# The Use of Electronic Fetal Monitoring

The use and interpretation of cardiotocography in intrapartum fetal surveillance

Evidence-based Clinical Guideline Number 8

Clinical Effectiveness Support Unit



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## Abbreviations and glossary of terms

#### **Abbreviations**

AFI Amniotic fluid index
bpm Beats per minute
BP Blood pressure
CTG Cardiotocograph(y)
ECG Electrocardiogram

EFM Electronic fetal monitoring
FBS Fetal blood sampling
FHR Fetal heart rate
FSE Fetal scalp electrode
IA Intermittent auscultation

LR Likelihood ratio
OR Odds ratio

RCT Randomised controlled trial RR Risk ratio/Relative risk

RTFM Radiotelemetric fetal monitoring VAS Vibroacoustic stimulation VE Vaginal examination

#### **Glossary of terms**

Case-control study The study reviews exposures or risk factors, comparing

the exposure in people who have the outcome of interest, for example the disease or condition (i.e. the cases) with patients from the same population who do

not have the outcome (i.e. controls).

Cohort study The study involves identification of two groups (cohorts)

of patients, one of which has received the exposure of interest and one of which has not. These groups are followed forward to see if they develop the outcome (i.e.

the disease or condition) of interest.

Likelihood ratio The likelihood that a given test result would be expected

in a patient with a disease compared with the likelihood that the same result would be expected in a patient

without that disease.

Meta-analysis An overview of a group of studies that uses quantitative

methods to produce a summary of the results.

and controls have been selected from among subjects in a cohort study. (i.e. a case–control study nested within a

cohort).

prevent one outcome.

Odds ratio Describes the odds that a case (a person with the

condition) has been exposed to a risk factor relative to the odds that a control (a person without the condition)

has been exposed to the risk.

Positive predictive value The percentage of people who have a positive test who

really have the condition. The predictive value is dependent upon the prevalence of the disease in the population being tested; i.e. if the disease is rare, the predictive value is low, due to the greater influence of

false positive tests.

Randomised controlled trial A group of patients is randomised into an experimental

group and a control group. These groups are followed up for the variables and outcomes of interest. This study is similar to a cohort study but the exposure is randomly assigned. Randomisation should ensure that both groups are equivalent in all aspects except for the exposure of

interest.

Risk ratio Risk is a proportion or percentage. The risk ratio is the

ratio of risk of developing the outcome of interest in an exposed group compared with the risk of developing the same outcome in the control group. It is used in

randomised controlled trials and cohort studies.

Risk difference The difference in risk of developing the outcome of

interest between the exposed and control groups.

Sensitivity The ability of the test to detect those who have the

disease, i.e. the proportion (%) of people with the condition who are detected as having it by the test.

Specificity The ability of the test to identify those without the

disease, i.e. the proportion of people without the condition who are correctly reassured by a negative test.

For further definitions readers are referred to the following link: http://cebm.jr2.ox.ac.uk/docs/glossary.html

For the purposes of this Guideline, data are presented as risk ratios (RR) where relevant (i.e. in RCTs and cohort studies). Where these data are statistically significant they are converted into numbers needed to treat.

## Guideline Development Group membership and acknowledgements

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#### **Peer reviewers**

The document was sent out to 58 peer reviewers (21 obstetricians, 16 midwives, 4 neonatologists, 3 public heath consultants, 11 consumers, 2 methodologists and 1 economist); 47 replied, 44 agreed and 3 declined. Of those who agreed to be reviewers and responded, 20 were obstetricians, 13 were midwives, 2 were public health specialists, 1 was a neonatologist, 1 was a health economist and 1 was an epidemiologist, 6 were consumers.

The peer reviewers and NICE stakeholders who responded were:

Martin Whittle, Astrid Osbourne, Deirdre Murphy, Sally Price, Charles Wolfe, David Field, Helen Glenister, Nancy Kohner, John Spencer, Gill Gyte, Zoe Penn, Andrew Stevens, Anthony Vintzileos, Jilly Rosser, Jane Munro, Jill Demilew, Clare Harding, Elizabeth Key, Harry Gee, Katie Yiannouzis, Cathy Winter, Denis Walsh, Sara Paterson-Brown, Stavros Petrou, Andrew Allman, Mike Marsh, Sarah Cunningham, Carol Grant-Pearce, Nigel Bickerton, Khalid Khan, Rick Porter, Stephen Thacker, Mary Menjou, Gill Harvey, Andrew Whitelaw, Verena Wallace, Tricia Andersen, Soo Downe, Jason Gardosi, Steve Robson, Patrick Chen, Mary Newburn, Dhushy Mahendran, Richard Johanson. No commercial companies provided comments.

Comments on the draft Guideline posted on the NICE website were received from: The Royal College of Anaesthetists, Margaret Biddle, Professor KG Rosen, Mary Newburn, Jayne Shepherd, Jilly Rosser, Annie Manketlow, Steve Walkinshaw, Sarah Paterson-Brown, Louise Pengelley and Alan Angilley.

The following hospitals piloted the clinical practice algorithm (Figure 1, Section 2.10):

Derriford Hospital, Plymouth Liverpool Women's Hospital Queens Medical Centre, Nottingham Royal Victoria Infirmary, Newcastle Southmead and St. Michael's Hospitals, Bristol

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### 1. Introduction

For this Guideline, electronic fetal monitoring (EFM) is defined as 'the use of electronic fetal heart-rate monitoring for the evaluation of fetal wellbeing in labour'.

Medical, social and economic advances transformed maternal birth outcomes in the 19th and 20th centuries. The aim of intrapartum EFM was to prevent harm, it became commercially available in the 1960s with the emphasis on improving fetal birth outcomes by detecting fetal hypoxia before it led to perinatal mortality or cerebral palsy. Epidemiological data suggest that only 10% of cases of cerebral palsy have potential intrapartum causes and, even in these cases, the signs of damaging hypoxia may have had antenatal origins.<sup>1</sup>

A recent international consensus statement defined a causal relationship between acute intrapartum events and cerebral palsy.<sup>2</sup> That document was not aiming to examine the failings of intrapartum monitoring techniques but highlighted the rarity with which acute intrapartum events were associated with cerebral palsy.

The basic principle of intrapartum monitoring is to detect developing fetal hypoxia with the aim of preventing subsequent acidaemia and cell damage. Intrapartum hypoxia can develop in a number of ways (see Chapter 4). Chronic uteroplacental perfusion due to vascular disease (e.g. as in growth restriction) could be exacerbated by reduced intervillous perfusion during uterine contractions or maternal hypotension. More acute fetal hypoxia could occur as a consequence of uterine hyperstimulation, placental abruption or cord compression.

The initial response to chronic or slowly developing hypoxia is to increase cardiac output and redistribute this to the brain and heart. The increase in cardiac output is achieved by an increase in heart rate. This may be followed by a reduction in heart-rate variability due to brainstem hypoxia. Continued and worsening hypoxia will eventually produce myocardial damage and heart-rate decelerations. Acute hypoxia, in contrast, results in a decrease in the fetal heart rate (decelerations or bradycardia) initially produced by chemoreceptor-mediated vagal stimulation but eventually by myocardial ischaemia. Metabolically, progressive fetal hypoxia results firstly in a respiratory acidaemia and secondly in a metabolic acidaemia with tissue injury.

With this underlying theoretical concept, EFM was introduced into the UK in the early 1970s. Subsequently, the intrapartum use of EFM increased rapidly. The expectation was that EFM would reduce hypoxia-induced intrapartum perinatal mortality. This has not occurred and the role of EFM in labour has been questioned.<sup>3</sup> Furthermore, the three most recent reports from the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI) have highlighted problems related to the use and interpretation of EFM.<sup>4-6</sup>

#### 1.1. Aim of the Guideline

Clinical guidelines have been defined as 'systematically developed statements which assist clinicians and patients in making decisions about appropriate treatment for specific conditions'. The parameters of practice included in this document were arrived at after careful consideration of the available evidence and should be considered as guidelines only. Clinicians involved in intrapartum care must use their professional knowledge and judgement when applying the recommendations to the management of individual women.

The Guideline Development Group has developed this Guideline with the following aims:

- to evaluate the impact of intrapartum EFM on neonatal and maternal outcomes
- to develop standards for the use of EFM, including:
- indications for use, definitions of normal and abnormal parameters
- which adjuvant or additional monitoring tests/techniques should be employed
- to evaluate methods for improving interpretation of CTG and the development of standards for training in evaluation of fetal heart-rate patterns
- to evaluate the impact of EFM on medico-legal aspects of perinatal medicine
- to increase awareness of the role of EFM in intrapartum care among medical practitioners, midwives and pregnant women
- to consider the resource implications of the use of EFM
- to suggest areas for future research from a review of the currently available evidence.

#### 1.2. Who has developed the Guideline?

The development of the Guideline was supported by funding from the Department of Health and the National Institute for Clinical Excellence (NICE).

The Guideline was developed by a multi-professional and lay working group (the Guideline Development Group) convened by the Royal College of Obstetricians and Gynaecologists. Members included representatives from:

- Royal College of Obstetricians and Gynaecologists
- Royal College of Midwives
- Royal College of Paediatricians and Child Health
- Royal College of General Practitioners
- British Maternal and Fetal Medicine Society
- British Association of Perinatal Medicine
- Faculty of Public Health
- Centre for Health Information Quality
- University of East Anglia (health economists)
- Confidential Enquiry into Stillbirths and Deaths in Infancy
- Consumer groups, including the National Childbirth Trust and the Stillbirth and Neonatal Death Society.

Staff from the RCOG Clinical Effectiveness Support Unit (CESU) provided support and guidance with the Guideline development process, undertook the systematic searches, retrieval and appraisal of the evidence and wrote successive drafts of the document.

The membership of the Guideline Development Group was established by the RCOG prior to the adoption of the Guideline by NICE. Following adoption of the Guideline, membership of the Group was modified to include additional consumer input as well as input from a health economist.

All members of the Group made formal declarations of interest at the outset, which were recorded. This record is kept on file at the RCOG. The RCOG was of the opinion that the interests declared did not conflict with the guideline development process.

#### 1.3. For whom is the Guideline intended?

The Guideline has been developed under the auspices of the RCOG CESU, funded by the Department of Health and NICE for practitioners in the UK. The Guideline is of relevance to:

- professional groups who share in caring for women in labour, such as obstetricians, midwives, general practitioners and paediatricians
- those with responsibilities for planning intrapartum services such as directors of public health and trust managers
- · pregnant women and their families.

#### 1.4. Local protocol development

It is anticipated that this national Guideline will be used as the basis for the development of local protocols or guidelines, taking into account local service provision and the needs of the local population. Ideally, local development should take place in a multidisciplinary group setting that includes commissioners of health care, general practitioners, specialists and service users.

#### 1.5. Methods used in the development of the Guideline

#### 1.5.1. Topic areas

The Guideline Development Group constructed a causal pathway to identify the link between EFM and the immediate surrogate and long-term health outcomes that EFM might influence. From this, specific clinical questions were developed.

#### 1.5.2. Literature search strategy

The aim of the literature review was to identify and synthesise relevant evidence within the published literature, in order to answer the specific clinical questions. Thus, clinical practice recommendations are based on evidence where possible. Gaps in the evidence for which future research is needed are identified.

Searches were carried out for each topic of interest. The Cochrane Library, up to Issue 3 (2000) was searched to identify systematic reviews (with or without meta-analyses) of randomised controlled clinical trials, and randomised controlled trials. The electronic database, MEDLINE (CD Ovid version), was searched for the period January 1966 to November 2000, including foreign language publications. The electronic database EMBASE was searched between 1988 to November 2000 to identify publications, usually European, not indexed on MEDLINE. MIDIRS (Midwives

Information and Resource Service), CINAHL (Cumulative Index to Nursing and Allied Health Literature) and the British Nursing Index were searched to ensure that relevant nursing and midwifery literature were included.

Guidelines by other development groups were searched for on the National Guidelines Clearinghouse database, as were the TRIP database and OMNI service on the Internet. The reference lists in these guidelines were checked against our searches to identify any missing evidence.

The Database of Abstracts and Reviews of Effectiveness (DARE) was searched. Reference lists of non-systematic review articles and studies obtained from the initial search were reviewed and journals in the RCOG library were hand-searched to identify articles not yet indexed.

There was no systematic attempt to search the 'grey literature' (conferences, abstracts, theses and unpublished trials).

The economic evaluation included a search of the NHS Economic Evaluation Database (The Cochrane Library, Issue 1, 2001), MEDLINE January 1966 to November 2000, and EMBASE 1988 to November 2000. Relevant experts in the field were contacted for further information.

Searches were performed using generic and specially developed filters, relevant MeSH (medical subject headings) terms and free-text terms. Details of all literature searches are available on application to the RCOG CESU.

#### 1.5.3. Sifting and reviewing the literature

A preliminary scrutiny of titles and abstracts was undertaken and full papers were obtained if the research question addressed the Guideline Development Group's question relevant to the topic. Following a critical review of the full version of the study, articles not relevant to the subject in question were excluded. Studies that did not report on relevant outcomes were also excluded.

For all the subject areas, evidence from the study designs least subject to sources of bias were included. Where possible, the highest levels of evidence were used, but all papers were reviewed using established guides (see below). Published systematic reviews or meta-analyses were used if available.

For subject areas where neither was available, other appropriate experimental or observational studies were sought.

#### 1.5.4. Synthesising the evidence

Identified articles were assessed methodologically and the best available evidence was used to form and support the recommendations. The highest level of evidence was selected for each clinical question. Using the evidence-level structure shown in Table 1.1, the retrieved evidence was graded accordingly. The definitions of the types of evidence used in this guideline originate from the US Agency for Health Care Policy and Research.<sup>8</sup>

The clinical question dictates the highest level of evidence that should be sought. For issues of therapy or treatment the highest level of evidence is meta-analyses of randomised controlled trials or randomised controlled trials. This would equate to a grade A recommendation using the system outlined below (Section 1.5.5).

For issues of prognosis, a cohort study is the best level of evidence available. The best possible level of evidence would equate to a grade B recommendation using the system below (Section 1.5.5). It should not be interpreted as an inferior grade of recommendation, as it represents the highest level of evidence attainable for that type of clinical question.

EFM represents both a screening and a diagnostic test but not a treatment. Studies examining the performance of this test may take the form of randomised controlled trials or cohort studies.

All retrieved articles have been appraised methodologically using established guides. Where appropriate, if a systematic review, meta-analysis or randomised controlled trial existed in relation to a topic, studies of a weaker design were ignored.

The evidence was synthesised using qualitative methods. These involved summarising the content of identified papers in the form of evidence tables and agreeing brief statements that accurately reflect the relevant evidence.

Quantitative techniques (meta-analysis) were not performed because of time constraints and the difficulty of combining studies of various designs.

For the purposes of this Guideline, data are presented as risk ratios (RR) where relevant (i.e. in RCTs and cohort studies). Where these data are statistically significant they are also presented as numbers needed to treat (NNT).

Where possible, the resource implications were discussed by the Guideline Development Group and formally appraised by the group economist when the recommendations would result in a significant change to current clinical practice. However, much of this discussion has been hampered by the lack of published data regarding the current use of different monitoring modalities in specific pregnancy groups. Furthermore, the proportion implied by the recommendations within the Guideline cannot be fully quantified as a result of this.

Table 1.1 Levels of evidence

Level	Evidence
la	Evidence obtained from systematic review of meta-analysis of randomised controlled trials
Ib	Evidence obtained format least one randomised controlled trial
lla	Evidence obtained from at least one well-designed controlled study without randomisation
IIb	Evidence obtained from at least one other type of well-designed quasi-experimental study
Ш	Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies
IV	Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

#### **1.5.5.** Forming and grading the recommendations

The Guideline Development Group was presented with the best available research evidence to answer their questions. From this, recommendations for clinical practice were derived using consensus methods. Where there were areas without available research evidence, consensus was again used.

Recommendations were based on, and explicitly linked to, the evidence that supported them. Consensus was reached using the nominal group technique. Using this method, the draft recommendations their previous grading were graded by the Guideline Development Group prior to the meeting (Table 1.2). These recommendations and the grading given to them were then considered during the meeting and a group opinion was reached. The recommendations were then graded according to the level of evidence upon which they were based. The grading scheme used was based on a

scheme formulated by the Clinical Outcomes Group of the NHS Executive.<sup>7</sup> The strength of the evidence on which each recommendation is based is shown.

It is accepted that, in this grading system, the evidence itself is not graded according to the individual methodological quality of the studies, although it is discussed in the text supporting each recommendation. Limited results or data are presented in the text and these data are available in full in the relevant evidence tables.

Grade 'C' recommendations and good practice points are not based on directly applicable research evidence. However, the views of the Guideline Development Group, combined with comments from the extensive peer review as detailed below, suggest that the recommendations attached to these gradings are acceptable to a wide body of expert opinion.

**Table 1.2 Grading of recommendations** 

Grade	Requirements
A	Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence levels Ia, Ib)
В	Requires the availability of well-conducted clinical studies but no randomised clinical trials on the topic of the recommendation (evidence levels IIa, IIb, III)
С	Requires evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates an absence of directly applicable clinical studies of good quality (evidence level IV)
Good pro	actice points
<b>✓</b>	Recommended good practice based on the clinical experience of the Guideline Development Group

#### 1.5.6. Peer review: scope and methods of peer review process

Successive drafts of the Guideline were written and discussed by the Guideline Development Group. At the fourth draft stage, a formal peer review process was undertaken. Reviewers included representatives from stakeholder organisations registered with NICE and individuals or organisations from the area of practice represented in the Guideline Development Group. The draft Guideline was submitted to these individuals or organisations with a request for appraisal and comment.

The comments made by the peer reviewers were collated and presented anonymously for consideration by the Guideline Development Group. All peer review comments were considered systematically by the Group and the resulting actions and responses were recorded; 361 responses to 331 peer review comments were agreed by the Guideline Development Group and 64.4% of the comments resulted in amendments to the Guideline. A breakdown is provided in Table 1.3. Further information is available upon request.

The Guideline was also reviewed by the NICE Guidelines Advisory Committee. The Guideline was sent to a further group of reviewers who particularly concentrated on the methodology used in its development under the independent guideline appraisal system approved by the NHS Executive. The recommendations made following this process have been incorporated into the Guideline.

The Guideline was made available for public comment on the NICE website for a period of four weeks. The Guideline Development Group received a

total of 11 individual sets of comments, over half of which resulted in minor amendments to the Guideline.

NICE sent the Guideline to a group of commercial organisations involved in the manufacturer of electronic fetal monitors, for their comments.

The clinical practice algorithm was piloted at six hospitals.

### 1.6. How will the Guideline be disseminated and reviewed?

The Guideline has been produced in both full and summary formats and a consumer version. Summaries have been disseminated to all Fellows and Members of the RCOG and to stakeholders, and are also available on the RCOG and NICE websites. Copies of the full printed Guideline are sold through the RCOG Bookshop.

Full copies of the Guideline are available on the RCOG website (www.rcog.org.uk) in PDF format and the summary through the National Electronic Library for Health NeLH (www.nelh.nhs.uk/) and National Guideline Clearinghouse (www.guidelines.gov).

A consumer version of the Guideline, produced in association with the Guideline Development Group and the Centre for Health Information Quality, is available through NHS Direct Online (www.nhsdirect.nhs.uk/).

A national launch meeting took place on 8 May 2001 to disseminate the findings of the Group to interested parties.

The Guideline will be reviewed and revised within three years by NICE.

# 2. Summary of recommendations and future research

#### 2.1. The development of fetal monitoring (see Section 3)

The key outcome measures that should be used to assess the impact and role of EFM are summarised below.

- Absolute outcome measures of fetal/neonatal hypoxia to be collected at a local and regional level should be:
  - perinatal death
  - cerebral palsy
  - neurodevelopmental disability.

Collection and interpretation at a national level would then be possible.

- B Intermediate fetal/neonatal measures of fetal hypoxia to be collected should be:
  - umbilical artery acid-base status
  - Apgar score at five minutes
  - neonatal encephalopathy.

These should be collected on a local (hospital/trust) level.

- B Umbilical artery acid-base status should be assessed by collection of paired samples from the umbilical artery and umbilical vein.
- C Umbilical artery acid-base status should be performed as a minimum after:
  - emergency caesarean section is performed
  - instrumental vaginal delivery is performed
  - a fetal blood sample has been performed in labour
  - birth, if the baby's condition at birth is poor.
- C Maternal outcome measures that should be collected include:
  - operative delivery rates (caesarean section and instrumental vaginal delivery)

This should be collected on a local (hospital/trust) level.

## 2.2. Indications for the use of continuous EFM (see Section 4)

There are a number of antenatal and intrapartum risk factors that have been shown to be associated with the development of neonatal encephalopathy, cerebral palsy or even perinatal death.

- Continuous EFM should be offered and recommended for high-risk pregnancies where there is an increased risk of perinatal death, cerebral palsy or neonatal encephalopathy.
- B Continuous EFM should be used where oxytocin is being used for induction or augmentation of labour.

#### 2.3. Care of women (see Section 5)

The assessment of fetal wellbeing is only one component of intrapartum care. It is an important area where due consideration must be given to maternal preference and priorities in the light of potential risk factors to both mother and baby, i.e. one that strikes the right balance between the objective of maximising the detection of potentially compromised babies and the goal of minimising the number of unnecessary maternal interventions. The provision of accurate information in these circumstances is essential to allow each woman to make the right decision for her.

- Women must be able to make informed choices regarding their care or treatment via access to evidence-based information. These choices should be recognised as an integral part of the decision-making process.
- Women should have the same level of care and support regardless of the mode of monitoring.
- Trusts should ensure that there are clear lines of communication between carers, and consistent terminology is used to convey urgency or concern regarding fetal wellbeing.
- Prior to any form of fetal monitoring, the maternal pulse should be palpated simultaneously with FHR auscultation in order to differentiate between maternal and fetal heart rates.
- If fetal death is suspected despite the presence of an apparently recordable FHR, then fetal viability should be confirmed with real-time ultrasound assessment.
- With regard to the conduct of intermittent auscultation:
  - the FHR should be auscultated at specified intervals (Section 6)
  - any intrapartum events that may affect the FHR should be noted contemporaneously in the maternal notes, signed and the time noted.

C With regard to the conduct of EFM:

- the date and time clocks on the EFM machine should be correctly set
- traces should be labelled with the mother's name, date and hospital number
- any intrapartum events that may affect the FHR should be noted contemporaneously on the EFM trace, signed and the date and time noted (e.g. vaginal examination, fetal blood sample, siting of an epidural)
- any member of staff who is asked to provide an opinion on a trace should note their findings on both the trace and maternal case notes, together with time and signature
- following the birth, the care-giver should sign and note the date, time and mode of birth on the EFM trace
- the EFM trace should be stored securely with the maternal notes at the end of the monitoring process.

## 2.4. Appropriate monitoring in an uncomplicated pregnancy (see Section 6)

- A For a woman who is healthy and has had an otherwise uncomplicated pregnancy, intermittent auscultation should be offered and recommended in labour to monitor fetal wellbeing.
- A In the active stages of labour, intermittent auscultation should occur after a contraction, for a minimum of 60 seconds, and at least:
  - every 15 minutes in the first stage
  - every 5 minutes in the second stage.
- A Continuous EFM should be offered and recommended in pregnancies previously monitored with intermittent auscultation:
  - if there is evidence on auscultation of a baseline less than 110 bpm or greater than 160 bpm
  - if there is evidence on auscultation of any decelerations
  - if any intrapartum risk factors develop.
- B Current evidence does not support the use of the admission CTG in low-risk pregnancy and it is therefore not recommended.

Term	Definition		
Baseline fetal heart rate	The mean level of the FHR when this is stable, excluding accelerations and decelerations. It is determined over a time period of 5 or 10 minutes and expressed in bpm." Preterm fetuses tend to have values towards the upper end of this range. A trend to a progressive rise in the baseline is important as well as the absolute values		
<ul> <li>Normal Baseline FHR</li> <li>Moderate bradycardia<sup>a</sup></li> <li>Moderate tachycardia<sup>a</sup></li> <li>Abnormal bradycardia</li> <li>Abnormal tachycardia</li> </ul>	110–160 bpm 100–109 bpm 161–180 bpm <100 bpm >180 bpm		
Baseline variability	The minor fluctuations in baseline FHR occuring at three to five cycles per minute. It is measured by estimating the difference in beats per minute between the highest peak and lowest trough of fluctuation in a one-minute segment of the trace		
Normal baseline variability	Greater than or equal to 5 bpm between contractions <sup>12</sup>		
Non-reassuring baseline variability	Less than 5 bpm for 40 minutes or more but less than 90 minutes		
Abnormal baseline variability	Less than 5 bpm for 90 minutes or more		
Accelerations	Transient increases in FHR of 15 bpm or more and lasting 15 seconds or more. The significance of no accelerations on an otherwise normal CTG is unclear		
Decelerations	Transient episodes of slowing of FHR below the baseline level of more than 15 bpm and lasting 15 seconds or more		
Early decelerations	Uniform, repetitive, periodic slowing of FHR with onset early in the contraction and return to baseline at the end of the contraction		
Late decelerations	Uniform, repetitive, periodic slowing of FHR with onset mid to end of the contraction and nadir more than 20 seconds after the peak of the contraction and ending after the contraction. <sup>12</sup> In the presence of a non-accelerative trace with baseline variability less than 5 bpm, the definition would include decelerations less than 15 bpm		
Variable decelerations	Variable, intermittent periodic slowing of FHR with rapid onset and recovery. Time relationships with contraction cycle are variable and they may occur in isolation. Sometimes they resemble other types of deceleration patterns in timing and shape		
Atypical variable decelerations	Variable decelerations with any of the following additional components:  - loss of primary or secondary rise in baseline rate - slow return to baseline FHR after the end of the contraction - prolonged secondary rise in baseline rate - biphasic deceleration - loss of variability during deceleration - continuation of baseline rate at lower level		
Prolonged deceleration	An abrupt decrease in FHR to levels below the baseline that lasts at least 60–90 seconds. These decelerations become pathological if they cross two contractions, i.e. greater than 3 minutes		
Sinusoidal pattern	a regular oscillation of the baseline long-term variability resembling a sine wave. This smooth, undulating pattern, lasting at least 10 minutes, has a relatively fixed period of 3–5 cycles per minute and an amplitude of 5–15 bpm above and below the baseline. Baseline variability is absent		

<sup>&</sup>lt;sup>a</sup> These ranges of baseline are not associated with hypoxia in the presence of accelerations, with normal baseline variability and no decelerations

#### 2.5. Interpretation of EFM (see Section 7)

Interpretation of EFM traces requires a definition of what is normal. The definition of normal should be derived by the identification of cases where values outside a given normal range increase the likelihood of the adverse outcomes identified above.

The definitions and descriptions of individual features of FHR traces shown in Table 2.1 are used in the Guideline and in the clinical practice algorithm.

- A grading system for FHR patterns is recommended. This incorporates both the proposed definitions of FHR patterns presented and categorisation schemes.
- Settings on CTG machines should be standardised, so that:
  - Paper speed is set to 1 cm/min
  - Sensitivity displays are set to 20 bpm/cm
  - FHR range displays of 50–210 bpm are used.

**Table 2.2 Categorisation of fetal heart rate traces** 

Category	Definition
Normal	A cardiotocograph where <b>all four</b> features fall into the reassuring category
Suspicious	A cardiotocograph whose features fall into <b>one</b> of the non-reassuring categories and the remainder of the features are
Pathological	reassuring A cardiotocograph whose features fall into <b>two or more</b> non-reassuring categories or one or more abnormal categories

**Table 2.3 Categorisation of fetal heart rate (FHR) features** 

Feature	Baseline (bpm)	Variability (bpm)	Decelerations	Accelerations
Reassuring Non-reassuring	110–160 100–109	≥5	None	Present
	161–180	<5 for ≥40 but less	Early deceleration Variable deceleration	
		than 90	Single prolonged	The absence of
		minutes	deceleration up to	accelerations with
			3 minutes	an otherwise normal
Abnormal	< 100	< 5 for	Atypical variable	cardiotocograph
	>180	≥90 minutes	decelerations	is of uncertain
	Sinusoidal		Late decelerations	significance
	pattern		Single prolonged	
	≥10 minutes	;	deceleration	
			>3 minutes	

- In cases where the CTG falls into the suspicious category, conservative measures should be used.
- In cases where the CTG falls into the pathological category, conservative measures should be used and fetal blood sampling where appropriate/feasible. In situations where fetal blood sampling is not possible or appropriate then delivery should be expedited.
- For definition of conservative measures please refer to the clinical practice algorithm (Figure 1).

## 2.6. Additional tests and therapies used in combination with EFM (see Section 8)

- A Units employing EFM should have ready access to fetal blood sampling facilities.
- A Where delivery is contemplated because of an abnormal fetal heartrate pattern, in cases of suspected fetal acidosis, fetal blood sampling should be undertaken in the absence of technical difficulties or any contraindications.
- B Contraindications to fetal blood sampling include:
  - maternal infection (e.g. HIV, hepatitis viruses and herpes simplex virus)
  - fetal bleeding disorders (e.g. haemophilia)
  - prematurity (< 34 weeks).
- Where there is clear evidence of acute fetal compromise (e.g. prolonged deceleration greater than three minutes), fetal blood sampling should not be undertaken and the baby should be delivered urgently.
- Prolonged use of maternal facial oxygen therapy may be harmful to the fetus and should be avoided. There is no research evidence evaluating the benefits or risks associated with the short-term use of maternal facial oxygen therapy in cases of suspected fetal compromise.
- B Fetal blood sampling should be undertaken with the mother in the left-lateral position.
- B During episodes of abnormal FHR patterns when the mother is lying supine, the mother should adopt the left-lateral position.
- In cases of uterine hypercontractility in association with oxytocin infusion and with a suspicious or pathological CTG, the oxytocin infusion should be decreased or discontinued.
- A In the presence of abnormal FHR patterns and uterine hypercontractility (not secondary to oxytocin infusion) tocolysis should be considered. A suggested regimen is **subcutaneous terbutaline 0.25 mg**.
- A In cases of suspected or confirmed acute fetal compromise, delivery should be accomplished as soon as possible, accounting for the severity of the FHR abnormality and relevant maternal factors. The accepted standard has been that, ideally, this should be accomplished within 30 minutes.

Table 2.4 Classification of fetal blood sample results

Fetal blood sample (FBS) result (pH) <sup>a</sup>	Subsequent action
≥ 7.25	FBS should be repeated if the FHR abnormality persists
7.21–7.24	Repeat FBS within 30 minutes or consider delivery if rapid fall since last sample
≤ 7.20	Delivery indicated

<sup>&</sup>lt;sup>a</sup> All scalp pH estimations should be interpreted taking into account the initial pH measurement, the rate of progress in labour and the clinical features of the mother and baby

#### 2.7. Education and training (see Section 9)

Continuous EFM only provides a printed recording of the FHR pattern. The interpretation of the FHR record is subject to human error. Education and training improve standards of evaluating the FHR.

- Trusts should ensure that staff with responsibility for performing and interpreting the results of EFM should receive annual training with assessment to ensure that their skills are kept up to date. For details of key elements of training, see Section 9.1.
- Trusts should ensure that resources and time are made available to facilitate training in both intermittent auscultation and EFM and no staff should be expected to fund their own training.
- Staff should have easy access to computer-assisted and/or interactive training programmes.
- Training should include instruction on documenting traces and their storage.
- Training should include instruction on appropriate clinical responses to suspicious or pathological traces.
- C Training should include instruction on the channels of communication to follow in response to a suspicious or pathological trace.
- Training should include a section on local guidelines relating to fetal monitoring, both intermittent auscultation and EFM.

#### 2.8. Risk management and the use of EFM

- C EFM traces should be kept for a minimum of 25 years.
- Tracer systems should be developed to ensure that CTGs removed for any purpose (e.g. risk management, teaching purposes) can always be located.

#### 2.9. Future research recommendations

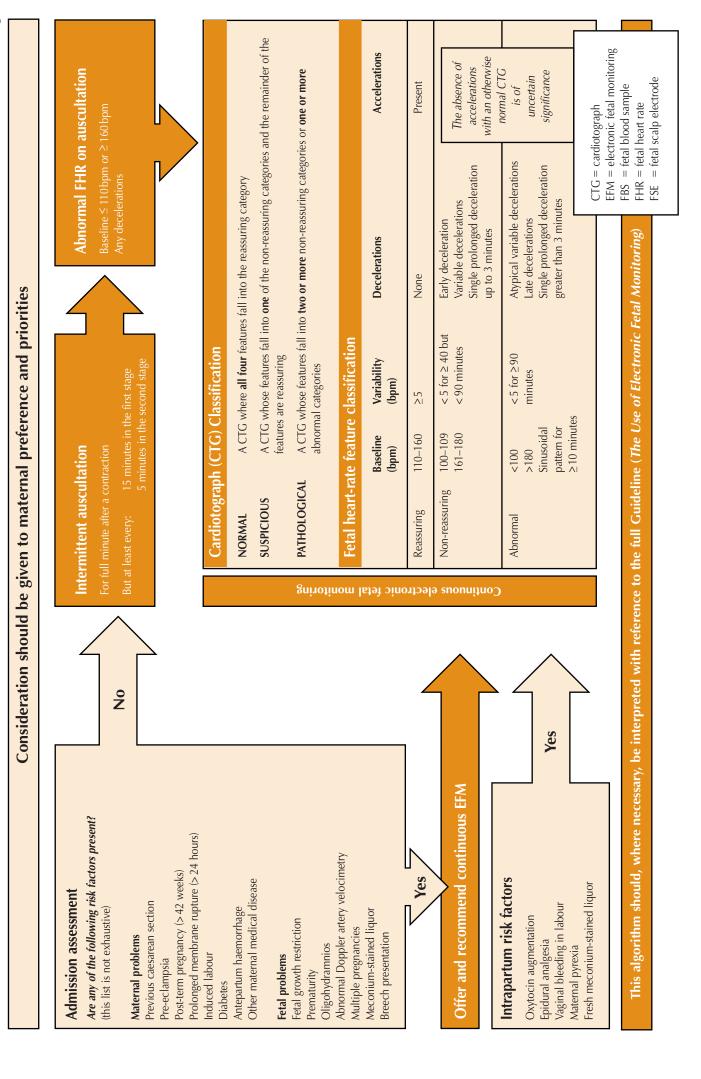
The following are recommendations for future research.

