal monitoring

4.7.1 Review question

What are women's views and experiences of fetal monitoring in labour?

4.7.2 Description of included studies

Six studies (Hansen 1985; Hindley 2008; Mangesi 2009; McCourt 2014; Parisaei 2011; Shields 1978) are included in this review. Of the studies, 3 were conducted in the UK (Hindley et al., 2008; McCourt 2014; Parisaei 2011), 1 in South Africa (Mangesi 2009), 1 in Denmark (Hansen 1985) and 1 in Canada (Shields 1978).

Each of the studies looked at different interventions or comparisons. A descriptive study (Parisaei 2011) evaluated the acceptability to women at a London Hospital of a fetal electrocardiographic (ST analysis) monitoring system (STAN). Another study (McCourt 2014) used qualitative methodology to explore women's experiences of continuous electronic fetal monitoring. A third study (Shields 1978) examined women's views and experiences of internal electronic fetal monitoring (using a fetal scalp electrode) during labour. A fourth study (Hindley 2008) surveyed women's preferences in relation to fetal heart rate monitoring methods before and after labour and birth by means of antenatal and postnatal questionnaires. A fifth study (Hansen 1985) compared women's views of cardiotocography (CTG) with views of intermittent auscultation. The final study (Mangesi 2009) examined women's preferences regarding 3 methods used to monitor their baby's heart rate: CTG, a fetal stethoscope and a hand-held Doppler ultrasound fetal heart rate monitor. Each method

was applied for 10 minutes and then the woman's preference was assessed. Further details of the included studies are provided in the relevant evidence tables (See Appendix G:).

One study (McCourt 2014) used a qualitative study design, although the author also reported additional information based on responses from questionnaires. The other 5 studies were observational in design with considerable limitations; some of these studies provided qualitative evidence, although this was obtained using survey methodology rather than qualitative study designs.

4.7.3 Evidence profile

The findings for women's views and experiences of fetal monitoring in labour are related to two categories of interventions used in fetal monitoring:

- women's views and experiences of ST analysis (specifically the STAN fetal electrocardiographic monitoring system)
- women's views and preferences for methods used to monitor fetal heart rate (a fetal stethoscope, Doppler ultrasound fetal heart rate monitor and CTG).

Table 65: Findings for women's views and experiences of fetal monitoring in labour

Women's views and experiences of ST analysis using the STAN device	
Parisaei 2011 Very low quality[a,b]	• Acceptability: 95% of women felt that the STAN device was an acceptable way of monitoring their babies in labour. • Reassurance: 96% of women felt reassured by having a fetal electrocardiogram (ECG) as an adjunct to electronic fetal monitoring (EFM) to monitor their babies in labour • Women's understanding: 95% of women felt that they understood the physiological basis behind the STAN device • Midwife: 93% of women reported that the midwife explained why their babies were being monitored continuously • Doctor: 99% of women reported that obstetricians explained why their baby was being monitored continuously • Future use: 93% of women reported that they would consent to the same form of monitoring in future labours • Recommendations: 89% of women reported that they would recommend the system to friends who were pregnant. The majority would only recommend the system if their friends were at high risk and needed continuous fetal monitoring
Women's views and preferences for different methods of fetal monitoring (fetal stethoscope, Doppler ultrasound monitor, CTG)	
Mangesi 2009 Very low quality[c]	• First maternal preference: Doppler n=72/97; fetal stethoscope n=13/97; CTG n=12/97 • p=0.001 (Doppler versus fetal stethoscope) • p=0.08 (fetal stethoscope versus. ECG) • Second maternal preference: fetal stethoscope n=58/97; CTG n=22/97; Doppler n=17/97 • The fetal stethoscope was disliked because it caused discomfort during use and CTG was disliked because it often confined women to bed while the use of securing belts associated with CTG restricted women's movements
Women's views and experiences of CTG compared with intermittent auscultation	
Hansen 1985	Maternal preference at antenatal interview (total n=655)

Women's views and experiences of ST analysis using the STAN device	
Very low quality[d]	• CTG n=259/655 (39.5%) • IA n=212/655 (32%) • Undecided n=184/655 (28%) Postnatal interview (total n=385): • from CTG preferred antenatally (CTG-p) and IA preferred antenatally (IA-p), n=179 had IA and n=102 had CTG. ○ of the n=104 undecided antenatally n=69 had IA and n=35 CTG • Advantages and disadvantages of IA mentioned postpartum by women who had their labour monitored by IA (IA-p n=85 and CTG-p n=94): ○ no pain to the baby: IA-p 11%; CTG-p 3%; p <0.05 ○ no discomfort from sensors and belt: IA-p 58%; CTG-p 30%; p<0.05 ○ increased contact with clinical personnel: IA-p 25%; CTG-p 15%; p<0.05 ○ more natural childbirth: IA-p 72%; CTG-p 45%; p<0.05 • Advantages and disadvantages of EFM mentioned postpartum by women who had their labour monitored by EFM (IA-p n=36 and CTG-p n=66): ○ EFM promoted the husband's involvement: IA-p 25%; CTG-p 45%; p<0.05 ○ positive influence of EFM signal (sound/trace of heartbeat): IA-p 31%; CTG-p 67%; p<0.01 ○ possibility of quick intervention: IA-p 44%; CTG-p 62%; p<0.05 ○ continuous, precise surveillance: IA-p 45%; CTG-p 70%; p<0.05 ○ enforced immobility: IA-p 22%; CTG-p 20%; p<0.05 ○ 'technical milieu': IA-p 25%; CTG-p 3%; p<0.05 ○ disturbance from EFM signals (sound): IA-p 20%; CTG-p 3%; p<0.05 ○ fear of trauma to the child: IA-p 5%; CTG-p 2%; p<0.05 • Distribution of postpartum preference as to future fetal surveillance: ○ preference in future pregnancy for CTG-p who had their labour monitored by IA: prefer IA again 53%; prefer CTG 42%; undecided 5% ○ preference in future pregnancy for IA-p who had their labour monitored by CTG: prefer IA 59%; prefer CTG again 32%; undecided 9% ○ preference in future pregnancy for women who were undecided and had their labour monitored by IA: prefer IA again 55%; prefer CTG 27%; undecided 19% ○ preference in future pregnancy for women who were undecided and had their labour monitored by CTG: prefer IA 17%; prefer CTG again 60%; undecided 23%
Women's preferences for fetal heart rate monitoring methods before and after labour	
Hindley 2008 Very low quality[e]	Sources of information assessed through antenatal survey:

Women's views and experiences of ST analysis using the STAN device	
	• felt midwife had not explicitly given any information on monitoring n=41/63 (65%) • felt they had information from the media n=36/63 (57%) • women relied on their past experience n=29/63 (46%) Women's preference for CTG: • assessed through antenatal survey (n=63) – women did not prefer one specific option, the majority preferred a combination of intermittent and continuous CTG, n=35/63 (56%) • assessed through postnatal survey (n=38) – number of women received CTG (intermittent or continuous), n=23/38 (61%) Women's preference for decision making about intrapartum fetal monitoring: • assessed through antenatal survey – women wanted to make the final decision after considering the midwife's view, n=28/63 (44%) • assessed through postnatal survey – women conceded decision making to the midwife during the intrapartum period, n=14/38 (37%) Choice/control preference: • assessed through antenatal survey – insufficient information and discussion to make a choice regarding fetal monitoring method, n=25/ 63 (40%) • assessed through postnatal survey – felt they had been given an informed choice, n=15/38 (39%) Importance of information: • assessed through antenatal survey – women aware of different types of monitoring, n=59/63 (94%); knew all types of monitoring except Pinard stethoscope, n=46/63 (73%); felt it very important to have information on intrapartum fetal monitoring, n=54/63 (86%) • assessed through postnatal survey – felt it very important to have information on intrapartum fetal monitoring, n=15/38 (39%)
Women's experiences of internal electronic fetal monitoring	
Shields 1978 Very low quality[f]	Women's experiences of internal electronic monitoring: • responses categorised as positive, n=22/30 (includes 3 classed as highly positive) • responses categorised as negative, n=8/30 (includes 2 classed as highly negative) • among the 3 women with responses classed as highly positive, one said she 'knew exactly what was going on and therefore was not afraid'; another was 'a little frightened' but she thought it was an 'exciting idea' and compared with her other birth said 'monitoring seemed to make it shorter and more interesting'; the third considered monitoring 'a fantastic, good idea' • among the 2 women with responses classed as highly negative, both only partially understood why they were monitored; one stated that there was 'too little information