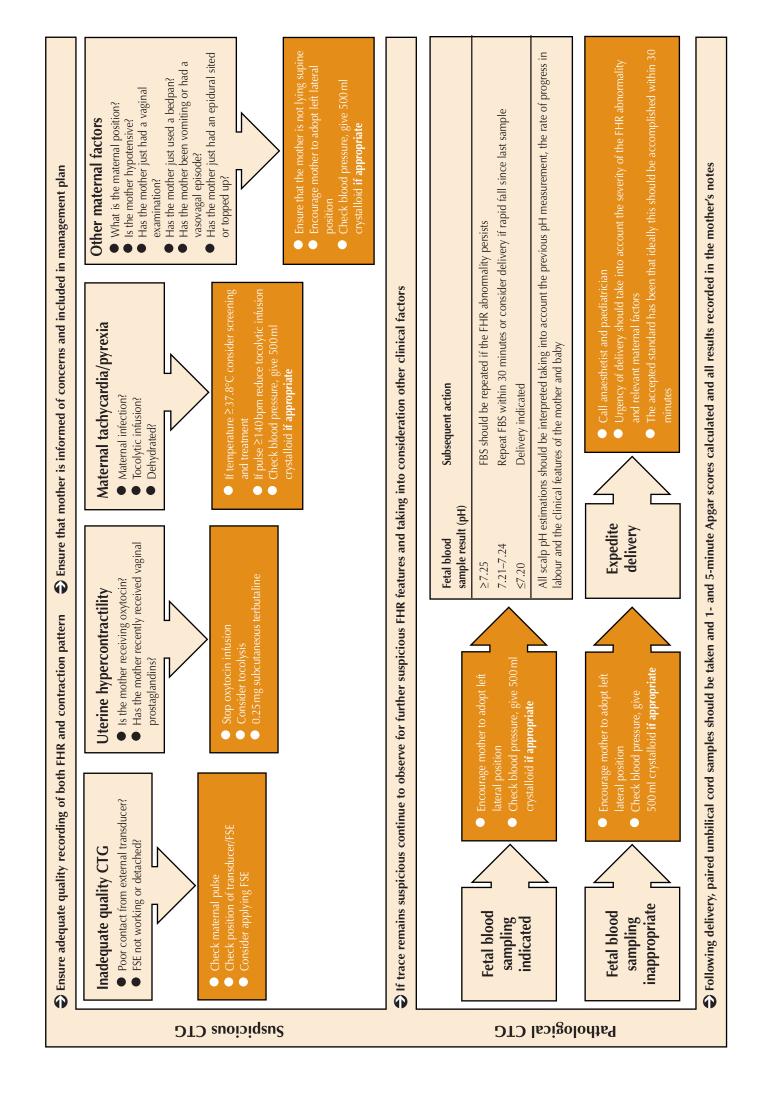
- Adequately powered randomised controlled trials are needed to evaluate the performance of:
  - EFM compared with intermittent auscultation in a low-risk pregnancy setting, with regard to perinatal mortality
  - admission CTG
  - intrapartum vibroacoustic stimulation testing as an alternative to fetal blood sampling
  - maternal facial oxygen therapy during a period of acute fetal compromise.
  - the performance of different forms of intermittent auscultation and how the performance of these modalities is affected by different frequencies of monitoring in comparison with EFM.
- Research evaluating measures of maternal satisfaction and response to intrapartum care (including fetal monitoring) is needed, to enable services to monitor the provision of patient centred care and also allow comparison between service providers.

#### 2.10. Clinical practice algorithm

The recommendations have been combined into a clinical practice algorithm, in order to allow the findings from this Guideline to be integrated and implemented in clinical practice. The algorithm aims to guide users through the decision pathways assessing the monitoring needs of any woman admitted in labour. The algorithm draws directly on the evidence presented in the Guideline and, hence, is not recommended for use without prior consultation of this evidence. This algorithm was modelled around a practice guideline developed at Nottingham City Hospital under the supervision of Rosemary Buckley<sup>6</sup> and the Guideline Development Group thanks them for allowing the use their guideline as a model for the development of this current algorithm.

Figure 1 Treatment algorithm for intrapartum fetal monitoring





## 3. Development of fetal monitoring

#### 3.1. History of fetal monitoring

The ability to diagnose fetal life through auscultation of the fetal heart by applying the ear to the pregnant woman's abdomen was discovered in Europe during the early 19th century. Stethoscopic auscultation of the fetal heart developed throughout the century, as its potential to recognise fetal wellbeing was realised. Interest grew in how to recognise changes in FHR that might foreshadow and prevent intrapartum fetal death through obstetric intervention. Pinard's version of the fetal stethoscope appeared in 1876. Criteria for the normal FHR set in the latter part of the 19th Century remained virtually unchanged until the 1950's. The same period saw interest and research into the significance of meconium staining of the amniotic fluid as a means of predicting fetal wellbeing. By the beginning of the 20th century, auscultation of the fetal heart was an established practice in Europe.

Evidence level

#### 3.2. Development of EFM

Advances in the techniques of auscultation were limited until the arrival of audiovisual technologies in the early 20th century. These promised the possibility of a continuous form of monitoring. Early electrocardiographic techniques were limited by their inability to sufficiently eliminate maternal complexes. This problem was addressed by the use of the fetal scalp electrode in 1960.

A considerable advance in technology with which to detect the fetal heartbeat came in 1964 when the Doppler principle was applied. In 1968, the first commercially available EFM applied Doppler's principle of a distinct change in frequency when a waveform is reflected from a moving surface. The monitoring of fetal scalp blood acid-base was developed in Germany in the 1960s and was introduced clinically as an adjunct to continuous electronic fetal heart-rate monitoring to increase its specificity. The obstetric use of continuous electronic fetal heart rate monitoring increased rapidly.<sup>13–16</sup>

Medical and socio-economic advances transformed maternal birth outcomes in the 19th and 20th centuries. While the original aim of intrapartum EFM was to prevent harm, it was introduced on to the labour wards in the 1950s with the emphasis on improving fetal birth outcomes by detecting fetal hypoxia, before it led to death or disability. Like intermittent auscultation in the 19th century, continuous EFM was introduced clinically before its effectiveness had been fully evaluated scientifically.

A number of retrospective observational studies published in 1972–76<sup>17–24</sup> reported a decrease in perinatal mortality in those women who had continuous EFM as opposed to those who had selective EFM or no EFM at all. While these studies were encouraging, the methodological biases of

observational studies (they may overestimate the true effects of a given intervention) prompted a need for randomised controlled trial evidence to more rigorously evaluate the use of intrapartum EFM on perinatal mortality and morbidity.

#### 3.3. Cerebral palsy and intrapartum events

A recent international consensus statement attempted to define a causal relationship between acute intrapartum events and cerebral palsy.<sup>2</sup> That document was not aiming to examine the failings of intrapartum monitoring techniques but to highlight the rarity with which acute intrapartum events were associated with cerebral palsy.

Epidemiological data suggest that only 10% of cases of cerebral palsy have potential intrapartum causes and, even in some of these there may have been an antenatal component.<sup>1</sup>

The document concluded that for a diagnosis of cerebral palsy to have been the result of intrapartum hypoxia certain criteria should be fulfilled (see Appendix 1). These included evidence of metabolic acidosis, moderate to severe neonatal encephalopathy and the presence of specific types of cerebral palsy. Similarly, the authors thought that there needed to be evidence of a 'sentinel hypoxic' event (see Appendix 1). In the absence of any of the essential criteria, an intrapartum cause could be assumed. The absence of any of the five remaining criteria similarly would cast doubt on the diagnosis of an intrapartum cause of cerebral palsy.

#### 3.4. EFM as a screening test

As highlighted above, EFM was introduced with an aim of reducing perinatal mortality and cerebral palsy. This reduction has not been demonstrated and, in turn, an increase in maternal intervention rates has been shown in systematic reviews and RCTs. However, the the lack of improvement in neonatal outcome and also the increase in intervention rates should be viewed with caution, given the low incidence of the outcomes EFM seeks to reduce.

Current prevalence rates for perinatal mortality, neonatal encephalopathy and cerebral palsy are shown below (Table 3.1). Of these, only a small proportion are thought to be attributable to intrapartum causes, hence the true preventable prevalence for these conditions is also shown.

With the low prevalence of these conditions, any screening test would require a specificity above 99% to avoid numerous unnecessary interventions.

Table 3.1 Overall and intrapartum prevalence rates for perinatal mortality, neonatal encephalopathy and cerebral palsy

Condition	Prevalence	Prevalence of intrapartum causes
Perinatal mortality <sup>6</sup>	8 per 1000ª	0.8 per 1000 <sup>a</sup>
Neonatal encephalopathy25	7 per 1000 <sup>b</sup>	_ '
Cerebral palsy <sup>26</sup>	1.1 per 1000°	0.1 per 1000°

<sup>&</sup>lt;sup>a</sup> per 1000 live births

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<sup>&</sup>lt;sup>b</sup> includes all grades of encephalopathy

<sup>&</sup>lt;sup>c</sup> per 1000 children who survived to three years of age (includes all birthweights)

All of the constituent trials in the systematic reviews comparing EFM to intermittent auscultation were underpowered to detect a significant reduction in perinatal death rates. The trials included a total of 18 927 babies. The current perinatal mortality rate in the UK is approximately 8.0 per 1000 live births. Assuming 10% are directly related to intrapartum causes, the intrapartum perinatal mortality rate would be 0.8 per 1000 live births. For an RCT comparing EFM with intermittent auscultation to demonstrate a 25% reduction of the overall perinatal mortality rate, it would require 56 000 women to be randomised (assuming an 80% power and a 5% type I error). This represents an optimistic reduction and would assume that all the intrapartum deaths are preventable. If a smaller effect size were to be seen then a proportionally larger sample would be necessary.

The sensitivity and specificity of a test, in association with the prevalence of the target condition, dictate the positive predictive value of that test. EFM represents a highly sensitive test with a diseases it is designed to detect being of low prevalence. This therefore results in a high false-positive rate and, hence, a poor positive predictive value. If the specificity of EFM were increased then the test becomes falsely reassuring, with a resulting reduction in the sensitivity, i.e. a reduction in the detection of potentially compromised babies.

#### 3.5. Selection of absolute outcomes

EFM has been assessed against a wide variety of both neonatal and maternal outcomes. A priority in the development of this Guideline was to reach agreement on which maternal and fetal outcomes (both beneficial and harmful) may be influenced by intrapartum EFM. The Guideline Development Group considered a wide range of maternal and neonatal outcomes. From an original list, consensus was reached on the outcomes thought to be of importance and these are considered below. Published research evidence evaluating the effectiveness EFM is as a diagnostic or screening test in predicting these agreed outcomes was then sought.

All studies relating to outcome measures are included in the Evidence Tables in Appendix 2.

#### 3.6. Neonatal outcome measures

Perinatal death, cerebral palsy and neurodevelopmental disability are important adverse clinical outcomes of fetal hypoxia, which EFM was intended to reduce. The Guideline Development Group considered that these were the important absolute outcomes against which EFM should be evaluated.

For the purpose of this Guideline, cerebral palsy is defined as non-progressive abnormal control of movement or posture and limited to the spastic quadriplegia and dyskinetic sub-types.<sup>2</sup> The Guideline Development Group defined neurodevelopmental disability as any restriction or lack (resulting from an impairment) of ability to perform an activity in the manner or within the range considered normal for a human being, with reference to difficulty in walking, sitting, hand use or head control.

All these outcomes are rare and, in the case of cerebral palsy and neurodevelopmental disability, only become apparent with the passage of time. Hence, studies evaluating the effectiveness of EFM in reducing the incidence of these outcomes need to be large and should follow up these

children over a number of years to allow the diagnosis to be established. Because of this, many studies have examined instead the effects of EFM on alternative more immediate intermediate measures that occur more commonly. However, in this approach there is an implicit assumption of a linear causal relationship between these intermediate measures and the long-term adverse absolute outcomes of cerebral palsy and neurodevelopmental disability (Figure 2).

In order to evaluate the validity of this assumption, research evidence evaluating the relationship between these intermediate measures and the absolute outcomes was sought. The intermediate measures reviewed for this Guideline include umbilical cord blood acid-base status, Apgar scores, neonatal convulsions, need for intubation/ventilation and neonatal encephalopathy.

The relationship between EFM and both sets of measures, as well as the relationship between the intermediate measures and absolute outcomes, are discussed below.

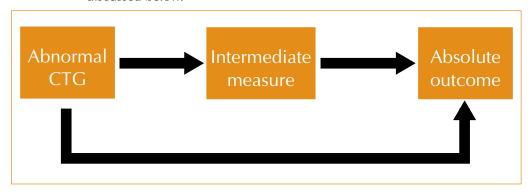


Figure 2 The relationship between predictors of outcome, intermediate measures and absolute outcomes.

#### 3.6.1. Perinatal death

Three systematic reviews have examined the effect of EFM in comparison with intermittent auscultation on perinatal death rates (Evidence Table 1).<sup>27–29</sup> None found a significant reduction in the perinatal death rate with EFM. In one review, a subgroup analysis for perinatal death was undertaken.<sup>28</sup> Deaths in each trial were allocated according to whether the deaths were due to hypoxia or other causes. A significant reduction in the odds of a perinatal death due to hypoxia with the use of EFM was found. However, this was a post-hoc analysis and therefore prone to subjective selection bias and thus the subgroup analysis result should be treated with caution.

The first systematic review undertaken to evaluate the impact of EFM<sup>29</sup> included a subgroup analysis evaluating the use of EFM in conjunction with FBS in comparison with the use of EFM alone. There was no significant difference between these groups. However, this review was written before data from a later RCT<sup>30</sup> were available. That subgroup analysis has been repeated in the current Cochrane systematic review,<sup>27</sup> including the data from the later RCT. There was no apparent difference in perinatal death rates between the two groups.

When analysed separately, none of the trials included in these reviews demonstrated a reduction in either intrapartum or neonatal deaths.

Finally, the trials in the three systematic reviews trials have included a mixture of low- and high-risk populations. It is not possible to quantify the actual effect of EFM on perinatal mortality in these specific populations.

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#### 3.6.2. Cerebral palsy and neurodevelopmental disability

There have been three studies (see Evidence Table 2) that followed up cohorts of babies included in three RCTs comparing EFM with intermittent auscultation.<sup>31–33</sup>

One of the studies found a significant increase in rates of cerebral palsy in the babies monitored by EFM compared with intermittent auscultation (19.5% versus 7.7%; RR 2.54; 95% CI 1.10–5.86; NNT 8).32 However, that cohort<sup>35</sup> included only preterm babies who weighed less than 1750 gm at birth. Prematurity is a risk factor for cerebral palsy and this must be considered when interpreting the results. Furthermore, in the original RCT,35 from which this cohort was derived, the management subsequent to the detection of a fetal heart-rate abnormality was not consistent in both arms of the study. There was a significantly longer mean delay between the onset of the fetal heart-rate abnormality and birth in the EFM group compared with the intermittent auscultation group (105 minutes vs. 45 minutes). This delay in delivery may have been the effect of fetal blood sampling being performed following suspicious fetal heart rate patterns in the EFM group but not in the intermittent auscultation group. This delay in delivery may well have contributed to the resulting difference in cerebral palsy rates between the two groups.

The remaining two cohort studies found no significant difference in the development of cerebral palsy between the groups at the end of the follow-up period.<sup>31,33</sup>

Two further large cohort studies, following over 105 000 babies, have examined the risk factors for the subsequent development of cerebral palsy. There was no significant association between intrapartum complications and the subsequent development of cerebral palsy. The main risk factors for cerebral palsy were congenital malformations and low birthweight.

In two of the larger case–control studies of cerebral palsy and the use of EFM, there was a significant association between abnormal cardiotocograph findings in the cases of cerebral palsy. However, the false positive rates were high.<sup>26,39</sup> The relationship between specific cardiotocograph patterns and neonatal outcome is discussed further in Section 5.2.

#### 3.6.3. Neonatal convulsions

A significant reduction in neonatal convulsion rates following the use of EFM was found in two of the systematic reviews (0.24% versus 0.50; RR 0.51; 95% CI 0.32–0.82; NNT 384) (see Evidence Table 1).<sup>29,27</sup> However, only one of the nine studies included in these reviews<sup>34</sup> provided a definition of seizure activity and, in one other study, a specific differentiation of uncertain significance was made between convulsions and 'jittery' babies.<sup>40</sup>

The relationship between convulsions and subsequent neurodevelopmental disability was examined in a study (see Evidence Table 2) which followed up infants included in one RCT.<sup>34</sup> The reduced convulsion rate seen in the EFM arm in the original trial was not translated into a significant reduction in the rate of cerebral palsy in the group on follow-up. Of the six babies from this cohort who subsequently developed cerebral palsy, five were thought to be attributable to antepartum factors.<sup>31</sup>

#### 3.6.4. Neonatal encephalopathy

Three case–control studies<sup>41,42</sup> (see Evidence Table 3) have examined whether abnormal EFM traces predict the subsequent development of neonatal encephalopathy.<sup>25</sup>

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In the first study, there was a significant increase in the odds of developing neonatal encephalopathy in the presence of an abnormal CTG in the first or last 30 minutes of labour.<sup>25</sup> Abnormal was defined as either 'suspicious' or 'ominous' patterns as defined by the International Federation of Gynecology and Obstetrics (FIGO) classification,<sup>11</sup> (first 30 minutes: OR 2.89, 95% CI 1.07–7.77; last 30 minutes: OR 7.5; 95% CI 2.14–26.33). However, no association with neonatal encephalopathy was seen if a different CTG scoring system was used.<sup>43</sup>

In the second study, the definition of an 'ominous' CTG was based on the classification used in the Dublin RCT.<sup>34</sup> This included any marked tachycardia or bradycardia (limits not defined), a moderate tachy/bradycardia with minimal variability, late decelerations or severe variable decelerations. A significant association with an 'ominous' CTG was seen with both first- and second-stage traces (first stage: OR 10.2, 95% CI 2.9–36.4; second stage: OR 7.2, 95% CI 2.1–24.4).<sup>42</sup>

In the last of these studies, an abnormal CTG (which was reported as those interpreted by the attending clinician as abnormal) was associated with a significant increase in the odds of neonatal encephalopathy (OR 1.98; 95% CI 1.26–3.10). However, as these are case–control studies, caution is needed in ascribing a causal relationship to the observed effect.

The relationship between neonatal encephalopathy and subsequent 'disability' has been examined in a systematic review of five cohort studies (see Evidence Table 4).<sup>44</sup> All the studies used a similar grading/staging system for defining the grade of neonatal encephalopathy and therefore data from each can be compared. The results suggest that the likelihood of death or developing severe handicap was proportional to the grade or severity of neonatal encephalopathy (Table 3.2).

One of the limitations of the studies examining neonatal encephalopathy as an outcome measure has been the absence of an agreed definition of the grading of babies with encephalopathy. An outline of a recommended system for grading is presented in Appendix 3.

Table 3.2 Likelihood ratios of death and severe disability in relation to grade of neonatal encephalopathy

Grade of neonatal encephalopathy	Likelihood ratios <sup>a</sup> for death(95% CI)	Likelihood ratios³ for severe disability (95% CI)
1: Mild	0.09 (0.03-0.30)	0.10 (0.03-0.28)
2: Moderate	0.39 (0.21–0.71)	1.51 (1.19–1.52)
3: Severe	10.98 (7.56–15.94)	16.60 (6.85–35.70)

<sup>&</sup>lt;sup>a</sup> refer to glossary for definition

#### 3.6.5. Umbilical cord blood acid-base status

A single RCT (see Evidence Table 5) has found that EFM was significantly more sensitive in detecting both respiratory and metabolic acidosis in comparison with intermittent auscultation.<sup>45</sup> However, the specificity was poor (detection of all acidosis: EFM: sensitivity 97%, specificity 84%; intermittent auscultation: sensitivity 34%, specificity 91%).

A number of studies have examined the relationship between acidaemia with both short- $^{46-48}$  and long-term $^{49-52}$  complications (see Evidence Table 6). In the short term, studies those babies with acidosis (pH < 7.00) were significantly more likely to suffer neonatal complications and, in one study, this relationship was only found for those babies with demonstrated metabolic

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acidosis.<sup>46-48</sup> In the long term, studies the association between acidaemia and neurodevelopmental disability was not significant, but was correlated more with the development of neonatal encephalopathy as highlighted in Section 3.6.4.<sup>49-52</sup> One nested case–control study followed a cohort of babies with pH < 7.00 at birth, the authors found a significantly lower pH in the group of babies that developed neonatal encephalopathy compared with those who did not.<sup>53</sup> Only two of the studies specified that the relationship studied was between metabolic acidosis and short-<sup>47</sup> and long-term<sup>52</sup> outcome.

One study specifically addressed the issue relating to the interpretation of umbilical cord blood gas analysis.<sup>54</sup> The study concluded that, in order to establish that the pH measurement obtained is arterial in origin, it is necessary to sample both umbilical vessels. Single-vessel sampling may lead to erroneous interpretation of acid-base measurement.

Metabolic acidaemia is comparatively common (2% of all births). However, the over 90% of such infants do not develop cerebral palsy. <sup>2,50</sup> Metabolic acidaemia at birth is one of three essential criteria for establishing an intrapartum cause for cerebral palsy. Hence, in situations where fetal compromise is suspected at birth, paired umbilical pH and base excess measurements are essential (e.g. operative delivery, instrumental or caesarean, where a fetal blood sample has been taken in labour or where the baby's condition is poor at birth).

#### 3.6.6. Apgar scores

Two of the systematic reviews (see Evidence Table 1) comparing EFM and intermittent auscultation showed no significant benefit for the use of EFM in reducing the number of depressed one-minute Apgar scores (using cut-offs of both four and seven). Five of the original RCTs reported five-minute Apgar scores (using a cut-off of seven) but demonstrated no significant benefit from the use of EFM. 30,36,40,55,56 These data are not reported in the systematic reviews.

In two cohort studies, <sup>37,38</sup> and two case–control studies <sup>39,57</sup> (see Evidence Table 2) there was a significant association between a depressed Apgar score and subsequent cerebral palsy. However, the relationship was seen only if the five-minute Apgar score was severely depressed (less than three) and when this depression persisted longer than 20 minutes. <sup>58</sup>

Two studies<sup>59,60,61</sup> (see Evidence Table 7) have shown no significant association between Apgar scores at one minute and acidosis. The relationship between acidosis and five-minute Apgar score of less than seven was also examined. In one study, there was a high concordance with metabolic acidosis (pH < 7.20) and five-minute Apgar score of less than seven (with four of the six babies with Apgar scores of less than seven at five minutes having metabolic acidosis). However, the vast majority of acidotic babies in that study had Apgar scores of less than seven at five minutes.<sup>59</sup> In the second study, only 19% of the babies with an Apgar score of less than seven at five minutes were severely acidotic (pH < 7.10). Conversely, 73% of babies with severe acidosis had five-minute Apgar scores less than seven.<sup>60</sup>

#### 3.6.7. Need for intubation/ventilation

No studies could be found examining the relationship between the use of EFM and the need for intubation/ventilation at birth alone. The value of the 'need for intubation' as an outcome measure has not been examined in isolation. However, it is part of the neonatal encephalopathy grading system and is a useful marker in that context.

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#### 3.7. Maternal outcome measures

The main maternal outcome measures used to measure the impact of EFM in the literature have been intervention rates and measures of maternal response such as satisfaction or anxiety. These were considered by The Guideline Development Group to be important outcomes against which to assess EFM.

#### 3.7.1. Intervention rates

The data from the two more recent systematic reviews<sup>28,62</sup> (see Evidence Table 1) showed that the rates of both operative vaginal delivery and delivery by caesarean section were significantly increased with the use of EFM in comparison with intermittent auscultation (Table 3.3). This effect was more pronounced if only those deliveries for presumed 'fetal distress' were considered. The increase in intervention rates was less pronounced in those trials using FBS as an adjunct to EFM.<sup>62</sup>

Table 3.3 Operative delivery rates comparing electronic fetal monitoring with intermittent auscultation

Outcome	Event rate in EFM group (%)	Event rate in IA group (%)	Relative risk (95% CI)	NNT (risk difference)
LSCS (Thacker)	464/9398 (4.9)	327/9394 (3.5)	1.41 (1.23–1.61)	71 (1.4)
LSCS (Vintzilleos)	484/9398 (5.1)	344/9163 (3.75)	1.31 (1.15–1.50)	74 (1.35)
LSCS for FD (Vintzilleos)	129/8778 (1.4)	47/8506 (0.6)	2.49 (1.78–3.49)	118 (0.8)
Instrumental delivery (Thacker)	1156/9276 (12.5)	965/9270 (10.4)	1.20 (1.11–1.30)	48 (2.1)
Instrumental delivery (Vintzilleos)	1147/9398 (12.2)	889/9163 (9.7)	1.22 (1.13–1.33)	40 (2.5)
Instrumental delivery for FD (Vintzilleos)	246/7679 (3.2)	96/7403 (1.3)	2.45 (1.93–3.10)	105 (1.9)
LSCS (EFM + FBS vs. IA (Thacker))	270/7482 (3.6)	218/7507 (2.9)	1.24 (1.05–1.48)	143 (0.7)
LSCS (EFM – FBS vs. IA (Thacker))	194/1916 (10.1)	109/1887 (5.8)	1.72 (1.38–2.15)	23 (4.3)

CI = confidence interval, EFM = electronic fetal monitoring, FD = fetal distress, IA = intermittent auscultation, LSCS = lower segment caesarean section, NNT = number needed to treat

#### 3.7.2. Maternal response

Maternal response, measured as expressions of levels of maternal satisfaction or anxiety related to methods of intrapartum fetal monitoring, is an important outcome by which to measure the impact on women of EFM and intermittent auscultation. Measures of satisfaction and anxiety are necessarily subjective yet can be measured usefully. Satisfaction and anxiety with EFM and intermittent auscultation can be affected by a number of variables including:

- issues of mobility
- · maternal control of events during labour

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- social and clinical support
- fear or reassurance about the health of the baby
- need for analgesia
- · amount of information about monitoring
- other factors.<sup>63</sup>

A qualitative review of the papers revealed that measures of satisfaction and anxiety were synonymous with expressions of reassurance, worry, enjoyment and positive or negative emotional responses.

Statistical pooling of data from these studies is problematic because of the degree of methodological and demographic variation. Published studies examining issues of maternal satisfaction and anxiety in this area vary in the manner in which they measure such responses. The lack of validated assessment tools to measure maternal response also prevents comparison between the studies. When EFM was first introduced on to labour wards, it was often used only on women considered to be at high risk of adverse outcomes. Only later was it used more extensively to monitor low-risk women. Thus, in some of the earlier studies, maternal response may reflect the emotional effects of having a high-risk pregnancy, as well as the effects of being monitored.

#### 3.7.3. Response to EFM versus radiotelemetry

One RCT examined the effects of standard EFM versus radiotelemetric monitoring (RTFM) on the maintenance of control during labour in a group of low-risk women. <sup>64</sup> The study found that those women monitored by RTFM were significantly more mobile, required less analgesia and scored higher on the revised labour Agentry scale (a rating scale designed to quantify feelings of maternal control in labour). The majority of women monitored by RTFM expressed the feeling that their labour was a more positive experience than expected, with only one woman exposed to EFM responding in the same way. The vast majority of women expressed positive perceived effects of RTFM, while only one-third of EFM monitored women expressed the same view

While RTFM may not be in common use, this study is included because it addresses issues of mobility that are commonly cited as having an impact upon maternal response. This study indicates that freedom from restraint appears to be a variable that affects ability to maintain control in labour and it also appears to affect ability to overcome and cope with pain. However, it is difficult to draw conclusions from the study as the sample size was too small to be generalisable, no details of randomisation method were given and it was unclear what comprised 'standard EFM'.

#### 3.7.4. Response to EFM versus intermittent auscultation

Three cross-sectional surveys reported the views of women exposed to either EFM or intermittent auscultation in a randomised controlled trial. <sup>65–67</sup> In a study of a randomly selected subset of the Dublin trial <sup>34</sup> there were no statistically significant differences in the degree of control or anxiety reported by women in either group. <sup>66</sup> There were no significant differences in the levels of social and nursing support enjoyed. Women in the intermittent auscultation groups experienced a significantly higher level of mobility. The EFM group were significantly more likely to be left alone, although only five women said that they had been left alone for more than a few minutes. Nearly three times as many of the intermittent auscultation group said that they would prefer to be monitored with EFM in their next labour, than women in the EFM group would chose to be monitored by intermittent auscultation if they had another a baby.

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The second study, consisting of a subset of women from a randomised trial of women in preterm labour,<sup>35</sup> found that the method of monitoring, either EFM or intermittent auscultation, did not significantly affect women's response to their labour.<sup>67</sup> While its findings are similar to the earlier study, they are difficult to compare, as only the former study relates to a low-risk population. In both studies women had one-to-one nursing or midwifery support. This may suggest that the overall similarity of women's responses is less a result of the experience of a particular form of monitoring than it is the result of supportive care by midwifery and nursing staff.

The third study investigated women's antenatal and postpartum preferences for mode of intrapartum fetal monitoring. Women with previous stillbirth or neonatal death and women with a high-risk pregnancy preferred EFM antenatally. They cited the advantages of EFM as continuous monitoring and the possibility of quick intervention. Intermittent auscultation was preferred by women who sought a natural childbirth and a non-technological milieu. They cited the disadvantages of EFM to be possible discomfort caused by belts and sensors. In postpartum interviews, the majority of women upheld the original preference, if it had been used. Of women who were randomised to EFM but would have preferred intermittent auscultation, less than half would choose EFM the next time. Of those women who were randomised to intermittent auscultation but would have preferred EFM, the majority would choose intermittent auscultation the next time. Postpartum data should be viewed with caution because of methodological problems in

#### 3.7.5. Response to EFM

the follow-up interviews.

In studies that consider the impact of information, a lack of information and understanding of EFM was mentioned by many subjects as being a contributing factor to negative impressions of EFM.<sup>68</sup> A survey comparing responses to EFM over a five-year period (1972–77) found that positive responses to EFM increased from 0% to 22% and that negative initial response rates fell from 62% to 22%.<sup>69</sup> This could reflect an increase in familiarity with EFM as well as a change in the information provided.<sup>70</sup> In one survey of women who had continuous EFM with a fetal scalp electrode, all those women with a highly negative response to monitoring indicated that they had little understanding of why they were being monitored or information about the monitor.<sup>70</sup> The majority acknowledged monitoring in positive terms. Negative responses included fears about the electrodes and difficulty in getting comfortable. The study was limited by its small sample size.

A survey of the maternal psychological effects of EFM in pregnancy and labour examined the emotional responses of pleasure and reassurance.<sup>68</sup> More subjects were reassured by the sound of the FHR if they had experienced EFM during pregnancy or pregnancy and labour. Anxiety was more frequently the reaction of women who experienced EFM for the first time in labour. Another survey, which investigated the psychological consequences of EFM, found that women who had suffered a high level of prior obstetric problems were more positive about EFM than women with no such history.71 In another study, women were randomly selected from a community hospital and a medical centre and interviewed two days postpartum to ascertain their reactions to internal EFM.72 There was little difference in level of obstetric complication in both groups and both groups were equally positive in their response to EFM. Both groups felt that they understood the purpose of monitoring. Aspects raising negative responses included machine breakdown, repeated detachment of the fetal scalp electrode and discomfort with the belt. Few women gave totally negative responses.

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Common observations in many of the studies were the negative impact of belts, wires and scalp electrodes causing discomfort, worry and reduced mobility.<sup>64,65,68-72</sup> In one survey it was also found that, while women in the intermittent auscultation group were significantly more mobile, some of the group objected to the physical discomfort of the Pinard stethoscope on the abdomen and found the need to be repositioned for intermittent auscultation annoying.<sup>66</sup>

#### 3.8. Summary

#### 3.8.1. Conclusions

Intermediate fetal/neonatal measures of fetal hypoxia

- Umbilical artery acidaemia at birth correlates with neonatal complications. However, in isolation it has not been shown to be a predictor of long-term neurological sequelae.
- A five-minute Apgar score equal to or less than three may be a sensitive marker of long-term sequelae. However, Apgar scores at one minute are not a robust marker.
- The development of moderate or severe neonatal encephalopathy appears to be the most robust intermediate outcome measure of potential long-term disability.
- Neonatal convulsions alone are a poor marker of intrapartum hypoxic injury.
- The need for either neonatal resuscitation/ventilation or admission to neonatal intensive care units in isolation are not predictive of long-term neurological sequelae.

Absolute outcome measures of fetal/neonatal hypoxia

- Perinatal death
- Cerebral palsy
- Neurodevelopmental disability.

The relationship between the two groups of valid outcomes may be illustrated thus:

#### Intermediate measures

Acid-base balance Five-minute Apgar score Neonatal encephalopathy

#### **Absolute outcomes**

Perinatal death Cerebral palsy Neurodevelopmental disability

Useful maternal outcome measures

- Operative delivery rates
- Maternal response.

#### 3.8.2. Practice recommendations

- Absolute outcome measures of fetal/neonatal hypoxia to be collected at a local and regional level should be:
  - perinatal death
  - cerebral palsy
  - neurodevelopmental disability.

Collection and interpretation at a national level would then be possible.

- B Intermediate fetal/neonatal measures of fetal hypoxia to be collected should be:
  - umbilical artery acid-base status
  - Apgar score at five minutes
  - neonatal encephalopathy.

These should be collected on a local (hospital/trust) level

- B Umbilical artery acid-base status should be assessed by collection of paired samples from the umbilical artery and umbilical vein.
- C Umbilical artery acid-base status should be performed as a minimum after:
  - emergency caesarean section is performed
  - instrumental vaginal delivery is performed
  - a fetal blood sample has been taken in labour
  - birth, if the baby's condition is poor.
- Maternal outcome measures that should be collected include:
  - operative delivery rates (caesarean section and instrumental vaginal delivery)

This should be collected on a local (hospital/trust) level.

#### 3.8.3 Future research recommendations

Adequately powered randomised controlled trials are needed to evaluate the performance of:

- EFM compared with intermittent auscultation in a low-risk pregnancy setting, with regard to perinatal mortality
- Further studies are needed to develop measures of maternal satisfaction and responses to intrapartum care (including fetal monitoring).

# 4. The indications for the use of continuous EFM

#### 4.1. Identification of 'at-risk' groups

Intrapartum EFM was intended to be a screening tool for intrapartum fetal hypoxia. In theory, the early detection of hypoxia and prevention of metabolic acidaemia should reduce the incidence of intermediate measures and absolute outcomes in the baby, as defined in Section 2.

In the recent consensus statement regarding acute intrapartum events and cerebral palsy,<sup>2</sup> a set of criteria was established for defining a cause of cerebral palsy related to an intrapartum event. However, that document emphasised that the percentage of cases of cerebral palsy relating directly to intrapartum events is approximately 10%. Furthermore, a proportion of these cases may have underlying antenatal risk factors, which reduce the capacity of a fetus to cope with the stress of labour. A list of important antenatal factors that have been associated with cerebral palsy are shown in Appendix 1. The relationship of antenatal and intrapartum risk factors to the development of neonatal encephalopathy, cerebral palsy or even perinatal death can be examined by observational, epidemiological, cohort and case—control studies (Table 4.1).

Some conditions listed in Table 4.1 have not been shown directly to be associated with an increased risk of adverse outcome but are significantly related to another proven risk factor. Thus, this list includes conditions that the Guideline Development Group considered, on the basis of the precautionary principle, warranted continuous EFM.

The pathophysiological mechanisms by which these conditions produce intrapartum hypoxia vary. In some cases, abnormalities of the fetal heart rate are not necessarily an indication of hypoxia (for example, uterine rupture and fetal thyrotoxicosis). In some cases, pathologies may operate in addition to hypoxia (for example, in infants of mothers with diabetes). In other cases, the underlying pathophysiology of fetal risk is unknown (for example, post-dates pregnancy).

Many of the conditions and pathophysiologies listed in Table 4.1 can occur in combination. Furthermore, each of these factors may be present in varying degrees. The list is not intended to be prescriptive. Finally, gestation and birthweight influence the outcome significantly in the presence of the above risk factors.<sup>37,38,74,75</sup>

#### 4.2. Specific risks

A number of observational studies have evaluated potential risk factors for the development of cerebral palsy, perinatal death and neonatal Evidence level

encephalopathy.<sup>37-39,41,42,74-78</sup> These associations are not absolute and caution must be taken in ascribing causality between these risk factors and outcome. The potential for interaction between risk factors is unclear. Also, there is a lack of consistency in the definitions used in the studies for the various risk factors.

Table 4.1 Indications for continuous electronic fetal monitoring (reproduced with permission from WB Saunders<sup>73</sup>)

Risk factor	Possible/presumed underlying pathophysiology
Antenatal	
Maternal conditions	
Hypertension/Pre-eclampsia	UPVD
Diabetes	UPVD, other
Antepartum haemorrhage	UPVD
Other maternal medical disease	andia diasas (suanstia) BUDO
	<ul><li>– cardiac disease (cyanotic) RUPO</li><li>– severe anaemia RUPO</li></ul>
	<ul><li>– severe anaerma – kor O</li><li>– hyperthyroidism – Other</li></ul>
	– vascular disease UPVD
	– renal disease UPVD
Fetal conditions	
Small fetus	
	<ul><li>– growth restriction UPVD, RFR</li></ul>
	<ul><li>constitutionally small RFR</li></ul>
Prematurity	RFR, FS
Oligohydramnios	CC
Abnormal umbilical artery Doppler velocimetry	UPVD
soimmunisation Multiple pregnancy	FA
Breech presentation	UPVD, other CC
·	
Intrapartum	
Maternal conditions	DUDO LIDVO FA
Vaginal bleeding in labour Intrauterine infection	RUPO, UPVD, FA FS
Epidural analgesia	rs RUPO
•	KOTO
Labour	
Previous caesarean section	CC
Prolonged membrane rupture nduced labour	FS RUPO
nduced labour Augmented labour	RUPO
Hypertonic uterus	RUPO
Fetal conditions	
Meconium staining of the amniotic fluid	
Suspicious fetal heart rate on auscultation	
Post-term pregnancy	Other

CC = cord compression; FA = fetal anaemia; FS = fetal sepsis; Other = other mechanisms, some unknown; RFR = reduced fetal nutritional reserves; RUPO = reduced uterine perfusion or oxygen delivery (no vascular disease); UPVD = uteroplacental vascular disease

#### 4.2.1 Antenatal risk factors

#### Hypertension

Pre-eclampsia is a risk factor for neonatal encephalopathy<sup>77</sup> but also increases the risk to the baby as a result of impaired fetal growth. Pre-eclampsia has a significant association with cerebral palsy and death but, in part, this may be accounted for by the effect of preterm birth.<sup>39</sup>

#### Small fetus

Small fetal size is associated with a significant increased risk of cerebral palsy<sup>37–39</sup> and death.<sup>39</sup> Co-existent maternal infection, has been reported to be associated with a significant increase in cerebral palsy rates.<sup>38</sup>

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#### Preterm fetus

Prematurity of less than 32 weeks is associated with a significant increased risk of cerebral palsy<sup>37–39</sup> and death.<sup>37–39</sup> Intrauterine growth restriction, in combination with prematurity, results in significantly increased rates of neonatal encephalopathy.<sup>77</sup>

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#### Multiple pregnancy

The risks associated with multiple pregnancy are complex. Fetal risks are complicated by increased rates of prematurity, intrauterine growth restriction and placental abruption. However, rates of cerebral palsy and neonatal death are independently significantly increased with multiple order pregnancies and also increase with plurality.<sup>79</sup>

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#### Breech presentation

Breech presentation is associated with an increase in both cerebral palsy and death.<sup>37,38</sup> This is independent of mode of delivery and gestation. However, an RCT comparing planned caesarean section versus planned vaginal birth found a significant reduction in perinatal mortality and neonatal morbidity in association with planned caesarean section.<sup>80</sup>

Ib/IIa

#### 4.2.2. Intrapartum risk factors

#### Vaginal bleeding in labour

Placental abruption is associated with an increased risk of death but not with cerebral palsy.<sup>38,39</sup> The Guideline Development Group was unable to locate evidence that subdivided the risks associated with vaginal bleeding according to the quantity of vaginal blood loss.

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#### Intrauterine infection

Maternal pyrexia alone has been shown to be associated with an increased risk of neonatal encephalopathy<sup>41,78</sup> and cerebral palsy.<sup>38,76</sup>

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#### Meconium staining of the liquor

Meconium-stained liquor was found to be associated with an increased risk of cerebral palsy and death<sup>39</sup> in one case–control study but not with cerebral palsy in a large cohort study. Meconium-stained liquor is a significant risk factor for neonatal encephalopathy.<sup>41,42</sup>

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#### Post-term pregnancy

There was an increase in the rate of neonatal encephalopathy with rising gestation after 39 weeks reported in two case–control studies. 41,77 Furthermore, there was a rise in perinatal death rate from 41 weeks. 81 Recent data have suggested that the risks of stillbirth increases from 1 per 3000 continuing pregnancies at 37 weeks, to 3 per 3000 continuing pregnancies

at 42 weeks, to 6 per 3000 continuing pregnancies at 43 weeks.<sup>81</sup> A similar increase in neonatal mortality is also reported.

#### Prolonged membrane rupture

Prolonged rupture of the membranes has been reported to be associated with an increased risk of death and cerebral palsy in babies of less than 2500 g but not in babies greater than 2500 g.<sup>38</sup> In such studies, the definition of prolonged membrane rupture was over 24 hours. This should not be confused with the conclusions from those trials that have examined short-term infective morbidity associated with prelabour rupture of the membranes.<sup>82</sup>

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#### Induction and augmentation of labour

The use of EFM during the early stages of induction of labour with prostaglandin agents is not within the remit of this Guideline. Further advice will be found in *Induction of Labour*, an RCOG/NICE evidence-based national clinical practice guideline due for publication June 2001. However, if induction or augmentation of labour is undertaken with oxytocin there is a significant risk of hypercontractility and EFM should be used.<sup>83</sup>

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#### Previous caesarean section

The rate of spontaneous scar dehiscence with a previous caesarean section is 0.3–0.7%, <sup>84</sup> as highlighted in the 5<sup>th</sup> CESDI report. <sup>5</sup> This may present with a variety of warning signs, including poor progress in labour, scar tenderness, vaginal bleeding or FHR abnormality. The report therefore recommends 'attentive intrapartum fetal an maternal surveillance in a setting where the baby can be delivered within 30 minutes'.

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#### 4.3. The use of EFM in high-risk cases

The studies discussed in Section 3, comparing EFM with intermittent auscultation in high-risk pregnancies, usually comprised many different risk factors, both in isolation and in combination. Four of the trials specifically examined the benefits of EFM exclusively in high-risk populations<sup>35,36,55,85</sup> but they included pregnancies with a wide number of indications. Two trials included a mixture of both high- and low-risk pregnancies but again the indications for monitoring were heterogeneous.<sup>30,56</sup> EFM has not been extensively and prospectively evaluated with respect to individual risk factors. Furthermore, the systematic reviews and the constituent trials do not contain sufficient participants to allow a subgroup analysis with respect to individual indications even if those data were provided.

Ib

#### 4.4. Summary

#### 4.4.1. Conclusions

There are significant associations between a number of factors in pregnancy and cerebral palsy, perinatal death and neonatal encephalopathy.

There are no studies evaluating the effectiveness of EFM compared with that of intermittent auscultation in relation to specific high-risk factors.

#### 4.4.2. Practice recommendations

- B Continuous EFM should be offered and recommended for high-risk pregnancies where there is an increased risk of perinatal death, cerebral palsy or neonatal encephalopathy.
- Where oxytocin is being used for induction or augmentation of labour, continuous EFM should be used.

#### **4.4.3.** Future research recommendations

- Research is needed to evaluate the relationship of risk-factor severity, abnormal FHR and fetal hypoxia.
- Future research focusing on the benefits of EFM in pregnancies with specific risk factors should assess its efficacy against recommended intermediate measures and absolute outcomes (see Section 3).

### 5. Care of women

#### 5.1. Woman-centred care

One of the priorities of intrapartum care is to enable women to make informed choices regarding their care or treatment. To do so, they require access to evidence-based information, professional advice and counselling to help them in making their choices.

Evidence level

Part of the dilemma of choice in relation to intrapartum monitoring can be summarised by the following quote. 'It is difficult to determine true "choice", especially for some clinical issues, but the extent to which women feel involved in such decisions may be one indicator of the quality of the interaction with the professional, from the women's perspective.'

Ia/IV

Continuous care of the mother in labour has been shown to reduce caesarean section rates and the use of analgesia significantly. One systematic review of continuous support in labour considered a variety of outcomes. Continuous support in the included trials was provided by healthcare workers or lay people. Therefore, no extrapolation to the provision of one-to-one midwifery care can be made from these data. The importance of one-to-one midwifery care has been highlighted in a number of expert reports.

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In systematic reviews of RCTs comparing EFM with intermittent auscultation, <sup>28,62</sup> over 80% of the 18 561 women included received one-to-one midwifery care, in both arms of the included studies. The Guideline Development Group believes that neither intrapartum EFM nor intermittent auscultation should be used as a replacement for continuous support in labour. The highest level of evidence available comparing these two modalities does so in the context of one-to-one midwifery care. The Guideline Development Group considers that to recommend either form of intrapartum monitoring without this would be contrary to current research evidence.

One-to-one midwifery staffing is a level to which labour units should aspire. However, the Guideline Development Group recognises that recommendations regarding adequate staffing levels are outside the scope of the Guideline.

The assessment of fetal wellbeing is only one component of intrapartum care. It is an important area, where due consideration must be given to maternal preference and priorities in light of potential risk factors to both mother and baby. The provision of accurate information in these circumstances is essential to allow each woman to make the right decision for her.

#### 5.2. Communication issues

With regard to intrapartum care, communication occurs on two related levels:

 communication between the mother (and her birth partner) and the healthcare professionals caring for her during labour (both midwifery and medical) III

communication between the healthcare professionals (midwives, obstetricians, anaesthetists, paediatricians etc.).

On the first level, it is imperative that all issues relating to the care of any woman in labour are discussed in an open and informative manner, so that the decisions reached reflect maternal preferences and priorities.

One of the main conclusions from the seventh CESDI report<sup>6</sup> was that, as well as incorrect interpretation of intrapartum FHR tracings, poor communication played an important role in the subsequent poor outcome of babies during labour, as well as incorrect interpretation of intrapartum FHR tracings. The report recommended that:

- there should be established paths of communication to allow concerns regarding intrapartum FHR traces to be dealt with effectively
- there should be established guidelines for communicating the urgency of situations and decisions about fetal wellbeing on an interprofessional level, to avoid unwarranted delays.

#### **Practical issues 5.3.**

#### Misdiagnosis of fetal wellbeing **5.3.1.**

There are well-documented cases<sup>91–101</sup> where fetal death is missed because a trace has been displayed by the monitor. Nine case studies of 13 labours involved monitoring by fetal scalp electrode. 91-96,98-101 Two of these cases resulted in emergency caesarean sections to 'save' babies with severe bradycardia.96,98

In one observational study, 30 intrauterine deaths, which had been confirmed by ultrasound scan, were electronically monitored by fetal scalp electrode during labour, to establish whether fetal relay of the maternal ECG could produce a false FHR trace. 102 Spurious FHR traces were recorded in all cases. Twenty cases involved signals of low quality, ten of high quality. The maternal heart rate transmitted through the fetus was reported as fetal bradycardia in 29 cases and one case had a 'normal' FHR

Six case reports were found that correctly diagnosed a suspected intrauterine death by simultaneous monitoring of the maternal pulse, which was seen to synchronise with the FHR.91-93,99,100 In another case report a suspected fetal death was diagnosed by ultrasound, prior to birth.95 Three case reports, two of which involved emergency caesarean sections, reported instances of suspected fetal death which remained unconfirmed until birth.96-98

Regardless of the method of intrapartum monitoring, it is essential that an accurate record of fetal wellbeing is obtained. Fetal and maternal heart rates should be differentiated whatever the mode of monitoring used.

#### 5.3.2. **Documentation**

Both the maternal notes and CTG are continuous records of intrapartum events. It is imperative that any events occurring during labour that may affect FHR are contemporaneously noted in both these records. These include change in maternal position, vaginal examination and administration of drugs. The notes should be timed, dated and signed.

If intermittent auscultation is being used then details of the features of FHR should be recorded contemporaneously in the maternal notes, together with any other intrapartum events that might affect the FHR.

A list of terms to describe FHR patterns and a system for the categorisation of FHR records is presented in Section 6 and Appendix 4.

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#### **5.4.** Summary

#### **5.4.1.** Practice recommendations

- Women must be able to make informed choices regarding their care or treatment via access to evidence-based information. These choices should be recognised as an integral part of the decision-making process.
- Women should have the same level of care and support regardless of the mode of monitoring.
- Trusts should ensure that there are clear lines of communication between carers, and consistent terminology is used to convey urgency or concern regarding fetal wellbeing.
- Prior to any form of fetal monitoring, the maternal pulse should be palpated simultaneously with FHR auscultation in order to differentiate between maternal and fetal heart rates.
- If fetal death is suspected despite the presence of a recordable FHR, then fetal viability should be confirmed with real time ultrasound assessment.
- With regard to the conduct of intermittent auscultation:
  - the FHR should be auscultated at specified intervals (see Section
  - any intrapartum events that may affect the FHR should be noted contemporaneously in the maternal notes, signed and the time noted.
- C With regard to the conduct of EFM:
  - the date and time clocks on the EFM machine should be correctly set
  - traces should be labelled with the mother's name, date and hospital number
  - any intrapartum events that may affect the FHR should be noted contemporaneously on the EFM trace, signed and the date and time noted (e.g. vaginal examination, fetal blood sample, siting of an epidural)
  - any member of staff who is asked to provide an opinion on a trace should note their findings on both the trace and maternal case notes, together with date, time and signature
  - Following the birth, the care-giver should sign and note the date, time and mode of birth on the EFM trace
  - The EFM trace should be stored securely with maternal notes at the end of the monitoring process.

# 6. Appropriate monitoring in an uncomplicated pregnancy

Fetal monitoring in labour should be discussed in detail by the woman and her caregiver. In pregnancies with recognised risk factors continuous EFM should be offered and recommended. Evidence level

Healthy women who have had an uncomplicated pregnancy should be offered and recommended the best form of fetal monitoring for them (i.e. one that strikes the right balance between the objective of maximising the detection of potentially compromised babies and the objective of minimising the number of unnecessary maternal interventions, such as caesarean section). These objectives may conflict to some extent, since greater sensitivity in detecting potentially compromised babies may be associated with greater numbers of 'false positives' and hence unnecessary interventions.

This section examines how different forms of intrapartum monitoring have been evaluated, both in terms of the clinical outcomes discussed in Section 3 and, where possible, economic outcomes.

#### 6.1. Intermittent auscultation

#### 6.1.1. **Definition**

For this Guideline, 'intermittent auscultation' is defined as intermittent surveillance of the fetal heart rate during labour, employing either a Pinard stethoscope or a hand-held Doppler ultrasound device. This process would normally be conducted at predetermined intervals.

#### 6.1.2. Intermittent auscultation versus no monitoring

No formal prospective study has examined the use of intermittent auscultation versus no monitoring. A study of pregnancy outcomes in the Faith Assembly, a religious group in Indiana, in comparison with non-religious groups in the same state who were receiving standard care, has been used previously as evidence relating to the merits of intermittent auscultation as compared with no monitoring.<sup>104</sup>

The Faith Assembly declined all medical intervention. Pregnant members had no prenatal care and were delivered by attendees with no formal obstetric or midwifery training. The study actually compares a system of no care versus a complete package of both antenatal and intrapartum care, with intermittent auscultation being only one part of that overall package. No details are given of the care received by the 'control' group.

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#### 6.1.3. Intermittent auscultation and 'fetal distress'

In one early randomised trial, reported in 1959 and conducted in Natal, South Africa, all women were monitored with intermittent auscultation and were allocated to operative delivery or conservative management when signs of 'fetal distress' were present.<sup>105</sup> The study only included 350 women and, even accounting for both geographical and historical changes in perinatal mortality, this study was underpowered to detect differences in perinatal mortality. No differences in perinatal mortality rates were found between the two groups but there was a significant number of neonatal deaths in the intervention group due to traumatic vaginal delivery. There was a marked increase in both caesarean and operative vaginal delivery rates in the intervention group. No data were provided on neonatal or maternal morbidity.

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#### 6.1.4. Comparison of different methods of intermittent auscultation

One RCT compared four methods of intermittent monitoring.<sup>106</sup> These included intermittent EFM, intermittent auscultation performed with a handheld Doppler ultrasound recorder, with a Pinard stethoscope by a research midwife or with a Pinard stethoscope by an attending midwife. The frequency that monitoring was undertaken in each group is shown in Table 6.1.

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Table 6.1 Monitoring frequencies comparing different forms of intermittent monitoring, used in trial in Harare, Zimbabwe<sup>106</sup>

Monitoring modality	Frequency of monitoring <sup>a</sup>
Intermittent EFM	10 minutes in every 30 minutes if normal
	10 minutes in every 20 minutes if abnormal
Hand-held Doppler	During last 10 minutes of every half hour, particularly before
	and immediately after a contraction
Intermittent auscultation	During last 10 minutes of every half hour, particularly before
by research midwife	and immediately after a contraction
Intermittent auscultation	Supposed to be recorded during last 10 minutes of every half
by attending midwife	hour

<sup>&</sup>lt;sup>a</sup>Lower segment caesarean section to be performed irrespective of baseline variability with any modality if any deceleration or if persistent late decelerations (unless vaginal delivery imminent)

Compared with intermittent auscultation performed with a Pinard used by the attending midwife, intermittent EFM was significantly more likely to detect FHR abnormalities than intermittent auscultation performed with a hand-held Doppler, which, in turn, was more sensitive than intermittent auscultation performed with a Pinard by a research midwife.

There was a significant increase in the caesarean section rate when FHR was monitored with either intermittent EFM or with a hand-held Doppler device.

There were no significant differences in other maternal or neonatal outcomes between the groups. However, the study only included 1255 women and, even accounting for the higher perinatal mortality rate, was underpowered to detect any difference in perinatal mortality. However, this study was conducted in Harare, Zimbabwe, and the reported adverse neonatal outcomes in the total study population were significantly higher than corresponding outcomes in the UK. Thus, generalisation of the results to the UK may not be appropriate.

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#### **6.1.5.** Frequency of intermittent auscultation

Intermittent auscultation has been assessed against EFM in a number of RCTs. 30,34–36,40,55,56,85,107 These have been combined in a number of systematic reviews. 27–29 The intermittent auscultation protocols used in these trials represent the only assessed regimens for intermittent auscultation and, as such, are the only ones that can be underpinned by robust outcome evidence.

The regimens used for intermittent auscultation and the devices used are outlined in Evidence Table 9. Overall, intermittent auscultation was used in the active stages of labour for 30–60 seconds after a contraction:

- during the first stage of labour, every 15 minutes
- during the second stage of labour, every 5 minutes.

In most studies, this was conducted with a Pinard stethoscope or with a hand-held Doppler device if there was difficulty in auscultating with the Pinard. The criteria used for normal/abnormal auscultation in these studies varied depending on the trial.

Previously published guidelines have made similar recommendations regarding intermittent auscultation. These tend to use similar protocols to the RCTs and are summarised below.

The American College of Obstetricians and Gynecologists (ACOG)<sup>108</sup> and the Society of Obstetricians and Gynaecologists of Canada (SOGC)<sup>12</sup> make the following recommendations:

- 'during the active phase of the first stage of labour, the FHR should be auscultated and recorded every 15 minutes'
- 'during the second stage of labour, the FHR should be auscultated every 5 minutes'.

SOGC make further detailed recommendations<sup>12</sup> regarding other aspects of the use of intermittent auscultation for fetal surveillance:

- intermittent auscultation should only be used by experienced practitioners, with experience of the technique of auscultation, the palpation of contractions and the auditory recognition of pertinent fetal heart rate changes
- there should be defined clinical interventions when non-reassuring findings are present
- once the fetal heart tones are required to be heard every 15 minutes, the nurse-to-fetus ratio is one to one
- the maternal pulse should be palpated to differentiate between maternal and fetal heart rates
- the auscultated fetal heart rate should be counted for 60 seconds to identify the average baseline rate, whether being measured between or after uterine contractions.

The Guideline Development Group was unable to find any studies evaluating different protocols for frequency of intermittent auscultation using recommended neonatal and maternal outcome measures.

#### 6.2. Intermittent auscultation versus continuous EFM

#### **6.2.1.** Clinical outcomes

In the systematic reviews comparing intermittent auscultation to EFM, <sup>27–29</sup> it was shown that continuous EFM, when compared with intermittent auscultation, was associated with:

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- an increase in operative delivery rates (both caesarean section and instrumental vaginal delivery)
- a reduction in neonatal seizures
- no difference in Apgar scores or neonatal intensive care unit admission
- no demonstrable reduction in perinatal mortality.

However, it should be noted that these trials, even when combined, are significantly underpowered to detect a difference in perinatal mortality (see Section 2).

#### **6.2.2.** Economic outcomes

Two published studies investigate the resource implications of a policy of continuous EFM versus intermittent auscultation in labour, one in the USA<sup>109</sup> and one in the UK.<sup>110</sup>

The UK study estimated the cost of continuous EFM based on a systematic review published in 1989.<sup>29</sup> The systematic review was substantially updated in 1999,<sup>62</sup> and the cost estimates have been re-worked accordingly for this Guideline.

Cost estimates show that continuous EFM is more costly than intermittent auscultation for two main reasons. The first and most important reason is the increased rate of caesarean section with EFM. The second is higher equipment and materials costs.

The increased caesarean section rate was demonstrated in a systematic review of RCTs comparing both intermittent auscultation and continuous EFM, where one-to-one midwifery care was used in over 80% of participating women.

The figures are based on intention-to-treat analysis, which includes in the intermittent-auscultation arm those women who move from intermittent auscultation to EFM. Pragmatically, the comparison made is between EFM and intermittent auscultation with EFM when indicated.

The analysis involves a number of assumptions:

- The equipment cost includes both capital and maintenance costs. The
  capital cost is based on a five-year working life for each EFM monitor,
  with a 5% discount rate, at a utilisation rate of 1000 women per year
  per machine. This may tend to overestimate the cost of EFM, if
  machines are used for longer than five years.
- Costs of formal maintenance contracts are included. The cost of midwife staff time in informal maintenance ('fiddling costs') are not included. This may tend to underestimate the cost of EFM.
- The costs of staff time are included in the analysis, including staff time input performing any subsequent operative delivery, as well as the staff time input during monitoring.
- Materials costs include costs of gloves and other sterile materials for vaginal examination and attaching scalp electrodes, external transducer and belt and/or fetal scalp electrodes, and recording paper. If FBS procedures are performed, materials costs include sterile vaginal examination pack, blade for blood sampling and blood test cartridge.
- The costs of archiving and storage are not included in the figures, as it
  is assumed that the costs of archiving are approximately the same for
  intermittent-auscultation medical notes as for EFM traces.
- The costs of training are not included, as it is assumed that training in both intermittent auscultation and EFM methods form part of routine essential training for all midwives.
- The costs of providing one-to-one care have not been included in the
  cost estimate as the decisions around the mode of monitoring should
  not impact on the level of care a woman receives in labour and are
  therefore beyond the scope of this Guideline.

 Theoretical long-term benefits of EFM in terms of clinical quality assurance, including litigation impact, are not included in the analysis.
 It is assumed that archiving of written notes from intermittent auscultation are as useful for quality-assurance purposes as the archiving of EFM computer traces.

The revised figures show that continuous EFM with FBS is £42,101 more costly than intermittent auscultation per 1000 births, at 1991 prices, or £53,706 at 2000 prices. Continuous EFM without FBS costs £80,076 more per 1000 births than intermittent auscultation, at 1991 prices, or £102,149 at 2000 prices. Prices have been reflated to 2000 prices using the Retail Price Index (RP02 All Items Index, Office for National Statistics).

The most important factor driving the higher costs associated with EFM was the cost of a higher caesarean section rate. If all operative delivery costs are set aside, and only the equipment and materials costs of monitoring are considered, the cost of continuous EFM is £22,000 higher than intermittent auscultation per 1000 births, at 1991 prices, or £28,064 at 2000 prices (again reflated using the Retail Price Index).

In the short term, the potential to achieve equipment cost savings will be limited by local circumstances, although in the long term, a phased reduction in the level of EFM equipment may be achieved where facilities have been over provided historically.

#### 6.3. Intermittent versus continuous EFM

One RCT randomised 4044 women to either continuous EFM or intermittent EFM.<sup>111</sup> In the intermittent group, the fetal heart was recorded for 15–30 minutes every second hour during the first stage of labour. In between, the FHR was auscultated every 15–30 minutes by the midwife. The length of monitoring was increased if the FHR became equivocal or ominous (as defined by the authors). Both groups received continuous monitoring during the second stage of labour. The population studies excluded high-risk pregnancies and those with non-reactive admission CTGs. It did not exclude those women who required epidural analgesia or oxytocin augmentation.

There were no significant differences between the groups with regard to mode of delivery, umbilical artery acidosis, Apgar scores or admission to neonatal intensive care unit. This study was powered to detect a difference between the groups with regard to the detection of 'ominous' traces and not in relation to neonatal outcome measures.

### 6.4. Converting from intermittent auscultation to continuous EFM

Based on the evidence compiled in the systematic reviews comparing intermittent auscultation with EFM,<sup>27–29</sup> and the evidence presented on normal and abnormal values in this Guideline, pregnancies being monitored by intermittent auscultation should be converted to continuous EFM following:

- evidence on auscultation of a baseline ≤110 or ≥160 bpm
- evidence of any decelerations
- the development of any intrapartum risk factors (see Section 4).

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#### 6.5. The admission CTG

A number of tests have been evaluated for assessing fetal wellbeing in early labour (see Section 8.2). The aim of these tests is to identify a group of women at greater risk of intrapartum fetal hypoxia.

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The admission CTG is a commonly used screening test in the UK. One study was identified which evaluated the performance of admission testing in a low risk population.<sup>112</sup> The authors used specific criteria in defining 'normal' and 'abnormal' and related these findings to low umbilical artery pH (< 7.15), caesarean section and instrumental delivery rates. The admission test identified 5% of the study population as being at risk of increased operative delivery. There was a significantly reduced risk of caesarean section for fetal distress with a reactive/normal test (RR 0.10; 95% Cl 0.03–0.28). Also, there was no overall increase in caesarean section rate in the monitored group. An 'equivocal' or 'ominous' test result was poorly sensitive for fetal acidaemia.

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Two further groups analysed the performance of labour admission testing in a medium-<sup>113</sup> and/or high-risk<sup>114</sup> population. The majority of cases included in these studies represent clinical situations where this Guideline would recommend continuous EFM (see Section 4). Hence, the results of these studies are not discussed further.

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#### 6.6. Summary

#### 6.6.1. Conclusions

#### Intermittent auscultation

- There are no studies examining the benefits of intermittent auscultation versus no monitoring.
- Intermittent EFM appears to be the most sensitive non-continuous method of detecting fetal heart rate abnormalities as defined by the authors of different studies.
- Intermittent EFM is associated with a significant increase in caesareansection rates in comparison with intermittent auscultation using a Pinard stethoscope.
- Variations in the frequency and duration of intermittent auscultation monitoring have not been assessed in relation to outcome measures.

#### Intermittent versus continuous EFM

 There are no differences in the rate of adverse neonatal outcome (umbilical artery acidosis or Apgar score of less than seven at five minutes) or mode of delivery when intermittent EFM was compared with continuous EFM.

#### Intermittent auscultation versus continuous EFM

From the available evidence, in healthy women who have had an uncomplicated pregnancy, continuous EFM increases maternal intervention rates without any demonstrable improvement in perinatal outcome.

#### The Admission CTG

- Admission CTGs are poor at predicting fetal compromise during labour.
- There is no current evidence that supports a recommendation of routine admission CTG testing in low-risk women.

#### **6.6.2. Practice recommendations**

- A For a woman who is healthy and has had an otherwise uncomplicated pregnancy, intermittent auscultation should be offered and recommended in labour to monitor fetal wellbeing.
- A In the active stages of labour, intermittent auscultation should occur after a contraction, for a minimum of 60 seconds, and at least:
  - every 15 minutes in the first stage
  - every 5 minutes in the second stage.
- A Continuous EFM should be offered and recommended in pregnancies previously monitored with intermittent auscultation:
  - if there is evidence on auscultation of a baseline less than 110 bpm or greater than 160 bpm
  - if there is evidence on auscultation of any decelerations
  - if any intrapartum risk factors develop.
- B Current evidence does not support the use of the admission CTG in low-risk pregnancy and it is therefore not recommended.

#### **6.6.3.** Future research recommendations

- Adequately powered RCTs are needed to evaluate the performance of:
  - admission CTG
  - the performance of different forms of intermittent auscultation and how the performance of these modalities is affected by different frequencies of monitoring in comparison with EFM.