Women's views and experiences of ST analysis using the STAN device	
	about the equipment' and she 'didn't like the idea of attaching it to the baby's head'; the other stated that she 'felt like a battery being charged with all those wires and connections' Understanding the reason for monitoring: • good understanding, n=27/30 • partial understanding, n=3/30 (2 of these were the women with responses classed as highly negative in the category above) Information received: • adequate, n=27/30 (20 said they had full information and 7 said they received as much as they requested) • inadequate information received, n=3/30 • Worries about monitoring: • no worries, n=7/30 • some worries different from pregnancy, n=11/30 (4 of these expressed fears related to the electrodes) • some worries the same as pregnancy, n=12/30 (fearing that the baby would die or be deformed in some way) Complaints about monitoring: • unable to get comfortable (noise of fetal heart beat), n=2 (both had fears that the heartbeat would stop; one woman stated that she was 'worried the whole time that baby's heart would stop if the machine stopped) Presence of nurse as a support: • all women wanted the nurse with them much or most of the time and n=17/30 wanted the nurse only for supportive care, they wanted 'someone to hold onto', 'someone who cares' Complaints about caregivers: • n=4 women expressed negative views about the clinicians; 2 of these considered the facial expression of the physician to be frightening; the other 2 thought that some staff were unfamiliar with the machine and they found this disturbing; 1 woman thought the clinicians had more interest in the machine than in her, stating 'they all came with the machine and they all left with the machine'
Women's experiences of continuous electronic fetal monitoring	
McCourt 2014 Moderate quality[g]	The following comments were reported from two interviews: • *'I could tell he was OK by the monitor I think' (Standard care, 418)* • *'I kept asking questions though… but otherwise it was just through my husband… he was in the delivery suite and in the operating theatre… he had had quite a good idea, he had been able to look at the graphs, baby's heartbeat and my contractions, and even though maybe not knowing exactly what to read into the graphs' (Standard care, 424)* The comments were chosen by the study author as examples of her impression that the baby and the labour were perceived to

Women's views and experiences of ST analysis using the STAN device	
	some extent as being in the monitor, not as part of the woman's body. The author specified that she formed this impression from listening to the women's narratives and from observation of medical staff, although the impressions were rarely articulated by the women The study author wrote that many women and partners, and medical staff, focused attention on the monitor screen to try to understand the labour. This tendency was increased for women who had an epidural (these women could not feel their contractions and watched the monitor to see when contractions were taking place) and for women in 'Standard care' (these women were less satisfied with information and support they received than those who experienced a caseload model of midwifery care) In addition to the main outcomes, the study author reported that responses to CTG monitoring were ambiguous. In questionnaire responses women were least likely to be critical of receiving CTG monitoring since they perceived this to be important for the safety of the baby; however, no quotations from women who participated in the study were reported in support of this

CTG cardiotocography, ECG electrocardiogram, EFM electronic fetal monitoring, IA intermittent auscultation

a Study population consisted of women with high-risk pregnancy (diabetes, pre-eclampsia, previous caesarean section) or intrapartum risk factors (meconium stained liquor, oxytocin augmentation; 78% of the women were believed to be low risk at the antenatal booking appointment

b Unclear whether or not the questionnaire was a validated too (questionnaire response rate was 61% (77/125)); unclear how and by whom data were analysed; unclear what explanation was given to participants about reasons why the baby was monitored continuously in labour; 13.3% of participants had difficulty understanding English; unclear if women received unbiased information about ST analysis and how the way baby's wellbeing was assessed

c No sample characteristics reported; women provided with information about the study when they were in labour; consent obtained verbally; intervention applied for a very short period of time (10 minutes with each monitoring method); unclear when participants were asked about their preferences; women's parity and previous experience not reported; poor report with limited information provided

d Unclear whether outcome assessors were blinded to study group allocation; no inclusion or exclusion criteria reported; significantly more women in EFM-p group had a high-risk pregnancy.; no subgroup analysis performed to take account of women's parity or their previous experience; 41% of study population were not available for postnatal interview (the reason for this was not reported)

e Participants recruited from two different hospitals and so potential influence of different settings should be considered when interpreting the data; 50% of the study population were multigravida; potential influence of previous experiences of fetal monitoring were not taken account of by the study authors; 40% loss to follow up

f Data and results poorly reported; very old study and so advances in technology should be considered when interpreting the data; a self-developed scale was used with unclear validity; 18/30 women were multiparous

g Low risk of bias in relation to aim of the research, use of qualitative methodology, research design, data collection, ethical issue, data analysis, statement of findings; unclear risk of bias in relation to recruitment strategy (insufficient details reported in relation to how women were selected for interviews), relationship between researcher and participants (not reported whether this was considered), research value (the study authors did not discuss whether findings could be transferred to other populations and they did not identify new areas of research

4.7.4 Evidence statements

One study (n=125) found that the majority of women whose babies had been electronically monitored using ECG analysis found this both acceptable and reassuring and felt that the reasons for its use had been well explained. The quality of the evidence was very low.

One study (n=100) comparing women's views of fetal monitoring using a fetal stethoscope, Doppler ultrasound device and CTG showed that the Doppler ultrasound device was the most popular first choice. This finding was statistically significant. The evidence was of very low quality.

Two studies (n=718) investigated women's choice and preferences for intrapartum fetal monitoring. One study (n=655) comparing women's antenatal and postnatal preferences for intermittent auscultation compared with CTG showed a fairly even spread of preferences antenatally. The most commonly cited advantages of intermittent auscultation were that it was associated with a more natural childbirth and there was no discomfort compared with that experienced from sensors and belts used in CTG. No specific disadvantages of intermittent auscultation were reported. The most commonly cited advantages of CTG were that it allowed continuous, precise surveillance and that women were positively influenced by hearing the baby's heartbeat and/or seeing it being traced out. The most commonly cited disadvantages were that it enforced immobility and was associated with a technical medicalisation of birth. The second study (n=63) found that there was no clear preference for mode of intrapartum fetal monitoring expressed antenatally. Although the majority of women reported that they had been given information about fetal monitoring antenatally, only a minority felt they had been given an informed choice of type of monitoring during labour. The evidence was of very low quality.

One study (n=30) investigated women's experiences of internal fetal monitoring using a fetal scalp electrode. The majority of women responded positively when asked their views of this type of monitoring. Positive responses were associated with receiving adequate information about the monitoring. The evidence was of very low quality.

One study (n=44) that focused on continuous electronic fetal monitoring found that many women and their partners, and medical staff, focused attention on the monitor screen to try to understand the labour. The study author had the impression that the baby and the labour were perceived to some extent as being in the monitor, not as part of the woman's body. The author specified that she formed this impression from listening to the women's narratives and from observation of medical staff, although the impressions were rarely articulated by the women. The author reported two quotations as examples of women's narratives: 'I could tell he was OK by the monitor I think'; 'I kept asking questions though… but otherwise it was just through my husband… he was in the delivery suite and in the operating theatre… he had had quite a good idea, he had been able to look at the graphs, baby's heartbeat and my contractions, and even though maybe not knowing exactly what to read into the graphs'. The evidence was of moderate quality.

4.7.5 Health economics profile

No published economic evaluations were identified for this review question.

4.7.6 Evidence to recommendations

4.7.6.1 Relative value placed on the outcomes considered

The Guideline Committee agreed that it was fundamental to consider women's views of, and satisfaction with, the type of fetal monitoring they receive. Monitoring has the potential to reduce a woman's fear and anxiety and provide reassurance. However, the Committee was aware that monitoring may have the opposite effect and increase a woman's anxieties and discomfort. It is therefore important to identify how best to ensure a women's satisfaction with the monitoring they receive and how best to support an informed and evidence-based choice.

4.7.6.2 Consideration of clinical benefits and harms

The Committee noted that there was very limited evidence available on women's preferences related to any particular fetal monitoring method.

The Committee recognised that 1 study investigating the use of ST wave analysis as a component of fetal monitoring demonstrated extremely positive findings. However, the Committee felt the findings from the study did not reflect their experience in practice and questioned the validity of the study. It was noted that a large proportion of the study sample comprised women with some form of risk factor and the Committee felt that this had the potential to impact on the findings.

The Committee recognised that some of the comments from the surveys included in the evidence review highlighted the importance of information giving and providing reassurance to women. It was agreed that it is of paramount importance that women are kept continuously informed throughout labour in order to enhance their birth experience.

In 1 survey, women expressed their concerns that the CTG monitor could become the focus of attention in labour rather than the woman. This matched the experience of some Committee members who stated that they were aware of this phenomenon. In 1 qualitative study the author had the impression that the baby and the labour were perceived to some extent as being in the monitor, not as part of the woman's body. The Committee agreed that whatever form of monitoring were used, it would be important to ensure that the woman and her baby remained the focus of attention.

The Committee noted a general trend in the evidence about women's monitoring preferences in favour of intermittent auscultation. Although the Committee considered that this should be recognised and supported by healthcare professionals, it was felt that there was insufficient evidence to support a strong recommendation to routinely offer intermittent auscultation at the onset of labour.

In addition to discussing the evidence identified for this review question, the Committee discussed broader issues of women's views and experiences linked to review questions elsewhere in the guideline. Their considerations are noted below.

An informed choice

The Committee agreed that individual women may have different preferences and all women should be supported to make an informed choice about which fetal monitoring method to use. In order to make an informed choice, it is paramount that women receive evidence-based information about risks, benefits and limitations associated with each intervention. Therefore, the Committee recommended that if a woman at low risk of complications requests CTG as part of the initial assessment, then health professionals should discuss the

risks, benefits and limitations with the woman and then support her in her choice. The Committee also recognised the importance of good antenatal discussion. The Committee agreed that women's preferences should be respected in relation to any further action once fetal monitoring has started and that women should be made aware from the beginning that their preferences will be respected.