## 7. Interpretation of EFM

#### 7.1. Introduction

Interpretation of EFM traces requires a definition of what is normal. Ideally, this definition of normal should be determined by the identification of a group where results outside of the normal range increases the likelihood of the adverse outcomes recommended in Section 3. This will include both intermediate measures and absolute outcomes.

Early work looking at EFM in relation to outcome focused on defining normal and abnormal in terms of statistical normality (i.e. the relationship to the 'normal range' defined either in terms of standard deviations or centiles). These studies appear to have been used as benchmarks for further work.

In clinical practice, CTGs are usually interpreted as a whole, accounting for the summative effect of a number of individual features. Hence, although these individual features are discussed in turn, the overall interpretation of CTGs by pattern recognition is also discussed. Furthermore, CTGs should be reviewed, taking into account maternal and fetal clinical factors and progress of the labour.

#### **7.2.** Specific FHR features and outcome

A number of studies have examined how individual features of the FHR relate to outcome and, in some cases, how the extent or duration of an 'abnormal' feature may relate to outcome.

Evidence in this section is presented relating to the specific types of FHR abnormality. Where possible, evidence from cohort studies is presented, as this represents the highest level of evidence applicable to the research questions developed by the Guideline Development Group in this section. The studies included relate these FHR features to the outcomes discussed in Section 3. The results of these studies are summarised in Evidence Table 10.

#### 7.2.1. Baseline fetal heart rate, bradycardia, tachycardia

A number of early studies<sup>115–121</sup> (see Evidence Table 10) evaluated changes in FHR pattern with advancing gestation and found a gradual fall in baseline with advancing gestational age up to 30 weeks. Similarly, an increase in variability was seen, <sup>117,119</sup> and an increase in the number of accelerations. <sup>117,119</sup> One study showed a significant difference between male and female basal FHR (male fetuses tended to have more FHR values of less than 120 bpm and fewer FHR values of greater than 150 bpm than did female fetuses (P < 0.0001). <sup>115</sup>

In the RCTs included in the systematic reviews comparing EFM with intermittent auscultation, baseline fetal heart rate was part of an overall assessment of 'normal' and 'abnormal' CTGs. 30,34-36,40,55,56,85,107 The ranges used

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specified a lower limit of normal between 100 bpm and 120 bpm and an upper limit of 150–160 bpm.

Previously published guidelines on EFM have published normal and abnormal values for baseline fetal heart rate, again with similar ranges used in the RCTs. 11,12,108,122 These are summarised in Evidence Table 18.

Two cohort studies examined the neonatal outcome in fetuses with uncomplicated bradycardia or tachycardia. Path studies defined a normal range as 120–160 bpm and focused on FHR baseline abnormalities in the second stage of labour. Uncomplicated bradycardia (90–119 bpm) and tachycardia (160–179 bpm) had a poor predictive value in both studies for an umbilical artery cord pH of less than 7.20, although the predictive value increased with the duration and the degree of the baseline abnormality. Both of these studies specifically excluded labours with infective complications and other FHR abnormalities.

From the limited evidence relating isolated baseline abnormalities to robust neonatal outcomes, it appears that the normal ranges for a term fetus lies between 110 bpm and 160 bpm. In the absence of infection, an uncomplicated baseline of 110–119 bpm or 161–179 bpm are probably not associated with adverse neonatal outcome, although in the presence of other non-reassuring FHR features or if there has been a rise in baseline, these baseline fetal heart rates should be investigated further (for a definition of baseline fetal heart rate see Table 2.1).

#### 7.2.2. Baseline variability

In one cohort study discussed in Section 3 (Evidence Table 2)<sup>26</sup> there was a marked increase in the odds of cerebral palsy seen in association with decreased baseline variability (OR 2.7, 95% CI 1.1–5.8), although the limit for reduced baseline variability is not specified in the report.

One large cohort study<sup>125</sup> (n = 2200) analysed outcome in relation to both the amplitude and frequency changes in baseline variability. The study examined five separate scoring systems for assessing baseline variability. Using a cut-off of 5 bpm for amplitude and five cycles per minute for frequency for baseline variability maximised the sensitivity for detection of neonatal acidosis (pH less than 7.20) or five-minute Apgar of less than seven, but caused a subsequent reduction in specificity compared with a cut-off of 3 bpm or three cycles per minute.

Two other smaller, underpowered cohort studies found conflicting results in the relationship between FHR variability and prediction of Apgar scores. 126,127

Reduced baseline variability is common during fetal sleep cycles and, hence, may occur commonly for up to 40 minutes during labour. In a small percentage of cases reduced variability may be seen for up to 90 minutes.<sup>126</sup> Baseline variability is defined in Table 2.1.

#### 7.2.3. Accelerations

Two cohort studies specifically examined the relationship between accelerations (defined in Table 2.1) and perinatal outcome. The presence of accelerations was a good indicator of good perinatal outcome. More than two accelerations in 20 minutes had a sensitivity of 97% for an Apgar score of greater than seven at five minutes.

The incidence of accelerations may be less prior to 30 weeks and then steadily increasing to term. The size of accelerations in the fetus prior to term may be less than 15 bpm above the baseline.

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#### 7.2.4. Early decelerations

Two cohorts found no significant difference in five-minute Apgar scores between two groups of fetuses with and without early decelerations (defined in Table 2.1).<sup>43,130</sup> Both studies recorded only whether early decelerations were present and did not examine whether the duration of these early decelerations in isolation influenced outcome. One case—control study failed to find any association between the presence of early decelerations and metabolic acidosis.<sup>131</sup>

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#### 7.2.5. Late decelerations

An association was seen in five studies between late decelerations (defined in Table 2.1) and either intermediate measures or absolute outcomes. There was a marked increase in the odds of cerebral palsy in association with multiple late decelerations (OR 3.9; 95% CI 1.7–9.3). This risk was further increased if both late decelerations and reduced baseline variability were present (OR 3.6;95% CI 1.9–6.7).<sup>26</sup> Late decelerations had a high sensitivity for predicting subsequent abnormal neurological examinations, which were performed at 2, 4, 6, 9 and 12 months.<sup>132</sup>

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Two cohort studies examined outcome in relation to presence of late decelerations and found a significant association with reduced Apgar. 133,134

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Two case–control studies found a significant increase in late decelerations in the groups with reduced Apgar scores at five minutes and metabolic acidosis. 131,135

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#### 7.2.6. Variable decelerations

Five studies specifically examined variable decelerations (defined in Table 2.1) in relation to outcome. <sup>136–140</sup> Uncomplicated variable decelerations were not consistently shown to be associated with poor neonatal outcome (reduced five-minute Apgar scores or metabolic acidosis). Variable decelerations were commonly associated with other FHR abnormalities, e.g. baseline changes and reduced variability. Variable decelerations with the following additional features were associated with poor adverse neonatal outcome in comparison with FHR traces with no decelerations or those with 'uncomplicated' variable decelerations:

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- loss of primary or secondary rise in baseline rate
- slow return to baseline FHR after the end of the contraction
- prolonged increase of secondary rise in baseline rate
- biphasic deceleration (variable followed by late component)
- loss of variability during deceleration
- continuation of baseline rate at lower level.

7.2.7. Prolonged deceleration

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Due to the nature of prolonged decelerations (defined in Table 2.1), finding evidence to link the duration of these decelerations to neonatal outcomes is problematic. One cohort study<sup>141</sup> examined the relationship between abnormal second stage FHR patterns and umbilical acid-base balance. Within this study, the categorisation system included two categories where the FHR was below 90 bpm (with decreased or low variability, with or without accelerations). Both of these groups had significantly lower mean arterial pH values compared with controls (pH  $7.06 \pm 0.07$  and  $7.09 \pm 0.06$  compared with  $7.24 \pm 0.06$ ). However, it is not clear how long these baseline abnormalities were ten minutes before delivery was associated with an increase in the number of babies with pH values of less than 7.20. The percentage of babies with acidosis increased with increasing degrees of bradycardia. 124

The Guideline Development Group was unable to identify any studies that examined outcome in relation to duration of prolonged decelerations and outcome in the first stage of labour.

#### 7.2.8. Sinusoidal patterns

The definition of sinusoidal FHR patterns varies in the literature (see Table 2.1). Earlier studies included a definition where the amplitude could be graded as mild, moderate or severe and included cases with amplitudes of up to 60 bpm.<sup>142</sup> The severe cases were associated with poor neonatal outcomes but do not fit the strict definition for a sinusoidal pattern used by many authors.

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The Guideline Development Group also only considered studies of sinusoidal FHR patterns detected in labour and those which excluded cases of fetal anaemia.<sup>143</sup> The latter has previously been reported as an associated risk factor for sinusoidal FHR patterns with poor neonatal outcome.<sup>144</sup>

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In one cohort study<sup>145</sup> no cases of 'true' sinusoidal FHR patterns were seen. In the second study  $(n=1280)^{146}$  the incidence of the abnormality was 4.2%. There was no difference in the low five-minute Apgar score (less than seven) rates between the sinusoidal and non-sinusoidal groups. The number of cases with recorded umbilical artery pH measurements was too small to draw any conclusions regarding this outcome.

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Overall, the incidence of perinatal death associated with sinusoidal FHR patterns appears to be low in uncomplicated labours. There has also been an association reported with the administration of alphaprodine but not with other parcotics.<sup>146</sup>

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These studies demonstrate the rarity of sinusoidal patterns. In uncompromised babies these patterns do not appear to be associated with poor outcome. In both studies the patterns had to be present for at least ten minutes. However, in clinical practice, if this pattern appears in labour, clinically a fetomaternal haemorrhage must be excluded and, hence, these patterns must be viewed with suspicion.

#### 7.3. Second-stage FHR traces

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During the second stage of labour, a number of the above FHR abnormalities become more common, e.g. early decelerations. The presence of early decelerations alone is not associated with poor neonatal outcome but during the second stage of labour the presence of further abnormal FHR factors must be viewed as suspicious.

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One study, which only analysed second-stage traces, found that the increasing presence of decelerations, either variable or late, and baseline abnormalities was associated with increasing acidosis at birth.<sup>141</sup>

#### 7.4. Categorisation of FHR traces and outcome

Clearly, the impact of individual FHR features on perinatal outcome is varied. In clinical practice, CTGs are not analysed on individual features. Instead, an overall assessment of a number of features is made and these are used to make clinical decisions in the light of clinical factors and the stage of labour.

In the RCTs that compared EFM to intermittent auscultation, FHR traces were categorised into groups to enable traces to be observed or acted upon

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accordingly (e.g. fetal blood sampling or delivery). However, these studies were designed to assess the performance of the different modalities of monitoring and not to assess the performance of these categorisation schemes directly.

Five cohort studies examined outcome in relation to normal and abnormal parameters<sup>43,133,141,147-151</sup> and four of these classified the FHR into distinct categories related to FHR features.<sup>141,147-149</sup> The classification varied from a simple division into two categories of normal and abnormal<sup>148</sup> to a more complicated seven-part classification of individual variables of the FHR pattern.<sup>141</sup> One cohort study employed a scoring system developed by the authors.<sup>43</sup>

The classification used in these studies not only varied in the number of categories used but also how individual features of the FHR pattern were classified into these categories, making comparison of results from these studies is difficult.

Overall there was a significant trend in all but one study<sup>150</sup> toward neonatal acidosis (pH less than 7.20) and five-minute Apgar score of less than seven with increasingly 'abnormal' FHR changes.

The performance of all the categorisation regimens was varied but overall the sensitivity was high, with poor specificity. The variation in performance seen did not appear to be related to the number of categories used.

Two of the cohort studies<sup>4,141</sup> specifically examined the FHR patterns in the second stage of labour. A similar association with poor outcome was found in these two studies as was seen when all studies were evaluated together.

In addition to the categorisation schemes used in the above studies, two more commonly referenced schemes are presented in Appendix 4. One relates to the categorisation used in the Dublin RCT<sup>34</sup> the other was developed by FIGO.<sup>11</sup> Both these systems have been used to study the association with 'ominous' CTGs and neonatal encephalopathy and cerebral palsy.

One case–control study found a significant increase in cerebral palsy (OR 5.6; 95% CI 1.9–16.7) with an 'ominous' CTG in the second stage of labour.<sup>42</sup> The definitions of 'ominous' relates to criteria set out in the Dublin RCT.<sup>34</sup> In two further case–control studies, <sup>25,42</sup> ominous CTGs were associated with a significant increase in the rate of neonatal encephalopathy (OR 2.9; 95% CI 1.07–7.77 and OR 10.2; 95% CI 2.9–36.4, respectively). This difference was seen for both first- and second-stage traces. In these two studies, the categorisation schemes were based on the Dublin study<sup>34</sup> and one system developed by FIGO.<sup>11</sup>

From these data, and the difficulty in relating most individual FHR features to neonatal outcome, it appears logical to interpret CTGs using a similar scheme. A proposed classification of FHR traces is presented in the conclusion section of this section, which divides individual FHR features into three categories of normal, suspicious and pathological, relating each feature where possible to the studies outlined above.

#### 7.5. Errors in interpretation

'For the monitoring (EFM) to be effective, the test must be performed correctly; its results must then be interpreted satisfactorily; and finally, this interpretation must provoke an appropriate response.'<sup>29</sup>

The evidence relating to errors in human interpretation of FHR traces (both inter- and intra-observer error) and the role that computer analysis may have

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in improving FHR interpretation are discussed here focusing on studies examining the interpretation of intrapartum FHR traces. Evidence relating to the improvement of interpretation by education and teaching are discussed in Section 8.

#### **7.5.1.** Observer error

Evidence Table 11 summarises the studies that examine the effects of both intra- and inter-observer error. Seven studies examined the ability of observers to agree on individual aspects of FHR patterns. The results of these studies were varied. The identification of the FHR baseline was 'fair' to 'good' in most studies. FHR variability showed no good agreement across studies. Identification of accelerations and decelerations was varied.

A second group of studies examined the variation in interpretation when studies were grouped into various categories. <sup>159,160</sup> The agreement between experts on 'normal' FHR traces was significantly better than that seen with suspicious or pathological traces.

The effect of experience on interpretation was examined in one study. A positive correlation was seen with correct interpretation and number of years clinical experience.<sup>161</sup>

#### 7.5.2. Computer interpretation

Comparisons between computer systems and human interpretation were examined in five studies. <sup>157,158,162–165</sup> In three of these studies, the abilities of the computer to identify various aspects of FHR patterns were compared with the abilities of the experts. <sup>157,158,162</sup> The correlation between experts and the computer was good, with excellent agreement on baseline, decelerations and accelerations.

In one study, comparisons were made between computer and experts in relation to not only interpretation but also to subsequent action.<sup>163</sup> The computer showed fair agreement with the group of experts and did not recommend any unnecessary interventions in babies with normal outcomes. The computer system identified as many compromised babies as the expert group.

In two other, earlier studies the computerised systems used were assessed for their ability to predict acidosis.<sup>164,165</sup> For both systems the sensitivity was high but the specificity was poor. In one of these studies, the ability of the computer system to predict acidosis was compared with that of experts.<sup>165</sup> The experts were found to have a much lower accuracy in predicting umbilical acidosis and depressed Apgar scores.<sup>165</sup>

#### 7.6. Technological contribution

There are a number of technical issues that affect interpretation of FHR traces. The Guideline Development Group is unaware of any prospective studies addressing the impact of these in relation to valid outcome measures of intrapartum hypoxia.

#### 7.6.1. Paper speed

The paper speed used for printing EFM traces varies between countries. In the USA, 3 cm/min is the standard paper speed, while 1 cm/min is used in the UK. No study has addressed whether paper speed affects the interpretation of CTGs in relation to valid neonatal outcomes. As highlighted in previously published guidelines,<sup>11,122</sup> there is debate over the best paper

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speed to use. However, the paper speed selected should be that familiar to the professionals responsible for intrapartum management and should be standard within any given unit. Faster paper speeds have the advantages of paper conservation and less storage space.

#### 7.6.2. FHR scale sensitivity and range

Two FHR sensitivity displays are available: 20 bpm/cm or 30 bpm/cm; 20 bpm/cm has been proposed as allowing the best resolution and clarity of interpretation.<sup>166</sup>

The FHR range displayed depends on the scale selected. However, for 20 bpm sensitivity, FHR monitor manufacturers have agreed to a standardised range of 50–210 bpm.

#### 7.6.3. Other issues

Other issues relating to signal acquisition, autocorrelation and sampling interval are not discussed here because the Guideline Development Group is unaware of any studies that have examined the variation in these factors in relation to visual interpretation of the FHR for valid neonatal outcomes. Discussion of these other factors in relation to the development of computerised interpretation packages is beyond the scope of this Guideline.

#### 7.7. Summary

#### 7.7.1. Conclusions

Specific FHR features and outcome

- Most FHR features in isolation, with the exception of late decelerations, are poor at predicting poor neonatal outcome.
- Uncomplicated baseline tachycardia (161–180 bpm) or bradycardia (100–109 bpm) do not appear to be associated with poor neonatal outcome.
- The predictive value of reduced baseline variability alone is unclear.
- The presence of FHR accelerations is associated with good outcome.
- Repeated late decelerations are associated with an increased risk of cerebral palsy, umbilical artery acidosis and an Apgar score of less than seven at five minutes.
- Reduced baseline variability, together with late or variable decelerations, is associated with an increased risk of cerebral palsy.
- Atypical variable decelerations alone are associated with an increased risk of umbilical artery acidosis and an Apgar score of less than seven at five minutes.
- Prolonged decelerations are associated with poor neonatal outcome.

#### Categorisation of FHR traces and outcome

When all abnormal FHR patterns are combined, those traces classified
as 'abnormal', by whichever system, appear to be associated with an
increase in neonatal encephalopathy, cerebral palsy rates, neonatal
acidosis and Apgar score of less than seven at five minutes.

#### Observer error

- Interpretation of FHR traces is significantly affected by intra- and interobserver error.
- Errors of interpretation are reduced if FHR traces are categorised as a whole, with reference to individual features and the clinical picture.
- The use of computerised systems for FHR analysis improves consistency of interpretation.

#### 7.7.2. Practice recommendations

The definitions and descriptions of individual features of FHR traces used in the Guideline and clinical practice algorithm (Figure 1) are shown in Tables 2.1, 2.2 and 2.3.

- Settings on CTG machines should be standardised to that:
  - paper speed is set to 1 cm/min
  - sensitivity displays are set to 20 bpm
  - FHR range displays of 50-210 are used.

**Table 2.2 Categorisation of fetal heart rate traces** 

Category	Definition
Normal	A cardiotocograph where <b>all four</b> features fall into the reassuring category
Suspicious	A cardiotocograph whose features fall into <b>one</b> of the non-reassuring categories and the remainder of the features are
Pathological	reassuring A cardiotocograph whose features fall into <b>two or more</b> non-reassuring categories or one or more abnormal categories

**Table 2.3 Categorisation of fetal heart rate (FHR) features** 

Feature	Baseline (bpm)	Variability (bpm)	Decelerations	Accelerations
Reassuring Non-reassuring	110–160 100–109	≥5	None	Present
	161–180	< 5 for	Early deceleration	
		≥40 but less	Variable deceleration	
		than 90	Single prolonged	The absence of
		minutes	deceleration up to	accelerations with
			3 minutes	an otherwise
				normal
Abnormal	< 100	< 5 for	Atypical variable	cardiotocograph
	> 180	≥90 minutes	decelerations	is of uncertain
	Sinusoidal		Late decelerations	significance
	pattern ≥10 minutes		Single prolonged deceleration > 3 minutes	

#### 7.7.3 Future research recommendations

- Further evaluation is needed of why professionals misinterpret FHR recordings and fail to respond to abnormal FHR recordings.
- Evaluation is needed of the effectiveness of computerised analysis or decision analysis programs in the interpretation of FHR traces.

# 8. Additional tests and therapies used in combination with EFM

#### 8.1. Alternative or adjuvant tests of fetal wellbeing

Alternative and adjuvant tests were examined, with particular reference to the recommended maternal and fetal outcomes described in Section 3. Evidence level

#### 8.1.1. Fetal blood sampling

The role of FBS as an adjuvant to EFM requires discussion of a number of factors:

- Does the use of FBS in conjunction with EFM reduce the increased operative delivery rates?
- How well do fetal scalp samples correlate with umbilical artery pH measurements and thus levels of fetal acidosis at which adverse neonatal outcome increases?
- Is there a detectable decline in fetal scalp pH with specific abnormal FHR patterns?
- Are there specific clinical conditions where FBS is associated with specific risks to the baby or where its use does not improve the performance of EFM?

All three systematic reviews<sup>27–29</sup> examining the effects of EFM in comparison with intermittent auscultation included studies using EFM with and without FBS.

Two of the systematic reviews have compared the performance of EFM with intermittent auscultation by separating the trials included according to whether an option for FBS was available. In the first systematic review, the trials were divided according to the use of FBS. A significant reduction in neonatal seizure rates was only seen in those trials with the FBS option.<sup>29</sup> This finding is repeated in the current Cochrane Review,<sup>27</sup> where the data from the later RCT<sup>30</sup> are included.

The increase in caesarean section rates seen with EFM when compared with intermittent auscultation is less marked when only those trials with an option for FBS are included (see Table 3.3).<sup>27</sup> The caesarean section rates with FBS, EFM vs. intermittent auscultation were 3.6% versus 2.9% (RR 1.27; 95% CI 1.08–1.51). The ( RR 1.41; 95% CI 1.23–1.61).

The correlation between fetal scalp samples and subsequent umbilical cord pH measurements was studied in a case series of 110 pregnancies.<sup>167</sup> In that study, FBS has a sensitivity of 93% with a false positive rate of 6% for detecting umbilical artery acidaemia (pH 7.25 or less). However, a

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proportion of babies within this study who had scalp pHs of 7.25 were still born with subsequent umbilical artery pH below 7.00. The fall in scalp pH in association with specific abnormal fetal heart rate patterns was evaluated in one study and showed an increasing decline with more abnormal FHR patterns.<sup>168</sup>

Umbilical artery pH below 7.00 is associated with an increase in both shortand long-term complications in the neonate (and with cerebral palsy if in combination with a 5-minute Apgar of less than seven). Hence, in order to avoid umbilical artery pH levels below 7.00 (and in line with previously published guidelines,<sup>108</sup>) the Guideline Development Group considers that intervening on a scalp pH of less than 7.20 is appropriate.

It is acknowledged that SOGC recommends intervention at a scalp pH of 7.15,<sup>12</sup> although the evidence supporting this is unclear. Furthermore, the Guideline Development Group has been unable to locate any evidence that specifically addresses this issue.

Maternal viral infections, including HIV, hepatitis and herpes simplex virus, are conditions that are associated with an increased transmission risk to the baby with the use of fetal blood sampling.<sup>169</sup> With known or suspected clotting disorders, such as haemophilia A, the use of FBS should be avoided.<sup>170</sup>

The use of FBS in the presence of abnormal FHR patterns in premature babies (less than 34 weeks of gestation) may be associated with an increase in adverse neonatal outcome. In one RCT,<sup>35</sup> which examined the role of EFM in comparison with intermittent auscultation in a group of premature babies less than 1750 gm, the use of FBS in the EFM group significantly delayed the birth of these babies and resulted in an increase in cerebral palsy in comparison with the group monitored with intermittent auscultation alone.<sup>32</sup>

Three studies have addressed the issue of FBS during vaginal breech birth. 171-173 All three studies were small and uncontrolled. One study found a significant association between fetal buttock samples and umbilical samples. 171 That study only included ten cases and a larger study would be needed to evaluate whether this is a valid method of fetal surveillance during vaginal breech birth.

It must be stressed that the Guideline Development Group was unable to locate any evidence that refuted the use of FBS in breech labours.

In the recent term breech trial of the women randomised to vaginal delivery who were delivered by caesarean section, <sup>80</sup> 29% were delivered for FHR abnormalities. Furthermore, this trial reported that there were significant increases in neonatal morbidity and mortality associated with vaginal breech delivery (perinatal mortality, neonatal mortality or serious neonatal morbidity, LSCS versus planned vaginal birth – 1.6% versus 5.0%; RR 0.33; 95% CI 0.19–0.56).

#### 8.1.2. Fetal scalp lactate measurement

One RCT (see Evidence Table 13) evaluated the use of fetal scalp lactate measurement in comparison to fetal scalp pH estimation as an adjuvant to EFM.<sup>174</sup> There were no significant differences in caesarean-section rates (20% versus 17% in the lactate and pH groups, respectively), Apgar scores of less than seven at five minutes (2.3% versus 2.6% in the lactate and pH groups, respectively) or umbilical artery pH (pH < 6.98; 2.3% versus 5.1% in the lactate and pH groups, respectively).

Lactate measurements were possible at an earlier cervical dilatation and used a smaller sample volume; pH measurements had a significantly higher sampling failure rate (39% vs. 2.3%, RR 16.79; 95% CI 6.26, 45.04).

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#### 8.1.3. Fetal pulse oximetry

Five case series (see Evidence Table 14) have demonstrated a significant correlation between oxygen saturation and subsequent umbilical artery pH measurement. S8,175,176–179 If a cut-off for normal oxygen saturation (SaO<sub>2</sub>) of greater than 30% is used, pulse oximetry has a sensitivity of up to 94% (for pH less than 7.13), but with a poor specificity (specificity for pH less than 7.13, 38%). In one study, fetal pulse oximetry was compared with umbilical cord-blood analysis (using a cut-off of less than 7.20). The performance of both tests was similar when the receiver—operator curves were compared. One of the limitations of these observational studies is that the 'gold standard' used as a comparison is EFM, which has poor specificity in itself.

An RCT comparing EFM plus adjuvant pulse oximetry with EFM alone showed a significant reduction in the rates of caesarean section for 'non-reassuring' fetal status (5% versus 10%; RR 0.45; 95% CI 0.28–0.72; NNT 20).<sup>181</sup> However, there was no overall reduction in caesarean section rate, due to an increase in caesarean section rate for dystocia in the EFM plus

The investigators also reported that the addition of pulse oximetry improved the prediction of babies with subsequent low one- and five-minute Apgar scores and low umbilical cord pH values. There were no overall differences in neonatal outcomes.

#### 8.1.4. Fetal ECG analysis

pulse oximetry group.

Fetal ECG analysis (using either the ST waveform, 182 P–R interval<sup>183</sup> or T/QRS ratio<sup>184</sup>) in combination with EFM compared with EFM alone has been investigated (see Evidence Table 15). Although all three modalities involve interpretation of the fetal ECG, the analysis of the ST segment and the analysis of time constants should be considered separately.

A systematic review of ST waveform-analysis studies showed an overall reduction in operative deliveries in the EFM plus ECG group, which was only significant for those deliveries related to 'fetal distress' (5% versus 9.1%; RR 0.55; 95% CI 0.40–0.74). There was a trend towards a reduction in FBS rates but this was not significant. The results of a further RCT in progress, comparing the use of ST waveform analysis in combination with EFM, are awaited.

A recent multicentre trial studying the P–R interval in combination with EFM failed to show any benefit over EFM alone with respect to any maternal or fetal outcomes. A preliminary report of that trial had found a significant reduction in FBS rates in the EFM plus ECG group but this was not seen in the final results. T/QRS ratio analysis of the fetal ECG in combination with EFM was found to have a poorer sensitivity in predicting pH less than 7.20 than EFM alone (sensitivity 13% vs. 50% for T/QRS ratio + EFM and EFM alone, respectively). 184

#### 8.1.5. Fetal stimulation testing

Five observational studies (see Evidence Table 16)<sup>186–189</sup> examined the ability of transabdominal vibroacoustic stimulation (VAS) to predict an acidotic fetal scalp blood pH.<sup>190</sup> There was considerable variation in sample size. All studies examined prediction at a pH level of 7.25.<sup>186–190</sup> Four studies examined performance at 7.20.<sup>186–190</sup> VAS performance was varied. In all studies, the specificity was poor with the specificity for pH 7.25 being 65–80%. The sensitivity in was sufficient to reduce FBS rates significantly in all studies except one<sup>188</sup> (sensitivity for pH 7.20, range 90–100%).<sup>190</sup> However, no RCT has been performed to assess the effect of using VAS in reducing the need for FBS.

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Five studies (see Evidence Table 11)<sup>191–195</sup> examined the ability of scalp stimulation (digital or VAS) and/or fetal scalp sampling to evoke an accelerative response in the fetus and the ability of this to predict subsequent pH. The pH thresholds were 7.25 and 7.20 again.

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These tests performed in a similar way to transabdominal VAS with good sensitivity (for pH 7.20, range 65–100%) but poor specificity (for pH 7.20, range 16–59%).

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All these studies included small numbers of acidotic babies and the power of the studies may have affected their ability to perform well. Also they are used in conjunction with EFM that has poor specificity itself. None of these studies demonstrated a significant reduction in caesarean section rates.

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One RCT examined the ability of transabdominal VAS to predict cord pH less than 7.20 and five-minute Apgar score (less than seven). <sup>196</sup> The study found no significant differences between control and intervention groups. The study group all had normal CTGs, leading to the expectation that the adverse-event rate in this group would be small, and the conclusion that this was an underpowered study.

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#### 8.1.6. Others

Near infrared spectroscopy (NIRS) is a developing monitoring modality. It measures cerebral oxygen concentration directly. The modality exploits the differing absorption characteristics of the oxygenated and reduced haemoglobin molecules. Via measurement of the changes in oxygenated and deoxygenated haemoglobin, observed during contractions, the mean oxygen saturation of cerebral haemoglobin can be calculated.

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One study found a significant correlation between mean cerebral oxygen saturation and base deficit and carbon dioxide pressure at birth.<sup>197</sup>

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One trial compared NIRS to fetal pulse oximetry.<sup>198</sup> The investigators found a positive correlation between the changes in oxygenated and deoxygenated haemoglobin measured with NIRS and upper-body saturation measured with fetal pulse oximetry.

There are no published trials that look at the ability of NIRS to assess fetal condition during labour. One of the main limitations in the use of this modality is the number of technical difficulties encountered during the trials, including difficulty with probe detachment and subsequent erroneous readings.

Continuous pH,  $PO_2$  and  $PCO_2$  monitoring and combinations of the three have been examined as alternative monitoring modalities.

Fetal blood sampling only provides an estimation of acid-base status at one point in time. Coupled with the technical problems of performing FBS, continuous pH measurement was developed. This technique has been hampered by technical problems.

Similar problems have been encountered with  $PO_2$  and  $PCO_2$  measurements. Hence, none of these methods is used currently in clinical practice.

#### 8.2. Tests of fetal wellbeing in early labour

A number of tests have been evaluated for assessing fetal wellbeing in early labour (see Evidence Table 12). The aim of these tests was to identify a group of women at greater risk of intrapartum fetal hypoxia. Only studies presenting evidence relating to the robust outcomes discussed in Section 2 are presented and in each case the highest level of evidence was used. As

many of the studies in this section are small or use 'unbalanced' cohorts, case-control evidence was also considered.

#### 8.2.1. Admission CTG

The admission CTG has been discussed in Section 6.5.

#### 8.2.2. Vibroacoustic stimulation

VAS has been used to predict fetal acidaemia in labour. It has been used alone and in combination with labour admission CTG. Two cohort studies examined the performance of VAS in early labour in low-risk populations. A non-reactive response to VAS was poorly sensitive for fetal and depressed Apgar scores less than seven at five minutes. In one study, a non-reactive test significantly increased the risk of caesarean section for fetal distress. In one

Two studies combined VAS and labour admission CTG testing.<sup>202,203</sup> In one study,<sup>202</sup> a positive response to VAS was associated with a reduction in the rate of 'fetal distress' in labour in those women with a reactive admission test. In those women with an 'ominous' admission test, an abnormal response to VAS was associated with an increase rate of subsequent 'fetal distress'.<sup>202</sup>

The second study,<sup>203</sup> which combined VAS with admission CTG testing, is poorly reported and outcome is related to poor fetal outcomes as a composite of perinatal death, five-minute Apgar less than seven, fetal distress requiring caesarean section, thick meconium-stained liquor or admission to peopatal intensive care unit.

#### 8.2.3. Amniotic fluid index

Five included studies examined the use of amniotic fluid index (AFI) as a screening test.<sup>204–208</sup> All but one study<sup>205</sup> found a significant increase in caesarean-section rates for fetal distress in cases with an AFI less than 5 cm, yet there was no significant difference in neonatal outcomes. None of these studies used spontaneous rupture of the membranes as an exclusion criterion and the percentage of included women with spontaneous rupture of the membranes varied from 20% to 50%.

#### 8.2.4. Intrapartum umbilical artery Doppler

One systematic review of a number of observational studies reported on the performance of intrapartum Doppler in relation to robust outcomes.<sup>209</sup> The different outcome parameters were not reported separately. Doppler was a poor predictor of umbilical artery acidosis and an Apgar score of less than seven at five minutes. A positive test was associated with a significant increase in caesarean section rates (OR for positive test 4.1; 95% CI 2.7–6.2).

#### 8.2.5. Fetal movements

Two studies examined the ability of maternal perceived fetal movements to predict adverse outcomes.<sup>210,211</sup> Both studies also reported on labour admission testing and found similar results to the studies examining labour admission testing alone. The addition of fetal movement assessment did not improve the performance of the test.

#### 8.2.6. Combined testing

One large (n = 1092) study performed AFI measurements, Doppler studies, labour admission testing and VAS on all women.<sup>212</sup> The authors found that a

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non-reactive labour admission test was associated with a significant increase in caesarean section for fetal distress (28% versus 4.3%; RR 6.54; 95% Cl 4.08–10.47; NNT 4) and an increased number of babies with five-minute Apgar scores less than seven (14% versus 0.6%; RR 23.97; 95% Cl 8.97–64.06; NNT 7). Adjuvant VAS improved the sensitivity of the labour admission test. A reduced AFI index measurement was found to correlate with increased caesarean section for fetal distress and a five-minute Apgar score less than seven. Umbilical artery Doppler studies were not predictive of adverse outcome. No comparative analysis was performed between the different modalities.

## 8.3. Additional therapies for suspected acute fetal compromise

This section discusses evidence relating to interventions to alleviate or treat acute fetal compromise and suspected fetal hypoxia.

#### 8.3.1. Maternal oxygen administration

Despite the widespread practice, the Guideline Development Group was unable to locate any RCTs that examined the role of maternal oxygen administration for the treatment of fetal distress in labour. One study randomised women about to undergo caesarean section to either preoperative oxygen or room air via a face mask. Maternal oxygenation significantly increased in the oxygen group, umbilical vein oxygen partial pressure ( $PO_2$ ) increased significantly but umbilical artery oxygen partial pressure ( $PO_2$ ) was not significantly increased.

A further study examined the effects of increasing the inspired concentrations of  $O_2$  ( $Flo_2$ ) to mothers undergoing elective caesarean section under spinal or epidural anaesthesia.<sup>214</sup> The study found that increasing the  $Flo_2$  from 21% to 47%, 74% and 100% significantly increased maternal  $Pao_2$  and also umbilical vain and artery  $Pao_2$ . There was no difference in Apgar scores. The study was small and the groups studies were undergoing elective caesarean sections.

Although inspired oxygen concentrations can be increased to 100% with anaesthetic masks, this is normally not possible with standard (Hudson) facemasks.

One study showed that delivery of maternal oxygen at an  $Flo_2$  of 41% did not improve fetal oxygenation. This is possibly the highest level that can be achieved with a well-fitting face mask.<sup>215</sup> Further work evaluating the delivery of maternal oxygen with well-fitting facemasks with attached rebreathing bags is needed.

One systematic review evaluated the benefits of maternal oxygen administration for fetal distress and this study was also unable to locate any relevant studies.<sup>216</sup> The review did report on one study that administered oxygen prophylactically in the second stage of labour. The authors of this paper found significantly lower umbilical cord pH values in the group receiving oxygen therapy (for pH lesss than 7.20: RR 4.83; 95% CI 1.11–21.04). The study was small and the authors of the original RCT concluded that the lower cord pH values were the result of longer-term use of oxygen, which may be secondary to the accumulation of free radicals.

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#### 8.3.2. Maternal position

A change of position has been proposed as a measure to alleviate fetal distress or suboptimal CTGs. Placing the mother in the left lateral or Sim's position reduces aortocaval compression. In one systematic review, upright or lateral positions in the second stage of labour were found to significantly reduce the rate of abnormal fetal heart-rate patterns (1.2% versus 4.2%; RR 0.28; 95% CI 0.08–0.98; NNT 33) when compared with supine or lithotomy positions.<sup>217</sup>

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Positions other than upright or left lateral have not been the subject of RCTs. However, the Guideline Development Group was unable to locate any studies that specifically related change in maternal position to robust neonatal outcome measures in situations of suspected fetal distress.

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It should be acknowledged that a study of this design is probably unethical, due to the assumed physiological benefits of the left lateral position on improving fetal wellbeing.

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#### 8.3.3. Reducing or abolishing uterine activity

The use of tocolytic agents for the treatment of fetal distress works on the theory that uterine relaxation improves uteroplacental bloodflow and therefore fetal oxygenation. This benefit has to be balanced against any adverse effects related to the use of tocolytic agents on the mother.

IV

Uterine hypercontractility with the use of oxytocin augmentation may produce abnormal FHR patterns. Stopping oxytocin infusions in the presence of such patterns will allow the uterus to relax and the FHR patterns to improve. <sup>218</sup> Ideally, when labour is augmented with oxytocin infusions the contraction pattern should be maintained at a maximum level of three to four contractions in any ten-minute period. <sup>219</sup>

One systematic review examined the benefits of tocolysis for the treatment of suspected fetal distress and outlined the results from three RCTs.<sup>220</sup>

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In one study, women with abnormal FHR patterns and a scalp pH less than 7.25 were randomised to either subcutaneous terbutaline or no treatment. In comparison with no treatment, subcutaneous terbutaline was associated with fewer failed improvements in FHR patterns (25% versus 95%; RR 0.26; 95% CI 0.13–0.53; NNT 1). There were no significant improvements in neonatal outcome measures. Specifically, there was no significant difference in the incidence of umbilical cord pH less than 7.20 or in Apgar scores less than seven at one or five minutes. As there was no placebo injection given to the control arm of this study, there is the possibility of bias in the interpretation of the 'improved' FHR patterns in the terbutaline arm.

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In the other two parts of the review, magnesium sulphate was compared with terbutaline and in a third study intravenous hexoprenaline was compared with placebo. In neither of these studies was there any improvement in neonatal outcome measures.

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The authors of the systematic review concluded that the use of tocolytic therapy may be a useful treatment in the presence of fetal distress, for reducing fetal stress during preparations for emergency delivery, but any reduction in intervention rates has not been demonstrated.

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One further study examined the use of terbutaline tocolysis with fetal bradycardia.<sup>221</sup> The FHR improved in 30 of the 33 patients treated. The regimen used for tocolysis in cases of abnormal FHR patterns was subcutaneous terbutaline 0.25 mg.<sup>220</sup>

#### 8.3.4. Amnioinfusion

One systematic review examined the role of amnioinfusion (either transcervical or transabdominal) for the treatment of suspected cord compression. Transcervical amnioinfusion was associated with a significant reduction in the incidence of fetal heart-rate decelerations (41% versus 78%; RR 0.54; 95% CI 0.43–0.68; NNT 3) and caesarean-section rates for fetal distress (6.3% versus 18.4%; RR 0.35; 95% CI 0.24–0.52; NNT 8). However, the authors noted that there was no mention in the included studies of the use of FBS. Hence, the reduction in caesarean-section rates is probably related to the reduction in the rate of variable decelerations. A significant reduction in the rate of umbilical cord pH less than 7.20 was seen in the amnioinfusion group. However, there was significant heterogeneity between the trials; hence, this result must be interpreted with caution.

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The numbers of women in the included trials were too small to comment on potential maternal adverse effects such as maternal sepsis.

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#### 8.3.5. Combination therapies

A combination of the above interventions has not been formally evaluated.

#### 8.3.6. Delivery interval in situations of suspected or confirmed fetal distress

In cases of suspected fetal distress (when FBS is not possible) or confirmed fetal distress (rapidly falling fetal scalp pH, pH less than 7.20 or persistent fetal bradycardia), the aim is rapid delivery of the baby. This should be accomplished as fast as possible without endangering the condition of the mother. The American College of Obstetricians and Gynecologists (ACOG)<sup>108</sup> recommends delivery of the infant within 30 minutes.

III

One of the problems highlighted in the CESDI report regarding obstetric delays was one of communication.<sup>6</sup> The report recommended that systems should be in place to communicate the urgency of the caesarean section to all involved parties. In situations where urgent delivery is undertaken, this should occur without undue risk to the mother.

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Two early cohort studies have examined neonatal outcomes in respect to delivery interval. One study found no relationship between decision to incision time and neonatal acidosis. In the second study, there was a reduction in the incidence of Apgar score less than six at five minutes in the group where the decision-to-incision interval was within 30 minutes but no difference in neonatal morbidity.

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Two further studies examined the outcome of cohorts of women who underwent emergency caesarean section for suspected 'fetal distress'.<sup>225,226</sup> One found no difference between Apgar scores but did find an increase in the rate of pH less than 7.00 and neonatal intensive care unit admission in the group where the decision-to-incision time was over 30 minutes. The second study found an increase in the risk of neonatal intensive care unit admission with increasing decision to delivery intervals.

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The first study did not include evidence of FBS in situations of suspected fetal distress and presented no data on decision-to-delivery interval which may be more relevant than decision to incision intervals.<sup>225</sup> No data are presented showing the mean delivery interval times in both groups. In the second study, the data are not divided into two groups with regard to delivery interval. Hence, no conclusions can be drawn regarding the hazards of delivery beyond a specific time frame.<sup>226</sup>

lla

With a falling scalp pH measurement, delivery is indicated. Thirty minutes is an arbitrary cut-off point and is not validated by the weak and inconclusive studies outlined above. Furthermore, in some instances (e.g.

placental abruption) a decision-to-delivery interval of 30 minutes would be too long and in some other cases of fetal compromise a delivery interval exceeding 30 minutes may not adversely affect neonatal outcome. The achievability of safe delivery within 30 minutes is currently unknown. The forthcoming results of the National Sentinel Caesarean Section Audit will provide useful data regarding the number of units able to meet this standard for specific categories of emergency caesarean section.

#### 8.4. Summary

#### 8.4.1. Conclusions

Tests of fetal wellbeing in early labour

- AFI, VAS, intrapartum umbilical artery Doppler and fetal movement assessment in early labour are poorly predictive of fetal compromise in labour and may lead to an increase in caesarean-section rate for 'fetal distress'.
- All forms of early labour assessment, if abnormal, are predictive of increased caesarean section for fetal distress.

Alternative or adjuvant tests of fetal wellbeing

- The use of FBS for pH estimation in conjunction with EFM is associated with a smaller increase in operative delivery rates compared with EFM alone.
- The use of fetal scalp lactate estimation is not associated with a reduction in adverse neonatal or maternal outcomes but is associated with a significant reduction in sampling failure in comparison to EFM with fetal scalp pH estimation.
- The use of fetal pulse oximetry in conjunction with EFM has not been demonstrated to reduce operative delivery rates or neonatal outcomes.
- The use of fetal ECG analysis (either ST segment analysis, P–R interval or T/QRS ratio) has not been demonstrated to be superior to EFM in improving either adverse neonatal or maternal outcomes overall.
- Fetal ECG analysis (ST segment analysis) reduces operative delivery rates in cases of suspected fetal distress.
- It appears that the use of intrapartum fetal stimulation testing may reduce the need for fetal blood sampling.

#### Additional therapies for suspected fetal compromise

- There is insufficient evidence to evaluate the effectiveness of maternal oxygen administration for the treatment of fetal distress or to support the use of prophylactic oxygen therapy in the second stage of labour.
- If lying supine, the mother assuming the left lateral position reduces the rate of abnormal FHR patterns.
- Stopping oxytocin infusions during periods of uterine hypercontractility with associated abnormal fetal heart-rate patterns improves FHR and reduces uterine hypercontractility.
- The use of tocolytic therapy during episodes of fetal distress reduces abnormal FHR patterns but does not reduce caesarean section rates.
- Transcervical amnioinfusion reduces the rate of variable decelerations but a reduction in operative delivery rates has not been demonstrated.
- 30 minutes has become accepted as the gold standard for decision to delivery interval in cases of confirmed fetal compromise.
- The evidence to support this standard is weak and inconclusive.
- The achievability of safe delivery within 30 minutes is uncertain.

#### 8.4.2. Practice recommendations

- A Units employing EFM should have ready access to FBS facilities.
- A Where delivery is contemplated because of an abnormal fetal heartrate pattern, in cases of suspected fetal acidosis, FBS should be undertaken in the absence of technical difficulties or any contraindications.
- B Contraindications to fetal blood sampling include:
  - Maternal infection such as HIV, hepatitis viruses or herpes simplex virus.
  - Fetal bleeding disorders such as haemophilia
  - Prematurity (less than 34 weeks).
- Where there is clear evidence of acute fetal compromise, e.g. prolonged deceleration (greater than three minutes), FBS should not be undertaken and the baby should be delivered urgently.
- Prolonged use of maternal facial oxygen therapy may be harmful to the fetus and should be avoided. There is no research evidence evaluating the benefits or risks associated with the short-term use of maternal facial oxygen therapy in cases of suspected fetal compromise.
- B FBS should be undertaken with the mother in the left lateral position.
- B During episodes of abnormal fetal heart-rate patterns when the mother is lying supine the mother should adopt the left lateral position.
- In cases of uterine hypercontractility in association with oxytocin infusion and with a suspicious or pathological CTG, the oxytocin infusion should be decreased or discontinued.
- A In the presence of abnormal FHR patterns and uterine hypercontractility (not secondary to oxytocin infusion) tocolysis should be considered. A suggested regimen is **subcutaneous terbutaline 0.25 mg.**
- In cases of suspected or confirmed acute fetal compromise, delivery should be accomplished as soon as possible, accounting for the severity of the FHR abnormality and relevant maternal factors. The accepted standard has been that, ideally, this should be accomplished within 30 minutes.

#### **8.4.3.** Future research recommendations

- RCTs are needed to evaluate the performance of ST waveform analysis in conjunction with continuous EFM. The assessment should be against its ability to reduce maternal intervention rates and improve recommended neonatal outcomes.
- RCTs are needed to evaluate the effectiveness of VAS as an adjuvant to EFM, especially in its ability to reduce the need for fetal blood sampling.
- Further work is warranted on the use of scalp lactate estimation as an adjuvant to EFM.
- Evaluation is needed of the value of short-term maternal facial oxygen in cases of suspected fetal distress in relation to robust neonatal outcomes.
- Trials on the use of tocolytic agents for the management of fetal distress should focus on recommended neonatal outcome measures.

## Education and training

#### 9.1. Education and outcome

Continuous EFM provides only a printed recording of the FHR pattern. The interpretation of the FHR record is subject to human error. Education and training are areas that improve standards of evaluating the pattern of the FHR.

Three randomised controlled trials were found, <sup>227–229</sup> which addressed the extent to which training in EFM and interpretation of CTG traces improved knowledge. None of these addressed the extent that improved knowledge impacts upon inter-and intra-observer variation of interpretation or whether clinical practice or maternal and neonatal outcomes improved with training. One group developed a computer-assisted teaching programme that covered both cardiotocography and acid-base balance. <sup>227</sup> Obstetricians and midwives were randomised to the programme either early or late and tested with multiple-choice questions four times over a period of months. Both groups significantly improved their knowledge base after completing the programme but the early group improved significantly between the first and fourth test (17.8% mean improvement in scores against a 13.3%

In one RCT the efficacy of computer-assisted instruction was compared against teacher-controlled lectures in basic fetal monitoring concepts.<sup>228</sup> Participants were junior baccalaureate nursing students with no prior exposure to fetal monitoring, fetal monitoring concepts or experience of FHR interpretation. They were tested one week after randomisation, prior to training (pre test) and six days after training (post test). Both groups demonstrated an increase in knowledge, with their mean scores improving by nearly 20% post test. There was no significant difference in mean test score improvement between those randomised to computer-assisted instruction as opposed to teacher-controlled lectures.

improvement) despite the late group having only recently completed the training programme. Midwives showed a greater improvement in their mean scores between the first and final tests than did doctors. Knowledge was retained largely intact for seven months following one exposure to the

package, which the authors suggest might be due to repeat testing.

While neither training format could be shown to be superior in terms of knowledge gains, the mean time for completion of the computer-assisted instruction programme was 132.5 minutes while for the teacher-controlled lecture programme it was 235 minutes.

As part of a multicentre randomised trial involving 109 registered nurses, the experimental group was randomised to participation in a one-day 'Fundamentals of Fetal Monitoring' workshop with a review session six months later. Participants sat two types of test on a number of occasions, a 45-item knowledge test and a 25-item clinical skills test. When both groups sat both tests immediately after the experimental group had attended the workshop there was a significant increase (P < 0.01) in the number of nurses

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in the experimental group who passed both tests (68.1% versus 6.5%, respectively). The experimental group's performance improved to an 85% pass rate of both tests after the six month review session. The control group took both tests at the same time but, instead of a review session, they participated in the workshop and achieved an 87.5% pass rate. These results demonstrate that the training workshop was effective in increasing nurses' knowledge and clinical skills and demonstrated the power of a short review session to aid knowledge and skill retention and enhancement.

CESDI has reported a recurring problem in the use and interpretation of CTGs.<sup>4-6</sup> In the 7th Annual Report<sup>6</sup> the findings of a 1998 CTG education survey of all maternity units in England, Wales and Northern Ireland are reported. The majority (97%) of responding units made CTG training available to midwifery and medical staff and the majority of training was multidisciplinary. However, while attendance at training could be confirmed for 88% of midwives, only half could confirm attendance for medical staff. Midwifery staff on grades E and F were the least likely (55% and 59%) to have received training but were most likely to be conducting deliveries. It was found that many midwives funded their own CTG training. The 7th Annual Report made five recommendations regarding CTG education:

- trusts should be able to confirm that all staff involved in intrapartum care have received CTG training within the last year.
- all staff providing intrapartum care should have access to CTG training.
- trusts should ensure that training is available and should not expect midwives to fund it themselves
- interactive training packages should be made available on or near most labour wards
- CTG training should include instruction on the documentation of traces and on their storage.

#### 9.2. Summary

#### 9.2.1. Conclusions

- Training in EFM improves knowledge for all staff.
- Training in EFM can improve clinical skills.
- Testing, repeat testing and review sessions aid knowledge retention and improvement.
- There is insufficient evidence to suggest a significant difference in the efficacy of different training formats (lecture-based, computer-assisted etc.).
- Compared with lectures alone, computer-assisted training packages offer greater flexibility to staff in terms of time, availability and attendance and assessment of knowledge.

#### 9.2.2. Practice recommendations

- Trusts should ensure that staff with responsibility for performing and interpreting the results of EFM should receive annual training with assessment to ensure that their skills are kept up to date.
- Trusts should ensure that resources and time are made available to facilitate training in both intermittent auscultation and EFM and no staff should be expected to fund their own training.
- Staff should have easy access to computer-assisted and/or interactive training programmes.

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- Training should include instruction on documenting traces and their storage.
- Training should include instruction on appropriate clinical responses to suspicious or pathological traces.
- C Training should include instruction on the channels of communication to follow in response to a suspicious or pathological trace.
- Training should include a section on local guidelines relating to fetal monitoring, both intermittent auscultation and electronic monitoring.

#### 9.2.3. Recommendations for future research

- Research should be undertaken to discover if training improves practice and clinical outcomes for mother and baby.
- Research should be undertaken to discover if training can reduce interand intra-observer variation in interpretation of traces.
- Research should be undertaken into the efficacy of different computerassisted training programmes.
- Research should be undertaken into the efficacy of different training formats.
- Research should be undertaken into the relative costs of all education packages for FHR interpretation.

# 10. Risk management and the use of EFM

#### **10.1.** Storage of EFM traces

The NHS Litigation Authority reports a figure of £242,782,343 as the total sum of claims paid out for obstetric cases since 1 April 1995.<sup>90</sup> This figure represented 64% of claims paid in all specialties. Of the obstetric legal cases involving suboptimal intrapartum care and subsequent neurodevelopmental disability, 70% are based on abnormalities or interpretation of EFM traces.<sup>230</sup>

Concise, accurate and contemporaneous documentation of intrapartum events is an important factor in obstetric litigation. Annotation of the EFM record is necessary as well as the woman's birth record. Monitoring by intermittent auscultation needs to be documented concisely and accurately in the woman's birth record. Poor documentation may lead to speculation that, if it was not documented, it did not happen. These recommendations for documentation come from expert opinion due to lack of relevant clinical studies.<sup>6,12,231</sup>

The information relating to monitoring and intrapartum events that should be recorded on CTGs and in maternal records is outlined in Section 4.

The format and storage of EFM traces is complicated by issues of security, retrieval, space and preservation. Traces are highly important medical and legal documents. The NHS Health Service Circular *For the Record*<sup>232</sup> identifies a minimum retention period of 25 years for all obstetric and midwifery records, including CTG traces.

According to the Medical Protection Society,<sup>233</sup> the period during which a person may make a negligence claim varies between countries, but usually dates from the time the person becomes aware that they have suffered harm.

For minors, the limit is often extended to the age of majority and beyond, where permanent disability has been caused. Once the claim is reported, it may take a number of years for the case to be resolved.

In one study,<sup>234</sup> the problems of handling and storing EFM traces were examined. In total, 100 sets of obstetric notes were selected alternately from 210 case notes selected for audit. In 72%, there was no security of traces (lying free in notes, in unsecured envelopes, pockets and bags) with 19% lying free in the notes. In 11%, traces were incomplete. In 33%, traces were not stored in the relevant case notes and in 14% there was complete loss of an EFM trace relevant to an important intrapartum event. The authors, in a telephone survey of 35 obstetric units in the Thames Region, found that more than 50% of those interviewed described their EFM trace storage as insecure, with traces described as too bulky and not easily retrievable.

The authors developed, introduced and tested a new CTG trace storage system (CASS) in a clinical trial. After its introduction, the thickness of stored

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records fell by a mean 50% and timed searches for important traces fell from a mean of 91 seconds to 21 seconds. This was not the only paper to report EFM traces missing completely. A further study<sup>235</sup> reported that 19 traces were found to be missing in an analysis of 64 case records of serious obstetric litigation held by the Medical Protection Society.

In a large study of risk factors for cerebral palsy, it was noted that there was an increased likelihood of a missing CTG trace in the first stage of labour in cases of neonatal death (OR 5.9; 95% CI 2.1–20.9). The authors also found an increased likelihood of a missing CTG trace for second stage (OR 3.3; 95% CI 1.0–12.8).<sup>39</sup>

The level of missing traces may not necessarily be a sinister finding. It is possible that many traces will have been separated from obstetric notes for teaching and research purposes, because of the poor neonatal outcomes that they relate to and the potential they offer to future risk management.

Storing paper records of such an unusual format, some of which will be repeatedly handled, for 25 years inevitably results in loss and deterioration of both paper and FHR recording. <sup>236,237</sup> At present, photocopying of traces for medico-legal purposes requires unbroken full-length copying, which inevitably has resource implications in terms of cost and time.

The above survey<sup>234</sup> revealed considerable variation in the methods of storing traces. There is a need to develop effective archival systems that incorporate preservation concerns.

## 10.2. Resource implications compared with existing practice

The recommended improvements in EFM trace archiving and storage systems are likely to be slightly cost-increasing for individual maternity units. However, they may yield long-term savings from an NHS perspective, due to reduced litigation costs. According to the NHS Litigation Authority, the total annual NHS litigation costs associated with failure to respond to abnormal EFM traces are currently running at about £100m a year. The bulk of this settlement cost comes from cerebral palsy settlements, which cost on average about £2.2m, ranging from £700,000 to £4.5m. Some of these costs are from claims that cannot be defended because of missing EFM documentation. This may often be due to poor storage systems rather than deliberate withholding of evidence.

Quantification of the potential savings from improved storage systems is difficult, since it is not known what proportion of these cases would be won if documentation were available. Given the large size of cerebral palsy claims, however, it would only require a litigation impact of one or two fewer successful claims per year for the proposed modest investment in storage systems to be cost-saving from an NHS point of view.

#### 10.3. Summary

#### 10.3.1. Conclusions

- Of all the medical specialties, obstetrics has the highest total of claims paid out in litigation.
- The majority of obstetric litigation claims revolve around CTG abnormalities and interpretation.

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- Storage of EFM traces is complicated by issues of security, retrieval, space and conservation.
- Litigation can ensue many years after alleged harm has been suffered.
- CTG traces related to adverse outcome for mother or baby are more likely to go missing.
- The quality of some CTG traces deteriorate over time. This could be due to a number of factors including poor quality storage, paper, or intense heat, light or moisture.

#### **10.3.2. Practice recommendations**

- C EFM traces should be kept for a minimum of 25 years.
- Tracer systems should be developed to ensure that CTGs removed for any purpose (risk management, teaching purposes) can always be located.

#### **10.3.3.** Future research recommendations

• Further research is needed into electronic archiving systems for CTG traces and umbilical cord blood values.

## 11. Audit standards

The implementation of this Guideline should be undertaken within the strategic framework of the health improvement plans for each local health community.

Local health communities will need to review existing service provision against this guidance. This review should result in a strategy which identifies the resources required to implement fully the recommendations set out in Section 2, the people and processes involved and the timeline over which full implementation is envisaged.

Clinicians with responsibility for the care of women should review their current practice in line with the recommendations set out in Section 2. To enable clinicians to audit their own compliance with this guidance it is recommended that comprehensive clinical records should at least include those items described in Section 6.2.

The following audit criteria can be used to support the evaluation of clinical practice and continuous improvement in intrapartum care of the mother and baby. The audit criteria require the recording of admission risk factors, in addition to the subsequent clinical observations and interpretations:

- number (and %) of women assessed as at high risk on admission and subsequently (based on the guidance in Section 4 and the clinical practice algorithm in Section 2.10).
- Number (and %) of women who receive continuous EFM and the main indication for continuous EFM (based on the recommendations in Section 2 and the clinical practice algorithm in Section 2.10.

This information should be incorporated into local audit data-recording systems and consideration given (if not already in place) to the establishment of appropriate categories in routine electronic record-keeping systems. Further local evaluation of the use of fetal monitoring may be needed and could include:

- clinical audit of aspects of structure (e.g. availability of blood sampling facilities, assessment and training of staff)
- process (fetal heart rate features, blood pH etc.)
- outcomes (maternal satisfaction and operative delivery rates, and neonatal outcomes such as cerebral palsy, perinatal deaths).

Prospective clinical audit programmes should record the proportion of treatments adhering to this guidance. Such programmes are likely to be more effective in improving patient care when they form part of the organisation's formal clinical governance arrangements and where they are linked to specific postgraduate activities.

Relevant local clinical guidelines and protocols for fetal monitoring should be reviewed in the light of this guidance.

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## **Appendix 1**

## **Conclusions from the International Cerebral Palsy Task Force consensus statement**

The following tables are reproduced with the kind permission of the authors.<sup>2</sup>

A Criteria to define an acute intrapartum hypoxic event.

#### **Essential** criteria

- 1. Evidence of a metabolic acidosis in intrapartum fetal umbilical arterial cord or very early neonatal blood samples (pH < 7.00 and base deficit ≥ 12 mmol/l).
- 2. Early onset of severe or moderate neonatal encephalopathy in infants  $\geq$  34 weeks of gestation.
- 3. Cerebral palsy of the spastic quadriplegic or dyskinetic type.

### Criteria that together suggest an intrapartum timing but by themselves are non-specific

- 1. A sentinel (signal) hypoxic event occurring immediately before or during labour.
- 2. A sudden, rapid and sustained deterioration of the fetal heart-rate pattern, usually after the hypoxic sentinel event where the pattern was previously normal.
- 3. Apgar score of 0–6 for longer than five minutes.
- 4. Early evidence of multisystem involvement.
- 5. Early imaging evidence of acute cerebral abnormality.

#### **Examples of sentinel hypoxic events**

- Ruptured uterus
- Placental abruption
- Cord prolapse
- Amniotic fluid embolism
- Fetal exsanguination (from vasa praevia or fetal–maternal haemorrhage).
- Factors that suggest a cause of cerebral palsy other than acute intrapartum hypoxia
  - 1. Umbilical arterial base deficit less than 12 nmol/l or pH greater than 7.00.
  - 2. Infants with major or multiple congenital or metabolic abnormalities.
  - 3. Central nervous system or systemic infection.
  - 4. Early imaging evidence of longstanding neurological abnormalities.
  - 5. Infants with signs of intrauterine growth restriction.
  - 6. Reduced fetal heart rate variability from the onset of labour.
  - 7. Microcephaly at birth.

- Major antenatal placental abruption. Extensive chorioamnionitis.
- 9.
- Congenital coagulation disorders in the child. 10.
- Presence of other major antenatal risk factors for cerebral 11. palsy – for example, preterm birth less than 34 weeks of gestation, multiple pregnancy or autoimmune disease.
- Presence of major postnatal risk factors for cerebral palsy 12. for example, postnatal encephalitis, prolonged hypotension or hypoxia due to severe respiratory disease.
- A sibling with cerebral palsy, especially of the same type. 13.

## Appendix 2. Evidence tables

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Evidence Table 1. Systematic reviews examining the relationship of continuous EFM and intermittent auscultation to various outcomes (short-term and clinical)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Thacker <i>et al.</i> <sup>27</sup>	High- and low-risk populations Various countries 9 RCTs <sup>30, 34-36,40,55,56,85,107</sup>	Continuous EFM vs. IA	CS, OVD 1-min Apgar < 7 1-min Apgar < 4 Neonatal seizures NICU admissions Mean length of stay Perinatal death	OR 1.44 (95% CI 1.24–1.66) OR 1.25 (95% CI 1.13–1.37) OR 1.05 (95% CI 0.92–1.19) OR 0.89 (95% CI 0.70–1.12) OR 0.50 (95% CI 0.31–0.80) OR 1.00 (95% CI 0.91–1.10) No pooled data OR 0.88 (95% CI 0.57–1.36) Increase in CS and OVD rates.	Reduction in seizure rates only seen in trials of 'high' quality. No effect on perinatal death rates. Seizure data from pooled data not pooled. RR from individual studies. Main influence of this was from Dublin study (55% of weight). Seattle study has 20% of weight but no difference between groups.  Control data from Denver trial entered twice in analysis. Invalid but does not alter results by removing either entry.	Systematic review	la
Vintzileos <i>et al.</i> <sup>28</sup>	High- and low-risk populations Various countries 9 RCTs <sup>30,34-36,40,55,56,85,107</sup>	Continuous EFM vs. IA	CS CS (fetal distress) OVD OVD (fetal distress) Perinatal death (fetal hypoxia)	OR 1.53 (95% CI 1.17–2.01) OR 2.55 (95% CI 1.81–3.53) OR 1.23 (95% CI 1.02–1.49) OR 2.50 (95% CI 1.97–3.18) OR 0.41 (95% CI 0.17–0.98)  Increase in CS and OVD rates. No overall reduction in perinatal death rates, except for group judged to have been secondary to 'fetal hypoxia'.	If data recalculated into RR outcomes similar to Thacker. <sup>27</sup> Perinatal deaths due to fetal hypoxia is post-hoc analysis and categorisation is partially by author and may be subject to bias.  Poor reporting of heterogeneity in some areas of analyses.	Systematic review	la
Grant <sup>29</sup>	High- and low-risk populations Various countries  9 RCTs <sup>34-36,40,55,56,85,107,238</sup>	Continuous EFM vs. IA Universal vs. selective EFM <sup>238</sup>	All operative deliveries  - no FBS  - with FBS CS  - no FBS  - with FBS CS (fetal distress)  - no FBS  - with FBS OVD  - no FBS  - with FBS Perinatal deaths  - no FBS  - with FBS 1-min Apgar < 7  - no FBS  - with FBS 1-min Apgar < 4  - no FBS  - with FBS Neonatal seizures  - no FBS  - with FBS NICU admissions  - no FBS  - with FBS NICU admissions  - no FBS  - with FBS - with FBS	OR 1.33 (95% CI 1.07–1.64) OR 1.34 (95% CI 1.21–1.47)  OR 2.70 (95% CI 1.92–3.31) OR 1.29 (95% CI 1.08–1.54)  OR 4.14 (95% CI 2.29–7.51) OR 1.98 (95% CI 1.33–2.94)  OR 0.90 (95% CI 0.71–1.13) OR 1.31 (95% CI 0.20–18.62) OR 0.98 (95% CI 0.20–18.62) OR 0.98 (95% CI 0.58–1.64)  OR 1.13 (95% CI 0.83–1.54) OR 0.98 (95% CI 0.84–1.14)  OR 0.99 (95% CI 0.51–1.94) OR 1.04 (95% CI 0.21–2.95) OR 0.49 (95% CI 0.29–0.82)  OR 1.03 (95% CI 0.76–1.38) OR 1.00 (95% CI 0.76–1.38) OR 1.00 (95% CI 0.90–1.12)	Differentiates trials into those that performed FBS and those that did not.  Levano et al. <sup>238</sup> included but analysed separately from others.  No heterogeneity statistics included, hence it is not possible to evaluate whether the division by FBS/no FBS valid subgroup analysis.  Due to small numbers of seizures in non-FBS studies very wide OR.  Other outcomes reported were intrapartum deaths, maternal infection and analgesia requirements.	Systematic review	la

CI = confidence interval; CS = caesarean section; EFM = electronic fetal monitoring; FBS = fetal blood sampling; NICU = neonatal intensive care unit; OR = odds ratio; OVD = operative vaginal delivery; RCT = randomised controlled trial; RR = risk ratio