The Committee acknowledged the importance of giving women accurate information about the value and limitations of CTG, so that they understand the reasons for considering the use of continuous electronic fetal monitoring and have realistic expectations about possible outcomes. For example, CTG may restrict a woman's mobility, particularly if conventional monitoring is used (rather than telemetry). In addition to addressing any concerns they may have, women should receive information on the type of findings that may occur. The Committee concluded that it is important to explain that changes in the fetal heart rate pattern are common and should not necessarily cause concern.

The importance of making an informed choice also applies to fetal blood sampling. The Committee noted that clinicians should involve the woman in a discussion about whether to perform fetal blood sampling. The Committee deleted the 2014 recommendation about informing the woman that the procedure could help to reduce the need for further, more serious interventions because the available evidence did not reflect this. The Committee also noted that according to some evidence there were benefits for the baby, however this evidence was not sufficiently strong enough to make a recommendation. The Committee expressed the view that a woman might be more likely to choose fetal blood sampling if she was informed there would be benefits for the baby. The Committee also recognised that some women might decline fetal blood sampling and other options such as caesarean section, and that this should be discussed.

Invasive procedures – fetal blood sampling and fetal scalp stimulation

The Committee agreed that women may have different perceptions about the invasiveness of fetal monitoring methods, as well as their perceived trade-off benefits. For example, some women may prefer the Pinard stethoscope over the Doppler ultrasound device because they find it less intrusive, while others prefer Doppler ultrasound because they can listen to the baby's heart beat themselves. The Committee noted that fetal blood sampling was generally perceived to be a very invasive procedure.

The Committee recommended that the less invasive conservative measures and digital fetal scalp stimulation should be offered and performed before fetal blood sampling to see if they result in an improvement in the fetal heart pattern. The Committee used the term 'digital' fetal scalp stimulation (meaning performed with the fingers) to emphasise that more invasive methods such as using tissue forceps should be avoided.

The Committee noted that the fetal blood sampling procedure may be quicker when lactate concentration rather than pH is measured because a smaller sample is needed for testing. However as there was no evidence showing whether pH or lactate concentration would be more useful clinically the Committee decided not to recommend the use of lactate concentration over pH. The Committee made a research recommendation about the clinical and cost effectiveness of fetal blood sampling using pH or lactate or both together, and specified that women's views and experiences should be amongst the outcomes included in any future research on this topic.

Language and behaviour during cardiotocography

The Committee discussed the language and behaviour of staff during electronic fetal monitoring and it was agreed that language should be — first and foremost — useful clinically. The Committee emphasised the importance of ensuring that the language and

terminology is easily understood by clinical staff, particularly during emergency situations. Given that women's satisfaction is influenced by positive staff behaviour, such as good communication and support in decision making, the Committee discussed how the language used during fetal monitoring should be clear and easily understood by women and their birth companions. Moreover, even though some phrases such as 'high risk' may sound alarming to some women, it was the Committee's experience that women generally accepted such phrases when they were used in a sensitive manner.

Mobilisation during cardiotocography

The Committee noted that women should be encouraged to mobilise as much as possible and/or to change their position during CTG monitoring, for example, by taking advantage of new wireless technologies that enhance mobility during electronic fetal monitoring (see CG190, Section 10.6, 'Cardiotocography using telemetry compared with conventional cardiotocography'). However it was noted that depending on what type of equipment is used, mobilisation may be restricted. Changing positions (and not just adopting the left-lateral position) was added to the recommendations so that women who cannot mobilise fully may at least adopt alternative positions (although clinicians should still encourage women to avoid a supine position during CTG monitoring, as in CG190).

One-to-one care

The Committee was aware of the potential for CTG monitoring to take the place of one-to-one care, with a woman being left alone and connected to the monitor. The Committee agreed that this would constitute poor practice and that clinicians should stay with the woman to provide one-to-one support and to monitor both the woman's and the baby's condition. The Committee agreed that decisions regarding the care of the woman should be based on a full clinical assessment, not just on CTG findings, and conservative measures should be implemented to assess whether the clinical situation is likely to improve. This would help avoid invasive interventions and thus enhance a woman's experience of fetal monitoring and birth.

Computerised interpretation of cardiotocography

The Committee noted that if electronic fetal monitoring was applied using computerised interpretation of the CTG trace then this may affect the model of one-to-one care provided by a midwife and thus affect the woman's experience of birth. However, the Committee did not discuss this issue in detail because computerised interpretation of CTG traces was not recommended, due to a lack of evidence supporting it.

4.7.6.3 Consideration of health benefits and resource use

There were no specific considerations related to resource use for this question.

4.7.6.4 Quality of evidence

The Committee noted that 5 of the studies included in this review were of very low quality, while the remaining study was of moderate quality. The Committee also noted that a number of the included studies included a significant proportion of women at high risk of complications. It was felt that this could potentially impact on the results as women identified as being at high risk of complications might be more likely to seek reassurance from electronic fetal monitoring.

The Committee recognised the difficulty in trying to determine women's preferences for a particular type of monitoring when each individual woman will generally only experience a

single type. They noted that 1 study had tried to ensure that women experienced all types of monitoring, however in this case each type of monitoring had been used for only 10 minutes.

The Committee noted that 2 of the studies were conducted more than 30 years ago and so they might not be relevant to current practice because women's expectations and preferences are likely to have changed over time.

4.7.6.5 Other considerations

The Committee acknowledged that the evidence base for this question was poor but that it was a topic that merited further investigation despite the discussions and formulation of recommendations having taken account of women's views and experiences using the consensus opinion of the Committee. CG190 had previously noted that while the use of central electronic fetal monitoring systems and telemetry was increasing, little was known about how this technology might impact upon a woman's experience of labour and birth and the care received during this period. In the light of this, the Committee concluded that women's experiences should be considered as part of future research, not only in the case of telemetry (see CG190, Section 10.6 which includes a recommendation for research comparing CTG using telemetry to conventional CTG) but also the 2017 research recommendations related to:

- comparing intermittent auscultation to CTG in otherwise low-risk pregnancies complicated by meconium-stained liquor
- comparing the use of pH testing to lactate testing or both together in fetal blood sampling.

See Section 3.1, Section 4.1, Section 4.3, Section 4.5 and Section 4.6 for recommendations arising from this review question.

4.8 Cardiotocography with fetal electrocardiogram analysis compared with cardiotocography alone

4.8.1 Review question

Does the use of fetal electrocardiogram (ECG) analysis with continuous electronic fetal monitoring (EFM) improve outcomes when compared with continuous EFM alone?

4.8.2 Description of included studies

Four studies (Belfort 2015; Neilson 2015; Olofsson 2014, van Wijngaarden 1996) are included in this review. Neilson (2015) is a systematic review with 7 component trials from a variety of locations. All of the included trials in the published systematic review compared the use in labour of continuous electronic fetal monitoring plus ECG with continuous electronic fetal monitoring alone. Six trials of ST waveform analysis and 1 trial of PR interval analysis are included in the systematic review (Neilson 2015). The women who participated in the trials were at high risk of developing complications in labour except in 1 study (Belfort 2015). The duration of the monitoring using continuous electronic fetal monitoring and ECG was not reported in the included studies. Two studies (Belfort 2015; Olofsson 2014) reported additional outcomes for ST waveform analysis of ECG and these have been included in the guideline review. The remaining study (van Wijngaarden 1996) is a randomised controlled trial (RCT) involving women at high risk which looked at PR interval analysis of ECGs.

Although the wording of this question refers to electronic fetal monitoring it is apparent that in practice studies are referring to electronic fetal monitoring plus monitoring of contractions.

This is more accurately termed cardiotocography (CTG) and therefore this term will be used in the remainder of this evidence summary and throughout the guideline.

4.8.3 Evidence profile

A fixed effect model was used for these analyses, with the exception of 2 outcomes (cord PH less than 7.05 plus base deficit more than 12 mmol/L; and fetal blood sampling) for which a random effects model was used due to high heterogeneity ($I^2 \geq 50\%$).

Sub-group analysis was performed for:

- PR interval analysis
- ST waveform analysis.

Table 66: Summary GRADE profile for comparison of continuous cardiotocography plus fetal electrocardiogram PR interval analysis with continuous cardiotocography alone in labour

Quality assessment		Number of women		Effect		
Number of studies	**Design**	**CTG plus fetal ECG**	**CTG alone**	**Relative (95% CI)**	**Absolute (95% CI)**	**Quality**
Caesarean section						
1 study (Neilson 2015)	Randomised trial	79/482 (16.4%)	98/475 (20.6%)	RR 0.79 (0.61 to 1.04)	43 fewer per 1000 (from 80 fewer to 8 more)	Very low
Instrumental vaginal birth						
1 study (Neilson 2015)	Randomised trial	116/482 (24.1%)	122/475 (25.7%)	RR 0.94 (0.75 to 1.17)	15 fewer per 1000 (from 64 fewer to 44 more)	Very low
Assisted birth (caesarean section or instrumental vaginal birth)						
2 studies (Neilson 2015; van Wijngaarden 1996)	Randomised trials	231/594 (38.9%)	262/577 (45.4%)	RR 0.86 (0.75 to 0.98)	64 fewer per 1000 (from 9 fewer to 114 fewer)	Very low
Fetal blood sampling						
2 studies (Neilson 2015; van	Randomised trials	86/594 (14.5%)	109/577 (18.9%)	RR 0.48 (0.12 to 1.95)	98 fewer per 1000 (from 166 fewer to 179 more)	Very low

Quality assessment		Number of women		Effect		
Number of studies	**Design**	**CTG plus fetal ECG**	**CTG alone**	**Relative (95% CI)**	**Absolute (95% CI)**	**Quality**
Wijngaarden 1996)						
Perinatal death						
1 study (Neilson 2015)	Randomised trial	1/482a (0.21%)	0/475 (0%)	RR 2.96 (0.12 to 72.39)	NC	Very low
Cord pH ≤ 7.15 (acidosis at birth)						
1 study (van Wijngaarden 1996)	Randomised trial	8/84 (9.5%)	14/100 (14%)	RR 0.68 (0.3 to 1.54)	45 fewer per 1000 (from 98 fewer to 76 more)	Very low
Admission to neonatal intensive care unit						
1 study (Neilson 2015)	Randomised trial	22/482 (4.6%)	28/475 (5.9%)	RR 0.77 (0.45 to 1.33)	14 fewer per 1000 (from 32 fewer to 19 more)	Very low
Apgar score < 7 at 5 minutes						
1 study (Neilson 2015)	Randomised trial	3/482 (0.62%)	7/475 (1.5%)	RR 0.42 (0.11 to 1.62)	9 fewer per 1000 (from 13 fewer to 9 more)	Very low
Neonatal intubation						
1 study (Neilson 2015)	Randomised trial	6/482 (1.2%)	8/475 (1.7%)	RR 0.74 (0.26 to 2.11)	4 fewer per 1000 (from 13 fewer to 19 more)	Very low

CI confidence interval, CTG cardiotocography, ECG electrocardiogram, NC not calculable RR relative risk

a Baby was born by forceps, the cord blood pH was 7.14 and the base excess was -12 mmol/l. Apgar was 8 at 1 minute and 9 at 5 minutes. The baby was in good condition for 36 hours then had respiratory arrest on the postnatal ward and died 12 hours later. No reason for this sudden death was found

Table 67: Summary GRADE profile for comparison of continuous cardiotocography plus fetal electrocardiogram ST waveform analysis with continuous cardiotocography alone in labour

Quality assessment		Number of women		Effect		
Number of studies	**Design**	**CTG plus fetal ECG**	**CTG alone**	**Relative (95% CI)**	**Absolute (95% CI)**	**Quality**
Spontaneous vaginal birth						
2 studies (Belfort 2015; Olofsson 2014)	Randomised trials	10046/13229 (75.9%)	9949/13217 (75.3%)	RR 1.01 (0.99 to 1.02)	8 more per 1000 (from 8 fewer to 15 more)	Low
Caesarean section						
1 meta-analysis of 6 studies (Neilson 2015)	Randomised trials	1810/13229 (13.7%)	1779/13217 (13.5%)	RR 1.02 (0.96 to 1.08)	3 more per 1000 (from 5 fewer to 11 more)	Low
Instrumental vaginal birth						
1 meta-analysis of 6 studies (Neilson 2015)	Randomised trials	1373/13229 (10.4%)	1489/13217 (11.3%)	RR 0.92 (0.86 to 0.99)	9 fewer per 1000 (from 1 fewer to 16 fewer)	Low
Fetal blood sampling						
1 meta-analysis of 4 studies (Neilson 2015)	Randomised trials	486/4870 (10%)	738/4801 (15.4%)	RR 0.61 (0.41 to 0.91)	60 fewer per 1000 (from 14 fewer to 91 fewer)	Very low
Fetal and neonatal death						
1 meta-analysis of 6 studies	Randomised trials	11/13229 (0.08%)	6/13217 (0.05%)	RR 1.71 (0.67 to 4.33)	0 more per 1000 (from 0 fewer to 2 more)	Very low

Quality assessment		Number of women		Effect		
Number of studies	**Design**	**CTG plus fetal ECG**	**CTG alone**	**Relative (95% CI)**	**Absolute (95% CI)**	**Quality**
(Neilson **2015)**						
Cord pH < 7.05 and base deficit > 12 mmol/l						
1 meta-analysis of 6 studies (Neilson 2015)	Randomised trials	81/12850 0.63%)	121/12832 (0.94%)	RR 0.72 (0.43 to 1.2)	3 fewer per 1000 (from 5 fewer to 2 more)	Very low
Neonatal encephalopathy						
1 meta-analysis of 6 studies (Neilson 2015)	Randomised trials	12/13210 (0.09%)	20/13200 (0.15%)	RR 0.61 (0.3 to 1.22)	1 fewer per 1000 (from 1 fewer to 0 more)	Very low
Admission to neonatal intensive care unit						
1 meta-analysis of 6 studies (Neilson 2015)	Randomised trials	1113/13210 (8.4%)	1155/13200 (8.8%)	RR 0.96 (0.89 to 1.04)	4 fewer per 1000 (from 10 fewer to 3 more)	Low
Apgar score < 7 at 5 minutes						
1 meta-analysis of 5 studies (Neilson 2015)	Randomised trials	103/7678 (1.3%)	107/7624 (1.4%)	RR 0.95 (0.73 to 1.24)	1 fewer per 1000 (from 3 fewer to 3 more)	Low
Apgar score ≤ 3 at 5 minutes						
1 study (Belfort 2015)	Randomised trial	17/5532 (0.31%)	6/5576 (0.11%)	RR 2.86 (1.13 to 7.24)	2 more per 1000 (from 0 more to 7 more)[a]	Low

Quality assessment		Number of women		Effect		
Number of studies	**Design**	**CTG plus fetal ECG**	**CTG alone**	**Relative (95% CI)**	**Absolute (95% CI)**	**Quality**
Neonatal intubation						
1 meta-analysis of 2 studies (Neilson 2015)	Randomised trials	49/6246 (0.78%)	36/6298 (0.57%)	RR 1.37 (0.89 to 2.11)	2 more per 1000 (from 1 fewer to 6 more)	Very low

CI confidence interval, CTG cardiotocography, ECG electrocardiogram, HIE hypoxic ischaemic encephalopathy, RR relative risk

a When expressed per 10,000 women, the absolute effect is 20 more per 10,000 (from 1 more to 67 more)

4.8.4 Evidence statements

4.8.4.1 PR interval analysis

Findings from 2 studies (n=1171) indicated that there was no evidence of a significant difference in the rate of caesarean section and instrumental vaginal birth for women and in the rate of fetal blood sampling, perinatal death, admission to neonatal intensive care unit (NICU), acidosis at birth (pH ≤ 7.15), Apgar score < 7 at 5 minutes and neonatal intubation for babies born to women who received continuous CTG plus fetal ECG compared with women who received continuous CTG only. The evidence was of very low to low quality.

The same 2 studies (n=1171) indicated that the rate of assisted birth (caesarean section or instrumental vaginal birth) was significantly lower for women who received continuous CTG plus fetal ECG compared with women who received continuous CTG only. The evidence was of very low quality.

4.8.4.2 ST waveform analysis

Evidence from 3 studies (n ≥ 25,000) was available. One study indicated that the rate of instrumental birth and need for fetal blood sampling were significantly lower for women who received continuous CTG plus fetal ECG compared with women who received continuous CTG only. The evidence for these findings was of low and very low quality, respectively.

The rate of Apgar score ≤ 3 at 5 minutes was significantly higher among babies born to women who received continuous CTG plus fetal ECG monitoring compared with those born to women who received continuous CTG only. However, there was no significant difference between groups for the less severe outcome of Apgar score < 7 at 5 minutes. The evidence for these findings was of low quality.

There was evidence of no significant differences in the rates of spontaneous vaginal birth and caesarean section for women and in rates of fetal and neonatal death, neonatal intensive care admission, acidosis (cord arterial pH less than 7.05 plus base deficit more than 12), neonatal encephalopathy and neonatal intubation for babies born to women who received continuous electronic fetal monitoring plus fetal CTG compared with women who received continuous CTG only. The evidence was of very low to low quality.

4.8.5 Review of published economic evaluations

The literature search identified 2 cost effectiveness analyses comparing CTG with ST analysis to CTG alone (Heintz 2008; Vijgen 2011). Neither of the analyses was set in the UK and so they were not useful as evidence for this guideline.

4.8.6 New economic evaluation

In the original (2007) NICE guideline on intrapartum care for healthy women and their babies (CG55), a costing analysis was developed for ECG ST analysis. This compared the additional equipment costs in purchasing ST analysis equipment to potential savings from reduced operative vaginal births and caesarean sections. The net cost of ECG ST analysis was £3.4 million.

In the 2014 update (CG190), a new economic evaluation was developed. The 2014 economic model was updated for the 2017 Guideline Committee to reflect the clinical evidence identified in the 2016 evidence review and the most recently available costs

(2014/15 rather than 2012/13). The results reported below refer to the evidence and costs considered by the 2017 Committee. A full description of the economic analysis undertaken for the 2017 Committee is presented in Appendix K.2.