#### **Evidence Table 2. Studies relating to the use of EFM and cerebral palsy**

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Grant et al.31	Original RCT 13 079. 9 cases of seizures from EFM group and 21 from IA group examined aged 4 year	EFM vs. IA	СР	Children from each who had suffered seizures had CP. Additional 16 cases identified (9 in EFM group and 7 in IA group). Probable antenatal factors involved in aetiology. No protective effect of EFM over IA.	Looks at EFM vs. IA, hence only comparison to another treatment. Cannot extrapolate to effect of EFM alone.	Cohort	lla
Shy et al.32	Original RCT 247 women, deliverin babies < 1750 gm prio to 34 weeks Examined at 4, 8 and 18 months		CP Bayley scale scores	80% follow-up at 18 months. 16 CP cases in EFM group, 7 in IA group, OR 2.9 (95% CI 1.2–7.3). Non-significant difference in Bayley scores.	All premature infants EFM arm had significant difference in delay between onset of EFM abnormality and delivery (45 mins vs. 104 mins), due to FBS being performed Probable cause of increase in CP rates, as not standard practice now to perform FBS on preterm infants	Cohort	lla
Langendoerfer <sup>33</sup>	Original RCT 690 mothers delivering 695 infants. Evaluated at birth and 9 months	EFM vs. IA	Bayley and Brazelton scores	70% follow up at 9 months. No significant difference between development/scores in either group.	30% of original cohort initially identified as at risk of developmental delay; only 70% of these reviewed at 18 months, hence justification for generalisation of results.	Cohort	lla
Nelson et al. <sup>38</sup>	Cohort of 51 285 pregnancies	-	CP Neonatal convulsions related to various complications of pregnancy	Overall CP rate 2%, no association with intrapartum-care complications. No association with neonatal seizures.	Only specific outcome related to EFM was lowest FHR below 100.	Cohort	lla
Nelson et al. <sup>37</sup>	Cohort of 54 000 pregnancies	-	CP rates Multivariate analysis of various pregnancy complications	189 cases of CP; 91% cases associated with congenital abnormality. 40 cases of CP associated with asphyxia, 15 had congenital abnormalities and 12 were < 2000 gm.	Only EFM marker examined was lowest FHR less than 60 bpm.	Cohort	lla
Nelson et al. <sup>26</sup>	95 infants with CP at aged 3 years with 378 matched controls; USA hospital	Continuous EFM (except in 9% of CP cases and 13% of controls)		Increased odds of CP with:  – multiple late decelerations (OR 3.9; 95% CI 1.7–9.3)  – decreased beat-to-beat variability (OR 2.7; 95% CI 1.1–5.8).  73% of cases had neither abnormality.  High false positive rate.  Increased rate of LSCS (OR 2.9; 95% CI 1.0–8.6). No actual traces available.	No actual definition of reduced beat-to-beat variability or multiple late decelerations.	Case-control	lla

**Evidence Table 2. Studies relating to the use of EFM and cerebral palsy (continued)** 

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Gaffney et al. <sup>39</sup>	141 infants with CP and 62 intrapartum or neonatal deaths, with 2 matched controls for each case. Singleton births; UK hospital	Continuous EFM or IA (continuous EFM if problems occurred)	Apgar scores	Significant association between lost EFM traces and subsequent CP or death. Ominous CTG more common in CP cases (only significant for 2nd stage), similar result for cases of death (only significant for 1st stage). Both cases of CP and death had significantly lower Apgar scores (< 2 at 5 minutes), absence of respiratory effort or heart rate lower than 100.	EFM traces graded used criteria from MacDonald study. <sup>4</sup> Criteria for suboptimal care adapted from Niswander et al. <sup>239</sup>	Case-control	lla
Melone et al. <sup>57</sup>	49 infants with CP at 1 year of age with 49 matched controls. Singleton births; US hospital	Continuous EFM or IA (continuous EFM if problems occurred)		Non-reassuring FHR tracing occurred in 35% of controls vs. 31% CP infants. Significant difference between Apgar scores at 5 min but not at 1 min between groups. No significant difference between umbilical artery pH measurements (< 7.20). No difference in CS rates (57 vs. 49)	inadequate.	Case-control	lla
Niswander et al. <sup>239</sup>	Four case series selected from cohort of 16 400 births 58 cases of death due to asphyxia or trauma 92 cases of terminal apnoea 36 cases of seizure within 48 hours of birth 34 cases of CP	Continuous EFM or IA (continuous EFM if problems occurred) With FBS where needed		No significant difference in standard of intrapartum care for any of the four groups.		Case-control	lla

CI = confidence interval; CP = cerebral palsy; CS = caesarean section; EFM = electronic fetal monitoring; FBS = fetal blood sampling; IA = intermittent auscultation; LSCS = lower segment caesarean section; NE = neonatal encephalopathy; OR = odds ratio; RCT = randomised controlled trial

Evidence Table 3. Studies relating to the use of EFM in the prediction of neonatal encephalopathy

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Spencer et al. <sup>25</sup>	91 cases of NE from term pregnancies 1 matched control pe case; Australian hospital	–	EFM scores (FIGO and Krebs scoring) First and last 30 minutes of trace assessed	CTGs from 38 cases and 35 controls reviewed. FIGO scoring correlated with chance of developing NE for both first and last 30 min of trace (OR 2.9; 95% CI 1.07–7.77). Examining only last 30 min of trace (OR 7.5; 95% CI 2.14–26.33). Krebs scoring not as reliable.	Small study Poor correlation on both scoring systems on Cohen's kappa coefficients	Case-control	lla
Adamson <i>et al</i> . <sup>41</sup>	89 cases of term NE. 1 matched control pe case; Australian hospital	–	Antenatal, intrapartum and neonatal factors	Only 15% of cases fulfilled criteria for intrapartum asphyxia (abnormal CTG – observer opinion).  Depressed Apgar score and/or meconium in labour), large proportion had additional antenatal factors.  Hence, only 6% attributable risk from intrapartum factors.	Probably same cohort of cases as Spencer et al. <sup>35</sup> CTGs performed on 55 cases and 39 controls. Poor definition of intrapartum asphyxia.	Case-control	lla
Gaffney et al. <sup>42</sup>	141 case of CP; UK hospital	-	Antenatal, intrapartum and neonatal factors	8% of controls and 48% of cases with encephalopathy had ominous CTGs (OR 10.2; 95% CI 2.9–36.4 in 1st stage; OR 7.2; 95% CI 2.1–24.4 in 2nd stage). Ominous trace duration longer in encephalopathy group.	Same cohort as Gaffney <i>et al</i> . <sup>39</sup>	Case-control	lla
				Follow-on data: significant association with major and minor impairment in encephalopathy group.  Quadraplegia (OR 4.8; 95% CI 2.2–10.5)  Hemiplegia (OR 0.3; 95% CI 0.1–0.8)			

CI = confidence interval; CP = cerebral palsy; CTG = cardiotocograph; EFM = electronic fetal monitoring; IA = intermittent auscultation; NE = neonatal encephalopathy; OR = odds ratio

Evidence Table 4. Studies relating to the use of neonatal encephalopathy in predicting outcome

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Peliowski <i>et al.</i> <sup>44</sup>	Five included trials	NE Sarnat staging or mild-moderate- severe staging	Death and disability	Likelihood ratios for death:  - mild 0.09 (95% CI 0.03–0.3)  - moderate 0.39 (95% CI 0.21–0.71)  - severe 10.98 (95% CI 7.56–15.94)  Likelihood ratios for severe disability:  - mild 0.1 (95% CI 0.03–0.28)  - moderate 1.51 (95% CI 1.19–1.52)  - severe 15.6 (95% CI 6.85–35.70)  Risks: 72% with severe encephalopathy, 20% with moderate and almost zero with mild.	Good review as highlights problems of definition of NE and also consistent definitions of disability.	Systematic reviews of cohorts	lla

CI = confidence interval; NE = neonatal encephalopathy

Evidence Table 5. Studies relating to the use of continuous EFM in relation to the detection of fetal acidaemia

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Vintzileos et al.45	1419 singleton live fetus > 26 weeks; Greek hospitals	EFM vs. IA	Umbilical artery and vein acid-base measurements	9% of EFM group vs. 7% in IA were acidotic (pH < 7.15). EFM: sensitivity 97%, specificity 84%. IA: sensitivity 34%, specificity 91% ( $P$ < 001 for both).	-	RCT	Ib
				Most common FHR abnormality either late or variable decelerations.			
				Overall EFM superior in detecting all types of acidaemia.			

EFM = electronic fetal monitoring; IA = intermittent auscultation; RCT = randomised controlled trial

#### Evidence Table 6. Studies relating to the use of umbilical acidaemia and outcome (short and long term)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Short-term cor	mplications						
Van den Berg et al. <sup>46</sup>	84 non-anomalous neonates with pH <7.00 matched to 84 nonanomalous neonates with pH >7.24; Dutch hospital	-	Neonatal complications including perinatal death, NICU admission, CNS, respiratory CVS and GI complication rates	pH < 7.00 significantly associated with seizures, abnormal tone, RDS, NEC and all CVS complications.  No association with renal complications or death.	No data on encephalopathy.	Cohort	lla
Low et al. <sup>47</sup>	59 fetuses with metabolic acidosis (buffer base < 30 mmol/l), matched controls; 51 fetuses with respiratory acidosis (CO <sub>2</sub> tension > 75 torr, base buffer > 38 mmol/l), matched controls; Canadian hospital	<u>-</u>	Neonatal complication score (0–20) Included CNS complications (NE, IVH), CVS, renal and respiratory complications	No increase in complications in fetuses in respiratory group. Increased complications in metabolic acidosis group (mean scores 4.2 vs. 0.9).	Unvalidated scoring system used for assessment of infants.	Cohort	lla
Gilstrap et al.48	Cohort of 2738 singleton term pregnancies; USA hospital	-	Apgar scores Acid-base measurements Neonatal complications	0.6% had pH < 7.00. 33% needed intubation, 17% hypotonic. 1 of the 5 infants who fitted had pH < 7.15. Good association between Apgar (1) < 3 and pH when < 7.00.	44% of cohort delivered by LSCS and 42% of these were elective procedures, i.e. almost 20% of total cohort.	Cohort	lla
Socol et al. <sup>49</sup>	28 neonates with Apgar < 3 at 5 min, with pH > 7.00 or > 7.10; USA hospital	-	Neonatal complications Subsequent CP rates	Neonates with pH < 7.10 > 7.00 more likely to have complicated neonatal period. No difference in two group with respect to CP rates.	Data analysed on outcome not on exposure.	Cohort	lla

#### Evidence Table 6. Studies relating to the use of umbilical acidaemia and outcome (short and long term) (continued)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Long- and sho	ort-term complications						
Ruth et al. <sup>50</sup>	Cohort of 982 infants Followed up at 1 yea		CP or neurodevelopmental delay	28 slight abnormalities 10 severe abnormalities Sensitivity (21%), specificity (89%), PPV (8%), NPV (96%) of poor outcome with low pH.	Actual outcomes not clearly reported. Abnormal pH levels set from reference population. 2 SD from mean = 7.18.	Cohort	lla
Low et al. <sup>51</sup>	37 children with defined fetal hypoxic episodes (UA buffer < 34 mEq/l) and 59 controls with no hypoxia (UA buffer > 34 mEq/l)	-	Physical growth Motor and cognitive disability between 1 year and 6 years	No difference in any outcomes between groups. Rates of motor, cognitive and language deficits 23% and 24% in the hypoxic and control groups, respectively.	_	Cohort	lla
Low et al. <sup>52</sup>	37 children who had experienced intrapartum asphyxia (buffer base < 34 mmol/l) compared with 76 controls assessed at 1 year; Canadian hospital	_	Major and minor neurological or cognitive deficits NE rates	Significantly higher rates of major deficits in asphyxia group (14% vs. 1%, $P$ < 0.01) and of minor deficits (27% vs. 6%, $P$ < 0.01). Significant association between encephalopathy and major and minor deficits.	Mean pH in asphyxia group with major and minor deficits 6.91 and 6.95, respectively.	Cohort	lla
Andres et al.53	93 neonates with umbilical artery pH < 7.00	-	Death Need for intubation and resuscitation Seizures NE	- 6.83 vs. 6.94, <i>P</i> < 0.001 6.75 vs. 6.93, <i>P</i> = 0.02 6.69 vs. 6.93, <i>P</i> = 0.03	-	Nested case- control	lla

CI = confidence interval; CNS = central nervous system; CP = cerebral palsy; CS = caesarean section; CVS = cardiovascular system; EFM = electronic fetal monitoring; FBS = fetal blood sampling; IA = intermittent auscultation; IVH = intraventricular haemorrhage; LSCS = lower segment caesarean section; NE = neonatal encephalopathy; NEC = necrotising enterocolitis; NPV = negative predictive value; OR = odds ratio; PPV = positive predictive value; RCT = randomised controlled trial; RDS = respiratory distress syndrome; SD = standard deviations; UA = umbilical artery

#### Evidence Table 7. Evidence relating to the relationship between Apgar scores and umbilical acidaemia and outcome

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Manganaro et al.59	613 consecutive high- risk pregnancies; Italian hospital	_	Apgar scores Umbilical artery pH Neonatal outcome	No correlation between 1-min Apgar and outcome or acidaemia. Good correlation between 5-min Apgar and metabolic acidaemia. Apgar more influenced by mode of delivery.	37% caesarean section, all had general anaesthesia	Case series	III
Sykes et al. <sup>61</sup>	1210 consecutive pregnancies; UK hospital	-	Apgar scores Umbilical artery pH	73% of babies with severe acidosis had 1-minute Apgar > 7 and 86% at 5 minutes	_	Case series	III

#### **Evidence Table 8. Studies on maternal response to EFM**

Study	Population	Intervention details	Outcomes	Results		Comments	Study type	Evidence level
Hodnett <sup>64</sup>	30 low-risk women in labour, who had attended prenatal classes	Continuous EFM vs. radiotelemetric monitoring Impact upon maintenance of control in labour	LAS Score (mean) Time ambulant (minutes mean) No. ambulant in 1st stage Epidural in 1st stage Labour experience more positive than expected Maintained control Lost control Positive perceived effect Negative perceived effect No perceived effect Length of labour  Maintenance of control during labour as defined by the 'Model of Control' and measured by revised LAS	Control 128.87 8.7 6/15 15/15 1/15 4/15 11/15 5/14 9/14 1/15	Exp 148.07 142.7 15/15 9/15 8/15 10/15 5/15 14/14 0/14 1/15	Freedom from restraint appears to be one variable on ability to maintain control in labour. It appears to affect ability to overcome/cope with pain.  The 'Model of Control' and LAS are useful tools for measuring experienced control.  This study is too low in power to generalise from the findings.	RCT	lb
Garcia <sup>66</sup>	200 women, randomly selected from 13 000 Dublin trial participants	views of women who were	a: Women with EFM restricted in movement. b: Women with EFM receive less support. c: Women with EFM feel more reassured. d: Women with EFM ask more questions and therefore receive more information from caregivers.  Left alone at any time Could move about freely Movement too restricted	restricted by EFM, <0.05) <b>b</b> , <b>c</b> , <b>d</b> : No statistic hypotheses.  At interview 32.1% would prefer EFM would prefer IA ne  EFM IA 33 22	orted by data; $17 = too$ $6 = too$ restricted by IA ( $P$ ally significant data to support of women in IA group next labour; $8\%$ of EFM group xt labour. $(P = < 0.05)$ $(P = < 0.05)$	Uses a non-validated questionnaire.	Cross-sectional survey by semi- structured questionnaire and interview	
Killien <sup>67</sup>	135 women in preterm labour (26–32 weeks). Originally included in the 1987 Luthy RCT <sup>35</sup>	perceptions of	Monitoring experience Nursing support Medical support Labour control Delivery control Response to labour Overall evaluation	Mean SD 5.6 0.9 5.5 0.8 6.0 1.1 4.6 1.1 4.3 1.1 4.1 0.9 5.8 1.4 Possible range of it was 1.0–7.0, with There was no signi 2 groups on the stu 44% of the variance	Auscultation Mean SD 6.1 0.7 5.7 0.8 6.1 1.0 4.5 1.4 4.2 1.2 3.9 0.9 6.2 1.0  em mean values for all scales 7.0 as positive end-point). ficant difference between the lidy measures. e in women's global ed by perceptions of nursing	Auscultation group were more positive in their responses though this did not reach statistical significance.  Small study size limits generalisability. Data presented incomplete (89/135) due to exclusion of those subjects who had missing data on some variables.	Cross-sectional survey by semi- structured questionnaire and interview	

#### **Evidence Table 8. Studies on maternal response to EFM (continued)**

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Hansen <sup>65</sup>	655 women participating in an RCT (655 women interviewed antepartum, only 358 interviewed postpartum)	EFM vs. Auscultation	Antepartum monitoring preference (total mean) Low-risk pregnancies High-risk pregnancies Information on monitoring With info on EFM Not heard of EFM	39.5% 32.4% 135 150 166 49 109 46 <i>n UD EFM-P AUS-P</i> 560 24% 41% 35% 95 51% 32% 18%	Study limitations: Of 655 women interviewed initially, only 358 interviewed postpartum. However, data for women who were undecided about the type of monitoring they would prefer ( <i>n</i> = 104) were excluded, as were the answers of 3% of women in each group who said that they 'were afraid of being left alone during labour due to the EFM technique'. Therefore, postpartum interview data is to be viewed with caution. Non-validated questionnaire.	Cross-sectional survey with follow up	III
Beck <sup>69</sup>	50 women on postpartum ward	To determine how and if women's responses to EFM changed over a 5-year period	Positive, negative and neutral measures of initial and subsequent responses Initial response = women's recollections of their reaction to being told that baby would be monitored with EFM Subsequent response = women's overall response to EFM	Positive 11 (22%) Negative 11 (22%) Neutral 28 (56%)  Subsequent response Positive 37 (74%) Negative 4 (8%) Neutral 9 (18%)	Increased familiarity with EFM improves women's responses.  Study limitations: Non-validated questionnaire used. Convenience sampling. Not repeated in the same setting, unclear what differences in nursing support women experienced. All data from 1972 not reported.	Survey	III
Shields <sup>70</sup>	30 women monitored by internal EFM	To explore women's reactions to EFM	Author developed a 'Mood and Feelings Inventory'. Women assessed 48 hours after birth. Measured by Likert scale (1–6) Enough information provided about monitors?	(highly positive 13.6%) 8/30 = negative response (highly negative 25%). 27/30= YES	Women with highly negative responses to EFM had little understanding of the monitor or why they were being monitored. Those women with a highly positive response had knowledge of and knew why they were being monitored.	Survey by structured interview	III

**Evidence Table 8. Studies on maternal response to EFM (continued)** 

Sioda"   212 women who underwent CFP, during labour (L) or during pregnancy and labour mentions of pregnancy and labour mentions of pressure (P&L) or during labour (L) or duri	Study	Population	Intervention details	Outcomes	Results			Comments	Study type	Evidence level
pregnancy (P), during labour (U) or during pregnancy and labour (P&U) or during pregnancy and labour (P&U) and the pregnancy and labour (P&U) and peasure (P&U) (P	Sioda <sup>68</sup>				Examination	performed during:		Negative responses included: physical		-
labour (L) or during prepanacy and labour (P&L) and preparacy and labour (P&L) are motions of preassurance and pleasure (P&L) are motions of measure (P&L) are motions of pleasure (P&L) are motions of measure (P&L) are motions of pleasure (P&L) are motions of measure (P&L) are motions of measure (P&L) are motions of pleasure (P&L) are motions of measure emotional responses. Study limitations: No indication of the type of questions asked was provided, and reporting of responses in this paper is limited.  Positive (n = 169) 58 63 48 15 is motion of the type of questions asked was provided, and reporting of responses in this paper is limited.  No indication of the type of questions asked was provided, and reporting of responses in this paper is limited.  It is unclear how participants were selected and how it is possible to generalise from these results.  Molfese <sup>22</sup> 180 women, randomly chosen, who had given birth in the previous 2 days and had experienced routine EFM.  2 settings: university medical centre and a community hospital monitoring a community hospital are motioning monitoring are motion for the provided provided in the Land Pt groups that in the Land			study of the		Р	L	P&L			
Peasure and labour (P&L)  Regative (n = 19) 7 11 1 1 datiributed to the CTG alone. It is clear from data in the L and PL groups that prior reassurance and pleasure  Regative (n = 19) 7 16 12 data in the L and PL groups that prior experience of CTG decreased the level of negative emotional responses. Study limitations:  No indication of the type of questions asked was provided, and reporting of responses in this paper is limited.  Pleasure response at sound of FHR Positive (n = 169) 7 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1					E1	E 2	20		interview	
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				Positive items (mean)	2.44	2 56				

CTG = cardiotocograph; EFM = electronic fetal monitoring; FHR = fetal heart rate

Evidence Table 9. Intermittent auscultation regimens used in randomised controlled trials evaluating intermittent auscultation vs. EFM

Study	IA how often	Timing with contractions	Duration of monitoring	Instrument used	Abnormal criteria requiring conversion to EFM/delivery	Study type	Evidence level
Vintzileos <i>et al.</i> <sup>30</sup>	1st stage: every 15 minutes 2nd stage: every 5 minutes	During and immediately after (for at least 30 seconds)	1 minute	Hand-held Doppler	<ol> <li>FHR during and immediately after a contraction repeatedly below 100 bpm, even if there was recovery to 120–160 bpm before the next contraction         <ul> <li>Moderate decelerations FHR 80–99 bpm</li> <li>Severe decelerations FHR &lt; 80 bpm</li> </ul> </li> <li>Persistent baseline rate (between contractions) of less than 100 bpm</li> <li>Persistent baseline rate (between contractions) of greater than 160 bpm</li> <li>Note: No cross-over to EFM, No FBS used.</li> </ol>	RCT	lb
Luthy et al. <sup>35</sup>	1st stage: every 15 minutes 2nd stage: every 5 minutes	Immediately after (for at least 30 seconds) and baseline estimation between contractions	At least 30 seconds	DeLee fetoscope or hand-held Doppler	<ol> <li>FHR less than 100 bpm persisting from more than 30 seconds after 3 or more consecutive contractions</li> <li>A baseline greater than 180 bpm for more than 15 minutes</li> <li>A baseline of less than 100 bpm for more than 60 seconds</li> <li>Baselines between 100–120 bpm and 160–180 bpm were followed with IA every 5 minutes until returned to normal or became ominous.</li> <li>Note: No crossover to EFM. Study restricted to babies 26–32 weeks</li> </ol>	RCT	lb
MacDonald <i>et al.</i> <sup>34</sup>	1st stage: every 15 minutes 2nd stage: interval between every contraction	Following a contraction	1 minute	Pinard stethoscope or hand-held Doppler if difficulty with auscultation	FHR > 160 bpm or < 100 bpm during three contractions and failed to respond to conservative measures.  Note: FBS used in both arms	RCT	lb
Neldham <i>et al.</i> <sup>56</sup>	1st stage: 2 per hour up to 5 cm, then ever 15 minutes 2nd stage: after every contraction or at least every 5 minutes	ycontraction	For 15 seconds up to 5 cm then for 30 seconds	Not specified	FHR < 100 bpm during three contractions and failed to respond to conservative measures.	RCT	lb
Wood et al. <sup>107</sup>	'The usual way'	Not specified	Not specified	Not specified	Not specified	RCT	lb

Evidence Table 9. Intermittent auscultation regimens used in randomised controlled trials evaluating intermittent auscultation vs. EFM (continued)

Study	IA how often	Timing with contractions	Duration of monitoring	Instrument used	Abnormal criteria requiring conversion to EFM/delivery	Study type	Evidence level
Haverkamp <i>et al</i> . <sup>36</sup>	1st stage: every 15 minutes 2nd stage: every 5 minutes	After a contraction	30 seconds	Not specified	<ol> <li>Fetal tachycardia (? Limit)</li> <li>FHR between 100 bpm and 120 bpm</li> <li>Irregular heart beat</li> </ol> Note: No FBS used, no crossover to EFM	RCT	lb
					Note. No FBS used, no crossover to ETM		
Kelso et al.40	Every 15 minutes or more frequently if	During or immediately after	1 minute	Pinard stethoscope or hand-held Doppler if difficulty with auscultation	FHR > 160 bpm or < 120 bpm	RCT	lb
	indicated	a contraction	•	uniculty with adscultation	Note: No FBS used, no crossover to EFM		
Haverkamp <i>et al.</i> <sup>55</sup>	1st stage: every 15 minutes 2nd stage: every 5 minutes	After a contraction	30 seconds	Not specified	Fetal tachycardia (? Limit)     FHR between 100 bpm and 120 bpm     Irregular heartbeat	RCT	lb
	illilities				Note: No FBS used, no crossover to EFM		
Renou et al.85	Not specified	Not specified	Not specified	Not specified	Not specified	RCT	lb
					Note: FBS used, high risk		

Conservative measures included: change in maternal posture, treatment of maternal pyrexia, stopping of oxytocin infusions, administration of oxygen, correction of hypotension; EFM = electronic fetal monitoring; FBS = fetal blood sampling; FHR = fetal heart rate;

#### Evidence Table 10. Studies examining the relationship between abnormal FHR patterns and outcome

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Berkus <i>et al</i> . <sup>148</sup>	2200 consecutive singleton term pregnancies 484 (26%) normal Last 30 minutes prior to delivery	Normal Baseline 120–160 bpm Variability > 5 bpm Presence of accelerations No variable or late decelerations  Abnormal Baseline 90–120 bpm or > 160 bpm Variability < 5 bpm No accelerations Any decelerations Prolonged bradycardia or any combination	1- and 5-minute Apgar <7 Umbilical cord pH <7.15	99.7% NPV for Apgar > 7 and 96.9% NPV for pH > 7.15 for normal traces.  If accelerations present no significant adverse outcome with any abnormal FHR pattern.  OR of pH < 7.15 and 5-minute Apgar < 7 only significant for prolonged bradycardia (OR 3.6; 95% CI 1.2–11), severe variable decelerations (OR 2.4; 95% CI 1.2–4), late decelerations (OR 6.9; 95% CI 2.1–23).	рН	Cohort	lla
Dellinger <i>et al</i> . <sup>147</sup>	898 singleton pregnancies > 32 weeks of gestation Divided into normal (627), stress (263) and distress (8) patterns	Normal pattern 110–160 bpm, minimal to moderate variability, with or without accelerations Stress pattern > 160 bpm > 5 minutes, minimal to moderate variability, moderate to severe variable decelerations, late decelerations or sinusoidal pattern Distress pattern < 110 bpm for > 5 minutes, moderate to severe variable decelerations with absent variability, late decelerations with absent variability, late decelerations with absent variability, and no accelerations	Apgar score <7 (1- and 5-minute)  Umbilical pH <7.00  Also NICU admission, LSCS rate, $PO_2$ , $PCO_2$ and base excess	Apgar < 7 at 5 minutes.  Stress/distress vs. normal. Sensitivity 68% Specificity 71% PPV 5% NPV 99%.  Umbilical cord pH < 7.00.  Stress/distress vs. normal. Sensitivity 100% Specificity 66% PPV 3% NPV 100% Results also on distress vs. normal.  NPV for all outcomes > 98%.	Underpowered cohort due to imbalance between groups. Analysis between distress and normal for pH and Apgar highly specific but interpret with caution in view of numbers in each group.	Cohort	lla
Dawes et al. <sup>115</sup>	1884 singleton deliveries	EFM traces during last hour of labour	Normal baseline variation with sex, gestational age, epidural anaesthesia and birthweight	Female fetus, epidural analgesia, firstborn baby, longer 1st (> 430 min) and 2nd (> 90 min) stages were associated with relative increase in FHR > 150 bpm.	Analysis of change with gestation limited due to analysis of term infants only. Results of limited practical application	Cohort	lla

Evidence Table 10. Studies examining the relationship between abnormal FHR patterns and outcome (continued)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Özden & Demirci <sup>136</sup>	167 'randomly' selected FHR traces Singleton primiparae at term 91 normal traces 76 with variable decelerations Divided into two groups those with and without poor prognostic factors (PPF)	Variable deceleration classified into 7 subtypes according to PPFs 1. Loss of primary acceleration 2. Loss of secondary acceleration 3. Loss of variability during deceleration 4. Slow return to baseline 5. Biphasic deceleration 6. Prolonged secondary acceleration 7. Prolonged deceleration	Apgar scores (1- and 5- min)  Umbilical cord pH and HCO <sub>3</sub>	Significantly lower Apgar scores, cord pH and HCO <sub>3</sub> between FHR with PPFs vs. controls.  Significantly lower Apgar scores and HCO <sub>3</sub> between FHR without PPFs and controls.  Significantly lower Apgar scores and cord pH between FHR with PPFs and those without.  Overall prolonged deceleration had highest specificity for 1-min and 5-min Apgar <7 and pH <7.20 (95%, 96.3%, 97.5%).  Loss of variability had highest sensitivity for same outcomes (66.7%, 72.3%, 63.9%).  Specificity increased with additional factors but sensitivity decreased.	Complex analysis Small sample size	Cohort	lla
Cardoso et al. <sup>141</sup>	293 singleton term pregnancies. Normal 1st stage traces, analysed on all of second stage. Classified on modified Melchior and Barnard classification. 293 type 0 used as controls	Type 0 Stable FHR during entire second stage  Type 1a Mild variable decelerations  Type 1b Moderate to severe variable decelerations or late decelerations with each contraction, returning to baseline in between  Type 2a Baseline 90–120 bpm with decelerations  Type 2b Basal FHR below 90 bpm, usually with reduced variability  Type 3 Basal FHR below 90 bpm, low variability, accelerations with contractions  Type 4 Basal FHR below 90bpm during final moments of 2nd stage only	Umbilical arterial and venous pH, PCO <sub>2</sub> , PO <sub>2</sub> , HCO <sub>3</sub> and BE	Arterial and venous pH values significantly lower in types 1b and below compared with controls. Mean pH only < 7.20 in types 2b and 3.	Unusual scoring system.  Analysis not based on specific FHR abnormalities.  Small numbers in more severe categories (2b: $n = 13$ , 3: $n = 14$ ).	Cohort	lla

#### **Evidence Table 10. Studies examining the relationship between abnormal FHR patterns and outcome (continued)**

Study	Population	Intervention details		Outcome	s	Results	Comments	Study type	Evidence level
Samueloff et al. <sup>125</sup>	Cohort of 2220 consecutive deliveries (see Berkus <i>et al.</i> <sup>4</sup> )	FHR variability follors prior to full dilatation second stage  Scoring using 5 scorona. FHR amplitude > B. FHR amplitude > C. FHR frequency oronic >< 3/min  D. FHR frequency oronic >< 5/min  E. Combination of (frequency)/2. < 3	ing systems < 3 bpm < 5 bpm f oscillations f oscillations amplitude +		20 Apgar <> 7 e adverse fetal		predictor of outcome.  y ower  % for 5- g system matched. Hence, performance of tests will be affected.  asing  y.	Cohort	lla
Cibils & Votta <sup>150</sup>	707 post-term pregnancies ( > 14 days post EDD)	All FHR variables	Apgar score < 5 minutes Umbilical pH			correlation between abnormal and 5-minute Apgar score or	High perinatal mortality rate in study, authors note those babies that died did not show expected signs of imminent demise and decompensated quickly.	Cohort	lla
Egly <sup>146</sup>	1280 consecutive monitored labours	Sinusoidal patterns	Apgar scores (a minutes) Umbilical arter		at 1 and 5 mir minute and 1. Insufficient da draw conclusion Significant inc	difference in Apgar scores <7 nutes (5.5% vs. 5.2% at 1 9% vs. 1.1% at 5 minutes). ta on umbilical artery pH to ons.  rease in rate of alphaprodine (16.7% vs. 7.0%).	Recently published study reporting on cohort from 1977.	Cohort	lla
Ellison et al. <sup>133</sup>	Original cohort from Dublin RCT <sup>34</sup> Two groups of FHR traces: EFM alone (2362) and EFM plus neurological examination (135)	All FHR variables	1 and 5 minute	10	decelerations a minutes  Significant cor decelerations a	relation between late and low Apgar score at 5 relation between late and marked bradycardia and normal neurological	No specifics of scoring for neurological examination specified	Cohort	lla

#### Evidence Table 10. Studies examining the relationship between abnormal FHR patterns and outcome (continued)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Murphy et al. <sup>145</sup>	1520 women requiring fetal monitoring in labour	Sinusoidal and pseudosinusoidal patterns	CS Apgar score (at 1 and 5 minutes) Umbilical artery pH	No significant difference in LSCS rates (10% vs. 12%), Apgar < 7 at 5 minutes (3% vs. 0%) or umbilical artery pH > 7.12 (14% vs. 9%).  Significant association with epidural analgesia (RR 1.84; 95% CI 1.24–2.76) and pethidine administration (RR 1.84; 95% CI 1.31–2.59) from multivariate analysis.	Data on pseudosinusoidal traces divided into minor, moderate and severe categories depending on amplitude of oscillations and frequency of cycles.	Cohort	lla
Tortosa et al. <sup>138</sup>	157 randomly selected FHR traces with variable decelerations 50 with normal FHR traces	Variable decelerations	Apgar scores (1 and 5 minutes) Umbilical artery pH NE	Significantly association between variable decelerations and 1 minute Apgar score < 7 and pH < 7.20.  When deceleration/contraction index calculated over 30 minutes, significant association between index > 12 and neonatal encephalopathy (7 cases vs. 0 cases).	Complicated analysis relating to various methods of interpreting deceleration/contraction index.	Cohort	lla
Gilstrap et al. <sup>124</sup>	833 cases with cord pH samples and interpretable traces in last 10 minutes of labour	Uncomplicated bradycardia: Mild (90–119 bpm) Moderate (60–89 bpm) Severe (<60 bpm)  Uncomplicated tachycardia Mild (160–179 bpm) Marked (>180 bpm)	Umbilical artery pH (< 7.20)	PPV of pH < 7.20 for: Mild tachycardia < 3minutes 10% > 3minutes 17%  Marked tachycardia < 3 minutes 40% > 3 minutes 13%  Mild bradycardia < 3 minutes 17% > 3 minutes 20%  Moderate to severe bradycardia < 3 minutes 26% > 3 minutes 29%	Not consecutive cases, hence subject to selection bias.	Cohort	lla
Spencer and Johnson <sup>126</sup>	301 consecutive FHR	Variability cycles  Change in long term variability > 5 bpm for > 5 minutes  More than 2 cycles required for positive result	Apgar scores (1 and 5 minutes)	No significant difference between Apgar scores in groups with or without cycles in variability.	Adverse event rate, i.e. depressed Apgar < 5 low in both groups ( for 5-min Apgar 0 and 1 in cycles present and absent groups respectfully), hence underpowered to detect difference.	Cohort	lla

#### **Evidence Table 10. Studies examining the relationship between abnormal FHR patterns and outcome (continued)**

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Gilstrap <i>et al</i> . <sup>123</sup>	277 cases with know arterial cord pH samples and satisfactory second stage traces	n Uncomplicated bradycardia:  Mild (90–119 bpm)  Moderate (60–89 bpm)  Severe (< 60 bpm)  or tachycardia (> 160 bpm)	Umbilical artery pH (< 7.20)	PPV of pH <7.20 for: Tachycardia 21% Mild bradycardia 30% Moderate to severe bradycardia 39%	Unclear for how long abnormalities present.  Not consecutive cases, hence subject to selection bias.	Cohort	lla
Heinrich <i>et al.</i> <sup>149</sup>	2694 unselected deliveries Unclear gestation range/risk range	All FHR variables. Grouped into scoring system  Normal Baseline 120–160 bpm, constant mild bradycardia, variability 10– 25 bpm, sporadic variable declarations, accelerations  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.	/	Significant difference between pH < 7.20 between severe and hypoxic categories compared to warning and normal categories.	Small numbers in hypoxic category.  Not possible to determine gestation or risk categories.	Cohort	lla
Krebs et al. <sup>137</sup>	1996 FHR traces from term singleton pregnancies	Variable decelerations	Apgar score < 7 at 1 and 5 minutes  Neonatal acid-case status	Pure variable rarely associated with poor outcome. Variable decelerations with atypia showed high incidence of acidosis and low Apgar scores: these included loss of initial or secondary acceleration, slow return to baseline, prolonged secondary acceleration, biphasic deceleration, loss of variability during deceleration, continuation of baseline at lower level. Variable decelerations commonly seen with other FHR abnormalities.	_	Cohort	lla

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Krebs et al. <sup>128</sup>	1996 FHR traces from term singleton pregnancies	Periodic variable and uniform accelerations	Apgar score < 7 at 1 and 5 minutes	Presence of accelerations had specificity of 97% for Apgar > 7 at 5 minutes for < 3 and < 5 accelerations in 30 minutes.	Unbalanced cohort with only 86 (4%) adverse outcomes.	Cohort	lla
				Poor sensitivity of poor outcome with absence of accelerations.			
Cibils <sup>130</sup>	1304 consecutive singleton labours with 60 minutes of FHR trace available prior to second stage 598 normal traces 247 traces with early decelerations	Early decelerations Associated baseline changes	Apgar scores (1 and 5 minutes)	No significant difference in outcome in relation to Apgar scores between the two groups.  Increased incidence of transient tachycardia in early deceleration group (10% vs. 5%).	Limited outcome data. Pathological depressed Apgar scores not defined.	Cohort	lla
	Same cohort as Cibils <sup>134</sup>						
Gaziano <sup>139</sup>	1011 consecutive traces	Variable decelerations ± other FHR variables	Apgar score (1 and 5 minutes)	Variable decelerations alone not significantly associated with Apgar < 7 at 5 minutes.	Some additional results compared to mean Apgar scores. Significant differences between various FHR parameters seen but no cut off	Cohort	lla
				Variable decelerations with associated bradycardia associated with significant increase in numbers of babies with Apgar < 7 at 5 minutes.	used for significant Apgar scores hence results not reported.		
Powell et al. <sup>129</sup>	1677 monitored labours	Uniform accelerations (> 3 in 15 minutes > 15 beats for > 15s)	PNMR Apgar score at 5minutes	5-min Apgar < 7.	Small sample from which to interpret PNMR rates.	Cohort	lla
			<7	0.84% vs. 10.49% accelerations vs. no accelerations.	No population data presented.		
				PNMR: 4 deaths vs. 20 deaths accelerations vs. no accelerations.			