The purpose of fetal monitoring is to identify fetal hypoxia before it is sufficient to lead to damaging acidosis and long-term neurological adverse outcome for the baby. Monitoring should provide a balance between correctly identifying babies who require intervention without over-identification resulting in levels of intervention that are too high.

The economic analysis undertaken for the guideline was designed to address the question of whether CTG monitoring plus ECG ST waveform analysis is more cost effective than CTG monitoring alone. Monitoring is necessary to identify babies in distress and in these cases intervention is necessary. Good monitoring will allow accurate identification of such situations and prevent unnecessary intervention where possible.

The number of instrumental vaginal births was statistically significantly lower for CTG plus ECG ST analysis. No other outcomes were found to be statistically significantly different. For PR analysis there was no statistically or clinically significant difference for any of the clinical outcomes included in the economic evaluation. Therefore, the model was developed only for CTG plus ECG ST analysis.

The main cost will be purchase of equipment for ST analysis. The cost of purchasing an ST monitor is approximately £25,000 per unit (see Appendix K.2). The ST monitor is fully automated, but if the ST analysis shows a problem then training would be required to interpret the scan to decide whether to intervene. Midwives would be trained to interpret the ST analysis, with obstetricians called if there is a problem.

The clinical evidence identified in the guideline review included serious adverse outcomes for the baby such as neonatal death and neonatal encephalopathy. The economic model should include long-term costs for these outcomes, however, identifying good quality inputs for long-term costs of neonatal intubation was a problem for previous economic evaluations in NICE guidelines (NICE 2011; NICE 2012) and for the Birthplace study (Schroeder 2012) and so long-term costs were not included in this analysis.

As with costs, long-term outcomes such as life -years lost and reduced quality of life should be included in the economic mode but no good quality evidence of long-term effects was identified. Therefore the estimates used in the NICE guideline on caesarean section (NICE 2011) were used for this model. The caesarean section guideline used mild cerebral palsy as a proxy for neonatal encephalopathy.

The incremental cost effectiveness results show CTG alone is less expensive and also more effective than CTG plus ECG ST analysis (Table 68). The number of fetal and neonatal deaths was slightly higher in the CTG plus ECG ST group (0.078% compared with 0.045%, although the difference was not statistically significant) and this drives the loss of quality adjusted life years (QALYs).

Table 68: Deterministic costs, effects, incremental costs and effects per woman needing monitoring and incremental cost effectiveness ratio for the comparison of CTG monitoring alone and CTG monitoring plus ECG ST analysis

Monitoring	Costs	Effects	Incremental costs	Incremental effects	ICER
CTG alone	£1819	27.666			
CTG plus ECG ST	£1820	27.660	£1	–0.006	Dominated

CTG cardiotocography, ECG electrocardiogram, ICER incremental cost effectiveness ratio.

A number of sensitivity analyses were undertaken to explore the impact of potential changes in the clinical evidence.

If the rate of mortality were the same between the 2 monitoring strategies then CTG plus ECG ST would dominate CTG alone, being both less expensive and more effective (Table 69).

Table 69: Sensitivity analysis – rate of fetal and neonatal death is equal in both groups; costs, effects, incremental costs and effects per woman needing monitoring and incremental cost effectiveness ratio for the comparison of CTG monitoring alone and CTG monitoring plus ECG ST monitoring

Monitoring	Costs	Effects	Incremental costs	Incremental effects	ICER
CTG alone	£1819	27.657			
CTG plus ECG ST	£1819	27.660	£0	0.003	Dominant

CTG cardiotocography, ECG electrocardiogram, ICER incremental cost effectiveness ratio

As the majority of outcomes were not found to be statistically significantly different, the model was run with these outcomes equal for both groups, with a different treatment effect included in the analysis only for instrumental vaginal births. In this analysis, CTG plus ECG ST dominated CTG alone (Table 70).

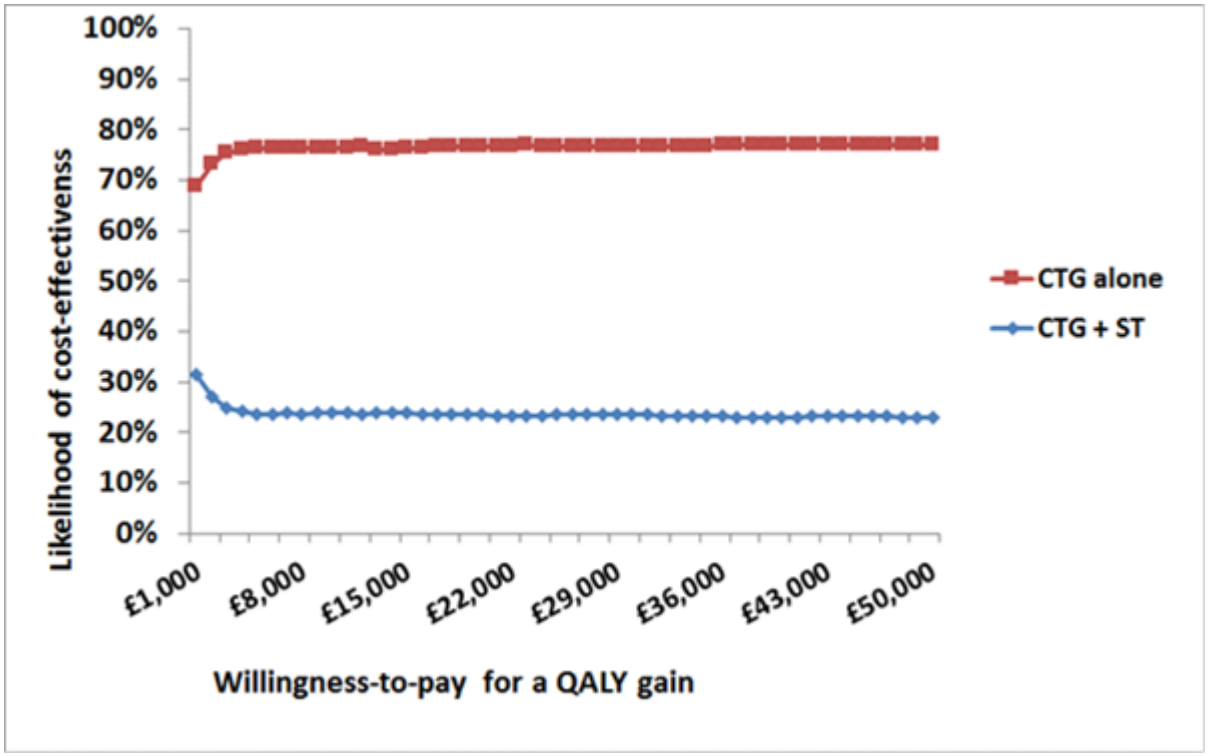
Table 70: Sensitivity analysis – all outcomes not statistically significantly different are held the same; costs, effects, incremental costs and effects per woman needing monitoring and incremental cost effectiveness ratio for the comparison of CTG monitoring alone and CTG monitoring plus ECG ST monitoring

Monitoring	Costs	Effects	Incremental costs	Incremental effects	ICER
CTG alone	£1819	27.666			
CTG plus ECG ST	£1814	27.666	–£5	0.000	Dominant

CTG cardiotocography, ECG electrocardiogram, ICER incremental cost effectiveness ratio.

The results of a further, probabilistic sensitivity analysis (PSA) demonstrated that CTG alone always had the highest probability of being the more cost effective strategy, irrespective of the willingness to pay for a QALY gain (see Figure 1).

Figure 1: Threshold analysis of CTG monitoring and CTG plus ECG ST monitoring



Long-term costs of neonatal encephalopathy were not included in the model because data on long-term outcomes and costs could not be identified. As the point estimate of neonatal encephalopathy was reduced when ECG ST monitoring was added to CTG monitoring, adding these long-term costs and outcomes would strengthen the case for adding ECG ST monitoring.

Other clinical outcomes of interest were not reported in the studies included in the review of clinical evidence and these could impact the cost effectiveness results. ECG analysis requires invasive procedures: amniotomy, which may increase pain associated with uterine contractions; and the application of a fetal scalp electrode, which can be associated with a small increase in the risk of infection in the baby.

Overall the economic analysis suggests that adding ECG ST monitoring to CTG monitoring has a negligible cost impact and that it does not provide any benefit in terms of health-related quality of life. Wide confidence intervals (CIs) and relatively small point estimates of effect sizes imply some uncertainty in the results but PSA does not make a case for adding ECG ST analysis to CTG monitoring at this time.

4.8.7 Evidence to recommendations

4.8.7.1 Relative value placed on the outcomes considered

For this review, the Committee prioritised the outcomes of mode of birth and neonatal encephalopathy as both of these were considered to be clinically relevant and to influence long-term morbidity. The Committee recognised that mode of birth is also important for the woman's experience of birth. The Committee considered that perineal trauma and neonatal

outcomes, including metabolic acidosis at birth (reflected by low pH at birth and a low Apgar score), use of fetal blood sampling, NICU admission and outcomes reflecting a requirement for assisted ventilation or resuscitation at birth should also evaluated.

4.8.7.2 Consideration of clinical benefits and harms

For PR waveform analysis, the Committee noted there was very low quality evidence from 2 trials demonstrating that the rate of assisted birth (instrumental vaginal birth or caesarean section) was lower for women who received additional ECG PR analysis compared with those who had CTG monitoring alone. However the Committee did not consider the effect size to be clinically important. There were no significant differences between groups for caesarean section or instrumental vaginal birth reported as individual outcomes in 1 trial, nor for any of the neonatal outcomes identified (perinatal death, acidosis at birth, NICU admission rate, Apgar score less than 7 at 5 minutes, fetal blood sampling or neonatal intubation). There was no evidence available for the prioritised outcome of neonatal encephalopathy. The Committee concluded that no important benefit was demonstrated for this type of ECG analysis.

The Committee next considered ST waveform analysis of the fetal ECG. Evidence reported for this intervention in the previous (2007 and 2014) NICE guidelines on intrapartum care for healthy women and their babies (CG55 and CG190, respectively) was included in the current update for the 2017 Committee. The Committee noted additionally a US trial with a study population of some 12,000 women which had been published after CG190. Outcomes from this study were incorporated into various meta-analyses conducted for the guideline to provide updated evidence for the 2017 Committee to consider.

Evidence for mode of birth was available from a total of 6 trials involving more than 25,000 women in total. There was no difference between groups for spontaneous vaginal birth or caesarean section rates, although the rate of instrumental vaginal birth was marginally and significantly lower for women who received additional continuous ECG ST waveform analysis. Although the Committee believed this finding was derived from a robust evidence base, it did not consider the effect size to be clinically significant. There was no evidence available for perineal trauma outcomes or outcomes related to women's satisfaction with or experience of labour and birth.

There were no differences between groups for the prioritised outcome of neonatal encephalopathy nor for fetal and neonatal death, metabolic acidosis or neonatal intubation. It was noted that the total number of women reflected in the meta-analyses presented in the guideline review was underpowered to identify rare events such as neonatal death. The addition of the newer, US trial to the meta-analyses moved the summary estimate for admission to NICU towards the null hypothesis to the extent that there was no difference in admission rates between the intervention and comparison groups (whereas in CG190, which had not included the newer US trial, the rate of admission to NICU was significantly lower in the group who received CTG plus fetal ECG ST analysis).

There was no significant difference in Apgar score less than 7 at 5 minutes (based on a meta-analysis of data from 5 trials involving more than 7,000 women for whose babies this outcome was reported). However, the large, new US trial provided low-quality evidence that babies born to women who received continuous CTG plus fetal ECG ST analysis were at increased risk of having an Apgar score of less than or equal to 3 at 5 minutes. The Committee noted that this was not consistent with the findings of the other included studies.

Rates of fetal blood sampling were lower when additional ECG ST analysis was performed, but the Committee considered that the evidence related to this finding was heterogeneous,

perhaps due to different populations or treatment protocols used in the various trials included in the guideline review.

The Committee also recognised potential disadvantages of using ECG analysis in conjunction with CTG monitoring. In order to monitor using ECG analysis, the invasive procedures of amniotomy and insertion of a fetal scalp electrode need to be performed. Amniotomy was felt by some members of the Committee to be associated with an increase in pain associated with uterine contractions and the application of a fetal scalp electrode was acknowledged to be associated with a small increase in the risk of trauma to, and infection in, the baby.

4.8.7.3 Consideration of health benefits and resource use

The Committee noted that use of ECG analysis involved the capital cost of purchasing ST analysis monitors (approximately £25,000 per machine) and investment in training all midwives and obstetricians involved in providing intrapartum care in the obstetric unit to use the monitors. Although the cost of purchasing the ST analysis monitors is high, the cost per use would be minimal given the lifetime of such a machine and the number of births requiring monitoring. However, where there were differences in clinical outcomes between the alternative monitoring strategies, they were small (for instrumental births it was 11.3% using CTG alone compared with 10.4% when also using ST monitoring) and for most outcomes there was no statistically significant difference (caesarean section, fetal and neonatal death, neonatal encephalopathy, neonatal intubation, and admission to NICU). Although the capital costs may be offset to some extent by 'downstream' cost reductions through fewer interventions during birth, there was considerable uncertainty as the differences in clinical outcomes between the monitoring strategies were so small. Overall the economic analysis conducted for the 2017 Committee suggested that adding ECG ST monitoring to CTG monitoring would have a negligible cost impact and would not confer any benefit in terms of health-related quality of life.

4.8.7.4 Quality of evidence

The Committee was satisfied that there was a broad evidence base (particularly for fetal ECG ST analysis) that was drawn from RCTs, was largely robust and described both maternal and neonatal outcomes, even though the evidence was graded largely as very low or low quality. The Committee was aware of observational studies exploring outcomes for women who experienced either CTG monitoring alone or additionally with ECG ST analysis, and discussed whether these might provide a better reflection of outcomes in clinical practice in maternity care compared to RCTs, in which establishing and implementing a trial protocol focuses attention on fetal monitoring, which might itself lead to improved outcomes in both treatment arms compared to routine care. The Committee concluded, however, that the RCTs included in the guideline review were large and adequately powered to detect differences in most of the prioritised outcomes.

4.8.7.5 Other considerations

There were no other considerations.

4.8.7.6 Key conclusions

Considering the prioritised outcomes and potential harms associated with performing fetal ECG analysis, the Committee believed that overall the evidence did not demonstrate sufficient clinical benefit to justify recommending a change in practice by introducing the use fetal ECG PR interval or ST waveform analysis. The Committee considered whether there

was sufficient evidence to justify a 'do not use' recommendation and concluded that as there were no differences in treatment effects between the intervention and comparison groups for many of the outcomes reported in the guideline review this would not be justified either. Noting the considerable uncertainty regarding the benefit of using ECG analysis highlighted by the results of the economic analysis the Committee concluded that, as in CG190, no recommendation should be made.

4.9 Computerised systems versus human interpretation

4.9.1 Review question

Does automated interpretation of cardiotocograph (CTG) traces using computer software improve consistency of interpretation and outcomes (neonatal and maternal)?

4.9.2 Description of included studies

Eleven studies were included in this review (Chen 2014; Chung 1995; Costa 2010a; Costa 2010b; Keith 1995; Mongelli 1997; Nielsen 1988; Parer 2010; Taylor 2000; Todros 1996; Wolfberg 2008).

Four studies are from the UK (Chung 1995; Keith 1995; Mongelli 1997; Taylor 2000), 2 from Portugal (Costa 2010a; Costa 2010b), 2 from the USA (Parer 2010; Wolfberg 2008), and 1 each from Denmark (Nielsen 1988), Italy (Todros 1996) and Taiwan (Chen 2014).

The vast majority of studies are retrospective cohort studies, while 1 study is a randomised comparative study (Costa 2010b) and another is a prospective cohort study (Taylor 2000).

All included studies consisted of predominantly low risk or mixed populations apart from 2 studies that included high risk populations (Keith 1995; Mongelli 1997). One study did not describe the study population (Nielsen 1988).

Nine studies compared computerised interpretation of CTG tracings with expert interpretation (Chen 2014; Costa 2010a; Costa 2010b; Keith 1995; Mongelli 1997; Parer 2010; Taylor 2000; Todros 1996; Wolfberg 2008). One study (Chung 1995) assessed the ability of computer software to analyse CTG tracings and predict neonatal outcomes. Although the remaining study (Nielsen 1988) reported results for both computerised and clinical experts' assessment of CTG tracings there was no direct comparison between the two.

Two studies (Chung 1995; Nielsen 1988) reported diagnostic test accuracy measures (sensitivity, specificity, positive and negative likelihood ratios) whereas the remaining studies reported correlation statistics (intraclass correlation coefficients (ICCs) and Kappa statistics).

4.9.3 Evidence profile

Evidence is reported in GRADE profiles for the following fetal heart rate (FHR) parameters:

- baseline heart rate
- variability
- accelerations
- decelerations (any, early, late, variable, prolonged or recurrent)
- overall categorisation of the CTG trace
- prediction of umbilical artery blood pH.

Evidence from randomised comparative studies and prospective observational studies was initially rated as high quality and was downgraded if there were any issues identified that would undermine the trustworthiness of the findings. Evidence from retrospective observational studies was initially rated as moderate quality and was downgraded if there were any quality-related issues.