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Krebs <i>et al.</i> <sup>43,127,151</sup>	1996 FHR traces from singleton >34 week pregnancies Evaluated in first and last 30 minutes of labour	Application of author's developed FHR scoring system from antenatal records  Baseline <100 > 180 (0), 100–119 or 161–180(1), 120–160(2)  Variability Amplitude < 3 (0), 3–5 (1), 6–26 (2)  Frequency <3(0), 3–6 (1), > 6 (2)  Accelerations 0 (0), periodic/1–4 sporadic (1), > 5 sporadic (2)  Decelerations Late, severe variable or atypical variable (0), moderate variable (1), early (2) Abnormal < 5 Suspicious 6 or 7 Normal > 8	Apgar <7 at 1 and 5 minutes.  Umbilical cord pH <7.20 (note: only available in 61 (3%) of cases.	Abnormal and suspicious patterns associated with significantly lower/number of Apgar scores < 7 at 5 minutes.  Insufficient data to calculate sensitivity or specificity.	No review of individual variables in FHR traces.	Cohort	lia
Cibils <sup>140</sup>	1304 consecutive singleton labours with 60 minutes of FHR trace available prior to second stage 312 normal traces 147 traces with late decelerations Same cohort as Cibils <sup>134</sup>	Variable decelerations  Variable with late component ('variable with hypoxic component') Associated baseline changes	Apgar scores (1 and 5 minutes)	Significant association between variable declarations and 'pathological' Apgar scores (4% vs. 1% at 5 minutes).  Significant increase in associated baseline changes in late deceleration group: tachycardia and saltatory or fixed baselines.  Significant association between variable decelerations with late component and Apgar scores in comparison to variable decelerations.	Limited outcome data. Pathological depressed Apgar scores not defined.  Results presented for significant difference between mean Apgar scores, but significance testing based on false assumption of Apgar scores being normally distributed.	Cohort	lia

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Painter et al. <sup>132</sup>	50 high-risk infants	Normal traces  Moderate–severe variable Decelerations to 70–80 bpm for > 60 seconds with 3 contractions  Severe variable Deceleration to < 70 bpm for > 60 seconds on > 2 occasions  Late decelerations	Neurological examinations at 48, 72 hours and at 2, 4, 6, 9 and 12 months of age.	Sensitivity of severe variable or late decelerations 94% for abnormal evaluations, specificity 56%.  6 children abnormal at one year, 2 had late decelerations, 4 had variable decelerations	Very small sample size.  No account of baseline rate or variability in scoring system used.  Analysis based on multiple examinations of same children.	Cohort	lla
Low et al. <sup>240</sup>	587 high-risk pregnancies FHR reviewed 2 hours prior to delivery	Total decelerations (% of contractions associated with decelerations)  Moderate if 5–29%, marked if > 30%  Late decelerations (% of contractions associated with late decelerations)  Moderate if < 10% contractions, marked if > 10%	buffer and PO <sub>2</sub> Normal buffer base > 38.6 mEq/l	Significant increase in total and late decelerations between normal and asphyxial group.  Significant increase in reduced Apgar scores in asphyxial group.	Tend data in the development of acidosis also presented.  Data difficult to extract regarding overall differences between normal and asphyxial groups as latter group is divided into three groups according to timing of development of acidosis.  Apgar data not divided into 1 and 5 minutes	Cohort	lla
Cibils <sup>134</sup>	1304 consecutive singleton labours with 60 minutes of FHR trace available prior to second stage 598 normal traces 147 traces with late decelerations	Late decelerations and associated a baseline changes	Apgar scores (1 and 5 minutes)	Significant association between late declarations and 'pathological' Apgar scores (12% vs. 1% at 5 minutes).  Significant increase in associated baseline changes in late deceleration group: tachycardia and saltatory or fixed baselines.	Limited outcome data. Pathological depressed Apgar scores not defined.  Results presented for significant difference between mean Apgar scores, but significance testing based on false assumption of Apgar scores being normally distributed.	Cohort	lla
Paul et al. <sup>127</sup>	167 labours  121 with average variability  46 with decreased variability	Variability  Divided using Hon's definitions <sup>246</sup> Divided into 5 groups according to variability decreased (A + B) < 5 bpm and average (C–E) > 6 bpm  Late decelerations as additional feature	Apgar scores (1 and 5 minutes) Scalp pH	Significantly higher Apgar scores in average variability group.	No measures of significance reported.  Small study. Data presented in continuous form.	Cohort	lla

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Saldana et al. <sup>241</sup>	620 high-risk pregnancies	Decelerations > 1 5 bpm below baseline > 30 seconds in duration,	1- and 5-minute Apgar scores	No significant association between any abnormal FHR pattern and	No description of time frame studiedSmall unbalanced cohort.	Cohort	lla
		relationship to contractions	Umbilical pH < 7.22	acidosis.			
Low et al. <sup>131</sup>	base deficits		Predictive value of abnormal FHR variables	minutes) with late and/or prolonged	Good NPV for all features individually.	Case-control	lla
	> 16 mmol/l 71 term infants with			decelerations: sensitivity 17%, specificity 46%.	Poor specificity in combination.		
	base deficits < 8 mmol/l  Studied over 4 hours			Minimal baseline variability (> 20 minutes) and late and/or prolonged decelerations (> 20 minutes): sensitivity 46%, specificity 89%.	Baseline tachycardia, variable and early decelerations not discriminative features		
	prior to delivery (divided into 10- minute cycles)			Minimal baseline variability (> 20 minutes) or late decelerations and/or prolonged decelerations (> 20 minutes): sensitivity 75%, specificity 57%.			
				Minimal baseline variability (10 minutes) and/or late and/or prolonged decelerations (10 minutes): sensitivity 93%, specificity 29%.			
Low et al. <sup>135</sup>	200 term infants with significant metabolic acidosis (base buffer < 36.1 mEg/l)	All FHR variables	Predictive value of abnormal FHR variables for acidosis	Baseline fetal heart rate, baseline variability and accelerations were not predictive of acidosis.	No analysis on combining factors for prediction.	Case-control	lla
	200 term infants without metabolic acidosis (base buffer			Total decelerations were significantly associated with acidosis for last hour prior to delivery.			
	> 36.1 mEq/l)			Late decelerations were significantly associated with acidosis for last hour			
	Studied over 8 hours prior to delivery (divided into 20- minute cycles)			prior to delivery but variable decelerations only for last 20 minutes.			

Evidence Table 10. Studies examining the relationship between abnormal FHR patterns and outcome (continued)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Visser et al.117	196 recordings	Continuous EFM	Normal baseline Accelerative patterns Variability patterns	Steady decline in mean FHR up to 30 weeks then slow increase.  Incidence of accelerations prior to 30 weeks was low then steadily increased.  All perameters of FHR variation increased with gestation.	No ranges given.	Case series	III
Wheeler and Murrills <sup>118</sup>	97 recordings from 59 pregnancies between 21 and 41 weeks of gestation	Continuous EFM	Normal baseline heart rate	Baseline FHR reducing with gestation. After 28 weeks baseline between 110 and 150 bpm.  Reduced variability reported during sleep periods.	Small study.	Case series	III
Beard et al. <sup>120</sup>	392 fetuses	Continuous EFM variables	Related to FBS pH in labour	Normal FHR pattern 120–160 bpm, mean pH 7.33.  Accelerations > 15 for 15 seconds, mean pH 7.34. Early deceleration mean pH 7.33. Baseline tachycardia, mean pH 7.30 Baseline bradycardia, mean pH 7.32. Variable decelerations with normal baseline, mean pH 7.31. Variable decelerations with abnormal baseline, mean pH 7.22. Reduced variability, mean pH 7.24. Late decelerations, mean pH dependent on lag time. No lag mean pH 7.29, with lag time mean pH 7.24.	_	Case series	III
Ibarra-Polo et al. <sup>116</sup>	24 healthy fetuses between 12 and 40 weeks of gestation	Continuous EFM	Normal baseline heart rate	Baseline reducing with gestation.  Mean value after 21 weeks of 140 bpm.	No ranges given.	Case series	III

FHR = fetal heart rate; NPV = negative predictive value; PNMR = perinatal mortality rate

#### **Evidence Table 11. Studies relating to errors in interpretation**

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Observer error							
Ayres-de-Campos et al. <sup>159</sup>	33 FHR tracings (16 antepartum and 17 intrapartum) from 22 high-risk pregnancies	FHR tracings classified using FIGO classification <sup>11</sup> Inter-observer error between 3 experts  Management options also assessed (no action, close monitoring or immediate intervention)	Proportion of agreement (Pa)  Kappa statistic and weighted Kappa	Classification Overall agreement of classification was fair to good $\kappa = 0.48$ (95% CI $0.34-0.62$ ). $\kappa w = 0.58$ (95% CI $0.44-0.72$ ). Reasonable agreement for normal tracings (Pa = $0.62$ ; 95% CI $0.51-0.73$ ). Poor agreement for suspicious (Pa = $0.42$ ; 95% CI $0.34-0.50$ ) and pathological (Pa = $0.25$ ; 95% CI $0.14-0.36$ ). Intrapartum separately ( $\kappa = 0.31$ ; 95% CI $0.11-0.51$ ). Clinical decision Overall agreement was good. $\kappa = 0.59$ (95% CI $0.43-0.76$ ) $\kappa w = 0.68$ (95% CI $0.49-0.86$ )	Agreement was significantly better for take 'no action' than for close monitoring or immediate intervention.  All disagreement was found in the adjacent class, e.g. normal–suspicious or suspicious–pathological.  Only three babies with poor outcomes, hence to small to relate agreement/disagreement to outcome.	Case series	III
Ayres-de-Campos <sup>15</sup>	52 33 FHR tracings (16 antepartum and 17 intrapartum) from 22 high-risk pregnancies	Deceleration defined as early, late or variable using FHR tracings classified using FIGO classification <sup>11</sup> Inter-observer error between 3 experts, initially independently, then with knowledge of each others opinion, then by consensus	Proportion of agreement (Pa) Kappa statistic	Independent agreement Early decelerations: $\kappa = 0.15$ and $Pa = 0.36$ (95% CI $0.26-0.46$ ). Late decelerations: $\kappa = 0.32$ and $Pa = 0.31$ (95% CI $0.18-0.44$ ). Variable decelerations: $\kappa = 0.03$ and $Pa = 0.27$ (95% CI $0.19-0.35$ ).  Following consensus Early decelerations: $\kappa = 0.64$ and $Pa = 0.55$ (95% CI $0.45-0.65$ ). Late decelerations: $\kappa = 0.59$ and $Pa = 0.48$ (95% CI $0.35-0.61$ ). Variable decelerations: $\kappa = 0.42$ and $Pa = 0.60$ (95% CI $0.53-0.67$ ).	Examining the difficulties in classifying different decelerative patterns.	Case series	III

# **Evidence Table 11. Studies relating to errors in interpretation (continued)**

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Bernardes <i>et al.</i> <sup>153</sup>	33 FHR tracings (16 antepartum and 17 intrapartum) from 22 high-risk pregnancies	Baseline segments, accelerations and decelerations classified according to FIGO guidelines <sup>11</sup> Inter-observer error between 3 experts Baseline segments classified as normal, reduced or increased variability  Decelerations classified as early, late or variable  Uterine activity divided into tonus or contractions	(Pa) Kappa statistic	Intrapartum Baseline: Pa 0.63/κ 0.51 (0.60–0.66) Accelerations: Pa 0.56/κ 0.52 (0.52–0.60) Decelerations: Pa 0.51/κ 0.49 (0.46–0.56)  Variability Normal: Pa 0.64/κ 0.34 (0.60–0.68) Reduced: Pa 0.40/κ 0.35 (0.34–0.61) Increased: Pa 0.13/κ 0.13 (0.04–0.31)  Decelerations Variable: Pa 0.27/κ 0.05 (0.19–0.35) Early: Pa 0.31/κ 0.23 (0.20–0.42) Late Pa 0.24/κ 0.21 (0.11–0.37)	Antepartum results not presented.	Case series	III
Beckmann et al. 16	11 fetal heart rate tracings	70 subjects (mixture of nursing and medical staff)  Traces divided into 5 categories: Reassuring: no action  Nonreassuring: no action  Nonreassuring: diagnostic intervention  Nonreassuring: therapeutic intervention  Nonreassuring: delivery required  Further prediction of Apgar scores and cord blood analysis (< 7.20, 7.21–7.25 and > 7.26)	Pearson product correlation coefficient	Positive correlation with increasing number of years of labour-ward experience and years from graduation and ability to diagnose traces correctly.  Significant correlation with provider classification (physician, registered nurse, certified nurse midwife).  Positive correlation with years of experience and provider classification in ability to predict 5-minute Apgar and also with ability to predict cord blood gases in group of physicians who looked after high-risk obstetric women.	Based on US practice, hence provider classification not valid in UK.  No mention of variation in interpretation of different groups of traces on original classification in group overall or within provider classification	Case series	III
Bernardes <i>et al.</i> <sup>154</sup>	33 FHR tracings (16 antepartum and 17 intrapartum) from 22 high-risk pregnancies	Baseline estimation according to FIGO guidelines <sup>11</sup> Inter-observer error between 3 expert Estimations assigned to 5 bpm categories	Proportion of agreement (Pa) s Kappa statistic	Intrapartum agreement: Pa 0.80/κ 1.00 (0.93–1.00)	Antepartum data not presented.  Proposal for one overall baseline calculation rather than wandering estimation.	Case series	III

#### **Evidence Table 11. Studies relating to errors in interpretation (continued)**

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Donker et al. <sup>155</sup>	13 obstetric cases from antepartum (3), intrapartum first stage (5) and intrapartum second stage (5)	Baseline and classification of accelerations and decelerations using authors modified classification, by 21 experienced obstetricians Followed by decisions on clinical assessment and obstetric managemen		Overall Fair agreement: $\kappa = 0.48$ Baseline Poor agreement $\kappa = 0.16$ Decelerations Poor agreement $\kappa = 0.11$ Clinical assessment Poor agreement $\kappa = 0.26$ Obstetric management Poor agreement $\kappa = 0.21$	No Confidence intervals reported.  No Proportion of agreement or weighted Kappa, hence not possible to distinguish results from chance or true agreement.	Case series	III
Nielsen <i>et al.</i> <sup>156</sup>	50 intrapartum traces from end of the first stage of labour.16 'compromised' fetuses34 normal	FHR traces analyses twice by four obstetricians (two months apart)	% agreement	Intra-observer error 21% of CTGs interpreted differently on second appraisal  Inter-observer error Overall agreement 69% Chance agreement 56%	Bias introduced as obstetricians aware that one-third of cases had poor outcome.  No accurate measures of agreement used and no confidence intervals or other measures of significance used.	Case series	III
Beaulieu <i>et al.</i> <sup>160</sup>	150 intrapartum FHR traces. 50 abnormal, 100 normal	Analysed by 5 high risk obstetricians on 3 separate occasions  Divided into normal, suspect or abnormal	-	Overall agreement on 80% traces between 5 reviewers.  Intra-observer error 74–84% agreement between readings.	No measure of agreement used, hence no confidence intervals.	Case series	III

# **Evidence Table 11. Studies relating to errors in interpretation (continued)**

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Computerised	interpretation						
Taylor et al. <sup>157</sup>	24 intrapartum FHR traces	Analysed by 7 experienced reviewers  Compared with analysis by algorithm for real-time computerised model  Analysis of baseline, variability, accelerations and decelerations using FIGO definitions <sup>11</sup>	Kappa statistics	Inter rater variability:  Baseline Correlation good (κ 0.93).  Baseline variability Correlation poor (κ 0.27).  Accelerations Correlation poor (κ 0.27).  Decelerations (all) Correlation good (κ 0.93).  Late decelerations Correlation poor (κ 0.79).  Computer agreement:  Baseline Agreement good (κ 0.91–0.98).  Decelerations (all) Correlation good (κ 0.82–0.92).  Late decelerations Agreement fair (κ 0.68–0.85).  Accelerations Fair (κ 0.06–0.80).  Variability Invalid (κ 0.00–0.34).	No confidence intervals or weighted Kappa given.  No mention of outcome of various cases, i.e. high–low mix.	Case series	III
Mongelli et al. <sup>162</sup>	60 intrapartum FHR recordings	Analysis by 12 experts and a computer  Analysis of baseline using FIGO classification <sup>11</sup>	Kappa statistic	Good agreement overall between assessors ( $\kappa$ > 0.89). Good agreement with computer and other assessors ( $\kappa$ > 0.89)	Only examining ability to determine low frequency line.	Case series	III
Todros <sup>158</sup>	high- and low-risk pregnancies	Analysed by 4 observers (2 experts, 2 with only 1 year's experience) and 2 computer systems  Definitions of baseline, accelerations and decelerations developed by authors	Kappa statistic	Inter-observer agreement varied depending on variable. Baseline 0.65. Variability 0.38. Accelerations 0.58. Decelerations: number 0.67, type 0.05.  No difference between 'grade' of interpreter.  Agreement between computer and observer varied: for baseline 0.18–0.48; variability 0.16–0.74; accelerations (n) 0.37–0.64; decelerations (n) 0.41–0.51.	No attempt to add weight to Kappa values or produce confidence intervals.	Case series	III

**Evidence Table 11. Studies relating to errors in interpretation (continued)** 

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Keith et al. 163	50 intrapartum FHR traces  All with known outcome data	Analyses by 17 experts and one computer system on 2 separate occasions at least 1 month apart  Each 20 minute segment of trace scored on a 5-point scale ranging from no concern to immediate delivery	Kappa statistic Intervention rates Comparison to poor outcomes	Each reviewer and between reviewer interpretation highly consistent across all 13 cases.   Intra-observer $\kappa$ 0.43–0.77.   Inter-observer $\kappa$ 0.12–0.46.   The system was highly consistent ( $\kappa$ 0.98) and concurred with experts.   Recommended no unnecessary interventions where outcome was good, identified as many birth asphyxiated cases as the experts.	Observer error not linked specifically with aspects of FHR pattern, more on subsequent action as a result of pattern recognition	Case series	III
Chung et al. 164	73 intrapartum FHR traces Related to outcome data	Analysed by computerised interpretation  Related to acidosis (pH < 7.15 or BE < 8 mmol/l)  Normal/abnormal CTG on criteria developed by authors	pH < 7.15/BE < 8mmol/l	For pH < 7.15 Sensitivity 88% Specificity 75%.  For BE < 8 mmol/l Sensitivity 76% Specificity 82%.	No comparison with human interpretation.  Classification of abnormal to normal not standardised.  Small unbalanced group of cases.	Case series	III
Nielsen et al. <sup>165</sup>	50 FHR traces from last 30 minutes of first stage of labour 16 with adverse outcomes	Assessed by computer program and by 4 experienced obstetricians Rated as normal or pathological, method unclear Outcomes on umbilical artery acidosis, 1-minute Apgar and need for IPPV	Predictive values of accuracy	Computer assessment Predictive value of CTG normal 86%. Predictive value if CTG abnormal 86%.  Expert review Accuracy 50–62%.	_	Case series	III

BE = base excess; CI = confidence interval; FHR = fetal heart rate; IPPV = intermittent partial pressure ventilation

Study	Population	FHR patterns studies	Outcomes	Results	Comments	Study type	Evidence level
Admission CTC	G alone						
Kulkarni <i>et al</i> . <sup>114</sup>	100 high-risk pregnancies	Admission traces  Same classification as	Apgar < 7 at 5 minutes  Operative delivery rates	No significant reduction in risk of reduced Apgar with reactive test compared with equivocal or ominous RR 0.29 (95% CI 0.06–1.42).		Cohort	lla
		Ingermarsson <sup>112</sup>		Significant reduction in operative delivery rates with reactive trace RR 0.22 (95% CI 0.06–0.74).	No separate data presented for LSCS rates.		
Umstad <sup>113</sup>	1192 FHR traces from medium and high risk labours	Admission traces (FHR taken before 4 cm dilated)  Normal Baseline 110–160 bpm, absent, early or mild variable deceleration  Abnormal All other criteria	Umbilical artery acidaemia (<7.20, <7.12)  Apgar <7 (at 1 and 5 minutes)  Operative delivery for fetal distress  Neonatal death/stillbirths	Predictive value of abnormal trace for:  Acidaemia < 7.20 Sensitivity 26.4% Specificity 88.7% PPV 28.3% NPV 87.7%  Acidaemia < 7.12 Sensitivity 24.1% Specificity 86.9% PPV 6.2% NPV 97.0%  Apgar < 7 at 5 minutes Sensitivity 27.3% Specificity 84.8% PPV 3.3% NPV 98.4%  Significant increased odds of pH < 7.20 (OR 2.82; 95% CI 1.77–4.49)  Operative delivery for fetal distress (OR 2.02; 95% CI 1.42–2.87)  Non-significant odds ratio for Apgar < 7 at 5 minutes, neonatal death or stillbirths.	Additional results on subgroups with meconium. Increased sensitivity marginally.  OR for acidaemia increased to 4.11 (95% CI 1.62–10.4).  No significant difference in subgroup less than 34 weeks (4% of total cohort).	Cohort	lla

Study	Population	FHR patterns studies	Outcomes	Results	Comments	Study type	Evidence level
Ingemarsson et al. 112	2 cohorts  130 with normal/abnormal admission tests related to acidaemia  1041 with normal/abnormal admission traces related to fetal distress  Low-risk cohort	Reactive/normal 2 accelerations (>15 bpm > 15 second). No accelerations but normal baseline and variability (10–25 bpm). Normal baseline, with early decelerations but with accelerations.  Equivocal Normal baseline no accelerations and reduced baseline variability (5–10 bpm). Abnormal baseline (> 160 bpm) with no accelerations. Variable decelerations without ominous signs.  Ominous Baseline variability (< 5 bpm) and abnormal baseline. Repeated late decelerations with: > 60 seconds, > 60 beats below baseline, rebound tachycardia, slow recovery, reduced	instrumental delivery rates.	Predictive value of fetal acidaemia (pH <7.15)  Ominous plus equivocal vs. reactive Sensitivity 62% Specificity 91% PPV 29% NPV 97%  Ominous vs. equivocal plus reactive Sensitivity 37% Specificity 97% PPV 50% NPV 96%  Significant reduced risk of LSCS for fetal distress with reactive trace vs. equivocal plus ominous traces  RR 0.10 (95% CI 0.03–0.28)  No significant reduction in LSCS	Unbalanced cohort.  Poor sensitivity with reactive trace alone not improved considerably by including equivocal traces.  Ominous/equivocal test predictive of poor outcome.  No delivery data presented for Part 1 cohort. No distinct outcome data presented for Part 2 data.	Cohort	level IIa
		variability between, late component.		overall for all LSCS RR 0.65 (95% CI 0.31–1.35)			

Study	Population	FHR patterns studies	Outcomes	Results	Comments	Study type	Evidence level
Vibroacoustic s	timulation (VAS) in earl	y labour					
Chauhan et al. <sup>201</sup>	271 singleton, vertex pregnancies. < 5 cm dilated in early labour	Fetal VAS 3-second stimulus, maximum of 3 pulses, 1 minute apart	Feat acidaemia (< 7.10 and < 7.00)  Caesarean section rates	Non-reactive response significantly associated with increase in RR for: LSCS for fetal distress RR 4.1 (95% CI 1.5–60.5) pH < 7.10 RR 5.5 (95% CI 2.2–11.6) pH < 7.00 RR 5.0 (95% CI 1.8–15.2)  Predictive value of non-reactive test LSCS for fetal distress Sensitivity 37% Specificity 91% PPV 11% NPV 97%  pH < 7.10 Sensitivity 44% Specificity 91% PPV 15% NPV 97%  pH < 7.00 Sensitivity 50% Specificity 91% PPV 7% NPV 99%	_	Cohort	lla
Sarno et al. <sup>200</sup>	201 low-risk pregnancies	Fetal VAS 3-second stimulus, maximum of 3 pulses, 1 minute apart	Apgar score at 5 minutes > 7 LSCS for fetal distress	Predictive value of non-reactive test  LSCS fetal distress Sensitivity 31.2% Specificity 95.1% PPV 35.7% NPV 94.1%  5-minute Apgar < 7 Sensitivity 33.1% Specificity 93.8% PPV 14.3% NPV 97.9%	Severely unbalanced cohort.	Cohort	lla

Study	Population	FHR patterns studies	Outcomes	Results	Comments	Study type	Evidence level
Vibroacoustic s	stimulation plus labour a	admission test (LAT) in early labour					
Ingemarsson et al. <sup>202</sup>	952 low-risk women	same as Ingemarsson et al. <sup>112</sup> Results of LAT analysed in	Fetal distess defined as when operative delivery needed or if 5-minute Apgar < 7 after spontaneous delivery	Use of VAS improved performance of admission testing alone.	Composite outcome of 'fetal distress'.  Data not presented in format to allow comparison between two methods.	Cohort	lla
Tannirandorn <i>et</i> al. <sup>203</sup>	140 low-risk women	30 minute LAT  Reactive 2 or more accelerations (15 bpm above for 15 seconds), no accelerations but normal baseline (120–160 bpm) and normal variability (10–25 bpm) Early deceleration  Abnormal Abnormal baseline, variability (< 5 bpm) repeated late or variable decelerations  TA VAS after 15 minutes. 3-second pulse, max of three	5 minute Apgar < 7 LSCS rates	Apgar < 7 at 5 minutes.  LAT Sensitivity 50% Specificity 96.3% PPV 16% NPV 99%  FAST Sensitivity 100% Specificity 97% PPV 33% NPV 100%	Poorly reported data.  Re-analyses necessary to evaluate impact on specific outcomes.  Risk of LSCS not possible to quantify.  No analysis on combination of methods.	Cohort	lla

ndex (AFI) in early labours 776 early labours > 26 weeks of gestation	AFI assessment in early labour Oligohydramnios AFI < 5 Borderline AFI 5.1–8.0 cm Abnormal > 8.0 cm Admission FHR tracing	Apgar scores at 1 and 5 minutes  FHR abnormalities  LSCS for FD	trace if AFI < 5 cm (variable decelerations RR 1.4 (95% CI 1.12–1.87).	High cut-off for normal AFI > 8 cm. Abnormal at < 5 cm.	Cohort	lla
> 26 weeks of	Oligohydramnios AFI < 5 Borderline AFI 5.1–8.0 cm Abnormal > 8.0 cm	minutes FHR abnormalities	abnormal FHR findings on admission trace if AFI < 5 cm (variable decelerations RR 1.4 (95% CI 1.12–1.87).	> 8 cm.	Cohort	lla
			Significant increase in RR for LSCS for fetal distress RR 6.83 (95% CI 1.55–30.0).  Sensitivity 78% Specificity 74% PPV 33% NPV 95%  No significant differences in Apgar scores at 5 minutes.	Increasing number of women with SROM in each group as AFI on admission goes down (20–40%).		
883 early labours > 26 weeks of gestation	AFI assessment in early labour Abnormal < 5	Abdominal delivery for fetal distress  Apgar score < 7 at 1 and 5 minutes	No difference in rates of abdominal delivery for fetal distress (7.1% vs. 6.1%) or Apgar score < 7 at 5 minutes (1.7% vs. 2.1%).	Randomisation to AFI or not AFI significantly increased rates of LSCS for FD (RR 2.02 95% CI 1.08–3.77) (differs from reported RR).	RCT/ Cohort	la/lla
341 women > 37 weeks gestation.	AFI estimation in early labour < 5cm abnormal	LSCS for fetal distress Apgar score < 5 at 5 minutes	No significant difference between LSCS rates and Apgar with AFI < 5 cm or above 5 cm	Actual measurement of AFI regardless of result increased likelihood of LSCS, see Chaunan. <sup>205</sup> 30% in each group had SROM.	Cohort	lla
120 women at term	AFV on admission	LSCS for fetal distress	Significant increase in LSCS for fetal distress with AFI < 5 cm (15% vs. 0%)	Small cohort, very unbalanced.	Cohort	lla
3	> 26 weeks of gestation 341 women > 37 weeks gestation.	> 26 weeks of gestation Abnormal < 5  841 women > 37 AFI estimation in early labour < 5cm abnormal	Abnormal < 5  Abnormal < 5  Apgar score < 7 at 1 and 5 minutes  AFI estimation in early labour < 5cm abnormal  AFI estimation in early labour < 5cm Apgar score < 5 at 5 minutes	PPV 33% NPV 95%  No significant differences in Apgar scores at 5 minutes.  AFI assessment in early labour Abdominal delivery for fetal distress Abnormal < 5  Apgar score < 7 at 1 and 5 minutes  AFI estimation in early labour < 5cm abnormal  AFI estimation in early labour < 5cm Apgar score < 5 at 5 minutes  AFI estimation in early labour < 5cm abnormal  AFI estimation in early labour < 5cm or above 5 cm  Significant increase in LSCS for fetal	PPV 33% NPV 95% No significant differences in Apgar scores at 5 minutes.  AFI assessment in early labour delivery for fetal distress Apgar score < 7 at 1 and 5 minutes  AFI estimation in early labour < Score    AFI estimation in early labou	PPV 33% NPV 95% No significant differences in Appar scores at 5 minutes.  AFI assessment in early labour Abdominal delivery for fetal distress (7.1% vs. 26 weeks of gestation)  AFI assessment in early labour Abdominal delivery for fetal distress (7.1% vs. 2.1%).  Appar score < 7 at 1 and 5 minutes  AFI estimation in early labour < 5cm abnormal  AFI est