Table 71: Summary GRADE profile for comparison of computerised cardiotocograph interpretation with human interpretation

Quality assessment				Measure of diagnostic accuracy (95% CI)				
Number of studies	Design	Definition of outcome	Total number of CTGs	Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	Quality
CTG interpretation identified as abnormal[a] by a computer software program								
1 study (Chung 1995)	Retrospective cohort	pH < 7.15	73	87.50 (46.7 to 99.3)[b]	75.40 (62.9 to 84.9)[b]	3.55 (2.16 to 5.86)[b]	0.17 (0.03 to 1.05)[b]	Very low
CTG interpretation of an outcome as abnormal[c] by a computer software program								
1 study (Nielsen 1988)	Retrospective cohort	1-minute Apgar score below 7 or acidosis (umbilical arterial pH < 7.15 or base excess below -10 meq/l), or primary resuscitation needed	50	68.8 (41.5 to 87.9)[b]	94.1 (78.9 to 99.0)[b]	11.7 (2.9 to 46.7)[b]	0.33 (0.16 to 0.69)[b]	Very low

CAS Cardiotocographic Assessment System; CI confidence interval; CTG cardiotocograph; FHR fetal heart rate

a An abnormal trace was defined by one or more of the following criteria

- *tachycardia (fetal heart rate > 160 bpm) for more than 30 minutes during labour*
- *bradycardia (fetal heart rate < 110 bpm) for more than 30 minutes during labour*
- *low variation (standard deviation of the fetal heart rate of ≤ 3 bpm) for more than 60 minutes during labour*
- *more than five late decelerations (minima of the FHR occurring 20-60 seconds after the maxima of the contraction) during labour*
- *more than 10 variable decelerations (minima of the FHR occurring more than 20 seconds prior to, or 60 seconds after, the maxima of the contraction) during labour*

b Calculated by the 2017 NGA technical team

c A computer system (CA) calculates the probability of the CTG belonging to a compromised infant by calculating a discriminant function, and a CTG is considered pathological if the probability is above 0.5. The computer system's calculation of the probability of a compromised infant is for each CTG based on the experience from the other 49 CTGs, thus excluding the possibility of "self-recognition"

Table 72: Summary GRADE profile for comparison of computerised cardiotocograph interpretation with human interpretation

Quality assessment		Comparison	Total number of CTGs	Intraclass correlation coefficient (95% CI)	Kappa statistic (95% CI)	Quality
Number of studies	Design					
Baseline FHR						
1 study (Chen 2014)[a]	Retrospective cohort	A computerised algorithm using LabVIEW 2010 software, compared to 8 individual obstetricians	62	0.91 (0.88 to 0.94)	NC	Low
1 study (Costa 2010a)[b]	Retrospective cohort	The OmniView SisPorto 3.5 system was compared to interpretation by 3 obstetricians (results are shown compared to the consensus view of the group)	50	0.85 (0.46 to 0.93)	NC	Very low
1 study (Mongelli 1997)[c]	Retrospective cohort	A computer algorithm was compared to interpretation by 12 clinical experts	60	> 0.9 (CI not reported)	NC	Moderate
1 study (Taylor 2000)[d]	Prospective cohort	A computer algorithm was compared to independent interpretation by 7 obstetricians	24	Range: 0.91 to 0.98	NC	Moderate
1 study (Todros 1996)[e]	Retrospective cohort	The 2CTG system was compared to interpretation by 4 obstetricians.	63	Range: 0.18 to 0.48	NC	Low
Variability						
1 study (Chen 2014)[a]	Retrospective cohort	A computerised algorithm using LabVIEW 2010 software, compared to 8 individual obstetricians	62	NC	0.68 (0.51 to 0.84)	Very low
1 study (Taylor 2000)[f]	Prospective cohort	A computer algorithm was compared to independent interpretation by 7 obstetricians	24	NC	Range: 0.00 to 0.34	Moderate
1 study (Todros 1996)[g]	Retrospective cohort	The 2CTG system was compared to interpretation by 4 obstetricians	63	Range: 0.16 to 0.74	NC	Low

Quality assessment		Comparison	Total number of CTGs	Intraclass correlation coefficient (95% CI)	Kappa statistic (95% CI)	Quality
Number of studies	Design					
1 study (Wolfberg 2008)[h]	Retrospective cohort	A computer algorithm was compared to interpretation by 4 perinatologists	30	0.62 (range 0.27 to 0.68)	NC	Low
Accelerations						
1 study (Chen 2014)[a]	Retrospective cohort	A computerised algorithm using LabVIEW 2010 software, compared to 8 individual obstetricians	62	0.85 (0.80 to 0.90)	NC	Low
1 study (Taylor 2000)[i]	Prospective cohort	A computer algorithm was compared to independent interpretation by 7 obstetricians	24	Range 0.06 to 0.80	NC	Moderate
1 study (Todros 1996)[j]	Retrospective cohort	The 2CTG system was compared to interpretation by 4 obstetricians	63	NC	Range: 0.37 to 0.64	Low
Decelerations						
1 study (Taylor 2000)[i]	Prospective cohort	A computer algorithm was compared to independent interpretation by 7 obstetricians	24	Range: 0.82 to 0.92	NC	Moderate
1 study (Todros 1996)[k]	Retrospective cohort	The 2CTG system was compared to interpretation by 4 obstetricians	63	NC	Range: 0.41 to 0.54	Low
Early decelerations						
1 study (Chen 2014)[a]	Retrospective cohort	A computerised algorithm using LabVIEW 2010 software was compared to 8 individual obstetricians	62	0.78 (0.71 to 0.84)	NC	Very low
Late decelerations						
1 study (Chen 2014)[a]	Retrospective cohort	A computerised algorithm using LabVIEW 2010 software was compared to 8 individual obstetricians	62	0.67 (0.59 to 0.76)	NC	Very low

Quality assessment		Comparison	Total number of CTGs	Intraclass correlation coefficient (95% CI)	Kappa statistic (95% CI)	Quality
Number of studies	Design					
1 study (Taylor 2000)l	Prospective cohort	A computer algorithm was compared to independent interpretation by 7 obstetricians	24	Range: 0.68 to 0.85	NC	Moderate
Variable decelerations						
1 study (Chen 2014)[a]	Retrospective cohort	A computerised algorithm using LabVIEW 2010 software was compared to 8 individual obstetricians	62	0.60 (0.51 to 0.70)	NC	Very low
Prolonged decelerations						
1 study (Chen 2014)[a]	Retrospective cohort	A computerised algorithm using LabVIEW 2010 software was compared to 8 individual obstetricians	62	NC	0.82 (0.58 to 1.00)	Very low
Recurrent decelerations						
1 study (Chen 2014)[a]	Retrospective cohort	A computerised algorithm using LabVIEW 2010 software was compared to 8 individual obstetricians	62	NC	0.82 (0.67 to 0.97)	Very low
Overall categorisation of CTG						
1 study (Chen 2014)[m]	Retrospective cohort	A computerised algorithm using LabVIEW 2010 software, compared to 8 individual obstetricians	62	NC	0.80 (0.67 to 0.94)	Very low
1 study (Parer 2010)h	Retrospective cohort	PeriCALM computer software was used to analyse the CTGs, and compared to the interpretation of 5 experts, who were asked to use a strict, rule-based system to categorise CTGs into a five-tier system of severity	30	NC	Exact agreement with the majority clinical decision: 0.52 (CI not reported)	Low

Quality assessment		Comparison	Total number of CTGs	Intraclass correlation coefficient (95% CI)	Kappa statistic (95% CI)	Quality
Number of studies	**Design**					
1 study (Keith 1995)[m]	Retrospective cohort	A computer algorithm was compared to a panel of 17 experts, who rated each 15 minute segment of the CTG according to a five-tier system	50	0.31 (CI not reported), p < 0.001	NC	Low
Prediction of umbilical artery blood pH						
1 study (Costa 2010b)	Randomised comparative study	CTG traces were interpreted by expert clinicians. Half of the traces were standard, and half were annotated with analysis from the OmniView SisPorto system. The ability of clinicians to predict umbilical arterial pH with and without the additional information provided by the computer was assessed. Further, the agreement in interpretation of the trace was compared between observers, with and without the computerised analysis	204 (100 visual interpretation only; 104 visual interpretation with computer analysis available)	NC	Agreement between the three clinicians: 1) with visual interpretation only: 0.29 (0.08 to 0.47) 2) with computer analysis and visual interpretation: 0.52 (0.34 to 0.66)	Low

BPM beats per minute; CTG cardiotocograph; FHR fetal heart rate; ICC intraclass correlation coefficient; NC not calculable

a NICHD 2008 criteria
b For baseline estimation, a previously developed very reproducible definition was used: "it is a single value, corresponding to the mean FHR of the lowest stable horizontal segment(s) lasting at least 2 min. For the selection of these segments the following conditions should preferably be met: long-term variability <15 bpm, absence of fetal movements and uterine contractions and mean FHR within physiological limits"
c A low-frequency line which would be stable under noisy conditions yet responsive to both gradual or sudden changes in the baseline. For this, the concept of modal values was developed. Values in a narrow modal range were used to calculate the mean and to generate a low frequency baseline FHR
d The running baseline FHR was produced by a three-stage iterative process that generated progressively improved intermediate baselines before obtaining the final baseline. Prior to this process the signal was low-pass filtered using a third-order, zero-phase (two-pass) Butterworth filter with a cut-off frequency of 0.008 Hz. This gave a coarse starting baseline. The iterative process consisted of the following: by selective thresholds removal of components of the fetal heart rate signal associated with accelerations and decelerations; linear interpolation across the gaps, and low-pass filtering. The selective thresholds started with deviations of ± 5 bpm from the initial baseline for the first bpm for values above and below the baseline respectively for the third iteration, to produce the final baseline. After removal of the deviations, the signal was interpolated and an improved intermediate baseline generated after applying a low-pass Butterworth filter with a cut-off frequency of 0.006 Hz. This was a lower cut-off

frequency than that used for obtaining the starting baseline, because many of the deviations from the baseline had already been removed in the first filtering process that generated the starting baseline. The mean value of the baseline for the period gave the baseline FHR for the segment
e Categorised in 10 bpm
f Classified as normal (≥ 5 bpm) or reduced (< 5 bpm)
g Long-term variability (amplitude < 5 bpm, between 5 and 10 bpm, >10 bpm)
h NICHD 1997criteria
i FIGO 1987 criteria
j The number of large accelerations (amplitude >15 bpm above the baseline lasting >15 minutes)
k The number of decelerations (amplitude >20 bpm below the baseline lasting >30 minutes or amplitude >10 bpm lasting > 60 minutes)
l Occurred where the minimum value was 20-60 seconds after the peak of a contraction
m CTGs were categorised as normal, intermediate or abnormal

4.9.4 Evidence statements

4.9.4.1 Neonatal outcomes

4.9.4.1.1 Fetal acidosis, 1-minute Apgar score below 7 and need for primary resuscitation

One study (n=73 CTGs) showed that computerised CTG analysis was not useful in predicting fetal acidosis. The evidence for this finding was of very low quality. Another study (n=50 CTGs) reported that computerised CTG analysis was very useful in predicting 1-minute Apgar score below 7 or acidosis (umbilical arterial pH < 7.15 or base excess below -10 meq/l) or the need for primary resuscitation. The evidence for this finding was of very low quality.

4.9.4.1.2 Baseline heart rate

Evidence from 4 studies (n=196 CTGs) showed excellent agreement between computerised CTG interpretation and interpretation by clinical experts for the baseline FHR. The evidence was of very low to moderate quality. One study (n=63 CTGs) showed poor to fair agreement between computerised CTG analysis and clinical experts for the baseline FHR. The evidence for this finding was of low quality.

4.9.4.1.3 Variability

Two studies (n=92 CTGs) reported good agreement between computerised CTG interpretation and interpretation by clinical experts for FHR variability. The evidence for this finding was of very low to low quality. However, another study (n=24 CTGs) showed poor agreement. The evidence for this finding was of moderate quality. A third study (n=63 CTGs) reported a range of poor to good agreement and the evidence was of low quality.

4.9.4.1.4 Accelerations

Evidence from 1 study (n=62 CTGs) showed excellent agreement between computerised CTG analysis and the interpretation of clinical experts for accelerations. The evidence for this finding was of low quality. However, evidence from 2 other studies (n=87 CTGs in total) showed that the agreement between computerised CTG analysis and interpretation by clinical experts varied from poor to excellent and from poor to good, respectively. The evidence for these findings was of low to moderate quality.

4.9.4.1.5 Decelerations

Any decelerations

Evidence from 2 studies (n=87 CTGs in total) showed fair to excellent agreement between computerised CTG interpretation and interpretation by clinical experts for any decelerations. The evidence for these findings was of low to moderate quality.

Early decelerations

Evidence from 1 study (n=62 CTGs) showed that the agreement between computerised CTG analysis and interpretation by clinical experts was excellent for early decelerations. The evidence for this finding was of very low quality.

Late decelerations

Evidence from 1 study (n=62 CTGs) showed that the agreement between computerised CTG analysis and interpretation by clinical experts was excellent for late decelerations. The evidence for this finding was of very low quality. However, another study (n=24 CTGs)

reported that the agreement between computerised CTG interpretation and interpretation by clinical experts varied from good to excellent. The evidence for this finding was of moderate quality.

Variable decelerations

Evidence from 1 study (n=62 CTGs) showed that the agreement between computerised CTG analysis and interpretation by clinical experts was good. The evidence for this finding was of very low quality.

Prolonged decelerations

One study (n=62 CTGs) reported that the agreement between computerised CTG analysis and interpretation by clinical experts was excellent. The evidence for this finding was of very low quality.

Recurrent decelerations

One study (n=62 CTGs) reported that the agreement between computerised CTG analysis and interpretation by clinical experts was excellent. The evidence for this finding was of very low quality.

4.9.4.1.6 Overall categorisation of cardiotocograph traces

Evidence from 1 study (n=62 CTGs) showed excellent agreement between computerised CTG analysis and interpretation by clinical experts for the overall categorisation of CTG traces. The evidence for this finding was of very low quality. However, 2 other studies (n= 80 CTGs in total) reported poor to fair agreement. The evidence for this finding was of low quality.

4.9.4.1.7 Prediction of umbilical artery blood pH

One study (n=204 CTGs) reported that agreement among clinical experts visually assessing CTG tracings was poor. An adjunct of computer analysis to visual interpretation increased the level of agreement to fair. The evidence for these findings was of low quality.

4.9.5 Health economics profile

No published economic evaluations were identified for this review question.

4.9.6 Evidence to recommendations

4.9.6.1 Relative value placed on the outcomes considered

The aim of this review was to determine whether the automated interpretation of CTG traces using computer software improves the accuracy and consistency of interpretation and clinical outcomes (both neonatal and maternal). Accuracy was evaluated using sensitivity, specificity, positive and negative likelihood ratios, while consistency was assessed using intra-rater reliability statistics. Specific clinical outcomes prioritised for consideration were serious neonatal outcomes (perinatal death, incidence of hypoxic ischaemic encephalopathy (HIE) or acidosis), admission to a neonatal intensive care unit (NICU) or need for fetal blood sampling, mode of birth and women's satisfaction with and experience of labour and birth, including mobility.

4.9.6.2 Consideration of clinical benefits and harms

The Committee felt it was important to consider this review question with a view to standardising the interpretation of CTG traces and improving neonatal and maternal outcomes. The Committee noted that it was important to consider women's satisfaction with and experience of labour and birth as this type of intervention may impact on one-to-one care and such care should not be replaced by automated interpretation of CTGs alone.

The Committee discussed and agreed that systems for automated interpretation of CTGs, if effective, may have both positive and negative effects on neonatal and maternal outcomes. For example, they could potentially reduce the effects of human errors in the interpretation of CTGs and reduce the likelihood of unnecessary interventions such as performing a caesarean section in a situation where it is safe for labour to continue. However, such software could be over-sensitive and thus increase the potential for inappropriate responses to alarms generated during automated analysis of CTG traces (for example, by inexperienced or untrained staff).This might result in an increase in rates of caesarean section and subsequently impact women's satisfaction, experience and morbidity.

4.9.6.3 Consideration of health benefits and resource use

In the absence of clinical evidence to support the use of technology for automated interpretation of CTG traces, the intervention is not considered cost effective and so no detailed evaluation of cost effectiveness was required.

4.9.6.4 Quality of evidence

The Committee considered the studies included in the guideline review and noted that they evaluated technologies that were not immediately relevant to UK NHS practice. There was little direct evidence related to the ability of automated systems to predict clinical outcomes such as fetal acidosis, and the evidence that was identified was of very low quality. The Committee discussed and acknowledged that evidence of intra- and inter-rater variability in CTG interpretation exists (indeed most of the included studies were designed to evaluate agreement between computerised systems and/or human interpretation). The Committee emphasised that CTG traces should, therefore, be interpreted taking into account the whole clinical picture.

4.9.6.5 Other considerations

A research recommendation about computerised expert systems was included in CG190 and the Committee was aware that two large, multicentre randomised controlled trials (RCTs) designed to evaluate the effectiveness of computerised systems for interpretation of CTG traces had recently been conducted in settings relevant to the UK NHS. It had been expected that the results of these studies would be published during the development period for the 2017 guideline update, but this did not occur. In the absence of publications in a format that allowed detailed quality assessment using GRADE for outcomes prioritised in the guideline review protocol, the Committee relied on their collective knowledge of the trials based on conference presentations. The RCTs discussed by the Committee were:

- FM-ALERT (n=7730) – a pragmatic, multicentre RCT conducted in 5 UK hospitals comprising 3 tertiary teaching units and 2 district general hospitals involved in the care of women at high risk during the intrapartum period (see www.ncbi.nlm.nih.gov/pmc/articles/PMC2987886/ [accessed 12/10/2016] for the study protocol and www.omniview.eu/Cache/binImagens/2015_UK_7730patient_RCT-647.pdf [accessed 12/10/2016] for a conference abstract describing preliminary results)
- INFANT (n=46,000) – a large, multicentre RCT conducted in the UK and Ireland (see www.ucl.ac.uk/cctu/research-areas/womens-health/infant/documents/finalprotocol

[accessed 12/10/2016] for the study protocol and www.ucl.ac.uk/cctu/research-areas/womens-health/infant [accessed 12/10/2016] for further details about the study).

The preliminary findings suggested that automated interpretation of CTG traces using computer software was no better than human interpretation at improving consistency or predicting outcomes. Based on this, the Committee concluded that no further studies would be required in this area and that the former research recommendation should, therefore, be deleted.

4.9.6.6 Key conclusions

In the absence of evidence to support the clinical and cost effectiveness of computerised systems for interpretation of CTG traces, the Committee agreed not to make a recommendation regarding the use of such technology.

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Appendices

The appendices are presented in separate files.

Appendix A: Committee members and NGA team

Appendix B: Declarations of interest

Appendix C: Review protocols

Appendix D: Search strategies

Appendix E: Summary of identified studies

Appendix F: Excluded studies

Appendix G: Evidence tables

Appendix H: Forest plots

Appendix I: GRADE tables

Appendix J: Fetal heart rate classifications

Appendix K: Health economics