Evidence Table 12. Studies relating to tests of fetal wellbeing in early labour (continued)

Study	Population	FHR patterns studies	Outcomes	Results	Comments	Study type	Evidence level
Sarno et al. <sup>208</sup>	200 women > 37 weeks of gestation	AFI estimation in early labour < 5cm abnormal	LSCS for fetal distress Apgar score < 5 at 5 minutes	No significant correlation between AFI and abnormal FHR patterns.  Significant increase in rates of LSCS for fetal distress in AFI < 5 cm group (11.9% vs. 2.5%) RR 4.7 (95% CI 1.32–16.7).  No significant difference for Apgar scores.	50% of cohort had SROM.  > 60% of those with AFI < 5 on admission had SROM.	Cohort	lla
Uterine artery	Doppler in early labou	r ± admission CTG					
Farrell et al. <sup>209</sup>	2700 unselected women at term 8 included studies	Intrapartum umbilical artery Doppler velocimetry	Apgar score < 7 (1-minute)  Apgar score < 7 (5-minute)  FHR abnormality  Umbilical artery acidosis  CS	LR: positive test 2.5 (95% CI 1.7–3.7); negative test 1.0 (95% CI 0.9–1.1)  LR: positive test 1.3 (95% CI 0.4–4.1); negative test 1.0 (95% CI 0.8–1.2)  LR: positive test 1.4 (95% CI 0.9–2.1); negative test 0.9 (95% CI 0.9–1.0)  LR: positive test 1.6 (95% CI 1.1–2.5); negative test 1.1 (95% CI 1.0–1.2)  LR: positive test 4.1 (95% CI 2.7–6.2); positive test 0.9 (95% CI 0.8,1.0)  Overall Doppler a poor predictor of adverse perinatal outcome, but positive test associated with increase in CS.	Well structured review.  Results subject to bias due to heterogeneity, but not possible to explore via sensitivity analysis due to small numbers of trials reporting individual outcomes and lack of reporting.	Systematic review (of non-RCT data)	lla

Study	Population	FHR patterns studies	Outcomes	Results	Comments	Study type	Evidence level
Fetal movemer	nts in early labour ± adm	nission CTG					
Farrell et al. <sup>210</sup>	182 low-risk women at term	Admission CTG (normal if baseline 110–150 bpm, variability > 10 bpm and no deceleration present)  Fetal movements in 10-minute epochs	5 minute Apgar < 7  Metabolic acidosis pH <7.20 BE > 8 mmol/l  Operative delivery for fetal distress	No significant difference in Apgar scores, acidosis or operative delivery rates between those with abnormal and normal CTGs.  Sensitivity 0%, 6% and19% Specificity 93%, 94% and 95% PPV 0%, 6% and 25% NPV 99%, 90 and 92%  No significant difference between outcomes in the groups with regard to fetal movements.	Small cohort.  No cut-off made for abnormal, normal movement count, hence data difficult to interpret.	Cohort	lla
Nyholm <i>et al.</i> <sup>211</sup>	59 term women	Admission CTG with fetal movement counts  Reactive if 2 accelerations > 15 bpm for > 15 seconds associated with 2 movements in 20-minute period  Non-reactive if no accelerations or decelerations associated with fetal movements	Umbilical artery pH	Significant increase in rates of LSCS for fetal distress in non-reactive group.  Non-significant difference in neonatal outcomes.	88% of cohort had reactive traces. Results should be interpreted with caution. Neonatal outcomes lumped together.	Cohort	lla

Study	Population	FHR patterns studies	Outcomes	Results	Comments	Study type	Evidence level
Combined test	ting						
Chua et al. <sup>212</sup>	1092 singleton term pregnancies	AFI estimation: normal > 5  Umbilical artery Doppler pulsarity index: normal < 1.2  Admission CTG: normal values based on FIGO recommendations <sup>11</sup> TA VAS following admission trace	Operative delivery (fetal distress)  Apgar score < 5 at 1 minute  Apgar score < 7 at 5 minutes  Assisted ventilation  Admission to NICU	Non-reactive admission CTG associated with significant increase in operative delivery for fetal distress (25% vs. 4.3%) (OR 8.71; 95% CI 4.78–15.85) and the number with 5-minute Apgar < 7 (10.3% vs. 0.5%) (OR 7.62; 95% CI 3.56–16.28)  VAS improved sensitivity of admission trace when reactive. No significant improvement in specificity in those with abnormal trace.  Maternal perceived fetal movements not predictive of fetal wellbeing.  AFI < 5 associated with increased rate operative delivery for fetal distress and low Apgar at 5 minutes.  Umbilical artery waveform did not correlate with outcome alone but did show a significant reduction in operative deliveries for fetal distress when combined with a normal admission CTG.		Cohort	lla

CTG = cardiotocograph; FAST = fetal acoustic stimulation test; FHR = fetal heart rate; LAT = labour admission test; LR = likelihood ratio; LSCS = lower segment caesarean section; NICU = neonatal intensive care unit; NPV = negative predictive value; OR = odds ratio; PPV = positive predictive value; RR = risk ratio; SROM = spontaneous rupture of membranes; TA = transabdominal; VAS = vibroacoustic stimulation

Evidence Table 13. Studies relating to the use of fetal scalp blood lactate measurement in relation to outcome

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Westgren <i>et al.</i> <sup>174</sup>	341 pregnancies with ominous FHR patterns; Swedish hospital	Fetal scalp lactate vs. FBS	Failure to obtain sample Number of scalp incisions Time taken for sample Neonatal outcomes Maternal outcomes	OR 16.1 (95% CI 5.8–44.7) Median 1.0 (IQR 1–1) vs. 2.0 (1–2) Median 120 seconds (90–147) vs. 230 seconds (180–300)  No difference in Apgar (1- and 5- minute) < 7 or umbilical artery pH studies.  No difference in CS or instrumental delivery rates.  Overall lactate measurement easier to obtain but no improvement in outcome.	Failure to obtain FBS inversely proportional to cervical dilatation.  Analysis not by ITT, 14 violations excluded from analysis. However re-analysis by ITT does not significantly change results.	RCT	Ib

FBS = fetal blood sampling; ITT = intention to treat

#### Evidence Table 14. Studies of the use of fetal pulse oximetry in relation to outcome

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Dildy et al. <sup>181</sup>	1010 women in 9 centres; USA hospitals	Continuous EFM ± fetal pulse oximetry	CS rates (overall and NRFS)  Apgar scores, cord pH, NICU admission and neonatal resuscitation.	Significant reduction in LSCS for NRFS (4.5% vs. 10.2%; OR 0.42; 95% CI 0.24–0.72).  No overall reduction in LSCS rates.  Increase in LSCS rates for dystocia (29% vs. 26%; OR 2.1; 95% CI 1.6–2.4).  Increased sensitivities for neonatal outcomes: Apgar scores < 4 at 1 minute, < 7 at 5 minutes, NICU admission, low umbilical cord pH (<7.15, <7.10, <7.05) and neonatal resuscitation.  No overall difference in neonatal outcomes.	EFM traces defined as normal, non-reassuring and pathological.  Pathological required immediate delivery and hence not analysed (prolonged deceleration <70 bpm > 7 minutes).  Non reassuring included: persistent late deceleration > 50% contractions, sinusoidal pattern, variable decelerations, recurrent prolonged decelerations, tachycardia > 160 bpm with reduced variability < 5 bpm or decreased variability < 5 bpm. All for > 15 minutes.	RCT	la
Bloom et al. <sup>175</sup>	129 singleton cephalic pregnancies; 1 USA hospital		Composite index of fetal compromise, including Apgar score (5-minute) < 3, umbilical artery pH < 7.20, NICU admission and CS for nonreassuring FHR tracing	Significant increase in potential fetal compromise with arterial saturations below 30% for $> 2$ minutes (54%) vs. those with saturations below 30% for less time (14%) ( $P < 1$ )	No difference in outcomes if level of saturation used as cut-off, i.e. 30%. Only significant if duration of saturation included.	Case series	III
Dildy et al. <sup>176</sup>	1101 singleton cephalic deliveries; 2 USA hospitals	Continuous fetal pulse oximetry	Umbilical cord pH values	pH > 7.13 in 99% cases when SaO2 > 30%,but, also when pH < 7.13 in 8.6% cases.When pH < 7.13 SaO2 < 30% in 82.6% of cases	Good sensitivity at 30% cut-off level, but appears to have poor specificity in this series is poor.	Case series	III
Seelbach-Göbel et al. <sup>177</sup>	400 singleton cephalic pregnancies; 2 German teaching hospitals		Umbilical artery pH Umbilical artery base excess Apgar score (1-minute)	Significant correlation between neonates with pH < 7.15, BE < 12 and Apgar (1-minute) < 7 and duration of periods of 'low' oxygen saturation (< 30%). No association seen with moderate or high saturation.	30% saturation seems to be critical boundary for fetal compromise during labour.  No drop in pH seen unless pH < 30% for > 10 minutes.	Case series	III

Evidence Table 14. Studies of the use of fetal pulse oximetry in relation to outcome (continued)

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Carbonne et al. <sup>178,180</sup>	174 singleton pregnancies with abnormal FHR patterns; 6 French teaching hospitals	Continuous fetal pulse oximetry vs. FBS with abnormal FHR tracing in both groups	Umbilical artery pH (= 7.15)  Abnormal neonatal outcome	FBS (= 7.20): Sensitivity 40% NPV 89% Fetal $O_2$ saturation (= 30%) Sensitivity 40% NPV 88% FBS (= 7.20): Sensitivity 35% NPV 83% Fetal $O_2$ saturation (=30%) Sensitivity 32% NPV 83% Fetal $O_2$ saturation (=30%) Sensitivity 32% NPV 83% FBS compared with fetal oximetry comparable if threshold raised to 40% increases sensitivity to 80% for pH and 76% for abnormal neonatal outcome but reduces specificity.	Abnormal neonatal outcome included any of: Apgar (5) = 7, secondary respiratory distress, NICU admission, arterial pH = 7.15 or neonatal death.	Case series	III
Van den Berg <i>et</i> al. <sup>179</sup>	119 intrapartum FHR traces ± fetal pulse oximetry data 4 experts	pulse oximetry	Number of interventions  Umbilical artery pH estimates	Reduction in number of interventions in non-acidotic group when oximetry added, leading to increased specificity. Also caused reduction in intervention rate in acidotic group and hence reduced sensitivity.  pH estimates higher in oximetry group.  Overall oximetry led to reduction in interventions but also led to unidentified acidosis.	Small study.	Case series	III

BE = base excess; CI = confidence interval; EFM = electronic fetal monitoring; FBS = fetal blood sampling; FHR = fetal heart rate; LSCS = lower segment caesarean section; NICU = neonatal intensive care unit; NPV = negative predictive value; NRFS = nonreassuring fetal status

Evidence Table 15. Studies relating to the use of the fetal electrocardiogram relation to outcome

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Mistry and Neilson <sup>182</sup>	1 included study (Westgate <i>et al.</i> <sup>242</sup> ) 2434 pregnant women; UK hospital High risk labours (39% of population during study period)	Continuous EFM (via fetal scalp electrode) vs. continuous EFM plus ST waveform analysis	Fetal blood sampling  Operative delivery: total fetal distress failure to progress  Apgar score (< 8 at 5 minutes)  Umbilical artery pH (< 7.15) (< 7.05) (< 7.05 + BE > 12)  Birth asphyxia	OR 0.80 (95% CI 0.60–1.06)  OR 0.85 (95% CI 0.72–1.02) OR 0.53 (95% CI 0.39–0.73) OR 1.05 (95% CI 0.87–1.27)  OR 0.62 (95% CI 0.36–1.08)  OR 1.09 (95% CI 0.82–1.45) OR 0.92 (95% CI 0.52–1.62) OR 0.41 (95% CI 0.16–1.03)  OR 0.75 (95% CI 0.17–3.30)  Overall a reduction in operative deliveries, significant for fetal distress deliveries, with a trend for a reduction in FBS. No difference in neonatal outcomes.	Good quality trial. Deliveries in fetal-distress group in both arms performed without FBS. Stringent definition of birth asphyxia, requiring all four of:  1. Cord artery pH < 7.05, BE > 12 2. Apgar (5-minute) = 7 3. Active resuscitation = 4 minutes 4. Hypoglycaemia or neurological abnormalities/need for ventilation or death.	Systematic review	la
P–R-interval and	alysis						
Strachan et al. <sup>183</sup>	1038 pregnant women UK (2), Hong Kong,	vs. continuous EFM plus P–R	Fetal blood sampling Caesarean section Assisted delivery Apgar score (< 7 at 5 minutes) Umbilical artery pH: (= 7.15) (= 7.05) Base excess (= 12) NICU admission Asphyxia/meconium aspiration Need for resuscitation	RR 0.91 (95% CI 0.69–1.19) RR 0.79 (95% CI 0.61–1.04) RR 0.94 (95% CI 0.75–1.17) RR 0.42 (95% CI 0.11–1.61)  RR 1.01 (95% CI 0.70–1.47) RR 1.25 (95% CI 0.47–3.33) RR 0.95 (95% CI 0.60–1.49) RR 0.77 (95% CI 0.45–1.33) RR 1.18 (95% CI 0.36–3.85) RR 0.93 (95% CI 0.65–1.33)  Overall no reduction in maternal or neonatal outcomes.	Reduction in FBS rates seen in preliminary trial report. <sup>185</sup> Not seen here due to analysis by ITT.  High intervention rates due to high-risk population.	RCT	lb
T/QRS ratio							
MacLachlan et al. <sup>184</sup>	113 term pregnancies; UK teaching hospital	Continuous EFM (via FSE) vs. T/QRS ratio.	Fetal scalp pH	No correlation between T/QRS ratio and fetal scalp pH. T/QRS ratio sensitivity pH (< 7.20) 13% vs. 50% for EFM alone.  Sensitivity for pH (< 7.12) 29% vs. 76% for	A raised T/QRS ratio (> 0.28) lower detection of fetal acidaemia than pathological CTG.	Case series	III
			Umbilical artery pH	EFM.			

BE = base excess; CI = confidence interval; CTG = cardiotocograph; EFM = electronic fetal monitoring; FBS = fetal blood sampling; ITT = intention to treat; LSCS = lower segment caesarean section; NICU = neonatal intensive care unit; NPV = negative predictive value; NRFS = nonreassuring fetal status; OR = odds ratio; RR = risk ratio

#### Evidence Table 16. Studies relating to the use of intrapartum fetal stimulation testing

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Response to vib	roacoustic stimulation	(VAS) in predictior	of FBS pH				
Irion et al. <sup>190</sup>	421 episodes on 253 consecutive women, with abnormal CTGs requiring FBS	seconds once	Acceleration/reactive test  Prediction of pH < 7.25 or  < 7.20	For pH < 7.25 Sensitivity 56% Specificity 65% PPV 78% NPV 40%  For pH < 7.20 Sensitivity 52% Specificity 77% PPV 97% NPV 11%	Only 30 acidotic babies (< 7.20) in sample.  Average of 2 FBS samples per woman.	Case series	III
Ingemarsson et al. <sup>186</sup>	51 women with abnormal CTGs requiring FBS	Single pulse TA VAS for 5 seconds FBS immediately after	Acceleration/reactive test  Prediction of pH < 7.25 or < 7.20 on FBS  Prediction of cord pH	For pH < 7.25 Sensitivity 82% Specificity 67% PPV 40% NPV 93%  For pH < 7.20 Sensitivity 50% Specificity 57% PPV 9% NPV 93%	Significant difference between cord pH samples of reactive and non-reactive VAS groups. (7.28 and 7.18, respectively)	Case series	III
Polzin <i>et al</i> . <sup>187</sup>	100 women with abnormal CTGs requiring FBS	Single pulse TA VAS for 5 seconds FBS immediately after	Acceleration/reactive test (divided into 15 beats for 15 seconds and 10 beats for 10 seconds)  Prediction of pH < 7.25 or < 7.20  Apgar scores  Cord pH	For pH < 7.25 Sensitivity 56% Specificity 79% PPV 43% NPV 86%  For pH < 7.20 Sensitivity 90% Specificity 80% PPV 39% NPV 98%	No significant difference in performance of test by altering acceleration definition.	Case series	III
Edersheim <i>et al.</i> <sup>188</sup>	188 episodes on 127 women with abnormal CTGs requiring FBS All with SROM	TA VAS for 3 seconds Once only 60 seconds prior to FBS	Acceleration/reactive test  Prediction of pH < 7.25 or < 7.20	For pH < 7.25 Sensitivity 61% Specificity 71% PPV 46% NPV 81% For pH < 7.20 Sensitivity 100% Specificity 63% PPV 8% NPV 100%	Larger study.  Comparison with accelerations, also scalp sampling	Case.series	III

#### Evidence Table 16. Studies relating to the use of intrapartum fetal stimulation testing (continued)

		0	•				
Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Smith et al. 189	64 women with abnormal CTGs requiring FBS/delivery	TA VAS for < 3 seconds up to maximum of 3 times	Acceleration/reactive test Prediction of pH < 7.25	Sensitivity 100% Specificity 65% PPV 53% NPV 100%	Small study. pH cut-off high at 7.25. Interval to FBS not specified.	Case series	III
Response to sca	alp stimulation or fetal k	plood sampling in	prediction of FBS pH				
Elimian et al. <sup>191</sup>	108 fetuses with CTGs suggestive of acidosis	15 seconds gentle digital scalp pressure followed by FBS	Accelerative response to test Prediction of pH <>7.20	For digital pressure: For pH < 7.20 Sensitivity 100% Specificity 54% PPV 26% NPV 100%  Similar results for fetal blood sampling. Minor increase in sensitivity and specificity is using positive response as 10 bpm for 10 seconds	Poor specificity for acidosis	Case series	III
Lazebnik <i>et al.</i> <sup>192</sup>	104 fetuses with	Fetal blood	Accelerative response	rather than 15 bpm for 15 seconds.  For $pH < 7.25$	_	Case series	
Euzemin et al.	CTGs suggestive of acidosis	sampling	Prediction of pH <>7.20 and 7.25	Sensitivity 74% Specificity 15% PPV 27% NPV 57%		Case series	111
				For pH < 7.20 Sensitivity 73% Specificity 16% PPV 12% NPV 78%			

#### **Evidence Table 16. Studies relating to the use of intrapartum fetal stimulation testing (continued)**

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Umstad et al. <sup>193</sup>	60 women with CTGs suggestive of acidosis	seconds	Accelerative response to tests  Prediction of pH <> 7.20	For scalp VAS for pH < 7.25 Sensitivity 100% Specificity 83% PPV 79% NPV 100%	_	Case series	III
				For pH < 7.20 Sensitivity 100% Specificity 59% PPV 27% NPV 100%			
				For FBS response for pH < 7.25 Sensitivity 82% Specificity 91% PPV 86% NPV 89%			
				For pH < 7.20 Sensitivity 62% Specificity 67% PPV 22% NPV 92%			
Spencer et al. <sup>194</sup>	138 episodes with comparable CTGs	Fetal blood sampling	Accelerative response to stimulus  Prediction of pH <> 7.25 and 7.20	For pH < 7.25 Sensitivity 65% Specificity 53% PPV 24% NPV 86%		Case series	III
				For pH < 7.20 Sensitivity 100% Specificity 52% PPV 8% NPV 100%			
Clark et al. <sup>195</sup>	108 fetuses with CTGs suggestive of acidosis	followed by scalp pinch if no response	Accelerative response FBS pH <> 7.19	All babies responding to scalp stimulation non-acidotic (100% specificity)  Pinch stimulation for pH<7.20 Sensitivity 100%	Poor specificity for acidosis	Case series	III
		Followed by FBS		Specificity 33% PPV 38% NPV 100%			

#### **Evidence Table 16. Studies relating to the use of intrapartum fetal stimulation testing (continued)**

Study	Population	Intervention details	Outcomes	Results	Comments	Study type	Evidence level
Response to VA	AS in prediction of umb	ilical cord pH and	Apgar scores				
Anyaegbunam et al. <sup>196</sup>	632 women in second stage of labour	TA VAS for 5 seconds	Acceleration/reactive test Prediction of cord pH	No significant difference between cord pH <7.20 (5.7% vs. 4.7%) or 5-minute Apgar < 7 (3.2% vs. 3.5%)	Underpowered study to detect intended differences also population studies had normal CTGs at recruitment	RCT	la
	Normal CTG pattern	Not activated for controls	5-minute Apgar < 7				

CTG = cardiotocograph; FBS = fetal blood sampling; NPV = negative predictive value; PPV = positive predictive value; SROM = spontaneous rupture of the membranes; TA VAS = transabdominal vibroacoustic stimulation

**Evidence Table 17. Studies relating to education and training** 

Study	Population	Intervention Outcome details	es Results					Comments	Study type	Evidence level
Beckley <sup>227</sup>	117 midwifery and obstetric staff from	Computer-assisted training programme (CTP) of CTG	Mean improvement in test scores	EG	LG	Sig	nificance	CTP led to improved knowledge of CTG and acid-base balance.	RCT	lb
	the same hospital	and acid-base balance	Test one to test two	19.4%	4.3%	(P <	< 0.0001)	Knowledge retained for almost 7 months.		
		Randomisation to either early (EG) or late (LG) completion of CTP	Test one to test four	17.8	.3%	(P =	= 0.03)	While all doctors and all midwives significantly improved their scores between tests one and four, the increase in		
		Assessment by 4 MCQ tests: 1st to assess baseline knowledge; 2nd test all sit after EG have completed CTP; 3rd test all sit then LG completes CTP; 4th test sat by EG 4 months after CTP and 4 months later for LG						knowledge was significantly higher in the midwives group ( $P < 0.0001$ ).		
Murray <sup>228</sup>	39 junior	Computer-assisted	Mean test scores	CAI		TCL		There was a non-significant positive trend	RCT	Ib
	baccalaureate nursing students	instruction (CAI) versus teacher-controlled	Pre-test	43.059	/ <sub>o</sub>	44.9	5% (N/S)	towards improved knowledge between tests for both groups. However, there was		
	from the same class	instruction (TCL) in basic fetal monitoring concepts	Post-test	63.659	<b>%</b>	62.6	8% (N/S)	no significant difference between the groups in terms of methods of training.		
	Prior exposure to CTGs was an exclusion criteria	Participants tested one week after randomisation (pretest), and 6 days after CAI or TCP						48 students were enrolled but only 39 sat both pre- and post-tests. Mean time for completion of CAI was 132.5 minutes and for TCL 235 minutes.		
Trepanier <sup>229</sup>	12 hospitals	EXP group a) Test 1 (time 1)	Primary outcome: % of nurses passing (75% correct) both tests	EXP		COI	NTROL	Test 1 = knowledge test.	RCT	lb
	109 registered nurses	b) EFM workshop	1 and 2 at time 2					Test 2 = clinical skills test.		
		c) Test 1 and 2 timed after workshop	Knowledge test:	N	% pass	Ν	% pass			
		(time 2)	Time 1		19.1	62	14.5			
		d) Tests 1 and2 six	Time 2		68.1	62	9.7			
		months later (time 3)	Time 3		50.0	56	25.0			
		e) Review session f) Tests 1 and 2 timed	Time 4	40	85.0	56	87.5			
		after review (time 4)	Clinical test:	47	97.9	62	54.8			
			Time 2	40	0.08	56	48.2			
		Control group	Time 3	40	100.0	56	100.0			
		a) Test 1 (time 1)	Time 4							
		b) Short break, then test								
		1 and 2 (time 2)	Both tests:							
		C Popost fort 1 and 1								
		c) Repeat test 1 and 2	Time 2	47	(0.1	( )	<i>(</i> =			
		(time 3)	Time 2		<b>68.1</b>	62	6.5			
			Time 2 Time 3 Time 4	40	<b>68.1</b> 45.0 85.0	<b>62</b> 56 56	<b>6.5</b> 14.3 87.5			

#### **Evidence Table 18. Previous published guidelines**

Organisation	Baseline	Baseline variability	Accelerations	Decelerations	Comments
American College of Obstetricians and Gynecologists 108,108	120–160 bpm	Variation of successive beats in the FHR	Common periodic changes in labour and are nearly always associated with fetal movements	Late: U-shaped decelerations of gradual onset and gradual return that are usually shallow (10–30 bpm) and that reach their nadir after the peak of the contraction.  Early: U-shaped decelerations of gradual onset and gradual return that are usually shallow (10–30 bpm) and that reach their nadir at the same time as the peak of the contraction.  Variable: U-shaped of gradual onset and gradual return that are usually shallow (10–30 bpm) and that reach their nadir after the peak of the contraction.  Prolonged deceleration: An isolated abrupt decrease in the FHR to levels below the baseline that lasts at least 60–90 seconds.	Non-multidisciplinary group.  Extensive discussion of management of non-reassuring FHR tracings in relation to concomitant therapy, etc., e.g. epidural therapy, maternal position, tocolysis, amnioinfusion.  Referenced.  No formal evidence or recommendation structure.  No definite documentation of evidence base/searches.
FIGO"	Mean level of the fetal heart when this is stable, accelerations and decelerations being absent. Determined over a time period of 5 or 10 minutes and expressed in beats per minute (bpm)  Normal: 110–150 bpm  Suspicious: 150–170 bpm or 100–110 bpm  Pathological: < 100 bpm or > 170 bpm	Under physiological conditions the fetal beat-to-beat intervals are constantly subject to small changes. This is called short-term variability.  Due to the periodicity in the direction and size of these changes they result in oscillations of the fetal heart rate around its mean level.  Normal: 5–25 bpm  Suspicious: 5–10 bpm > 40 minutes or increased variability > 25 bpm  Pathological: variability < 5 bpm for > 40 minutes	Transient increase > 15 bpm for > 15 seconds or more	Transient slowing > 15 bpm for > 10 seconds or more.  Normal: no decelerations.  Suspicious: variable decelerations.  Pathological: severe variable or persistent early decelerations, prolonged decelerations, late decelerations.	FHR patterns classified into normal, suspicious and pathological.  Non-multidisciplinary group. No consensus methods used.  Unreferenced.  No formal evidence or recommendation structure.  No definite documentation of evidence base/searches.

#### **Evidence Table 18. Previous published guidelines (continued)**

Organisation	Baseline	Baseline variability	Accelerations	Decelerations	Comments
Society of Obstetricians and Gynaecologists of Canada <sup>12,12,243,244</sup>	Average heart rate between contractions (excluding accelerations and decelerations)  Baseline rate: 120–160 bpm	Long-term variability refers to the minor fluctuations in baseline fetal heart rate occurring at three to five cycles per minute. Measured by estimating the difference in beats per minute between the peaks and valleys of fluctuation  *Baseline variability: reduced variability less than 5 bpm between contractions	Periodic increase in FHR associated with fetal activity, contractions or decelerations.  Prolonged: > 2 minutes; > 10 minutes is change in baseline	Late: gradual decrease and return to baseline, > 20 seconds after peak of contraction.  Early: gradual decrease and return to baseline, nadir and peak of contraction coincide.  Variable: periodic slowing with rapid onset and recovery Prolonged deceleration: not defined	Multidisciplinary group.  No consensus methods used. Independent report writing.  Referenced.  No formal evidence or recommendation structure.  No definite documentation of evidence base/searches.
National Institute of Child Health and Human Development Research Planning Workshop <sup>122</sup>	Baseline FHR is the approximate mean FHR rounded to increments of 5 bpm during a 10-minute segment, excluding periodic or episodic changes, periods of marked FHR variability and segments of the baseline that differ by > 25 bpm  Baseline rate: 110–160 bpm  < 110 bpm bradycardia  > 160 bpm tachycardia	Baseline variability is deemed as fluctuations in the baseline FHR of two cycles per minute or greater.  These fluctuations are irregular in amplitude and frequency and are visually quantified as the amplitude of the peak-to-trough in beats per minute.  Baseline variability: (1) undetectable (2) minimal < 5 bpm (3) moderate 6–25 bpm (4) marked > 25 bpm	Accelerations: >15 bpm above the baseline for >15 seconds and start to return to baseline <2 minutes.  Before 32 weeks >10 bpm above baseline for >10 seconds  Prolonged acceleration > 2 minutes, >10 minutes is change in baseline	Late: gradual decrease and return to baseline, > 30 seconds to nadir, occurring after peak of contraction.  Early: gradual decrease and return to baseline, nadir and peak of contraction coincide.  Variable: abrupt decrease, < 30 seconds from onset to nadir, > 15 bpm below for > 15 seconds but < 2 minutes.  Prolonged: > 15 bpm below baseline, lasting > 2 minutes but < 10 minutes.  Prolonged deceleration of > 10 minutes is a baseline change.  Recurrence defined as occurring with > 50% of contractions in any 20-minute segment.	Non-multidisciplinary group.  Good recommendations for further research, including reliability, observer error, validity of EFM, correlation with outcomes and development of new techniques.  Unreferenced.  No formal evidence or recommendation structure.  No definite documentation of evidence base/searches.

# Appendix 3. Staging of Neonatal Encephalopathy

The staging of neonatal encephalopathy referred to in the Guideline relates to a staging on neonatal encephalopathy developed by Sarnat.<sup>245</sup>

The grading system proposed can be summarised as follows:

Level of	Stage 1	Stage 2	Stage 3	
consciousness	Hyperalert	Lethargic or obtunded	Stuporous	
Neuromuscular control				
Muscle tone Posture	Normal Mild distal flexion	Mild hypotonia Strong distal flexion	Flaccid Intermittent decerebration	
Stretch reflexes Segmental myoclonus	Overactive Present	Overactive Present	Decreased or absent Absent	
Complex reflexes				
Suck Moro Oculovestibular Tonic neck	Weak Strong: low threshold Normal Slight	Weak or absent Weak: incomplete high threshold Overactive Strong	Absent Absent Weak or absent Absent	
Autonomic function	Generalised	Generalised parasympathetic	Both systems	
Pupils	sympathetic Mydriasis	Miosis	depressed Variable: often unequal; poor light reflex	
Heart rate	Tachycardia	Bradycardia	Variable	
Bronchial and salivary secretions Gastrointestinal motility	Sparse Normal or decreased	Profuse Increased; diarrhoea	Variable Variable	
Seizures	None	Common; focal or multifocal	Uncommon (excluding decerebration)	
EEG findings	Normal (awake)	Early: low-voltage continuous delta and theta Later: periodic pattern (awake) Seizures: focal 1–1.5 HZ spike-and-wave	Early: periodic pattern with isopotential phases Later: totally isopotential	
Duration	< 24 hours	2–14 days	Hours-weeks	

# Appendix 4. FHR categorisation systems

	Categorisation
Dublin RCT <sup>34</sup>	
Normal	Baseline 120–160 bpm
	Baseline variability > 5 bpm
	No decelerations
	Accelerations present
Non-reassuring	Moderate tachycardia (160–180 bpm) with normal variability (> 5 bpm)
	Mild variable deceleration pattern (amplitude < 50 bpm
	irrespective of duration or > 50 bpm < 30 seconds)
	Early deceleration pattern
	Reduced variability (3–5 bpm)
Suspicious	Marked tachycardia (> 180 bpm)
'	Moderate tachycardia (160–180 bpm) with reduced variability (3-5bpm)
	Moderate bradycardia (100–120 bpm) with reduced variability (3–5bpm)
	Minimal variability (< 3 bpm)
	Moderate variable deceleration pattern (amplitude > 50 bpm,
	with duration > 30 seconds < 60 seconds)
Ominous	Marked tachycardia (> 180 bpm) with reduced variability
Ommous	(3–5 bpm)
	Prolonged marked bradycardia (< 100 bpm)
	Late deceleration pattern
	Severe variable deceleration pattern (amplitude > 50 bpm
	with duration > 60 seconds)
Action	Suspicious or ominous CTGs required conservative measures
rectori	followed by FBS or delivery as appropriate
FIGO <sup>11</sup>	onowed by 100 of derivery as appropriate
Normal	Baseline 110–150 bpm
Tionnai	Baseline variability 5–25 bpm
Suspicious	Baseline 100–110 bpm or 150–170 bpm
ouspierous -	Baseline variability 5–10 bpm for > 40 minutes or > 25 bpm
	Variable decelerations
Pathological	Baseline < 100 bpm or > 170 bpm
raniologicai	Baseline variability < 5 bpm for > 40 minutes
	Severe variable decelerations
	Severe repetitive early decelerations
	Prolonged decelerations
	Late decelerations
	Sinusoidal pattern
Action	Suspicious or ominous CTGs required conservative measures
/ ICHOIT	followed by FBS or delivery as appropriate

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